

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number:	G1722093	Mfg.Date :	Oct-22
Stage:	ROBUSTNESS-HIGH DISSOLUTION MEDIUM PH (Ph 7.6)	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900 ml
Speed	100 RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.49	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.49	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	2840070	2840095	2841235	2840494	2839236	2840226	727	0.026
With Bracketing std.	2833446	2833345	2833986			2837738	3482	0.123

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	553756	11.67	19.45	0.22	18.0	16.8
Unit-2	521992	11.00	18.33	0.20		Maximum %
Unit-3	490483	10.33	17.22	0.19		
Unit-4	520052	10.96	18.26	0.20		
Unit-5	478156	10.07	16.79	0.19		
Unit-6	504391	10.63	17.71	0.20		19.4

5th Hour					Limit:Between 35.0-75.0%		
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Average %	Minimum %
Unit-1	1435138	30.24	50.40	0.560	50.61	46.6	43.9
Unit-2	1347909	28.40	47.33	0.526	47.54		Maximum%
Unit-3	1244931	26.23	43.72	0.486	43.91		
Unit-4	1350481	28.45	47.42	0.527	47.63		
Unit-5	1277550	26.92	44.86	0.498	45.05		50.6
Unit-6	1271585	26.79	44.65	0.496	44.85		

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2654931	55.94	93.23	94.00	90.9	86.9	3.2
Unit-2	2590544	54.58	90.97	91.70			
Unit-3	2483147	52.32	87.20	87.87		Maximum %	
Unit-4	2452599	51.67	86.12	86.85			
Unit-5	2580335	54.37	90.61	91.29		94.0	
Unit-6	2644247	55.71	92.85	93.55			

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor
	Standard area x sample dilution X 100
Correction factor	Drug release % in respective time point / 900 X 10

Drug release in %	Drug release in mg /tablet x 100 Labeled claim
-------------------	---

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by :

C.K.SARAVANAN

Date :

16-10-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number:	G1722093	Mfg.Date :	Oct-22
Stage:	ROBUSTNESS-LOW DISSOLUTION MEDIUM PH (Ph 7.2)	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900 ml
Speed	100 RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.49	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.49	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	2840070	2840095	2841235	2840494	2839236	2840226	727	0.026
With Bracketing std.	2839077	2838028	2836176			2839301	1596	0.056

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	602145	12.69	21.14	0.23	22.3	19.0
Unit-2	728725	15.35	25.59	0.28		Maximum %
Unit-3	695541	14.65	24.42	0.27		
Unit-4	542508	11.43	19.05	0.21		
Unit-5	542180	11.42	19.04	0.21		
Unit-6	702746	14.81	24.68	0.27		25.6

5th Hour					Limit:Between 35.0-75.0%		
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Average %	Minimum %
Unit-1	2052957	43.25	72.09	0.801	72.32	62.5	52.1
Unit-2	1785521	37.62	62.70	0.697	62.98		
Unit-3	1818976	38.32	63.87	0.710	64.15		Maximum%
Unit-4	1477347	31.13	51.88	0.576	52.09		
Unit-5	1476772	31.11	51.86	0.576	52.07		72.3
Unit-6	2021474	42.59	70.98	0.789	71.26		

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2673017	56.32	93.86	94.90	91.8	88.6	2.7
Unit-2	2542029	53.56	89.26	90.24			
Unit-3	2539847	53.51	89.19	90.17		Maximum %	
Unit-4	2637910	55.58	92.63	93.42			
Unit-5	2637217	55.56	92.61	93.39			
Unit-6	2492175	52.51	87.51	88.58		94.9	

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor Standard area x sample dilution X 100
-----------------------------	---

Drug release in %	Drug release in mg /tablet x 100 Labeled claim
-------------------	---

Correction factor	Drug release % in respective time point / 900 X 10
-------------------	--

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by :

C.K.SARAVANAN

Date :

16-10-2023

Checked by :

Date :

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number :	G1722093	Mfg.Date :	Oct-22
Parameter :	ROBUSTNESS (Effect of variation of Dissolution parameters)	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006 & ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	---------------------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900ml with Paddle
Time & Speed	100RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	About 66 mg	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.6666	1	ml to --->	1	ml to --->	1	ml to --->	1

Chromatographic variation's	Gliclazide Dissolution in %	Mean value of Method precision
Low volume Dissolution Medium (at final interval)	89.53	90.6
	87.29	
	86.48	% Difference
	90.06	
	84.35	2.7
	89.52	
Average	87.9	Not applicable
% RSD	2.54	

Chromatographic variation's	Gliclazide Dissolution in %	Mean value of Method precision
High volume Dissolution Medium (at final interval)	90.95	90.6
	90.17	
	94.77	% Difference
	93.24	
	90.93	-1.5
	92.7	
Average	92.1	Not applicable
% RSD	1.89	

Chromatographic variation's	Gliclazide Dissolution in %	Mean value of method precision
Low pH Dissolution Medium (at final interval)	94.9	90.6
	90.24	
	90.17	% Difference
	93.42	
	93.39	-1.2
	88.58	
Average	91.8	Not applicable
% RSD	2.68	

Chromatographic variation's	Gliclazide Dissolution in %	Mean value of Method precision
High pH Dissolution Medium (at final interval)	94.00	90.6
	91.70	
	87.87	% Difference
	86.85	
	91.29	-0.3
	93.55	
Average	90.9	Not applicable
% RSD	3.23	

- Acceptance criteria:
1. % Dissolution result shall meet the specification.
 2. Relative standard deviation of % dissolution results should not be more than 5.0%.
 3. The difference in average % dissolution with actual dissolution medium volume and with changed dissolution medium volume shall NMT 5.0

Analysed by :
Date :C.K.SARAVANAN
16-10-2023Checked by :
Date :

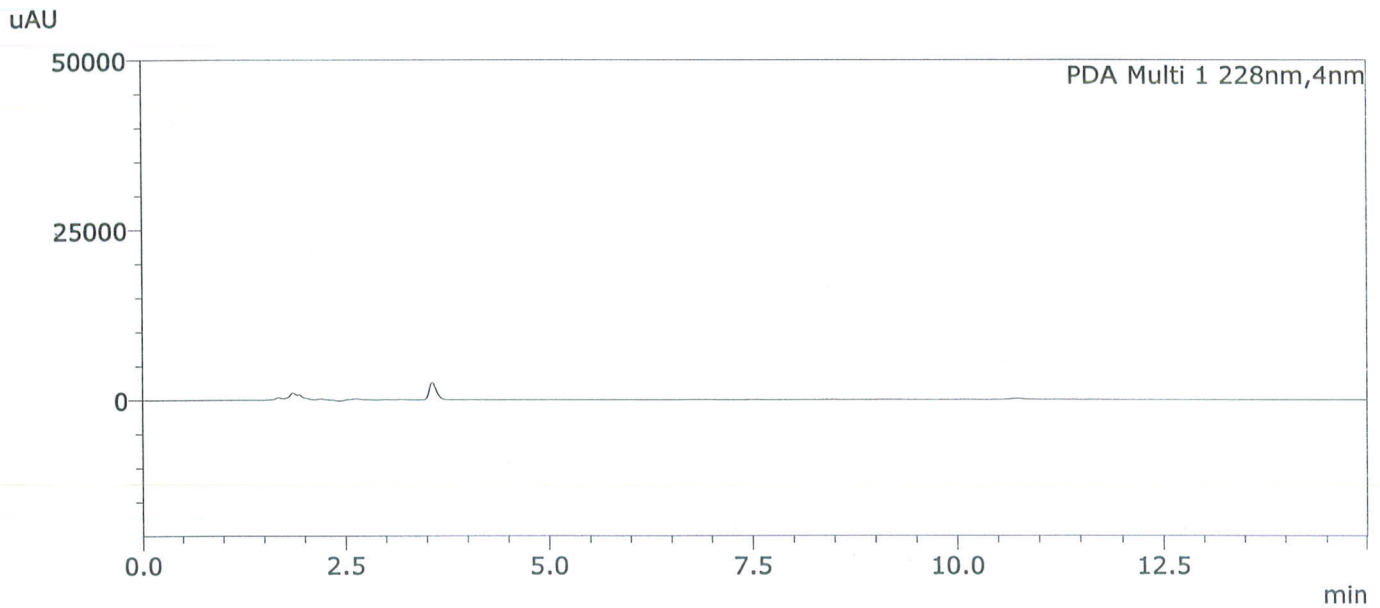
16/10/23

17/10/23


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : BLANK-DS
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-01.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-1
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 13:56:46
 Date Processed : 16-10-2023 15:50:03

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

 18/10/23
Analysed By

 S.A.
 18/10/23
Checked By



GENERIC HEALTHCARE PVT. LTD.

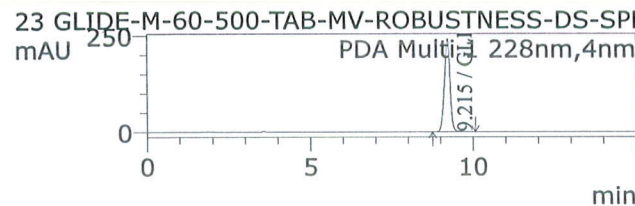
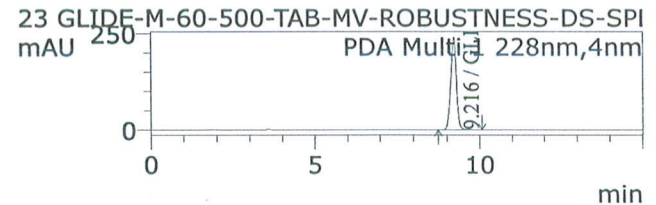
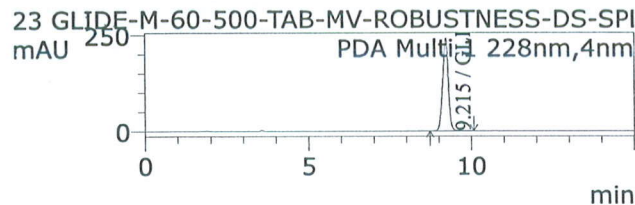
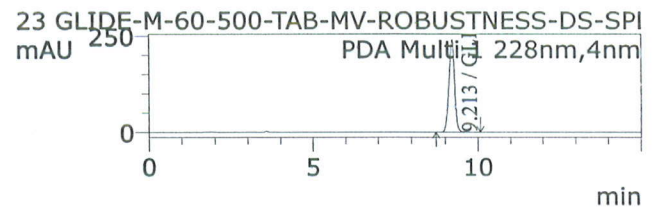
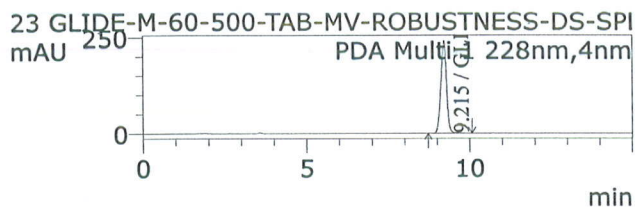
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-02.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 14:12:18
 Date Processed : 16-10-2023 15:50:03

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	GLICLAZIDE-DS-STD-1	9.21	2840070	13153	0.93
2	DS-SPL-03.lcd	GLICLAZIDE-DS-STD-2	9.21	2840095	13122	0.93
2	DS-SPL-04.lcd	GLICLAZIDE-DS-STD-3	9.21	2841235	13128	0.93
2	DS-SPL-05.lcd	GLICLAZIDE-DS-STD-4	9.22	2840494	13135	0.94
2	DS-SPL-06.lcd	GLICLAZIDE-DS-STD-5	9.22	2839236	13130	0.93
	Average		9.21	2840226	13133	0.93
	%RSD		0.010	0.026	0.090	0.099

Analysed By

Handwritten signature and date 15/10/23

Checked By

Handwritten signature and date 15/10/23



GENERIC HEALTHCARE PVT. LTD.

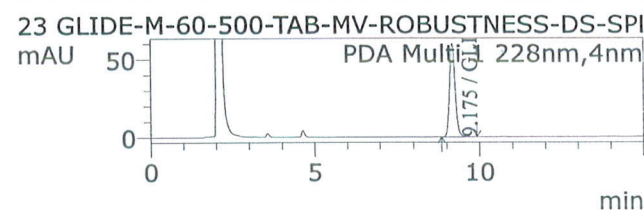
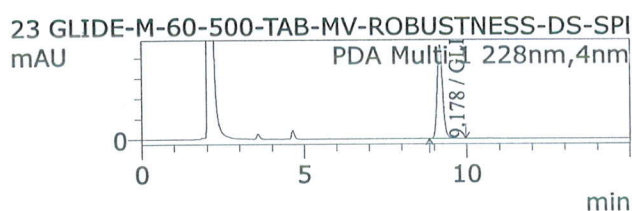
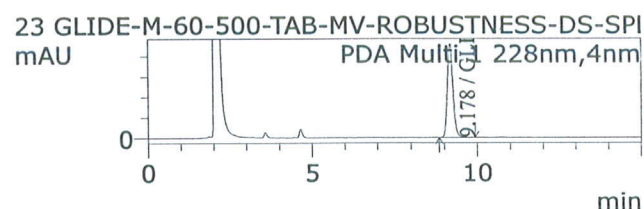
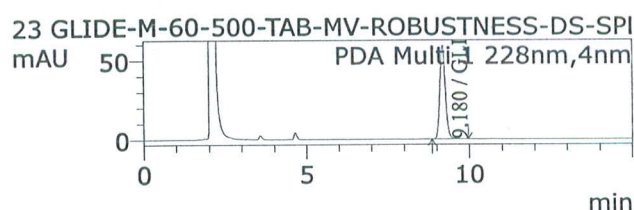
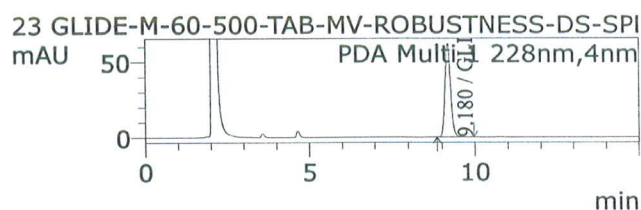
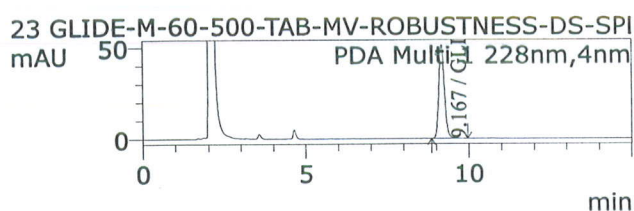
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLIDE-M-60-500-LPH-2HR-DS-SPL-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-07.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 15:30:00
 Date Processed : 16-10-2023 15:50:04

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	DS-SPL-07.lcd	GLIDE-M-60-500-LPH-2HR-DS-SPL-1	9.17	602145	13336	1.13
4	DS-SPL-08.lcd	GLIDE-M-60-500-LPH-2HR-DS-SPL-2	9.18	728725	13419	1.11
5	DS-SPL-09.lcd	GLIDE-M-60-500-LPH-2HR-DS-SPL-3	9.18	695541	13414	1.12
6	DS-SPL-10.lcd	GLIDE-M-60-500-LPH-2HR-DS-SPL-4	9.18	542508	13374	1.13
7	DS-SPL-11.lcd	GLIDE-M-60-500-LPH-2HR-DS-SPL-5	9.18	542180	13372	1.14
8	DS-SPL-12.lcd	GLIDE-M-60-500-LPH-2HR-DS-SPL-6	9.17	702746	13358	1.11
	Average		9.18	635641	13379	1.12
	%RSD		0.057	13.216	0.241	0.912

Analysed By

16/10/23

Checked By

17/10/23

D:\HPLC DATA-QCLC-006\DATA\GLIDE-M-60-500-850-TAB-AMV-DS\15102023
 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-07.lcd


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

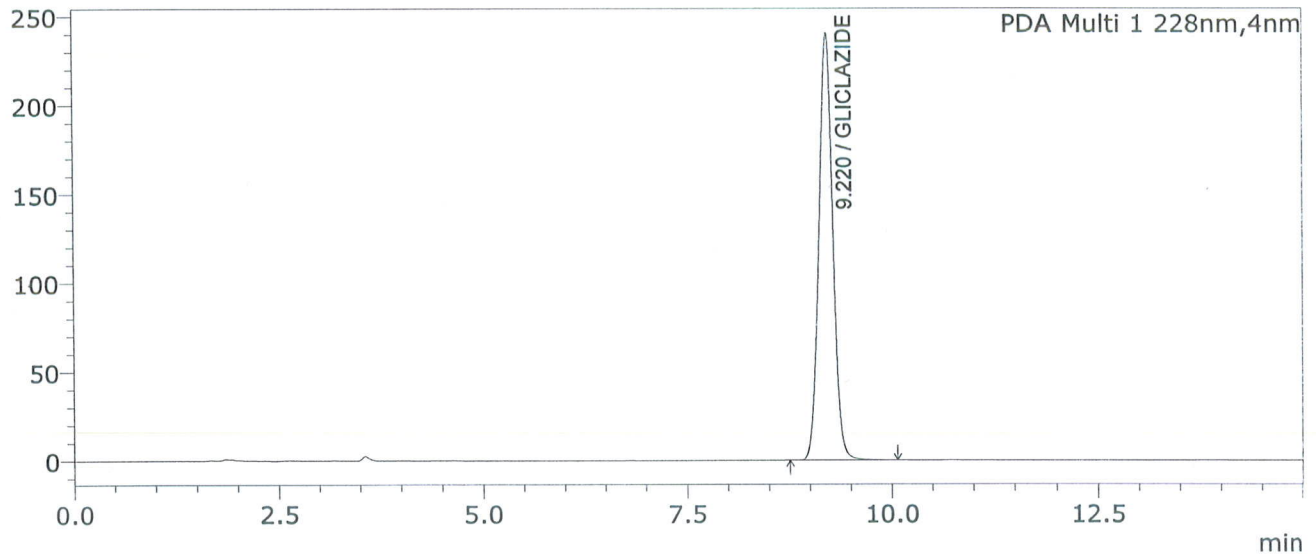
<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-BKT-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-13.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 17:03:14
 Date Processed : 16-10-2023 15:50:05

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2839077	100.00	13124	0.934	--	--
Total			2839077	100.00				

Analysed By

Checked By

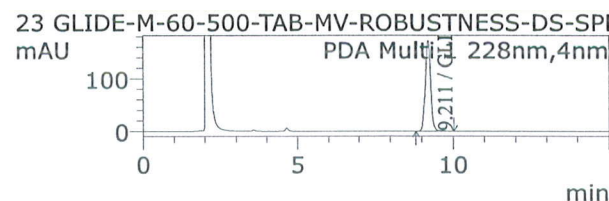
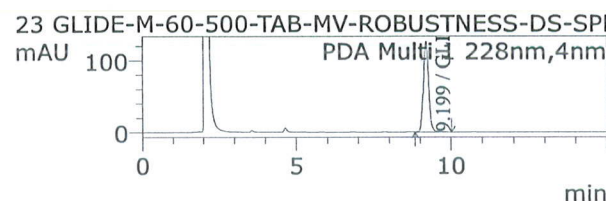
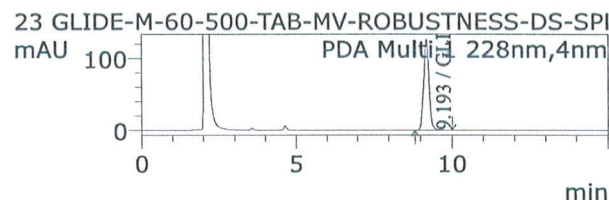
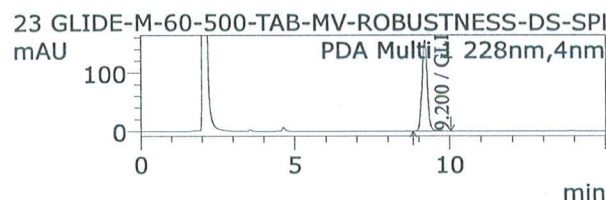
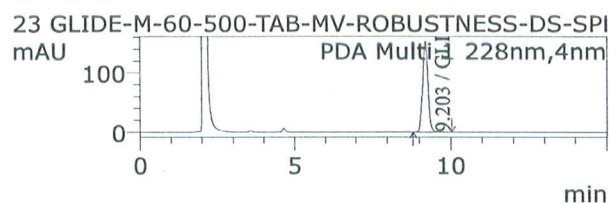
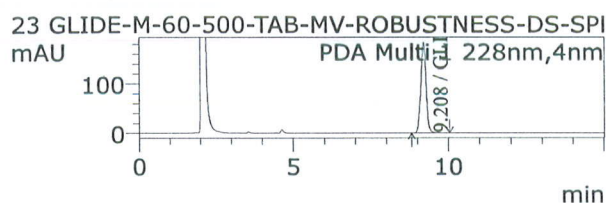

GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLIDE-M-60-500-LPH-5HR-DS-SPL-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-14.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-9
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 17:18:48
 Date Processed : 16-10-2023 15:50:06
 Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	DS-SPL-14.lcd	GLIDE-M-60-500-LPH-5HR-DS-SPL-1	9.21	2052957	13309	0.98
10	DS-SPL-15.lcd	GLIDE-M-60-500-LPH-5HR-DS-SPL-2	9.20	1785521	13415	1.01
11	DS-SPL-16.lcd	GLIDE-M-60-500-LPH-5HR-DS-SPL-3	9.20	1818976	13361	1.01
12	DS-SPL-17.lcd	GLIDE-M-60-500-LPH-5HR-DS-SPL-4	9.19	1477347	13469	1.04
13	DS-SPL-18.lcd	GLIDE-M-60-500-LPH-5HR-DS-SPL-5	9.20	1476772	13445	1.04
14	DS-SPL-19.lcd	GLIDE-M-60-500-LPH-5HR-DS-SPL-6	9.21	2021474	13346	0.99
	Average		9.20	1772175	13391	1.01
	%RSD		0.068	14.220	0.462	2.215

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

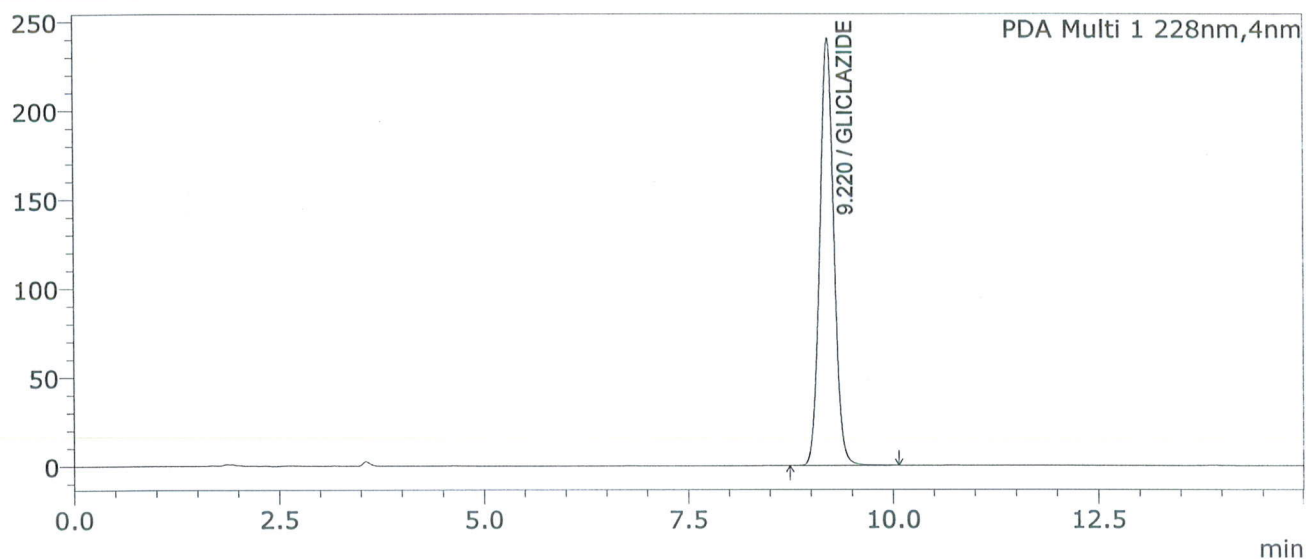
<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-BKT-2
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-20.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 18:52:02
 Date Processed : 16-10-2023 15:50:07

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2838028	100.00	13128	0.932	--	--
Total			2838028	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

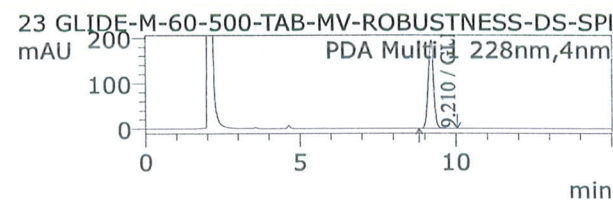
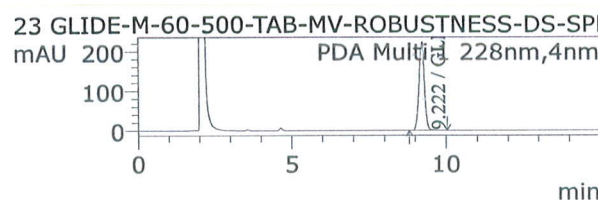
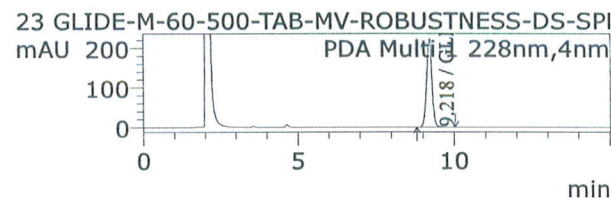
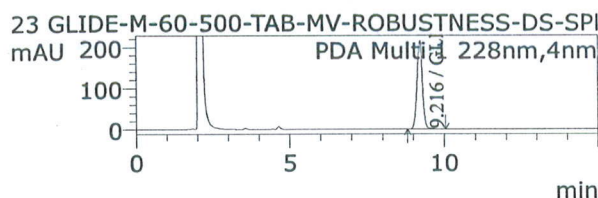
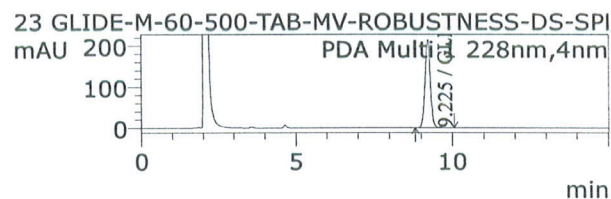
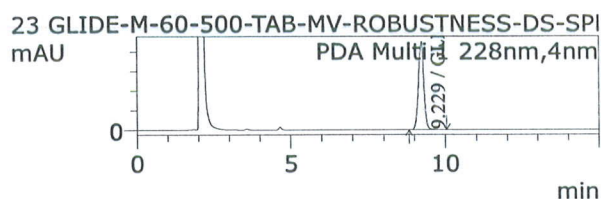
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLIDE-M-60-500-LPH-12H-DS-SPL-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-21.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-15
 Injection Volume : 20 µL
 Date Acquired : 15-10-2023 19:07:35
 Date Processed : 16-10-2023 15:50:08

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	DS-SPL-21.lcd	GLIDE-M-60-500-LPH-12H-DS-SPL-1	9.23	2673017	13078	0.95
16	DS-SPL-22.lcd	GLIDE-M-60-500-LPH-12H-DS-SPL-2	9.22	2542029	13150	0.96
17	DS-SPL-23.lcd	GLIDE-M-60-500-LPH-12H-DS-SPL-3	9.22	2539847	13127	0.96
18	DS-SPL-24.lcd	GLIDE-M-60-500-LPH-12H-DS-SPL-4	9.22	2637910	13090	0.95
19	DS-SPL-25.lcd	GLIDE-M-60-500-LPH-12H-DS-SPL-5	9.22	2637217	13052	0.95
20	DS-SPL-26.lcd	GLIDE-M-60-500-LPH-12H-DS-SPL-6	9.21	2492175	13234	0.97
	Average		9.22	2587033	13122	0.96
	%RSD		0.072	2.774	0.497	0.905

Analysed By

[Signature]
16/10/23

Checked By

[Signature]
17/10/23

D:\HPLC DATA-QCLC-006\DATA\GLIDE-M-60-500-850-TAB-AMV-DS\15102023
GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-21.lcd



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

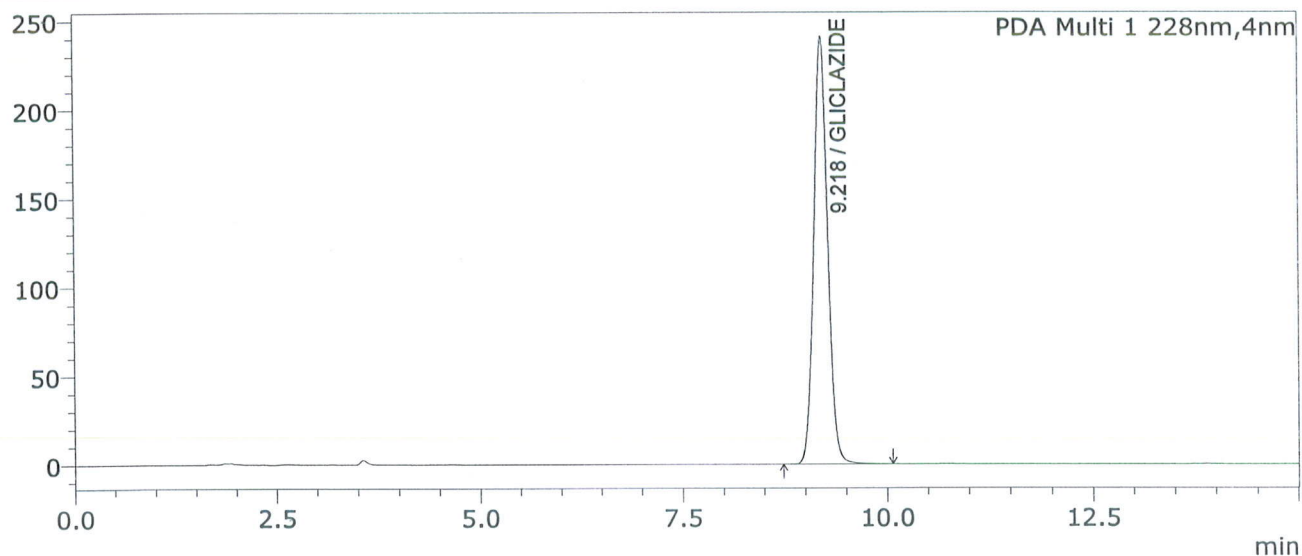
<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-BKT-3
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-27.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 20:40:51
 Date Processed : 16-10-2023 15:50:09

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2836176	100.00	13178	0.932	--	--
Total			2836176	100.00				

Analysed By

16/10/23

Checked By

15/10/23



GENERIC HEALTHCARE PVT. LTD.

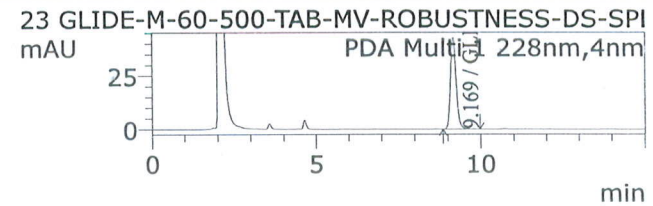
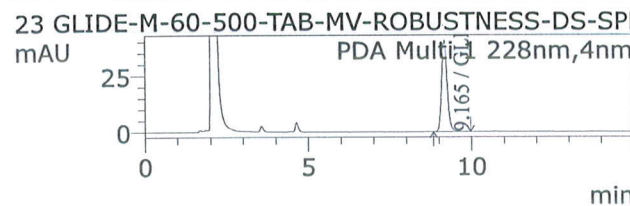
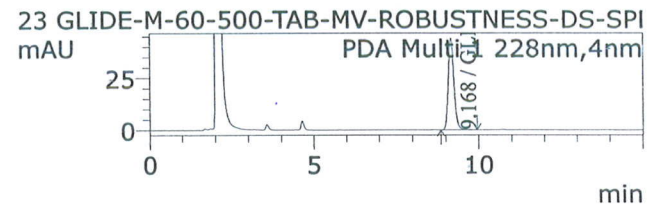
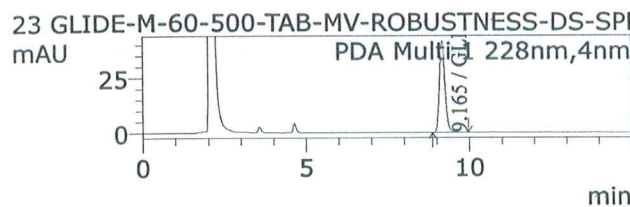
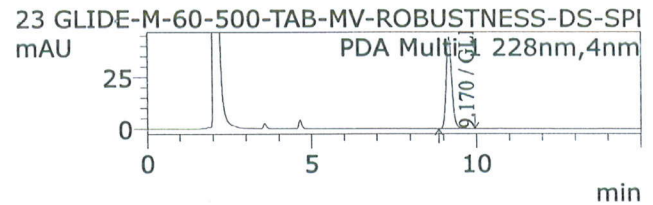
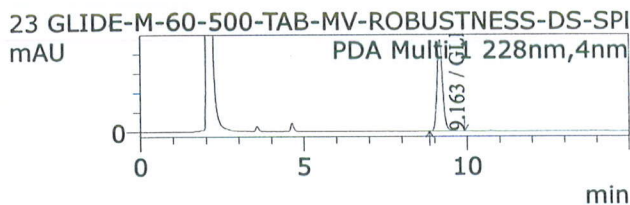
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLIDE-M-60-500-HPH-2HR-DS-SPL-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-28.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-21
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 20:56:24
 Date Processed : 16-10-2023 15:50:10

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
21	DS-SPL-28.lcd	GLIDE-M-60-500-HPH-2HR-DS-SPL-1	9.16	553756	13338	1.13
22	DS-SPL-29.lcd	GLIDE-M-60-500-HPH-2HR-DS-SPL-2	9.17	521992	13379	1.14
23	DS-SPL-30.lcd	GLIDE-M-60-500-HPH-2HR-DS-SPL-3	9.17	490483	13309	1.14
24	DS-SPL-31.lcd	GLIDE-M-60-500-HPH-2HR-DS-SPL-4	9.17	520052	13364	1.14
25	DS-SPL-32.lcd	GLIDE-M-60-500-HPH-2HR-DS-SPL-5	9.17	478156	13312	1.14
26	DS-SPL-33.lcd	GLIDE-M-60-500-HPH-2HR-DS-SPL-6	9.17	504391	13372	1.14
	Average		9.17	511472	13346	1.14
	%RSD		0.028	5.226	0.229	0.325

Analysed By

16/10/23

Checked By

16/10/23

D:\HPLC DATA-QCLC-006\DATA\GLIDE-M-60-500-850-TAB-AMV-DS\15102023
 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-28.lcd



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

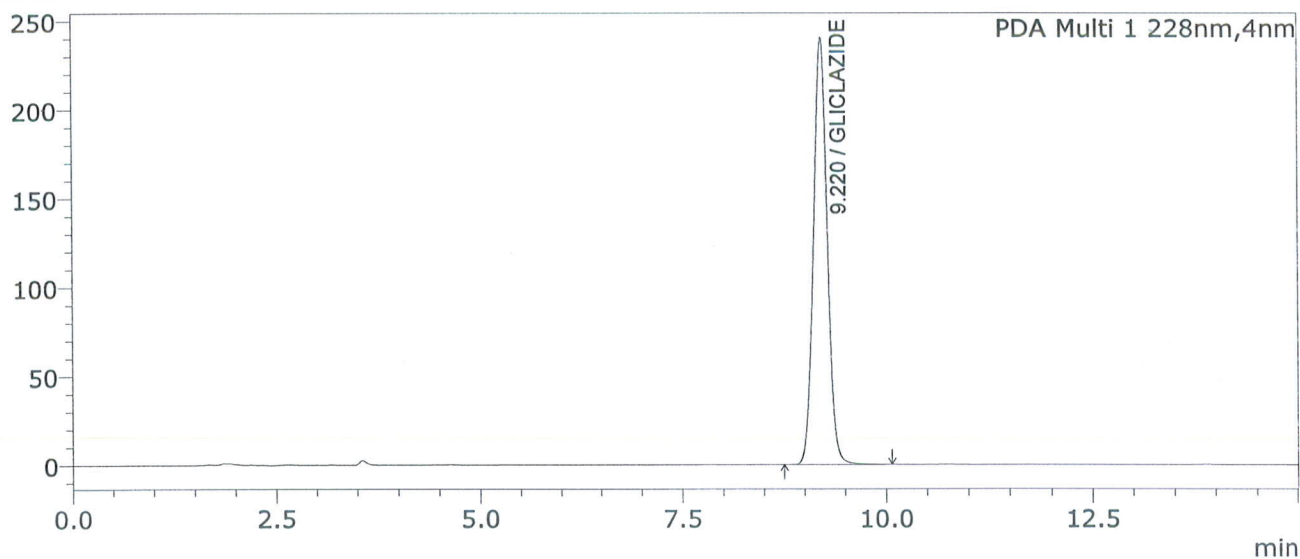
<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-BKT-4
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-34.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 22:29:37
 Date Processed : 16-10-2023 15:50:11

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2833446	100.00	13160	0.930	--	--
Total			2833446	100.00				

Analysed By

16/10/23

Checked By

16/10/23



GENERIC HEALTHCARE PVT. LTD.

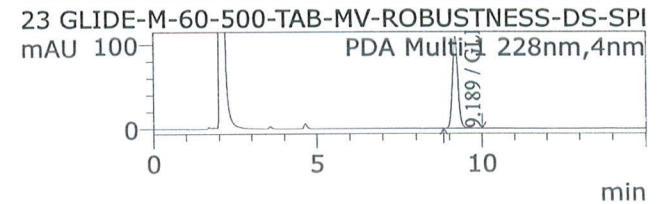
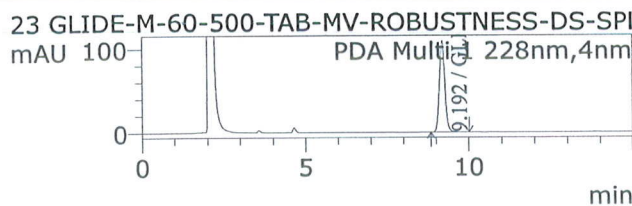
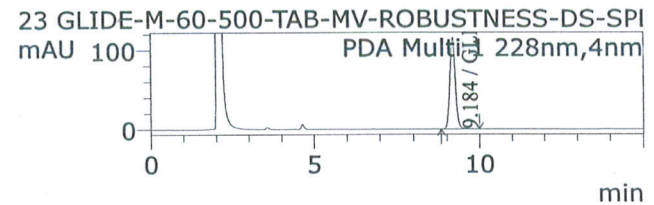
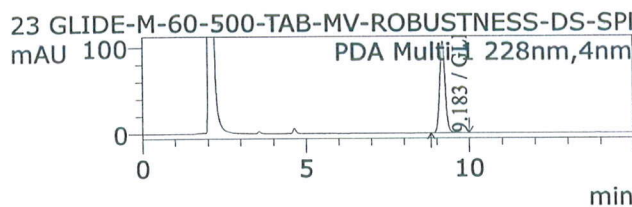
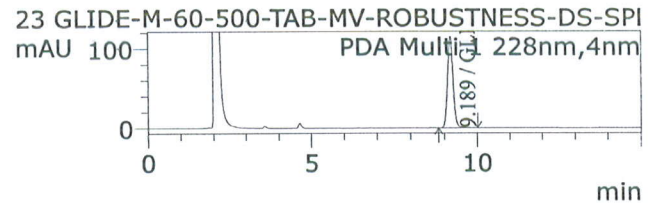
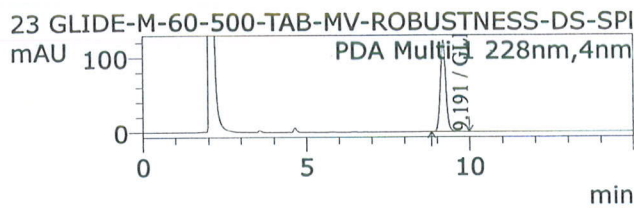
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLIDE-M-60-500-HPH-5HR-DS-SPL-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-35.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-27
 Injection Volume : 20 uL
 Date Acquired : 15-10-2023 22:45:10
 Date Processed : 16-10-2023 15:50:11

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
27	DS-SPL-35.lcd	GLIDE-M-60-500-HPH-5HR-DS-SPL-1	9.19	1435138	13455	1.04
28	DS-SPL-36.lcd	GLIDE-M-60-500-HPH-5HR-DS-SPL-2	9.19	1347909	13436	1.05
29	DS-SPL-37.lcd	GLIDE-M-60-500-HPH-5HR-DS-SPL-3	9.18	1244931	13446	1.06
30	DS-SPL-38.lcd	GLIDE-M-60-500-HPH-5HR-DS-SPL-4	9.18	1350481	13446	1.05
31	DS-SPL-39.lcd	GLIDE-M-60-500-HPH-5HR-DS-SPL-5	9.19	1277550	13480	1.05
32	DS-SPL-40.lcd	GLIDE-M-60-500-HPH-5HR-DS-SPL-6	9.19	1271585	13466	1.05
	Average		9.19	1321266	13455	1.05
	%RSD		0.041	5.323	0.118	0.633

Analysed By

16/10/23

Checked By

16/10/23

D:\HPLC DATA-QCLC-006\DATA\GLIDE-M-60-500-850-TAB-AMV-DS\15102023
 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-35.lcd



GENERIC HEALTHCARE PVT. LTD.

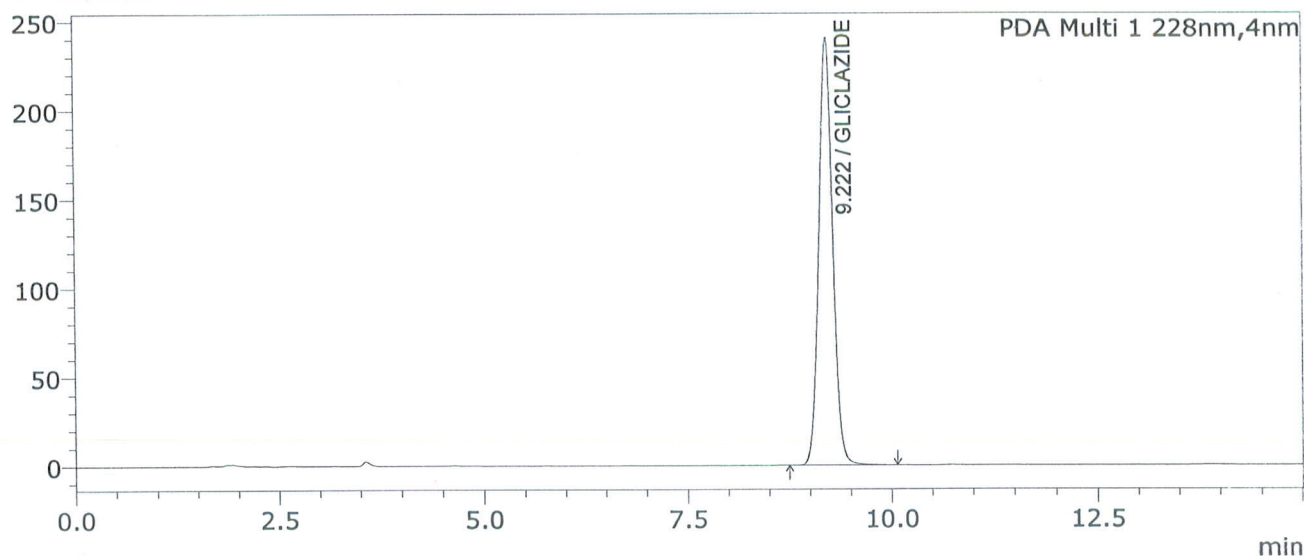
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-BKT-5
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-41.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 16-10-2023 00:18:24
 Date Processed : 16-10-2023 15:50:12
 Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2833345	100.00	13138	0.929	--	--
Total			2833345	100.00				

Analysed By

16/10/23

Checked By

17/10/23



GENERIC HEALTHCARE PVT. LTD.

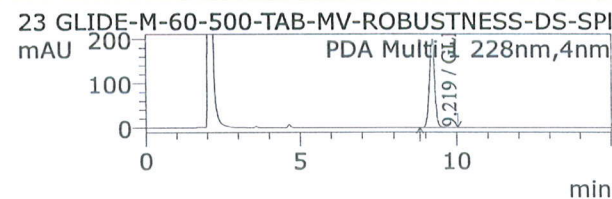
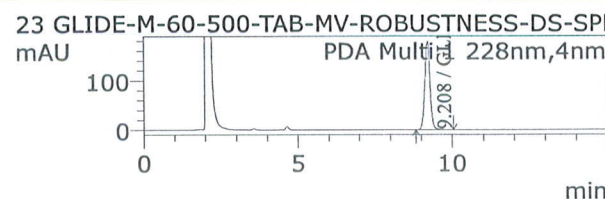
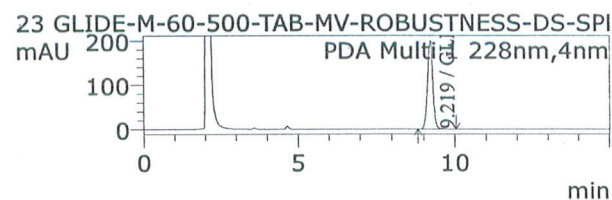
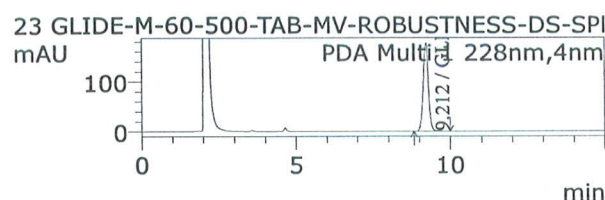
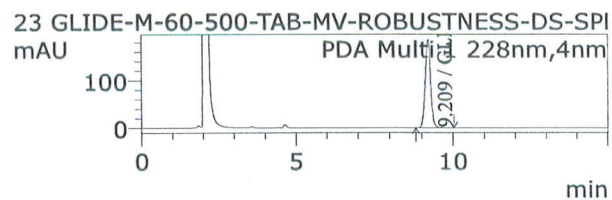
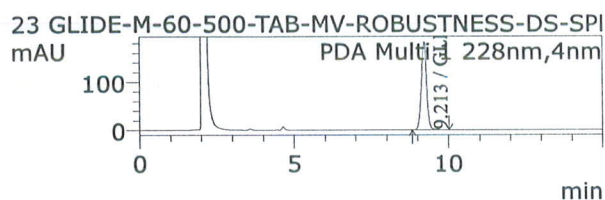
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLIDE-M-60-500-HPH-12H-DS-SPL-1
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-42.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-33
 Injection Volume : 20 µL
 Date Acquired : 16-10-2023 00:33:56
 Date Processed : 16-10-2023 15:50:13

Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
33	DS-SPL-42.lcd	GLIDE-M-60-500-HPH-12H-DS-SPL-1	9.21	2654931	13269	0.98
34	DS-SPL-43.lcd	GLIDE-M-60-500-HPH-12H-DS-SPL-2	9.21	2590544	13239	0.98
35	DS-SPL-44.lcd	GLIDE-M-60-500-HPH-12H-DS-SPL-3	9.21	2483147	13296	0.99
36	DS-SPL-45.lcd	GLIDE-M-60-500-HPH-12H-DS-SPL-4	9.22	2452599	13255	0.97
37	DS-SPL-46.lcd	GLIDE-M-60-500-HPH-12H-DS-SPL-5	9.21	2580335	13288	0.99
38	DS-SPL-47.lcd	GLIDE-M-60-500-HPH-12H-DS-SPL-6	9.22	2644247	13263	0.97
	Average		9.21	2567634	13268	0.98
	%RSD		0.050	3.237	0.160	0.881

Analysed By

[Signature]
16/10/23

Checked By

[Signature]
17/10/23


GENERIC HEALTHCARE PVT. LTD.

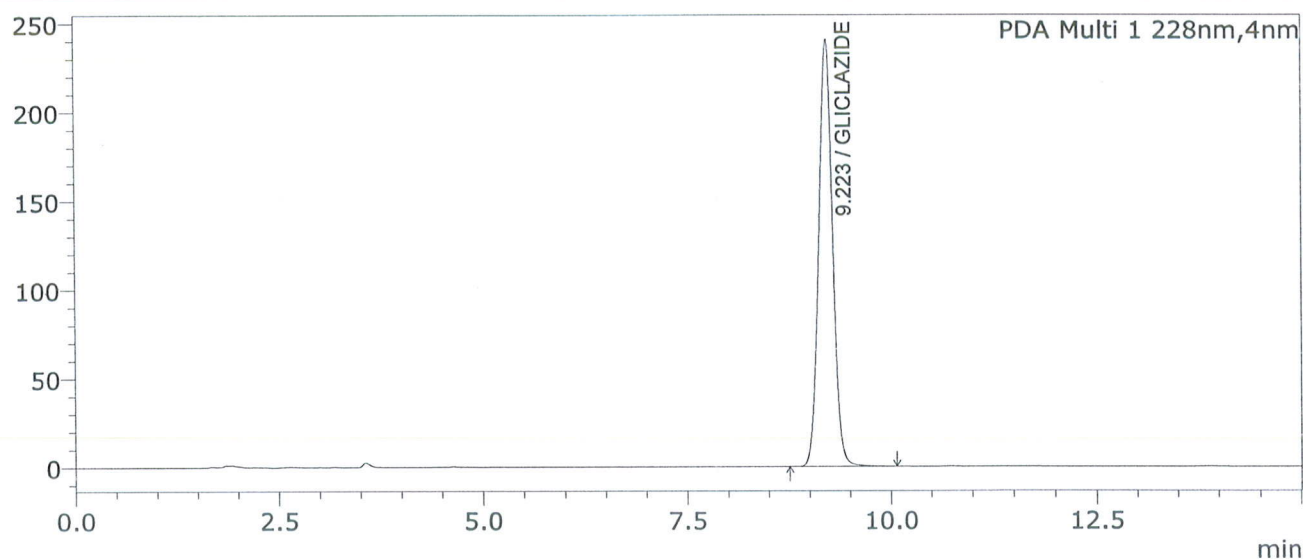
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-DS
 Sample ID : GLICLAZIDE-DS-STD-BKT-6
 Data Filename : 15102023 GLIDE-M-60-500-TAB-MV-ROBUSTNESS-DS-SPL-48.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15102023 GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 16-10-2023 02:07:11
 Date Processed : 16-10-2023 15:50:14
 Acquired by : C.K.SARAVANAN.
 Processed by : C.ALBINJOSE

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2833986	100.00	13163	0.928	--	--
Total			2833986	100.00				

Analysed By

16/10/23

Checked By

16/10/23



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table_15102023_GLIDE-M-60-500-TAB-MV-DS-ROBUSTNESS.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	3	ROBUSTNESS-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-01.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-02.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-03.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-04.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-05.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-06.lcd	20.0	QC/CL/23/041
3	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-2HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-07.lcd	20.0	QC/CL/23/041
4	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-2HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-08.lcd	20.0	QC/CL/23/041
5	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-2HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-09.lcd	20.0	QC/CL/23/041
6	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-2HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-10.lcd	20.0	QC/CL/23/041
7	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-2HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-11.lcd	20.0	QC/CL/23/041
8	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-2HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-12.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-BKT-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-13.lcd	20.0	QC/CL/23/041
9	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-5HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-14.lcd	20.0	QC/CL/23/041
10	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-5HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-15.lcd	20.0	QC/CL/23/041
11	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-5HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-16.lcd	20.0	QC/CL/23/041
12	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-5HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-17.lcd	20.0	QC/CL/23/041
13	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-5HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
14	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-5HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-19.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-BKT-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-20.lcd	20.0	QC/CL/23/041
15	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-12H-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-21.lcd	20.0	QC/CL/23/041
16	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-12H-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-22.lcd	20.0	QC/CL/23/041
17	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-12H-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-23.lcd	20.0	QC/CL/23/041
18	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-12H-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-24.lcd	20.0	QC/CL/23/041
19	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-12H-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-25.lcd	20.0	QC/CL/23/041
20	3	ROBUSTNESS-DS	GLIDE-M-60-500-LPH-12H-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-26.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-BKT-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-27.lcd	20.0	QC/CL/23/041
21	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-2HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-28.lcd	20.0	QC/CL/23/041
22	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-2HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-29.lcd	20.0	QC/CL/23/041
23	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-2HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-30.lcd	20.0	QC/CL/23/041
24	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-2HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-31.lcd	20.0	QC/CL/23/041
25	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-2HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-32.lcd	20.0	QC/CL/23/041
26	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-2HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-33.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-BKT-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-34.lcd	20.0	QC/CL/23/041
27	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-5HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-35.lcd	20.0	QC/CL/23/041
28	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-5HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-36.lcd	20.0	QC/CL/23/041
29	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-5HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-37.lcd	20.0	QC/CL/23/041
30	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-5HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-38.lcd	20.0	QC/CL/23/041
31	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-5HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-39.lcd	20.0	QC/CL/23/041
32	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-5HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-40.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-BKT-5	AB-DS_GLICLAZIDE.lcm	TNESS-DS-SPL-41.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
33	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-12H-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-42.lcd	20.0	QC/CL/23/041
34	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-12H-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-43.lcd	20.0	QC/CL/23/041
35	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-12H-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-44.lcd	20.0	QC/CL/23/041
36	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-12H-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-45.lcd	20.0	QC/CL/23/041
37	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-12H-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-46.lcd	20.0	QC/CL/23/041
38	3	ROBUSTNESS-DS	GLIDE-M-60-500-HPH-12H-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-47.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS-DS	GLICLAZIDE-DS-STD-BKT-6	AB-DS_GLICLAZIDE.lcm	NESS-DS-SPL-48.lcd	20.0	QC/CL/23/041
-1	3	ROBUSTNESS-DS	WASH	IOD\WASH METHOD.lcm	NESS-DS-SPL-49.lcd	20.0	QC/CL/23/041
-1	3	ROBUSTNESS-DS	SHUTDOWN	HUTDOWN METHOD.lcm	NESS-DS-SPL-50.lcd	20.0	QC/CL/23/041

15/10/23

Analysed By

15/10/23
Checked By



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number:	G1722093	Mfg.Date :	Oct-22
Stage:	ROBUSTNESS-LOW VOLUME DISSOLUTION MEDIUM (891ml)	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900 ml
Speed	100 RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.53	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.53	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	to --->	891	ml to --->	1	ml to --->	1
Test.conc (in ppm)-67.34	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60

mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	3022310	3021547	3039497	3050163	3053674	3037438	15093	0.497
With Bracketing std.	3069022	3069559	3067547			3049165	19809	0.650

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	626133	12.22	20.37	0.23	17.8	15.8
Unit-2	578055	11.28	18.80	0.21		Maximum %
Unit-3	503184	9.82	16.37	0.18		
Unit-4	566112	11.05	18.41	0.20		
Unit-5	526743	10.28	17.13	0.19		20.4
Unit-6	485022	9.47	15.78	0.18		

5th Hour					Limit:Between 35.0-75.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Minimum %
Unit-1	1597605	31.18	51.96	0.577	52.19	42.9
Unit-2	1431672	27.94	46.57	0.517	46.78	
Unit-3	1328372	25.92	43.21	0.480	43.39	
Unit-4	1370071	26.74	44.56	0.495	44.77	Maximum %
Unit-5	1312940	25.62	42.71	0.475	42.90	
Unit-6	1591003	31.05	51.75	0.575	51.92	52.2

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2727967	53.24	88.73	89.53	87.9	84.4	2.5
Unit-2	2661462	51.94	86.57	87.29			
Unit-3	2638354	51.49	85.82	86.48		Maximum %	
Unit-4	2747210	53.61	89.36	90.06			
Unit-5	2572899	50.21	83.69	84.35		90.1	
Unit-6	2725691	53.19	88.66	89.41			

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor Standard area x sample dilution X 100
-----------------------------	---

Drug release in %	Drug release in mg /tablet x 100 Labeled claim
-------------------	---

Correction factor	Drug release % in respective time point / 900 X 10
-------------------	--

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by : E.MEENA
Date : 26-09-2023

Checked by :
Date :

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number:	G1722093	Mfg.Date :	Oct-22
Stage:	ROBUSTNESS-HIGH VOLUME DISSOLUTION MEDIUM (909ml)	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QALC/009	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900 ml
Speed	100 RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.53	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.53	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	to --->	909	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.00	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60

mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	3012587	3013362	3013884	3014196	3014425	3013691	735	0.024
With Bracketing std.	3014262	3016206	3017680			3014575	1624	0.054

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	869810	17.45	29.09	0.32	26.3	18.5
Unit-2	553445	11.11	18.51	0.21		Maximum %
Unit-3	795041	15.95	26.59	0.30		
Unit-4	774127	15.53	25.89	0.29		
Unit-5	873798	17.53	29.22	0.32		29.2
Unit-6	846193	16.98	28.30	0.31		

5th Hour					Limit:Between 35.0-75.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Minimum %
Unit-1	2082283	41.79	69.64	0.774	69.97	66.0
Unit-2	1481677	29.73	49.55	0.551	49.76	
Unit-3	2086988	41.88	69.80	0.776	70.09	
Unit-4	2014232	40.42	67.37	0.749	67.65	
Unit-5	2083111	41.80	69.67	0.774	69.99	
Unit-6	2038445	40.91	68.18	0.758	68.49	70.1

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2686700	53.91	89.86	90.95	92.1	90.2	1.8
Unit-2	2673474	53.65	89.41	90.17			
Unit-3	2801707	56.22	93.70	94.77		Maximum %	
Unit-4	2756977	55.32	92.21	93.24			
Unit-5	2685880	53.90	89.83	90.93		94.8	
Unit-6	2739523	54.97	91.62	92.70			

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor Standard area x sample dilution X 100
Correction factor	Drug release % in respective time point / 900 X 10

Drug release in %	Drug release in mg /tablet x 100 Labeled claim
-------------------	---

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by :

E.MEENA

Date :

26-09-2023

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

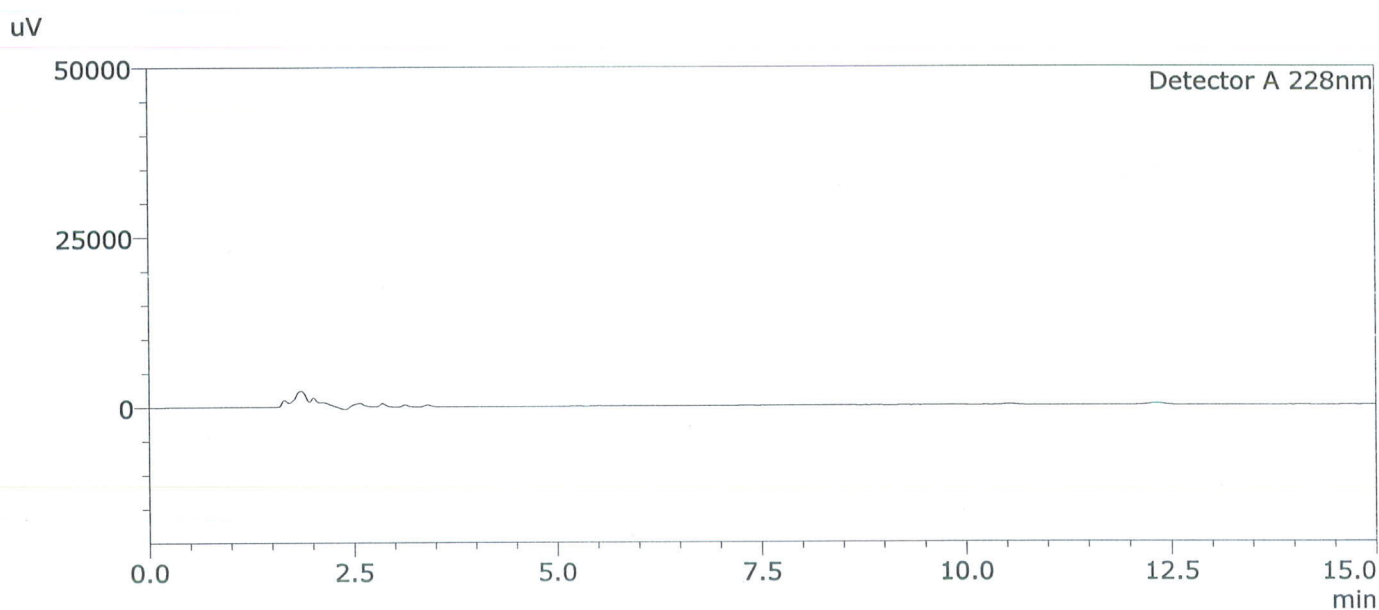
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-BLANK
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-1
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 12:41:59
 Date Processed : 26-09-2023 09:17:15

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

26/09/23

Analysed By

26/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

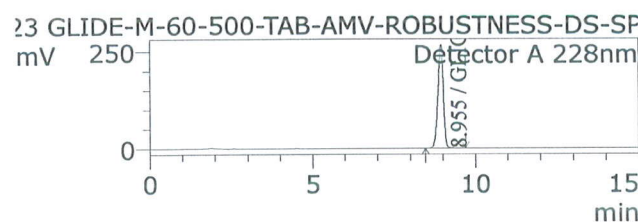
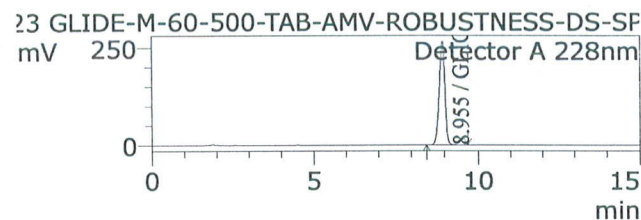
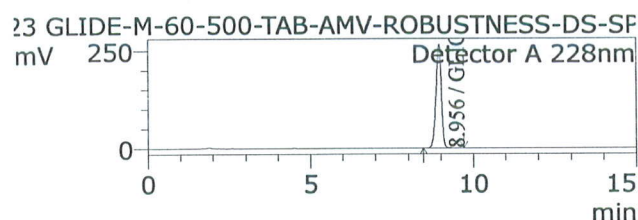
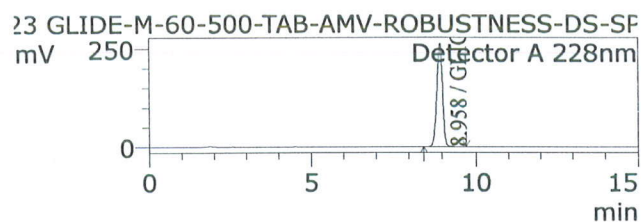
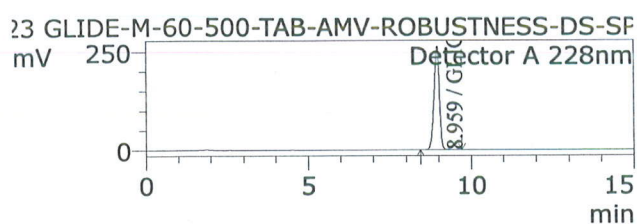
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 µL
 Date Acquired : 25-09-2023 12:57:30
 Date Processed : 26-09-2023 09:17:15

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	GLICLAZIDE-DS-STD-01	8.96	3022310	13184	0.87
2	DS-SPL-03.lcd	GLICLAZIDE-DS-STD-02	8.96	3021547	13194	0.87
2	DS-SPL-04.lcd	GLICLAZIDE-DS-STD-03	8.96	3039497	13182	0.86
2	DS-SPL-05.lcd	GLICLAZIDE-DS-STD-04	8.95	3050163	13180	0.86
2	DS-SPL-06.lcd	GLICLAZIDE-DS-STD-05	8.96	3053674	13188	0.86
	Average		8.96	3037438	13186	0.86
	%RSD		0.020	0.497	0.041	0.124

Analysed By

 26/09/23

Checked By

 26/09/23



GENERIC HEALTHCARE PVT. LTD.

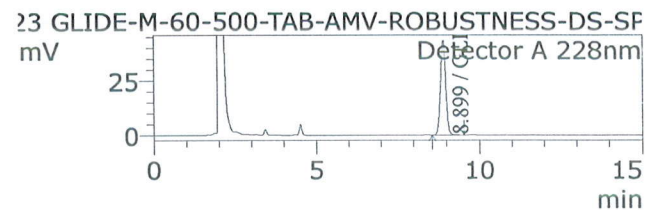
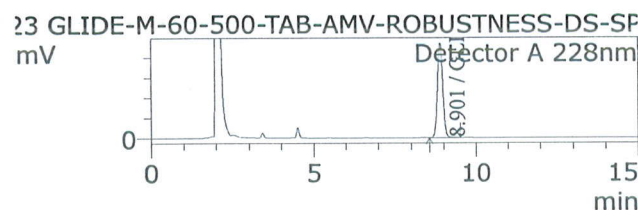
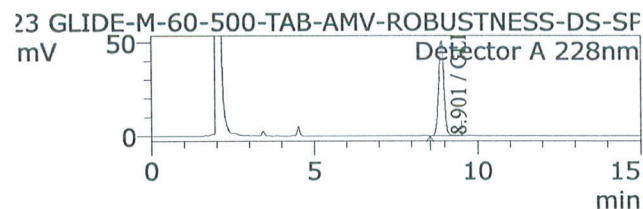
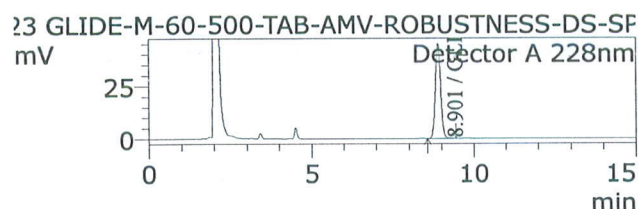
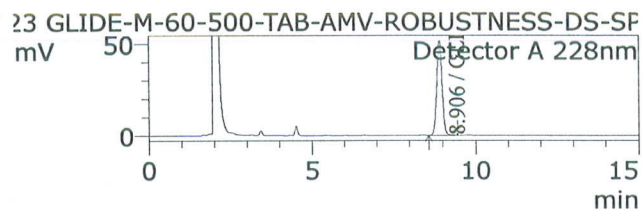
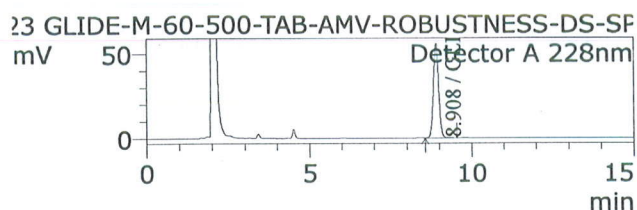
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDEM-60-500-891ML-2H-DS-SPL-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-07.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 14:15:07
 Date Processed : 26-09-2023 09:17:15

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	DS-SPL-07.lcd	GLIDEM-60-500-891ML-2H-DS-SPL-1	8.91	626133	13875	1.01
4	DS-SPL-08.lcd	GLIDEM-60-500-891ML-2H-DS-SPL-2	8.91	578055	13875	1.01
5	DS-SPL-09.lcd	GLIDEM-60-500-891ML-2H-DS-SPL-3	8.90	503184	13909	1.02
6	DS-SPL-10.lcd	GLIDEM-60-500-891ML-2H-DS-SPL-4	8.90	566112	13913	1.01
7	DS-SPL-11.lcd	GLIDEM-60-500-891ML-2H-DS-SPL-5	8.90	526743	13913	1.02
8	DS-SPL-12.lcd	GLIDEM-60-500-891ML-2H-DS-SPL-6	8.90	485022	13886	1.02
	Average		8.90	547542	13895	1.01
	%RSD		0.042	9.581	0.135	0.435

Analysed By

26/09/23

Checked By

26/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

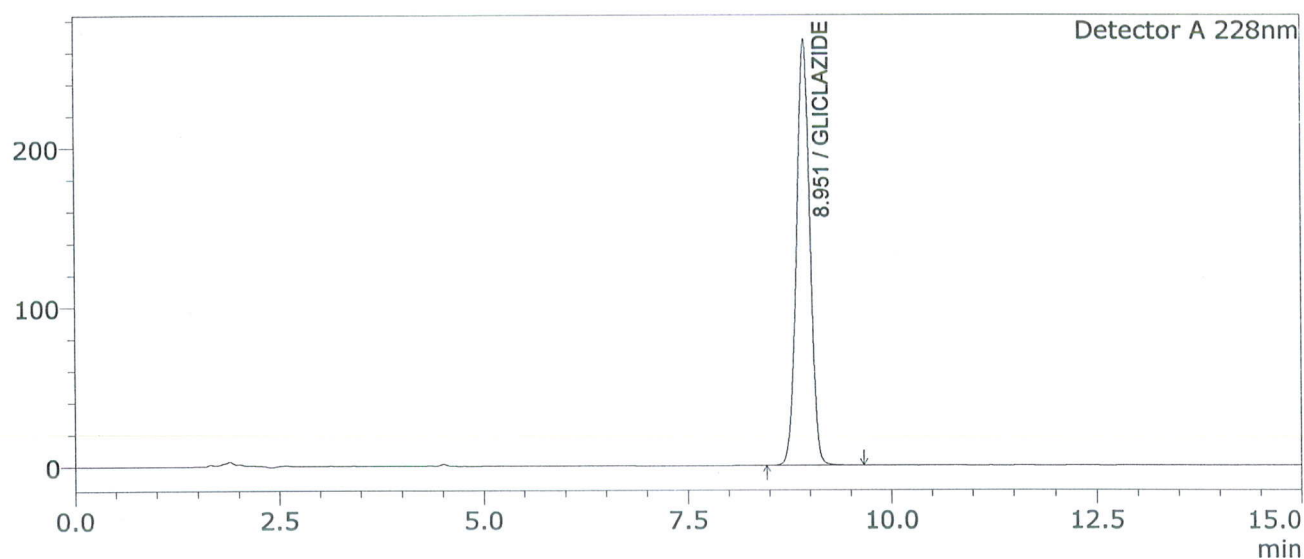
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-BKT-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-13.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 15:48:13
 Date Processed : 26-09-2023 09:17:16

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.95	3069022	100.00	13178	0.864	--	--
Total			3069022	100.00				

26/09/23

Analysed By

26/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

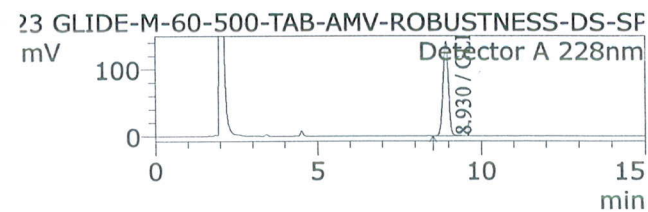
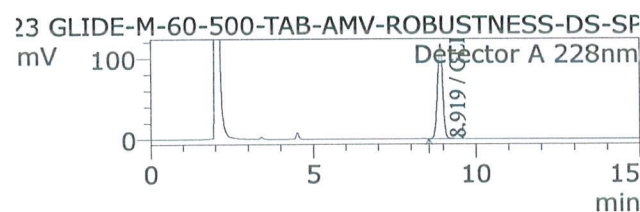
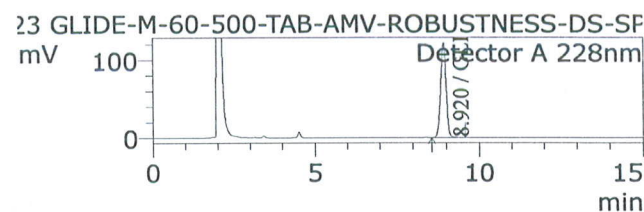
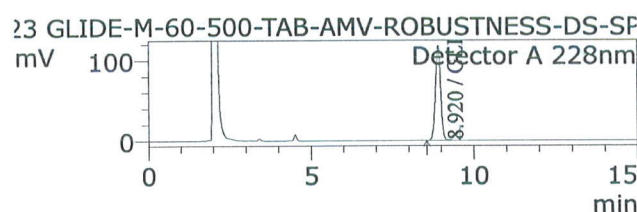
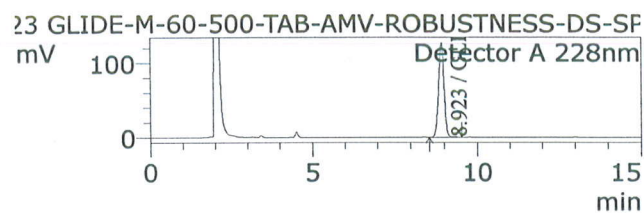
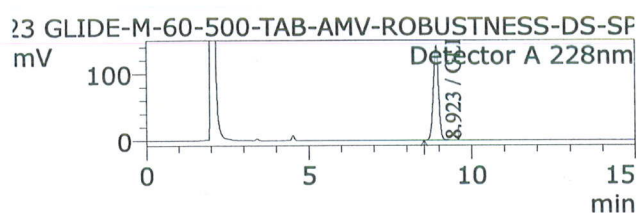
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDEM-60-500-891ML-5H-DS-SPL-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-14.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-9
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 16:03:45
 Date Processed : 26-09-2023 09:17:16

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

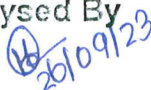
<Chromatogram>



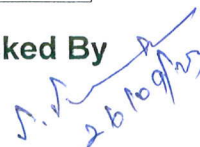
<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	DS-SPL-14.lcd	GLIDEM-60-500-891ML-5H-DS-SPL-1	8.92	1597605	13696	0.94
10	DS-SPL-15.lcd	GLIDEM-60-500-891ML-5H-DS-SPL-2	8.92	1431672	13711	0.95
11	DS-SPL-16.lcd	GLIDEM-60-500-891ML-5H-DS-SPL-3	8.92	1328372	13770	0.96
12	DS-SPL-17.lcd	GLIDEM-60-500-891ML-5H-DS-SPL-4	8.92	1370071	13774	0.96
13	DS-SPL-18.lcd	GLIDEM-60-500-891ML-5H-DS-SPL-5	8.92	1312940	13800	0.96
14	DS-SPL-19.lcd	GLIDEM-60-500-891ML-5H-DS-SPL-6	8.93	1591003	13750	0.95
	Average		8.92	1438611	13750	0.95
	%RSD		0.047	8.858	0.291	0.754

Analysed By

 25/09/23

Checked By


 26/09/23


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

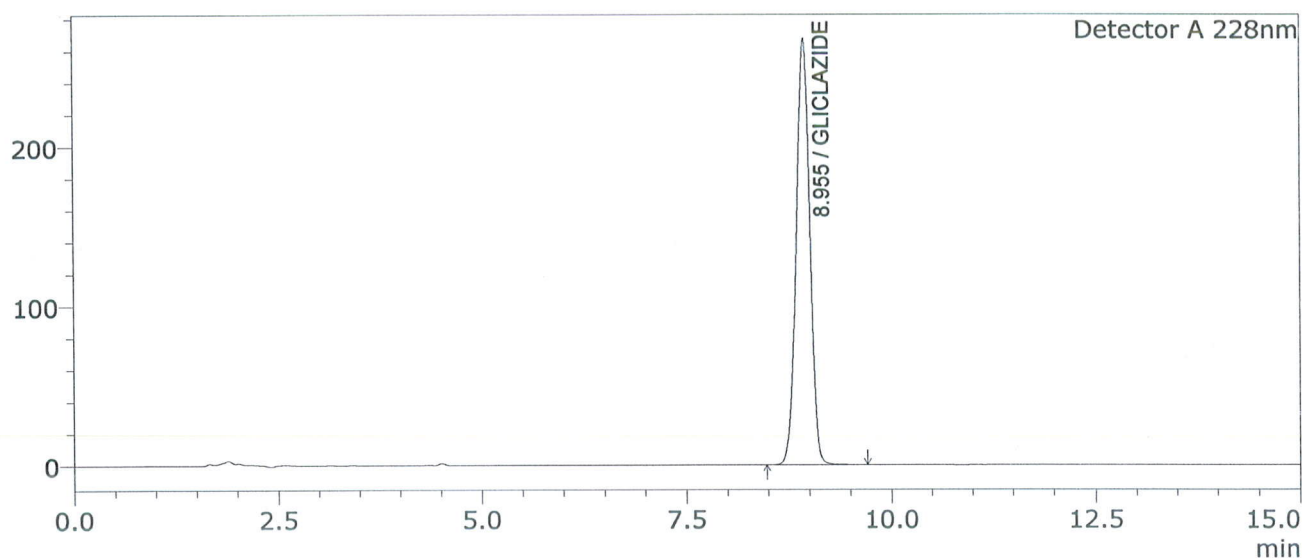
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-BKT-2
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-20.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 17:36:52
 Date Processed : 26-09-2023 09:17:16

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.95	3069559	100.00	13202	0.864	--	--
Total			3069559	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

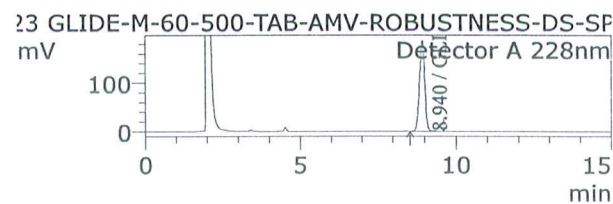
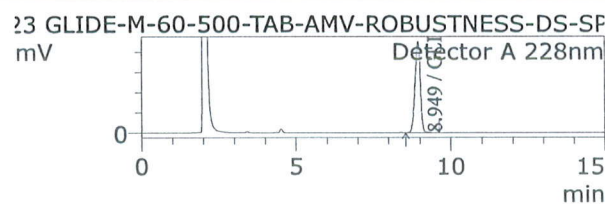
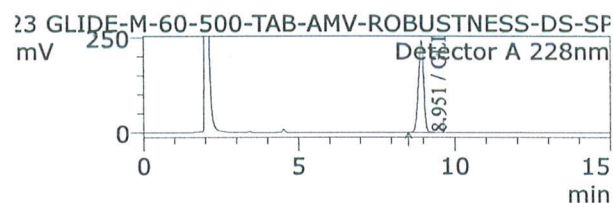
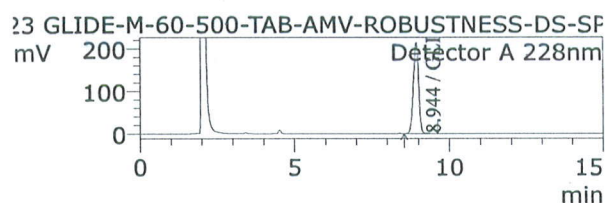
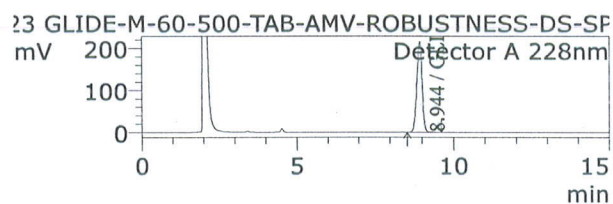
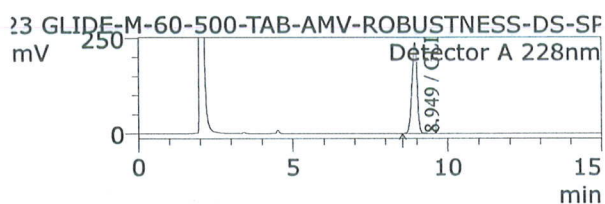
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDEM60-500-891ML-12H-DS-SPL-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-21.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-15
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 17:52:23
 Date Processed : 26-09-2023 09:17:16

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	DS-SPL-21.lcd	GLIDEM60-500-891ML-12H-DS-SPL-1	8.95	2727967	13255	0.88
16	DS-SPL-22.lcd	GLIDEM60-500-891ML-12H-DS-SPL-2	8.94	2661462	13384	0.90
17	DS-SPL-23.lcd	GLIDEM60-500-891ML-12H-DS-SPL-3	8.94	2638354	13386	0.90
18	DS-SPL-24.lcd	GLIDEM60-500-891ML-12H-DS-SPL-4	8.95	2747210	13263	0.89
19	DS-SPL-25.lcd	GLIDEM60-500-891ML-12H-DS-SPL-5	8.95	2572899	13309	0.89
20	DS-SPL-26.lcd	GLIDEM60-500-891ML-12H-DS-SPL-6	8.94	2725691	13491	0.91
	Average		8.95	2678931	13348	0.89
	%RSD		0.046	2.501	0.677	1.188

Analysed By

26/09/23

Checked By

26/09/23


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

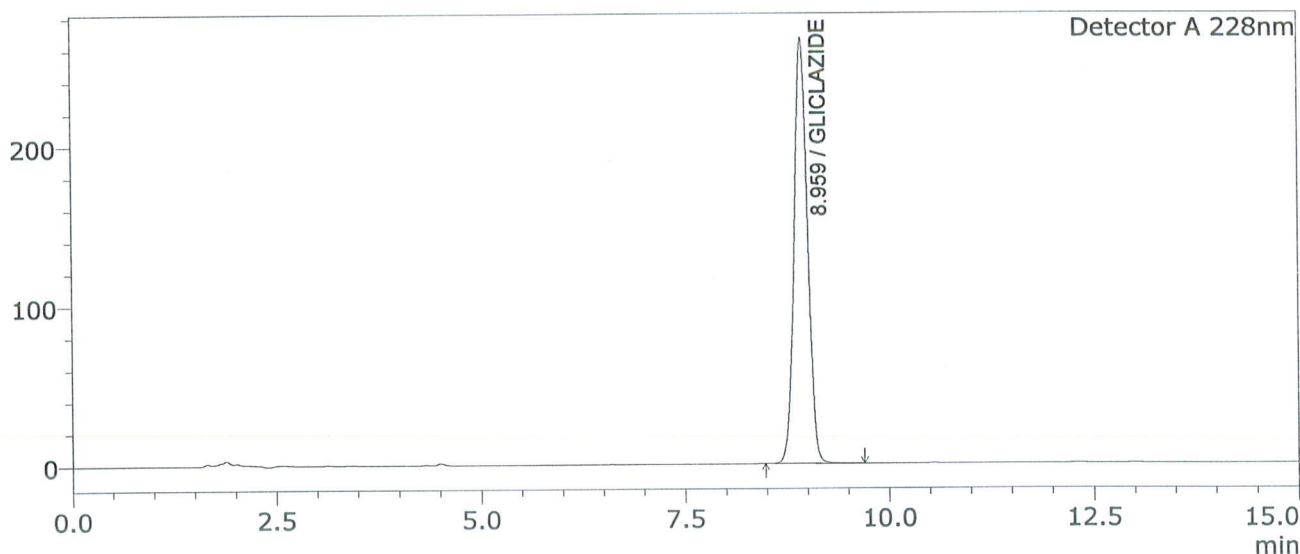
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-BKT-3
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-27.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 19:25:31
 Date Processed : 26-09-2023 09:17:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.96	3067547	100.00	13137	0.864	--	--
Total			3067547	100.00				

26/09/23

Analysed By

26/09/23

Checked By

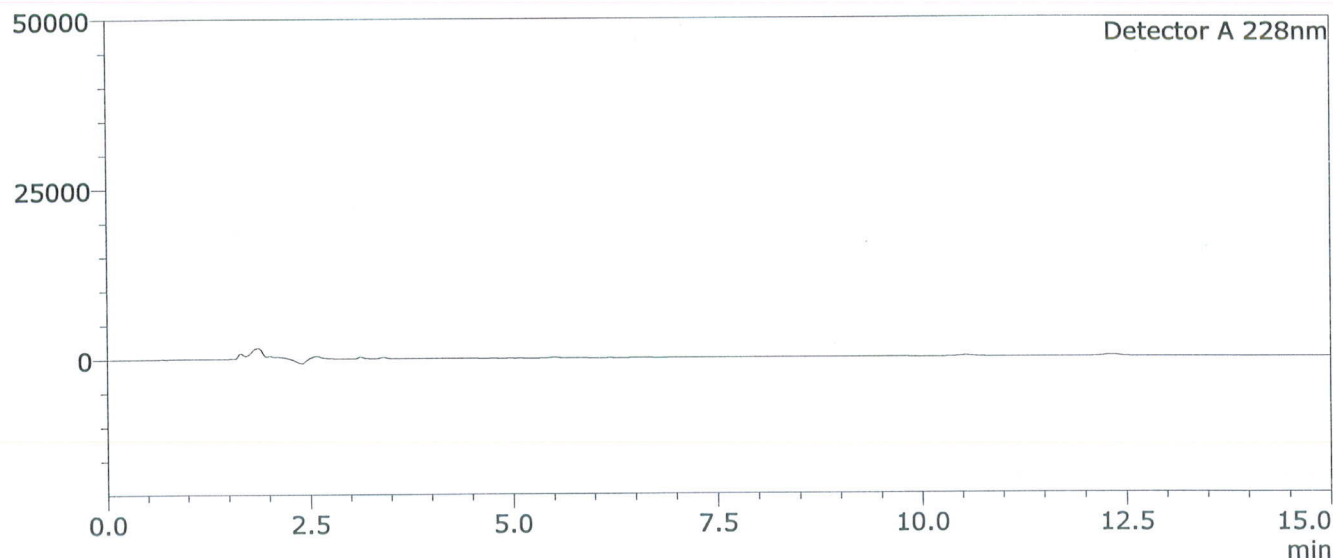

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-BLANK
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-28.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-21
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 19:41:02
 Date Processed : 26-09-2023 09:17:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV


<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

26/09/23

Analysed By

26/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

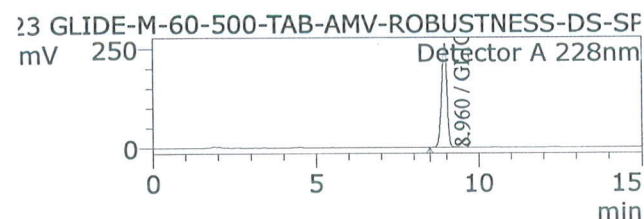
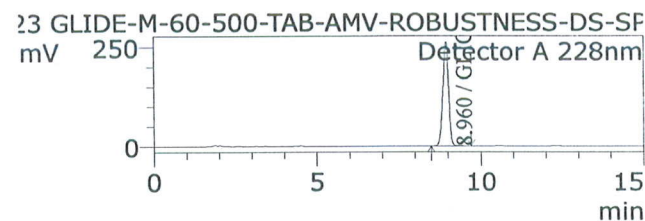
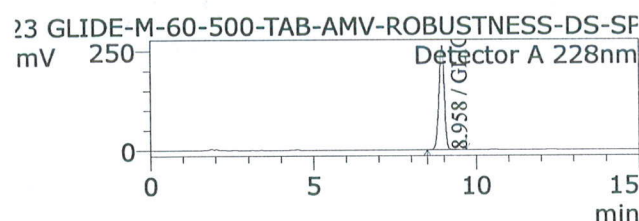
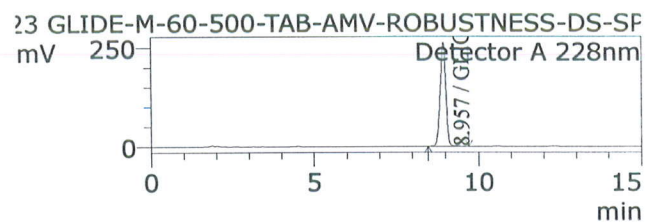
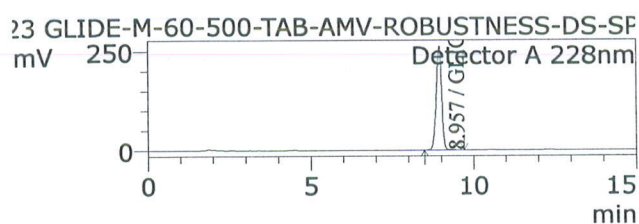
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-29.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-22
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 19:56:32
 Date Processed : 26-09-2023 09:17:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
22	DS-SPL-29.lcd	GLICLAZIDE-DS-STD-01	8.96	3012587	13185	0.87
22	DS-SPL-30.lcd	GLICLAZIDE-DS-STD-02	8.96	3013362	13173	0.87
22	DS-SPL-31.lcd	GLICLAZIDE-DS-STD-03	8.96	3013884	13157	0.87
22	DS-SPL-32.lcd	GLICLAZIDE-DS-STD-04	8.96	3014196	13174	0.87
22	DS-SPL-33.lcd	GLICLAZIDE-DS-STD-05	8.96	3014425	13170	0.87
	Average		8.96	3013691	13172	0.87
	%RSD		0.017	0.024	0.078	0.034

Analysed By

26/09/23

Checked By

26/09/23



GENERIC HEALTHCARE PVT. LTD.

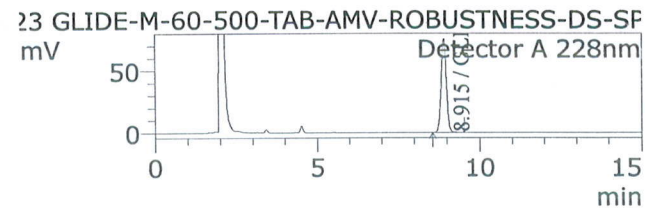
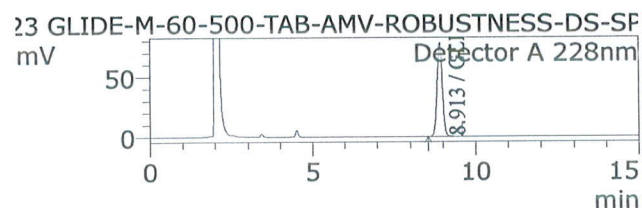
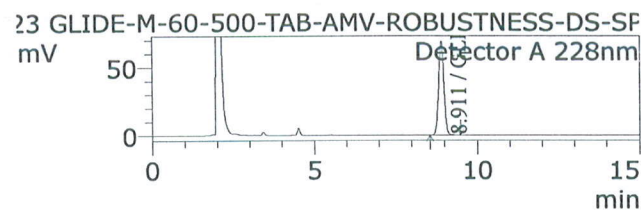
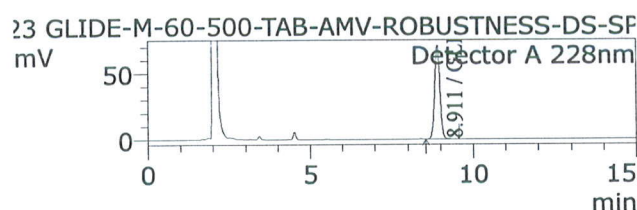
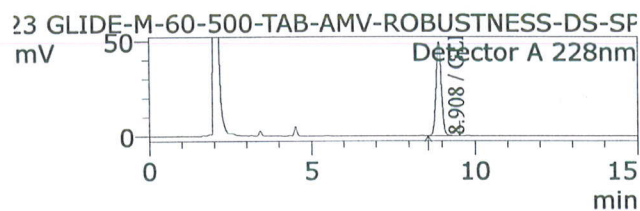
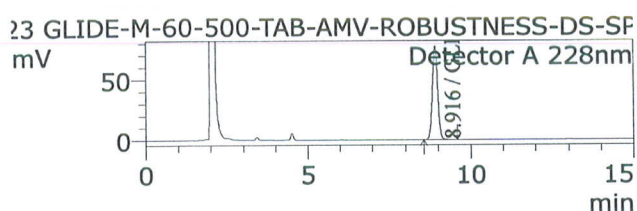
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDEM-60-500-909ML-2H-DS-SPL-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-34.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-23
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 21:14:06
 Date Processed : 26-09-2023 09:17:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
23	DS-SPL-34.lcd	GLIDEM-60-500-909ML-2H-DS-SPL-1	8.92	869810	13860	0.99
24	DS-SPL-35.lcd	GLIDEM-60-500-909ML-2H-DS-SPL-2	8.91	553445	13874	1.01
25	DS-SPL-36.lcd	GLIDEM-60-500-909ML-2H-DS-SPL-3	8.91	795041	13904	1.00
26	DS-SPL-37.lcd	GLIDEM-60-500-909ML-2H-DS-SPL-4	8.91	774127	13906	1.00
27	DS-SPL-38.lcd	GLIDEM-60-500-909ML-2H-DS-SPL-5	8.91	873798	13867	0.99
28	DS-SPL-39.lcd	GLIDEM-60-500-909ML-2H-DS-SPL-6	8.91	846193	13860	0.99
	Average		8.91	785403	13879	1.00
	%RSD		0.034	15.348	0.152	0.934

Analysed By

26/09/23

Checked By

26/09/23

D:\ST-QCLC-009\DATA-2023\GLIDE-M-60-500-850-TAB-AMV-DS\25092023
 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-34.lcd



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

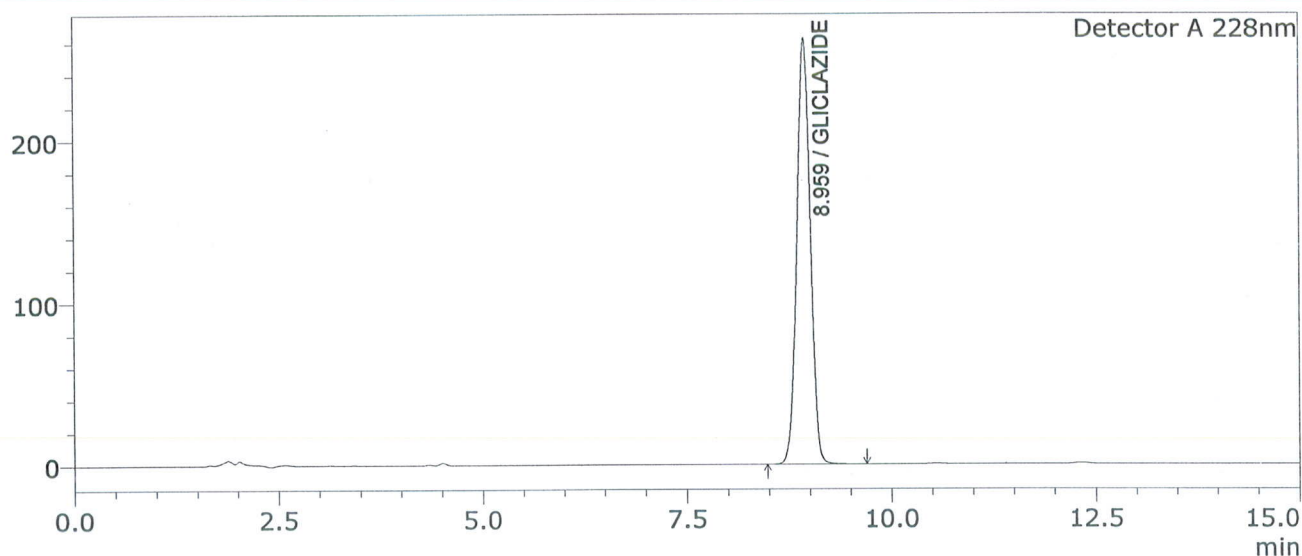
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-BKT-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-40.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-22
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 22:47:13
 Date Processed : 26-09-2023 09:17:18

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.96	3014262	100.00	13164	0.866	--	--
Total			3014262	100.00				

26/09/23

Analysed By

26/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

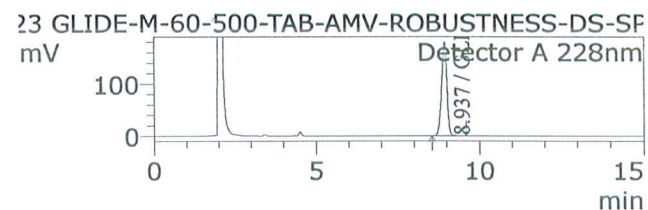
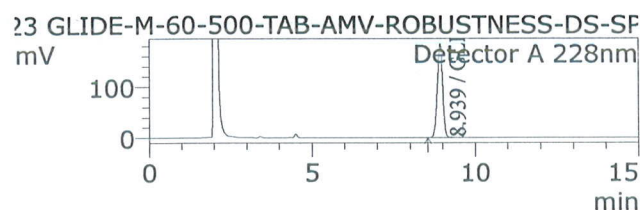
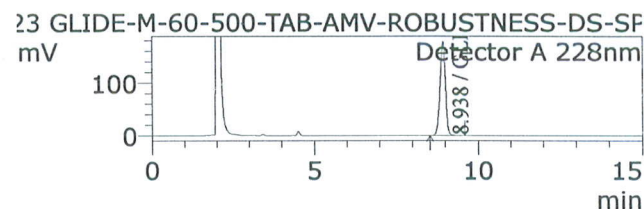
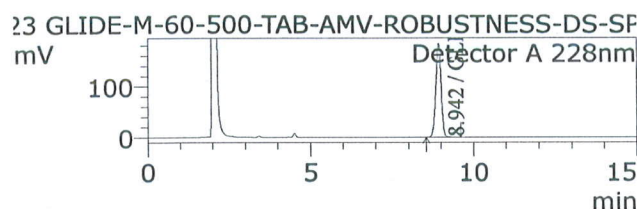
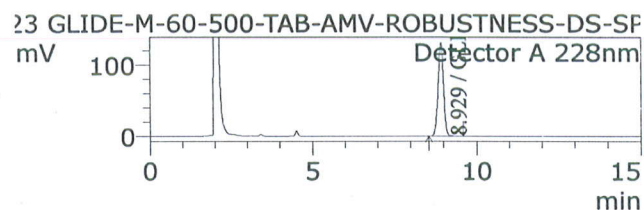
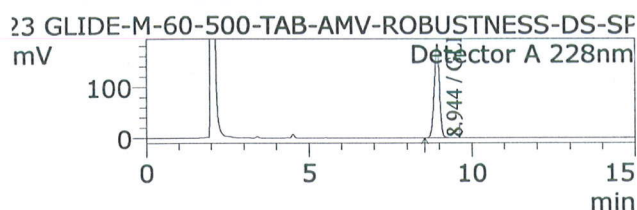
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDEM-60-500-909ML-5H-DS-SPL-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-41.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-29
 Injection Volume : 20 uL
 Date Acquired : 25-09-2023 23:02:44
 Date Processed : 26-09-2023 09:17:18

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
29	DS-SPL-41.lcd	GLIDEM-60-500-909ML-5H-DS-SPL-1	8.94	2082283	13521	0.91
30	DS-SPL-42.lcd	GLIDEM-60-500-909ML-5H-DS-SPL-2	8.93	1481677	13731	0.95
31	DS-SPL-43.lcd	GLIDEM-60-500-909ML-5H-DS-SPL-3	8.94	2086988	13537	0.91
32	DS-SPL-44.lcd	GLIDEM-60-500-909ML-5H-DS-SPL-4	8.94	2014232	13568	0.92
33	DS-SPL-45.lcd	GLIDEM-60-500-909ML-5H-DS-SPL-5	8.94	2083111	13568	0.91
34	DS-SPL-46.lcd	GLIDEM-60-500-909ML-5H-DS-SPL-6	8.94	2038445	13571	0.92
	Average		8.94	1964456	13583	0.92
	%RSD		0.058	12.132	0.554	1.479

Analysed By

26/09/23

Checked By

26/09/23

D:\ST-QCLC-009\DATA-2023\GLIDE-M-60-500-850-TAB-AMV-DS\25092023
 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-41.lcd



GENERIC HEALTHCARE PVT. LTD.

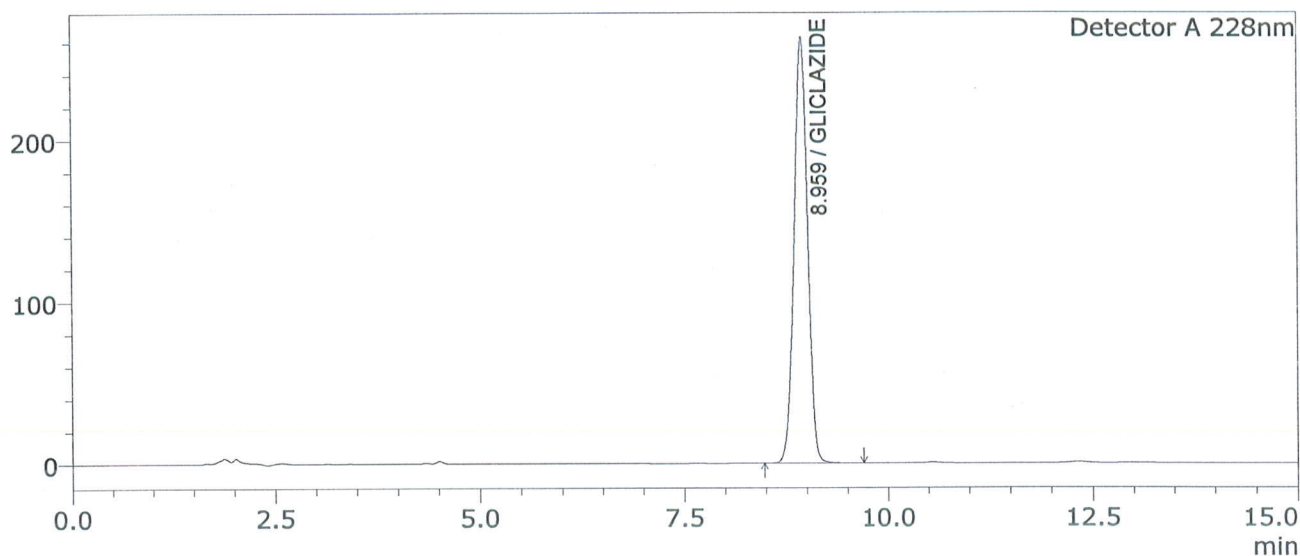
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-BKT-2
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-47.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-22
 Injection Volume : 20 uL
 Date Acquired : 26-09-2023 00:35:50
 Date Processed : 26-09-2023 09:17:18
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.96	3016206	100.00	13212	0.866	--	--
Total			3016206	100.00				

26/09/23

Analysed By

26/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

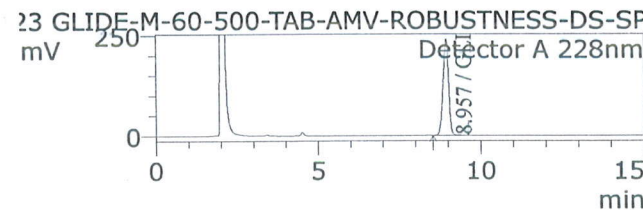
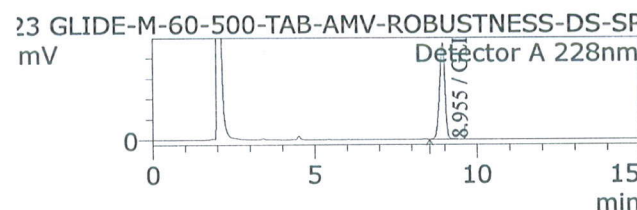
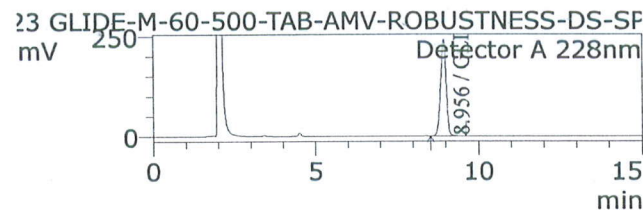
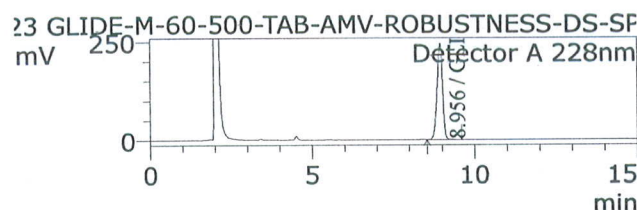
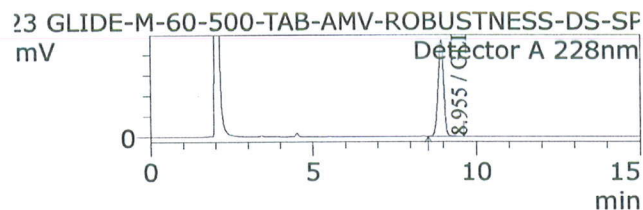
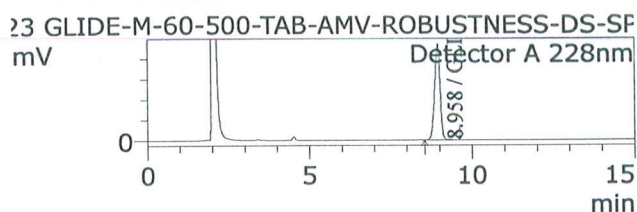
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDEM60-500-909ML-12H-DS-SPL-1
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-48.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-35
 Injection Volume : 20 uL
 Date Acquired : 26-09-2023 00:51:22
 Date Processed : 26-09-2023 09:17:18

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
35	DS-SPL-48.lcd	GLIDEM60-500-909ML-12H-DS-SPL-1	8.96	2686700	13328	0.89
36	DS-SPL-49.lcd	GLIDEM60-500-909ML-12H-DS-SPL-2	8.96	2673474	13334	0.89
37	DS-SPL-50.lcd	GLIDEM60-500-909ML-12H-DS-SPL-3	8.96	2801707	13277	0.88
38	DS-SPL-51.lcd	GLIDEM60-500-909ML-12H-DS-SPL-4	8.96	2756977	13281	0.88
39	DS-SPL-52.lcd	GLIDEM60-500-909ML-12H-DS-SPL-5	8.96	2685880	13315	0.89
40	DS-SPL-53.lcd	GLIDEM60-500-909ML-12H-DS-SPL-6	8.96	2739523	13274	0.88
	Average		8.96	2724043	13301	0.88
	%RSD		0.013	1.855	0.206	0.239

Analysed By

26/09/23

Checked By

26/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

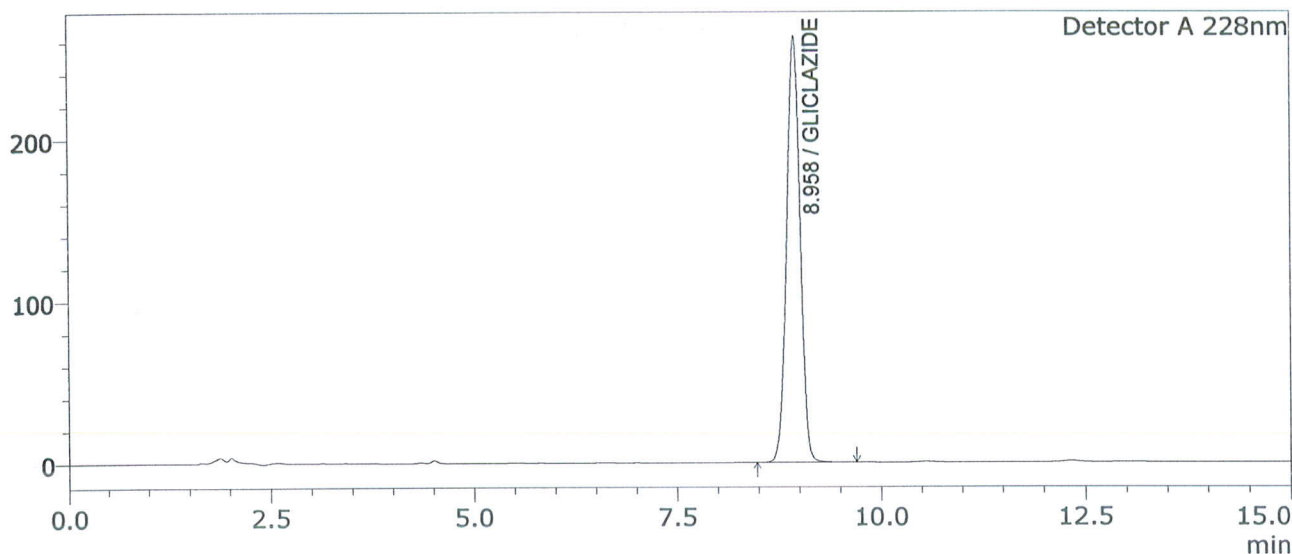
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-STD-BKT-3
 Data Filename : 25092023 GLIDE-M-60-500-TAB-AMV-ROBUSTNESS-DS-SPL-54.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 25092023 GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb
 Vial # : 3-22
 Injection Volume : 20 uL
 Date Acquired : 26-09-2023 02:24:28
 Date Processed : 26-09-2023 09:17:19

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV

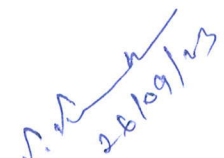


<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.96	3017680	100.00	13194	0.868	--	--
Total			3017680	100.00				


 26/09/23
 Analysed By


 26/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 25092023_GLIDE-M-60-500-AMV-DS-ROBUSTNESS.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	3	ROBUSTNESS	DS-BLANK	50-500-850-TAB-DS.lcm	NESS-DS-SPL-01.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-01	50-500-850-TAB-DS.lcm	NESS-DS-SPL-02.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-02	50-500-850-TAB-DS.lcm	NESS-DS-SPL-03.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-03	50-500-850-TAB-DS.lcm	NESS-DS-SPL-04.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-04	50-500-850-TAB-DS.lcm	NESS-DS-SPL-05.lcd	20.0	QC/CL/23/041
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-05	50-500-850-TAB-DS.lcm	NESS-DS-SPL-06.lcd	20.0	QC/CL/23/041
3	3	ROBUSTNESS	GLIDEM-60-500-891ML-2H-DS-SPL-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-07.lcd	20.0	QC/CL/23/041
4	3	ROBUSTNESS	GLIDEM-60-500-891ML-2H-DS-SPL-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-08.lcd	20.0	QC/CL/23/041
5	3	ROBUSTNESS	GLIDEM-60-500-891ML-2H-DS-SPL-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-09.lcd	20.0	QC/CL/23/041
6	3	ROBUSTNESS	GLIDEM-60-500-891ML-2H-DS-SPL-4	50-500-850-TAB-DS.lcm	NESS-DS-SPL-10.lcd	20.0	QC/CL/23/041
7	3	ROBUSTNESS	GLIDEM-60-500-891ML-2H-DS-SPL-5	50-500-850-TAB-DS.lcm	NESS-DS-SPL-11.lcd	20.0	QC/CL/23/041
8	3	ROBUSTNESS	GLIDEM-60-500-891ML-2H-DS-SPL-6	50-500-850-TAB-DS.lcm	NESS-DS-SPL-12.lcd	20.0	QC/CL/20/017
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-BKT-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-13.lcd	20.0	QC/CL/20/017
9	3	ROBUSTNESS	GLIDEM-60-500-891ML-5H-DS-SPL-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-14.lcd	20.0	QC/CL/20/017
10	3	ROBUSTNESS	GLIDEM-60-500-891ML-5H-DS-SPL-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-15.lcd	20.0	QC/CL/20/017
11	3	ROBUSTNESS	GLIDEM-60-500-891ML-5H-DS-SPL-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-16.lcd	20.0	QC/CL/20/017
12	3	ROBUSTNESS	GLIDEM-60-500-891ML-5H-DS-SPL-4	50-500-850-TAB-DS.lcm	NESS-DS-SPL-17.lcd	20.0	QC/CL/20/017
13	3	ROBUSTNESS	GLIDEM-60-500-891ML-5H-DS-SPL-5	50-500-850-TAB-DS.lcm	NESS-DS-SPL-18.lcd	20.0	QC/CL/20/017

Vial #	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
14	3	ROBUSTNESS	GLIDEM-60-500-891ML-5H-DS-SPL-6	50-500-850-TAB-DS.lcm	NESS-DS-SPL-19.lcd	20.0	QC/CL/20/017
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-BKT-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-20.lcd	20.0	QC/CL/20/017
15	3	ROBUSTNESS	GLIDEM60-500-891ML-12H-DS-SPL-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-21.lcd	20.0	QC/CL/20/017
16	3	ROBUSTNESS	GLIDEM60-500-891ML-12H-DS-SPL-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-22.lcd	20.0	QC/CL/20/017
17	3	ROBUSTNESS	GLIDEM60-500-891ML-12H-DS-SPL-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-23.lcd	20.0	QC/CL/20/017
18	3	ROBUSTNESS	GLIDEM60-500-891ML-12H-DS-SPL-4	50-500-850-TAB-DS.lcm	NESS-DS-SPL-24.lcd	20.0	QC/CL/20/017
19	3	ROBUSTNESS	GLIDEM60-500-891ML-12H-DS-SPL-5	50-500-850-TAB-DS.lcm	NESS-DS-SPL-25.lcd	20.0	QC/CL/20/017
20	3	ROBUSTNESS	GLIDEM60-500-891ML-12H-DS-SPL-6	50-500-850-TAB-DS.lcm	NESS-DS-SPL-26.lcd	20.0	QC/CL/20/017
2	3	ROBUSTNESS	GLICLAZIDE-DS-STD-BKT-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-27.lcd	20.0	QC/CL/20/017
21	3	ROBUSTNESS	DS-BLANK	50-500-850-TAB-DS.lcm	NESS-DS-SPL-28.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-01	50-500-850-TAB-DS.lcm	NESS-DS-SPL-29.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-02	50-500-850-TAB-DS.lcm	NESS-DS-SPL-30.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-03	50-500-850-TAB-DS.lcm	NESS-DS-SPL-31.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-04	50-500-850-TAB-DS.lcm	NESS-DS-SPL-32.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-05	50-500-850-TAB-DS.lcm	NESS-DS-SPL-33.lcd	20.0	QC/CL/20/017
23	3	ROBUSTNESS	GLIDEM-60-500-909ML-2H-DS-SPL-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-34.lcd	20.0	QC/CL/20/017
24	3	ROBUSTNESS	GLIDEM-60-500-909ML-2H-DS-SPL-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-35.lcd	20.0	QC/CL/20/017
25	3	ROBUSTNESS	GLIDEM-60-500-909ML-2H-DS-SPL-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-36.lcd	20.0	QC/CL/20/017
26	3	ROBUSTNESS	GLIDEM-60-500-909ML-2H-DS-SPL-4	50-500-850-TAB-DS.lcm	NESS-DS-SPL-37.lcd	20.0	QC/CL/20/017
27	3	ROBUSTNESS	GLIDEM-60-500-909ML-2H-DS-SPL-5	50-500-850-TAB-DS.lcm	NESS-DS-SPL-38.lcd	20.0	QC/CL/20/017
28	3	ROBUSTNESS	GLIDEM-60-500-909ML-2H-DS-SPL-6	50-500-850-TAB-DS.lcm	NESS-DS-SPL-39.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-BKT-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-40.lcd	20.0	QC/CL/20/017
29	3	ROBUSTNESS	GLIDEM-60-500-909ML-5H-DS-SPL-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-41.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
30	3	ROBUSTNESS	GLIDEM-60-500-909ML-5H-DS-SPL-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-42.lcd	20.0	QC/CL/20/017
31	3	ROBUSTNESS	GLIDEM-60-500-909ML-5H-DS-SPL-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-43.lcd	20.0	QC/CL/20/017
32	3	ROBUSTNESS	GLIDEM-60-500-909ML-5H-DS-SPL-4	50-500-850-TAB-DS.lcm	NESS-DS-SPL-44.lcd	20.0	QC/CL/20/017
33	3	ROBUSTNESS	GLIDEM-60-500-909ML-5H-DS-SPL-5	50-500-850-TAB-DS.lcm	NESS-DS-SPL-45.lcd	20.0	QC/CL/20/017
34	3	ROBUSTNESS	GLIDEM-60-500-909ML-5H-DS-SPL-6	50-500-850-TAB-DS.lcm	NESS-DS-SPL-46.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-BKT-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-47.lcd	20.0	QC/CL/20/017
35	3	ROBUSTNESS	GLIDEM60-500-909ML-12H-DS-SPL-1	50-500-850-TAB-DS.lcm	NESS-DS-SPL-48.lcd	20.0	QC/CL/20/017
36	3	ROBUSTNESS	GLIDEM60-500-909ML-12H-DS-SPL-2	50-500-850-TAB-DS.lcm	NESS-DS-SPL-49.lcd	20.0	QC/CL/20/017
37	3	ROBUSTNESS	GLIDEM60-500-909ML-12H-DS-SPL-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-50.lcd	20.0	QC/CL/20/017
38	3	ROBUSTNESS	GLIDEM60-500-909ML-12H-DS-SPL-4	50-500-850-TAB-DS.lcm	NESS-DS-SPL-51.lcd	20.0	QC/CL/20/017
39	3	ROBUSTNESS	GLIDEM60-500-909ML-12H-DS-SPL-5	50-500-850-TAB-DS.lcm	NESS-DS-SPL-52.lcd	20.0	QC/CL/20/017
40	3	ROBUSTNESS	GLIDEM60-500-909ML-12H-DS-SPL-6	50-500-850-TAB-DS.lcm	NESS-DS-SPL-53.lcd	20.0	QC/CL/20/017
22	3	ROBUSTNESS	GLICLAZIDE-DS-STD-BKT-3	50-500-850-TAB-DS.lcm	NESS-DS-SPL-54.lcd	20.0	QC/CL/20/017
-1	3	ROBUSTNESS	WASH	THOD-100%-WATER.lcm	NESS-DS-SPL-55.lcd	20.0	QC/CL/20/017
-1	3	ROBUSTNESS	WASH	WASHING METHOD.lcm	NESS-DS-SPL-56.lcd	20.0	QC/CL/20/017
-1	3	ROBUSTNESS	SHUTDOWN	ETHOD\SHUTDOWN.lcm	NESS-DS-SPL-57.lcd	20.0	QC/CL/20/017

26/09/23

Analysed By

26/09/23

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	ROBUSTNESS	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QC/LC/009	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	--------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution.:	66.48	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.48	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution.:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.666	1	ml to --->	1	ml to --->	1	ml to --->	1

Chromatographic variation's	Theoretical plate	Tailing factor	% RSD	Remarks
Limits	Not less than 2000	Not more than 2.0	Not more than 2.0%	Not applicable
Assuch (system suitability)	14026	0.927	0.016	Not applicable
Low wavelength (225nm)	12709	0.870	0.038	Robustness
High wavelength (231nm)	12646	0.870	0.049	Robustness
Low flow rate (0.9ml/minute)	13440	0.860	0.034	Robustness
High flow rate (1.1ml/minute)	11952	0.880	0.024	Robustness
Low Oven Temperature 20°C	12323	0.890	0.025	Robustness
High Oven Temperature 30°C	12737	0.850	0.019	Robustness

Results:

Each chromatographic Condition Variation System suitability parameters are within limits.

Acceptance criteria:

System suitability should comply for each variable.

Analysed by :

E.MEENA

Date :

25-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

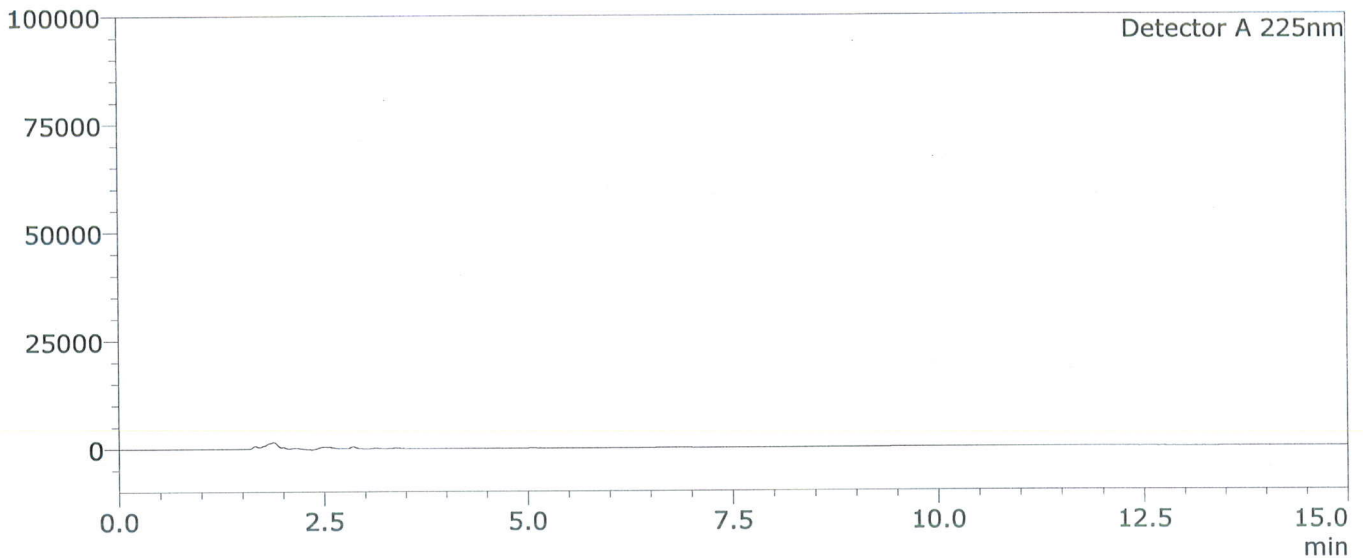
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-LWL-BLANK
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-01.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-LOW WAVE LENGTH_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-41
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 13:04:24
 Date Processed : 25-09-2023 09:57:47
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV



<Peak Table>

Detector A 225nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

25/09/23

Checked By

25/09/23



GENERIC HEALTHCARE PVT. LTD.

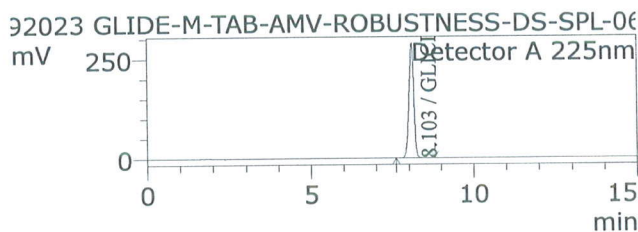
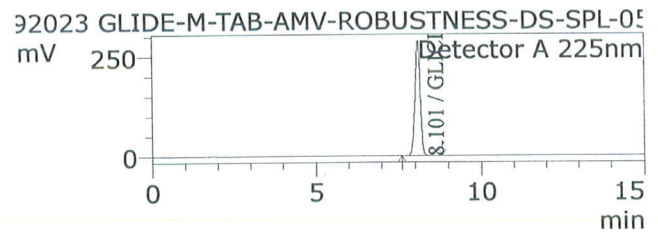
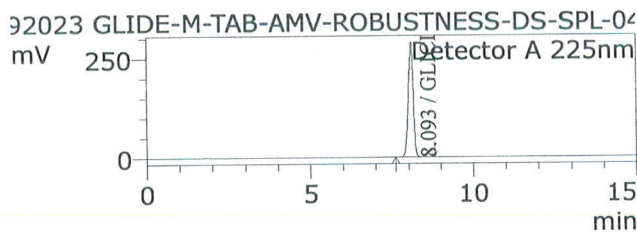
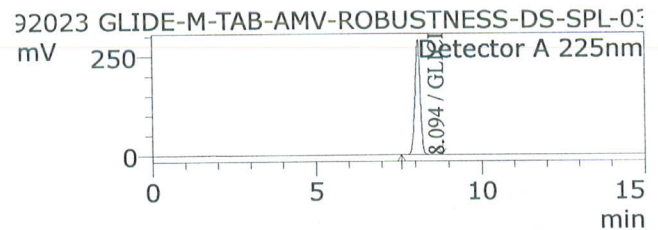
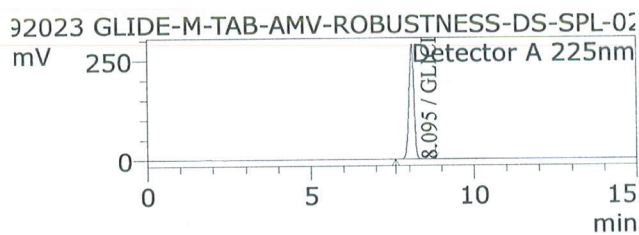
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-LWL-STD-1
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-02.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-LOW WAVE LENGTH_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-42
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 13:19:57
 Date Processed : 25-09-2023 09:57:47

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
42	DS-SPL-02.lcd	GLICLAZIDE-DS-LWL-STD-1	8.10	3034569	12702	0.87
42	DS-SPL-03.lcd	GLICLAZIDE-DS-LWL-STD-2	8.09	3035007	12727	0.87
42	DS-SPL-04.lcd	GLICLAZIDE-DS-LWL-STD-3	8.09	3032872	12727	0.87
42	DS-SPL-05.lcd	GLICLAZIDE-DS-LWL-STD-4	8.10	3032411	12706	0.87
42	DS-SPL-06.lcd	GLICLAZIDE-DS-LWL-STD-5	8.10	3032991	12684	0.87
	Average		8.10	3033570	12709	0.87
	%RSD		0.055	0.038	0.142	0.158

Analysed By

25/09/23

Checked By

25/09/23



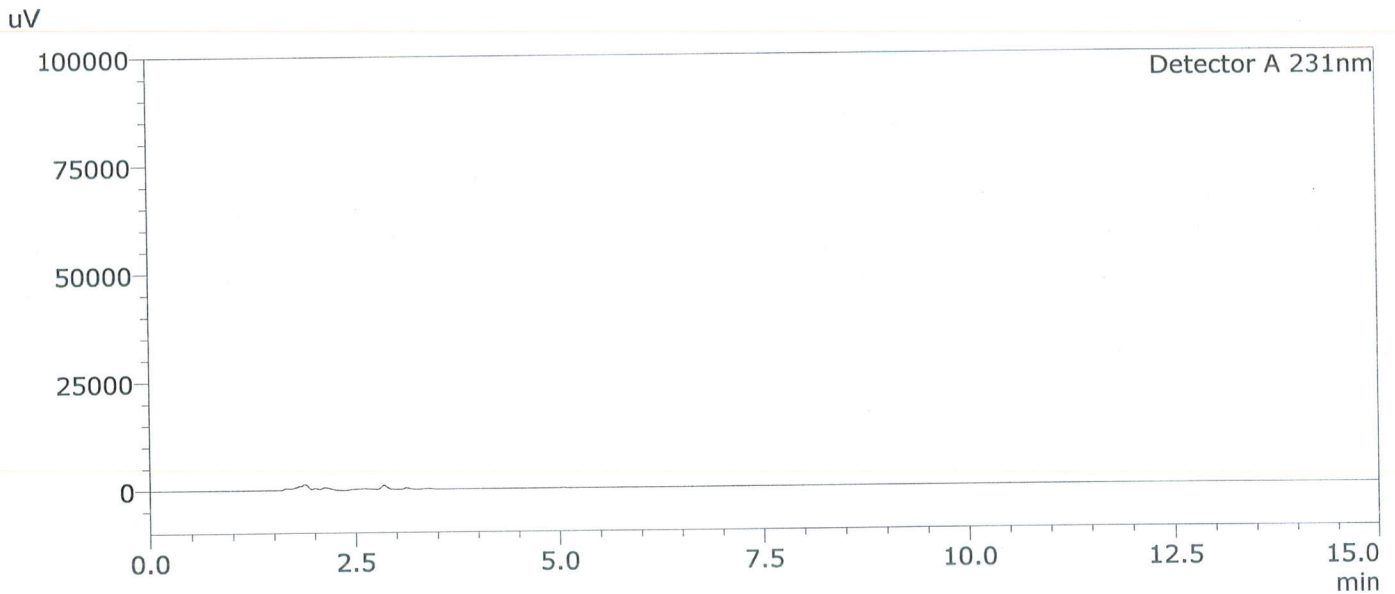
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-HWL-BLANK
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-07.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-HIGH WAVE LENGTH_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-43
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 14:37:45
 Date Processed : 25-09-2023 10:02:02
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 231nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

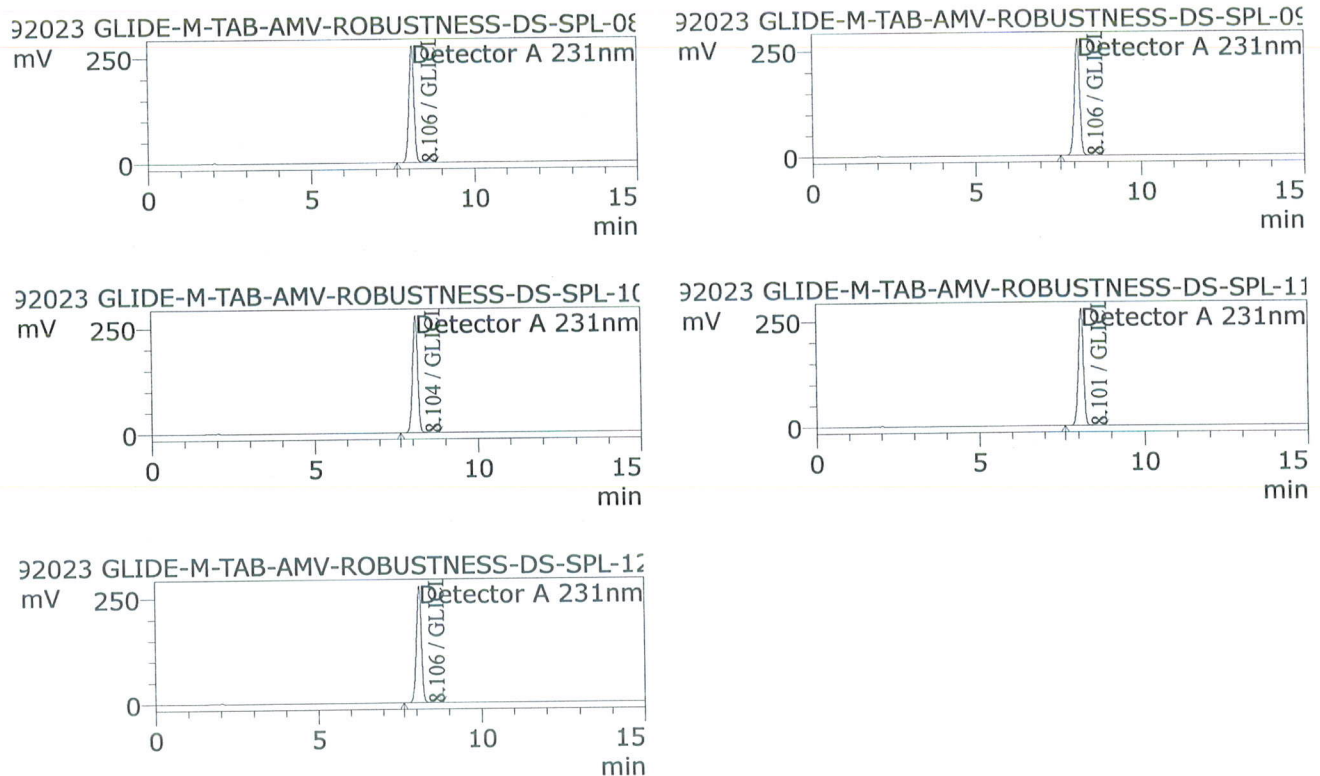
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-HWL-STD-1
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-08.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-HIGH WAVE LENGTH_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-44
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 14:53:19
 Date Processed : 25-09-2023 10:02:02

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
44	DS-SPL-08.lcd	GLICLAZIDE-DS-HWL-STD-1	8.11	2918652	12620	0.87
44	DS-SPL-09.lcd	GLICLAZIDE-DS-HWL-STD-2	8.11	2921750	12644	0.87
44	DS-SPL-10.lcd	GLICLAZIDE-DS-HWL-STD-3	8.10	2921464	12670	0.87
44	DS-SPL-11.lcd	GLICLAZIDE-DS-HWL-STD-4	8.10	2920098	12680	0.87
44	DS-SPL-12.lcd	GLICLAZIDE-DS-HWL-STD-5	8.11	2918868	12617	0.87
	Average		8.10	2920166	12646	0.87
	%RSD		0.028	0.049	0.226	0.036

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

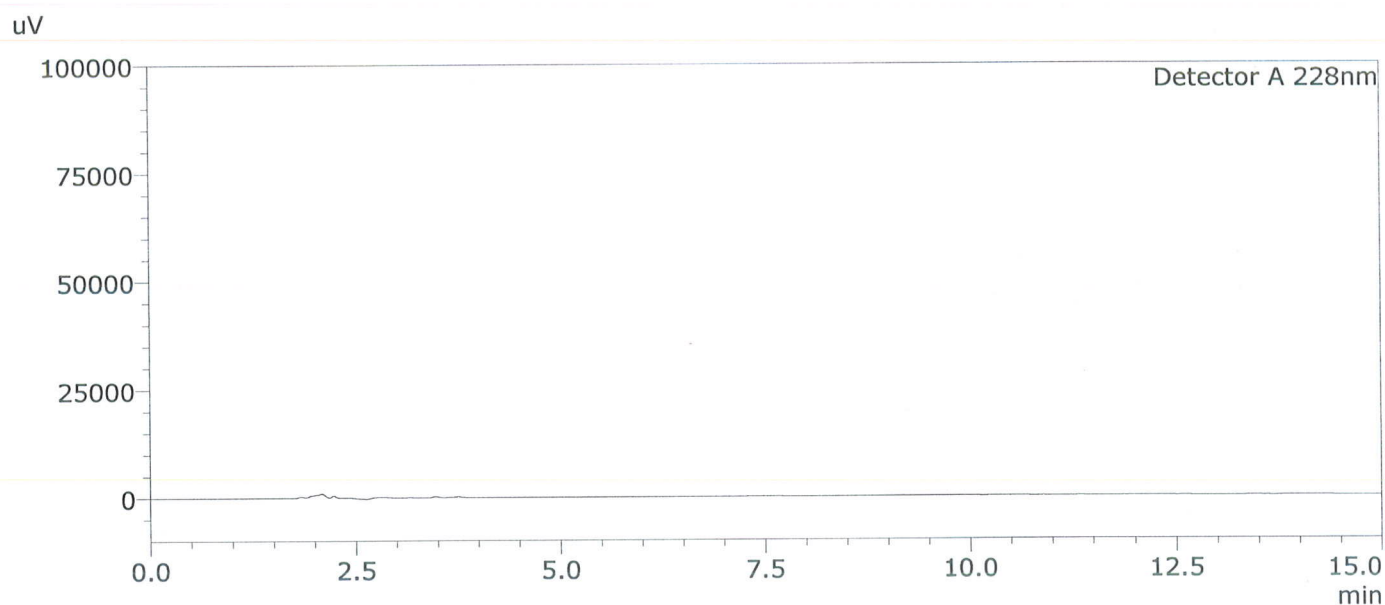
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-LOW FLOW-BLANK
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-13.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-LOW FLOW_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-45
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 16:11:10
 Date Processed : 25-09-2023 10:05:40

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

25/09/23

Analysed By

25/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

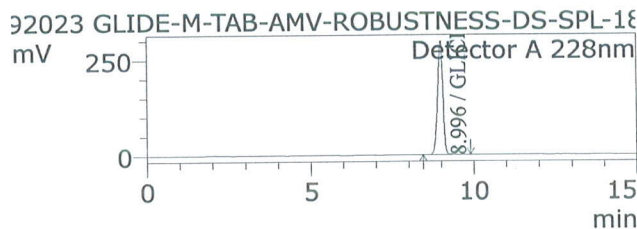
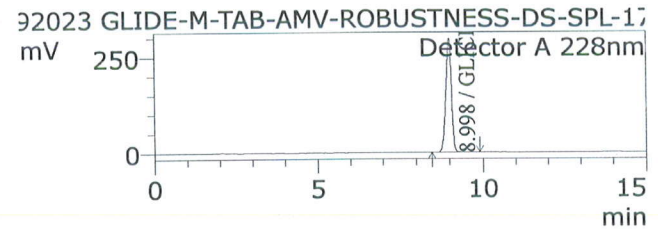
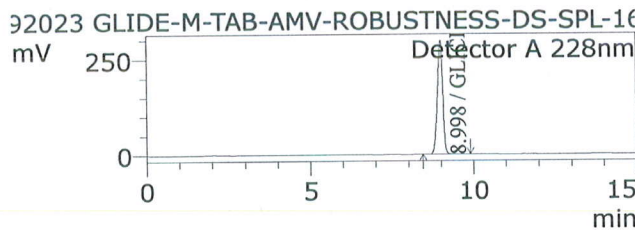
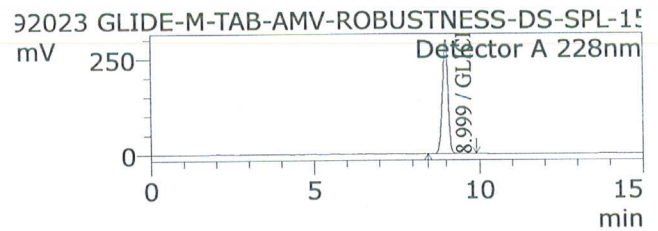
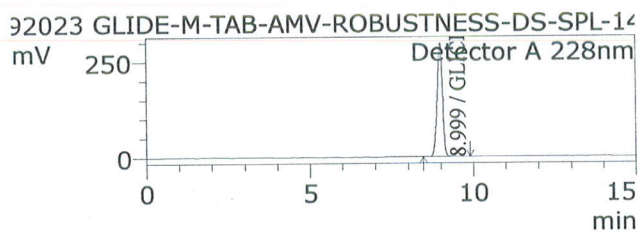
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-LOW FLOW-STD-1
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-14.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-LOW FLOW_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-46
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 16:26:43
 Date Processed : 25-09-2023 10:05:40

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
46	DS-SPL-14.lcd	GLICLAZIDE-DS-LOW FLOW-STD-1	9.00	3394062	13434	0.86
46	DS-SPL-15.lcd	GLICLAZIDE-DS-LOW FLOW-STD-2	9.00	3393471	13440	0.86
46	DS-SPL-16.lcd	GLICLAZIDE-DS-LOW FLOW-STD-3	9.00	3396048	13431	0.86
46	DS-SPL-17.lcd	GLICLAZIDE-DS-LOW FLOW-STD-4	9.00	3396046	13447	0.86
46	DS-SPL-18.lcd	GLICLAZIDE-DS-LOW FLOW-STD-5	9.00	3395118	13448	0.86
	Average		9.00	3394949	13440	0.86
	%RSD		0.015	0.034	0.056	0.039

Analysed By

(Signature)
25/09/23

Checked By

(Signature)
25/09/23

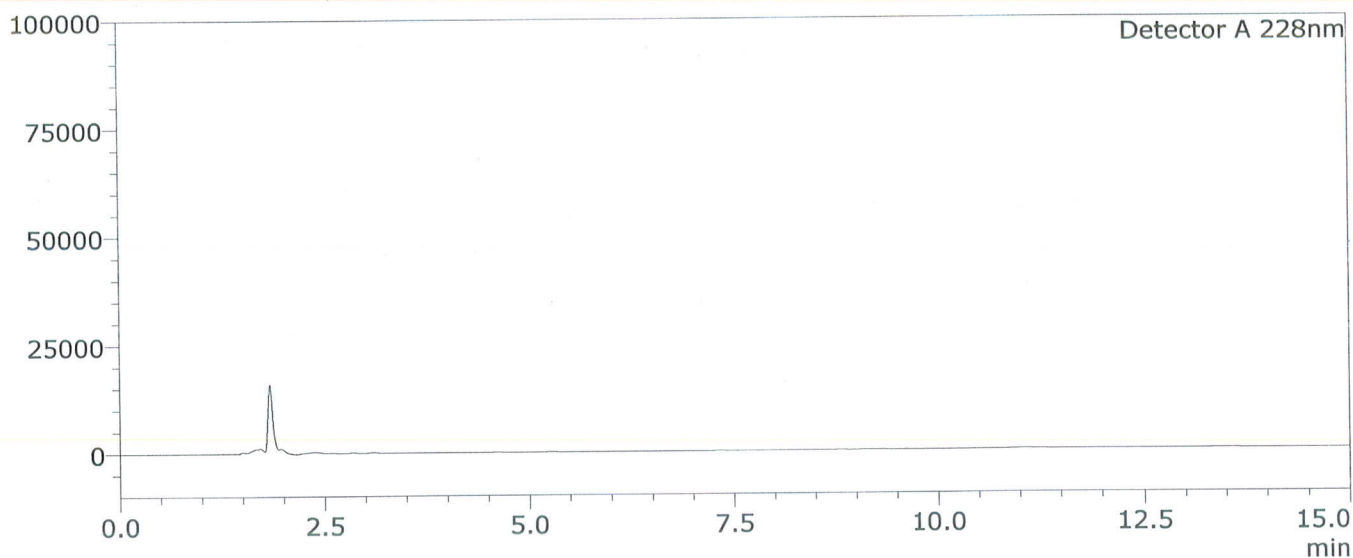

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-HIGH FLOW-BLANK
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-19.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-HIGH FLOW_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-47
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 17:44:27
 Date Processed : 25-09-2023 10:08:19

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV


<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By
Checked By



GENERIC HEALTHCARE PVT. LTD.

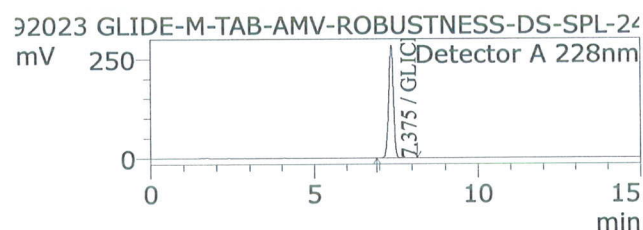
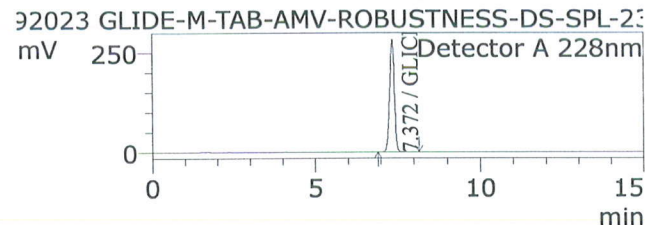
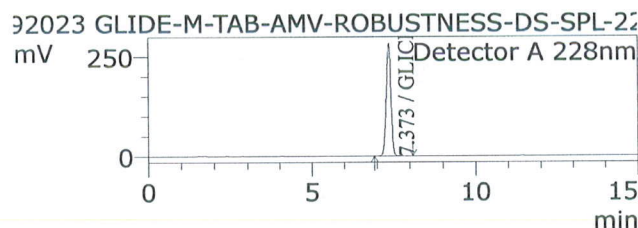
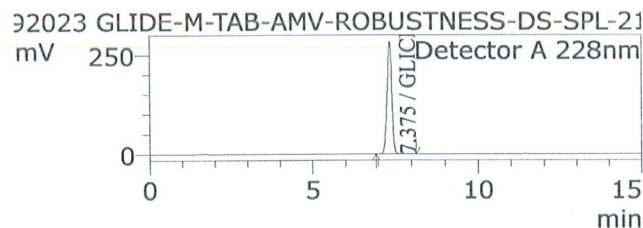
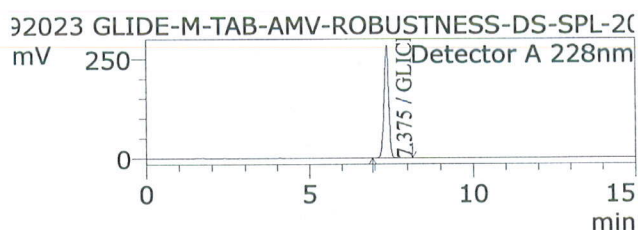
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-HIGH FLOW-STD-1
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-20.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-HIGH FLOW_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-48
 Injection Volume : 20 µL
 Date Acquired : 23-09-2023 17:59:58
 Date Processed : 25-09-2023 10:08:19

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
48	DS-SPL-20.lcd	GLICLAZIDE-DS-HIGH FLOW-STD-1	7.38	2782851	11941	0.88
48	DS-SPL-21.lcd	GLICLAZIDE-DS-HIGH FLOW-STD-2	7.37	2783265	11943	0.88
48	DS-SPL-22.lcd	GLICLAZIDE-DS-HIGH FLOW-STD-3	7.37	2783771	11964	0.88
48	DS-SPL-23.lcd	GLICLAZIDE-DS-HIGH FLOW-STD-4	7.37	2782813	11973	0.88
48	DS-SPL-24.lcd	GLICLAZIDE-DS-HIGH FLOW-STD-5	7.38	2784373	11937	0.88
	Average		7.37	2783414	11952	0.88
	%RSD		0.019	0.024	0.133	0.028

Analysed By

(Signature)
25/09/23

Checked By

(Signature)
25/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

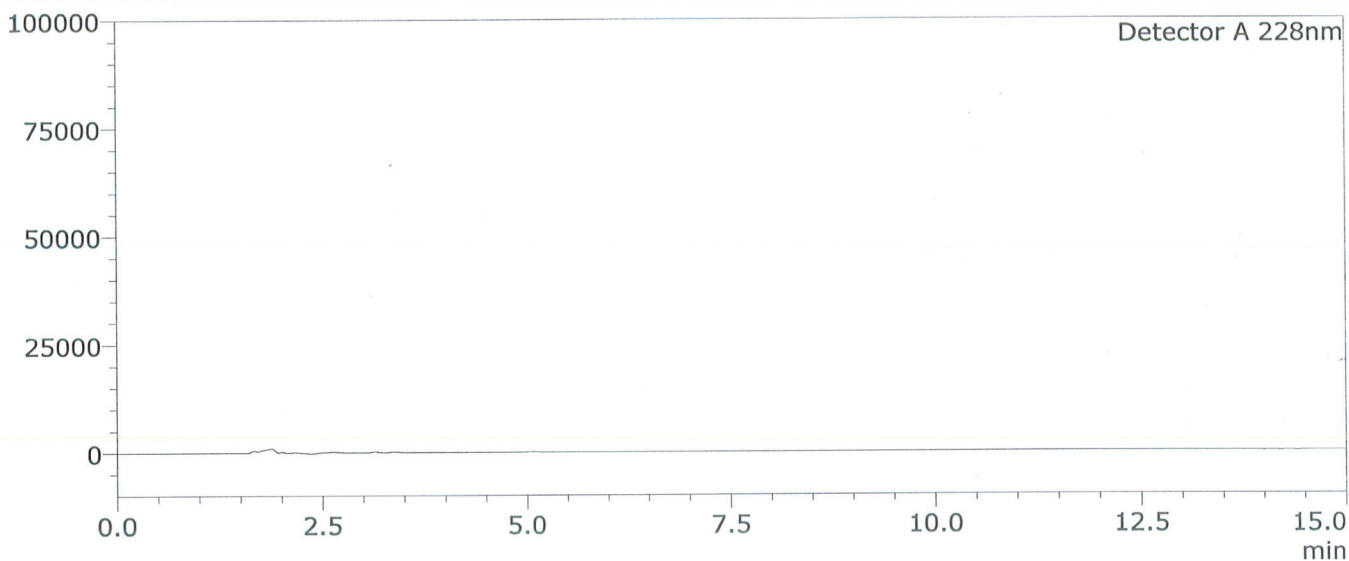
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-LOW TEMP-BLANK
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-25.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-LOW TEMP_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-49
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 19:22:51
 Date Processed : 25-09-2023 10:10:29

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

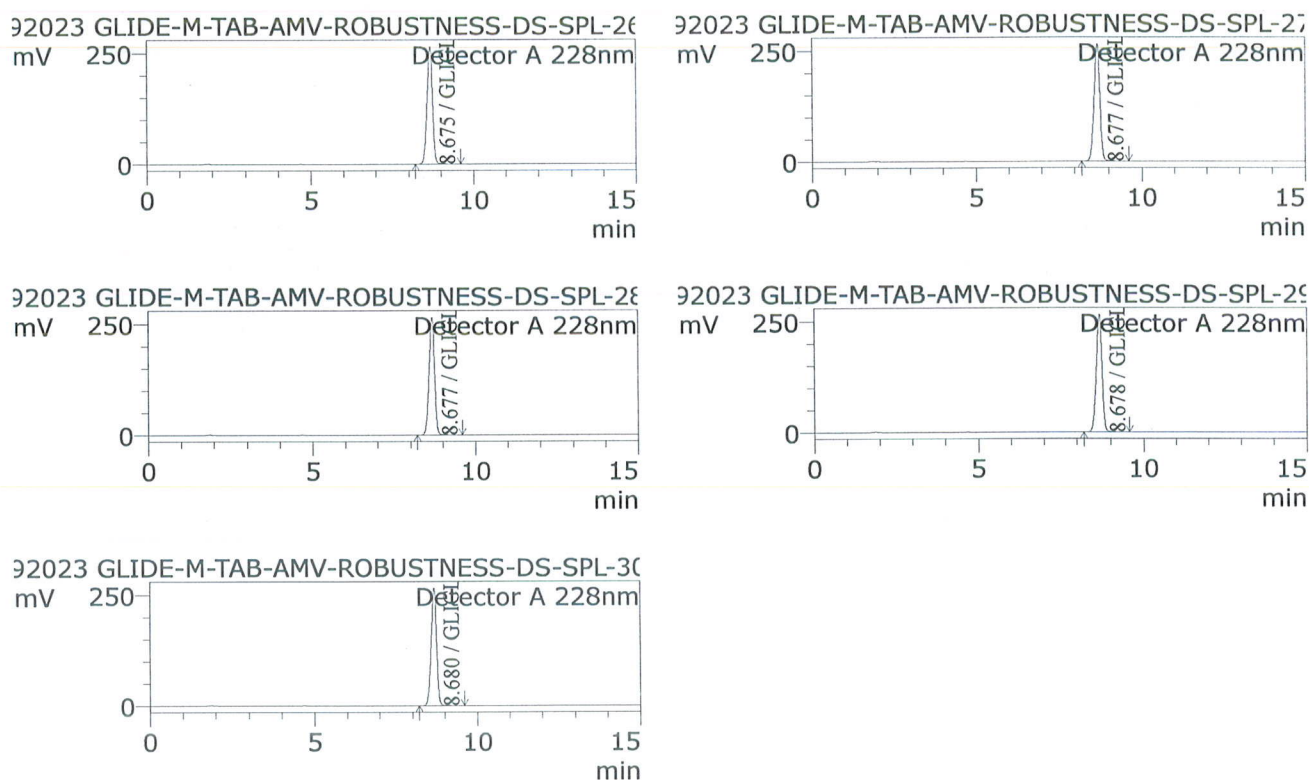
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-LOW TEMP-STD-1
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-26.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-LOW TEMP_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-50
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 19:38:23
 Date Processed : 25-09-2023 10:10:30

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
50	DS-SPL-26.lcd	GLICLAZIDE-DS-LOW TEMP-STD-1	8.68	3056143	12323	0.89
50	DS-SPL-27.lcd	GLICLAZIDE-DS-LOW TEMP-STD-2	8.68	3057423	12323	0.89
50	DS-SPL-28.lcd	GLICLAZIDE-DS-LOW TEMP-STD-3	8.68	3055654	12323	0.89
50	DS-SPL-29.lcd	GLICLAZIDE-DS-LOW TEMP-STD-4	8.68	3056399	12312	0.89
50	DS-SPL-30.lcd	GLICLAZIDE-DS-LOW TEMP-STD-5	8.68	3055510	12336	0.89
	Average		8.68	3056226	12323	0.89
	%RSD		0.018	0.025	0.070	0.027

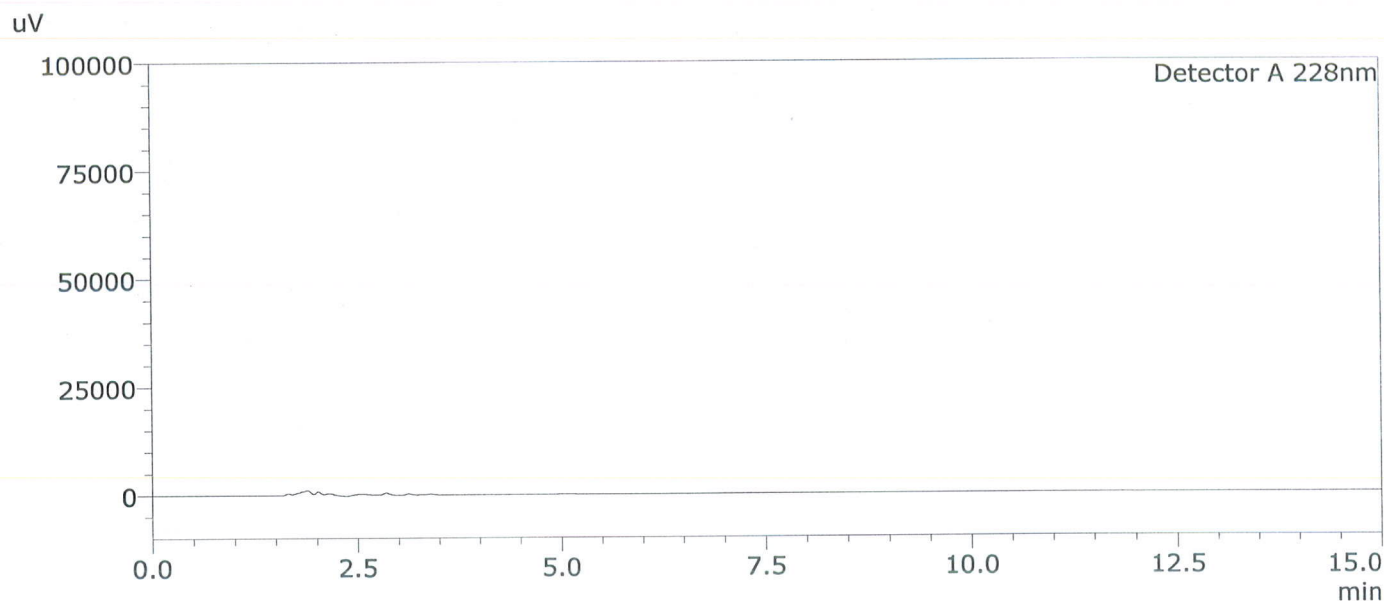
Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : DS-HIGH TEMP-BLANK
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-31.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-HIGH TEMP_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-51
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 21:01:55
 Date Processed : 25-09-2023 10:12:45

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

25/09/23

Analysed By

25/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

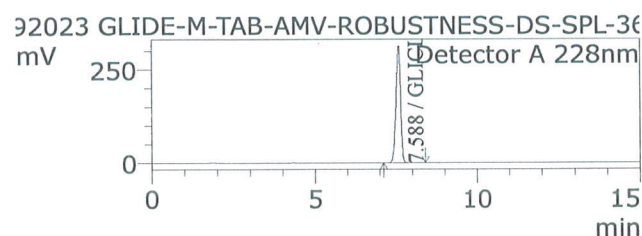
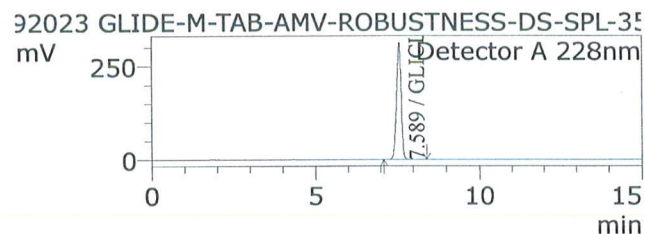
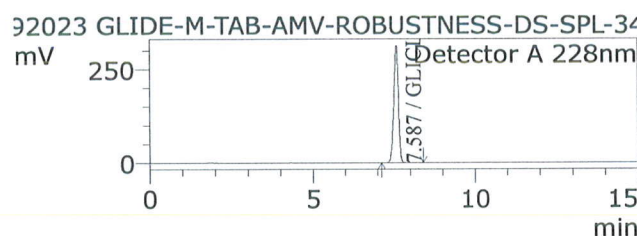
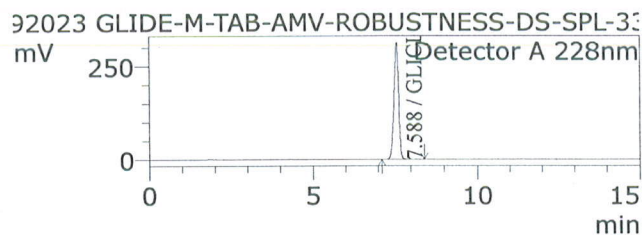
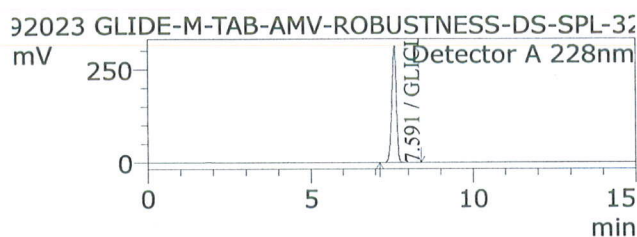
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLAZIDE-DS-HIGH TEMP-STD-1
 Data Filename : 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-32.lcd
 Method Filename : GLIDE M-60-500-850-TAB-DS-HIGH TEMP_P.lcm
 Batch Filename : 23092023 GLIDE-M-60-500-850-AMV-DS-ROBUSTNESS.lcb
 Vial # : 1-52
 Injection Volume : 20 µL
 Date Acquired : 23-09-2023 21:17:27
 Date Processed : 25-09-2023 10:12:45

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
52	DS-SPL-32.lcd	GLICLAZIDE-DS-HIGH TEMP-STD-1	7.59	3062923	12730	0.85
52	DS-SPL-33.lcd	GLICLAZIDE-DS-HIGH TEMP-STD-2	7.59	3063550	12745	0.85
52	DS-SPL-34.lcd	GLICLAZIDE-DS-HIGH TEMP-STD-3	7.59	3064548	12734	0.85
52	DS-SPL-35.lcd	GLICLAZIDE-DS-HIGH TEMP-STD-4	7.59	3063748	12741	0.85
52	DS-SPL-36.lcd	GLICLAZIDE-DS-HIGH TEMP-STD-5	7.59	3063741	12736	0.85
	Average		7.59	3063702	12737	0.85
	%RSD		0.021	0.019	0.047	0.034

Analysed By

25/09/23

Checked By

25/09/23



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 23092023 GLIDE-M-TAB-AMV-ROBUSTNESS-DS-SPL-32.lcd

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
41	1	ROBUSTNESS	DS-LWL-BLANK	-DS-LOW WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-01.lcd	20.0	QC/CL/20/017
42	1	ROBUSTNESS	GLICLAZIDE-DS-LWL-STD-1	-DS-LOW WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-02.lcd	20.0	QC/CL/20/017
42	1	ROBUSTNESS	GLICLAZIDE-DS-LWL-STD-2	-DS-LOW WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-03.lcd	20.0	QC/CL/20/017
42	1	ROBUSTNESS	GLICLAZIDE-DS-LWL-STD-3	-DS-LOW WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-04.lcd	20.0	QC/CL/20/017
42	1	ROBUSTNESS	GLICLAZIDE-DS-LWL-STD-4	-DS-LOW WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-05.lcd	20.0	QC/CL/20/017
42	1	ROBUSTNESS	GLICLAZIDE-DS-LWL-STD-5	-DS-LOW WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-06.lcd	20.0	QC/CL/20/017
43	1	ROBUSTNESS	DS-HWL-BLANK	DS-HIGH WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-07.lcd	20.0	QC/CL/20/017
44	1	ROBUSTNESS	GLICLAZIDE-DS-HWL-STD-1	DS-HIGH WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-08.lcd	20.0	QC/CL/20/017
44	1	ROBUSTNESS	GLICLAZIDE-DS-HWL-STD-2	DS-HIGH WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-09.lcd	20.0	QC/CL/20/017
44	1	ROBUSTNESS	GLICLAZIDE-DS-HWL-STD-3	DS-HIGH WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-10.lcd	20.0	QC/CL/20/017
44	1	ROBUSTNESS	GLICLAZIDE-DS-HWL-STD-4	DS-HIGH WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-11.lcd	20.0	QC/CL/20/017
44	1	ROBUSTNESS	GLICLAZIDE-DS-HWL-STD-5	DS-HIGH WAVE LENGTH.lcm	ROBUSTNESS-DS-SPL-12.lcd	20.0	QC/CL/20/017
45	1	ROBUSTNESS	DS-LOW FLOW-BLANK	-850-TAB-DS-LOW FLOW.lcm	ROBUSTNESS-DS-SPL-13.lcd	20.0	QC/CL/20/017
46	1	ROBUSTNESS	GLICLAZIDE-DS-LOW FLOW-STD-1	-850-TAB-DS-LOW FLOW.lcm	ROBUSTNESS-DS-SPL-14.lcd	20.0	QC/CL/20/017
46	1	ROBUSTNESS	GLICLAZIDE-DS-LOW FLOW-STD-2	-850-TAB-DS-LOW FLOW.lcm	ROBUSTNESS-DS-SPL-15.lcd	20.0	QC/CL/20/017
46	1	ROBUSTNESS	GLICLAZIDE-DS-LOW FLOW-STD-3	-850-TAB-DS-LOW FLOW.lcm	ROBUSTNESS-DS-SPL-16.lcd	20.0	QC/CL/20/017
46	1	ROBUSTNESS	GLICLAZIDE-DS-LOW FLOW-STD-4	-850-TAB-DS-LOW FLOW.lcm	ROBUSTNESS-DS-SPL-17.lcd	20.0	QC/CL/20/017
46	1	ROBUSTNESS	GLICLAZIDE-DS-LOW FLOW-STD-5	-850-TAB-DS-LOW FLOW.lcm	ROBUSTNESS-DS-SPL-18.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
47	1	ROBUSTNESS	DS-HIGH FLOW-BLANK	850-TAB-DS-HIGH FLOW.lcm	ROBUSTNESS-DS-SPL-19.lcd	20.0	QC/CL/20/017
48	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH FLOW-STD-1	850-TAB-DS-HIGH FLOW.lcm	ROBUSTNESS-DS-SPL-20.lcd	20.0	QC/CL/20/017
48	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH FLOW-STD-2	850-TAB-DS-HIGH FLOW.lcm	ROBUSTNESS-DS-SPL-21.lcd	20.0	QC/CL/20/017
48	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH FLOW-STD-3	850-TAB-DS-HIGH FLOW.lcm	ROBUSTNESS-DS-SPL-22.lcd	20.0	QC/CL/20/017
48	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH FLOW-STD-4	850-TAB-DS-HIGH FLOW.lcm	ROBUSTNESS-DS-SPL-23.lcd	20.0	QC/CL/20/017
48	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH FLOW-STD-5	850-TAB-DS-HIGH FLOW.lcm	ROBUSTNESS-DS-SPL-24.lcd	20.0	QC/CL/20/017
49	1	ROBUSTNESS	DS-LOW TEMP-BLANK	850-TAB-DS-LOW TEMP.lcm	ROBUSTNESS-DS-SPL-25.lcd	20.0	QC/CL/20/017
50	1	ROBUSTNESS	GLICLAZIDE-DS-LOW TEMP-STD-1	850-TAB-DS-LOW TEMP.lcm	ROBUSTNESS-DS-SPL-26.lcd	20.0	QC/CL/20/017
50	1	ROBUSTNESS	GLICLAZIDE-DS-LOW TEMP-STD-2	850-TAB-DS-LOW TEMP.lcm	ROBUSTNESS-DS-SPL-27.lcd	20.0	QC/CL/20/017
50	1	ROBUSTNESS	GLICLAZIDE-DS-LOW TEMP-STD-3	850-TAB-DS-LOW TEMP.lcm	ROBUSTNESS-DS-SPL-28.lcd	20.0	QC/CL/20/017
50	1	ROBUSTNESS	GLICLAZIDE-DS-LOW TEMP-STD-4	850-TAB-DS-LOW TEMP.lcm	ROBUSTNESS-DS-SPL-29.lcd	20.0	QC/CL/20/017
50	1	ROBUSTNESS	GLICLAZIDE-DS-LOW TEMP-STD-5	850-TAB-DS-LOW TEMP.lcm	ROBUSTNESS-DS-SPL-30.lcd	20.0	QC/CL/20/017
51	1	ROBUSTNESS	DS-HIGH TEMP-BLANK	850-TAB-DS-HIGH TEMP.lcm	ROBUSTNESS-DS-SPL-31.lcd	20.0	QC/CL/20/017
52	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH TEMP-STD-1	850-TAB-DS-HIGH TEMP.lcm	ROBUSTNESS-DS-SPL-32.lcd	20.0	QC/CL/20/017
52	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH TEMP-STD-2	850-TAB-DS-HIGH TEMP.lcm	ROBUSTNESS-DS-SPL-33.lcd	20.0	QC/CL/20/017
52	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH TEMP-STD-3	850-TAB-DS-HIGH TEMP.lcm	ROBUSTNESS-DS-SPL-34.lcd	20.0	QC/CL/20/017
52	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH TEMP-STD-4	850-TAB-DS-HIGH TEMP.lcm	ROBUSTNESS-DS-SPL-35.lcd	20.0	QC/CL/20/017
52	1	ROBUSTNESS	GLICLAZIDE-DS-HIGH TEMP-STD-5	850-TAB-DS-HIGH TEMP.lcm	ROBUSTNESS-DS-SPL-36.lcd	20.0	QC/CL/20/017
-1	1	ROBUSTNESS	WASH	1 METHOD-100%-WATER.lcm	ROBUSTNESS-DS-SPL-37.lcd	20.0	QC/CL/20/017
-1	1	ROBUSTNESS	WASH	HOD\WASHING METHOD.lcm	ROBUSTNESS-DS-SPL-38.lcd	20.0	QC/CL/20/017
-1	1	SHUTDOWN	SHUTDOWN	D9\METHOD\SHUTDOWN.lcm	ROBUSTNESS-DS-SPL-39.lcd	20.0	QC/CL/20/017

Analysed By



Checked By



23/09/23

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	SPECIFICITY	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Gliclazide std:	66.22	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.22	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.666	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No.	Sample ID.	Peak Name	Retention time	Peak purity
1	Blank	Blank peaks	Refer chromatogram	Not applicable
2	Standard preparation	Gliclazide	9.213	1.000
3	Blank	Blank peaks	Refer chromatogram	Not applicable
4	Gliclazide WS	Gliclazide	9.215	1.000
5	Metformin WS	Metformin	2.033	1.000
6	Blank	Blank peaks	Refer chromatogram	Not applicable
7	Plain placebo for Glide-M 60/500	Placebo peaks	Refer chromatogram	Not applicable
8	Plain placebo for Glide-M 60/850	Placebo peaks	Refer chromatogram	Not applicable
9	Plain placebo with Gliclazide WS	Gliclazide	9.22	1.000
10	Plain placebo with Metformin Hcl WS	Metformin	2.04	0.995
11	Plain placebo + Gliclazide WS+ Metformin Hcl WS	Gliclazide	9.218	0.987
		Metformin	2.037	0.995
12	Blank	Blank peaks	Refer chromatogram	Not applicable
13	Test preparation for Glide-M 60/500 B.No: G1722093	Gliclazide	9.215	0.994
		Metformin	2.053	0.999
14	Test preparation for Glide-M 60/850 B.No: G17230801	Gliclazide	9.219	0.999
		Metformin	2.064	0.991

Results :

- 1) Blank peaks, Placebo peaks are not interfere with test preparation.
- 2) Peak purity passes within specified limits.

Acceptance criteria:

- 1) Should No significant interference from blank, placebo peaks.
- 2) Peak purity should not be less than 0.995 according to Lab Solution Software.

Analysed by :

E.MEENA

Date :

20-09-2023

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

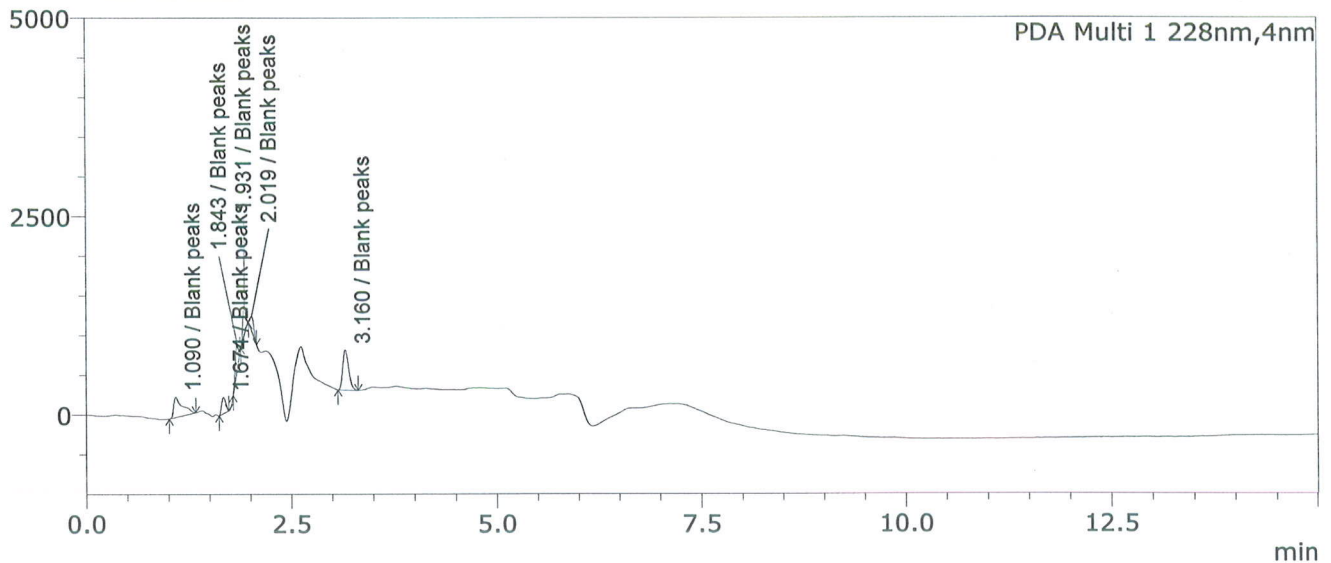
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-98.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 18:34:22
 Date Processed : 20-09-2023 10:05:41

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peaks	1.09	1946	25.21	629	2.633	--	--
2	Blank peaks	1.67	759	9.83	3873	1.117	4.144	--
3	Blank peaks	1.84	1029	13.33	9974	0.841	1.873	--
4	Blank peaks	1.93	961	12.46	11312	1.021	1.200	--
5	Blank peaks	2.02	498	6.45	8512	1.344	1.100	--
6	Blank peaks	3.16	2525	32.72	7026	1.295	9.569	--
Total			7718	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

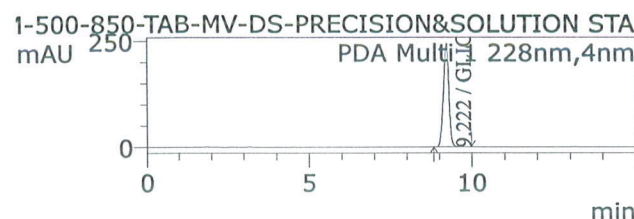
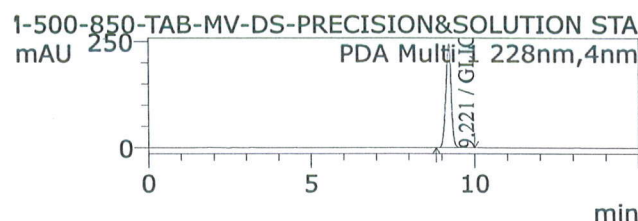
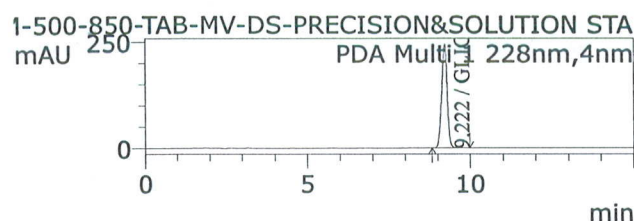
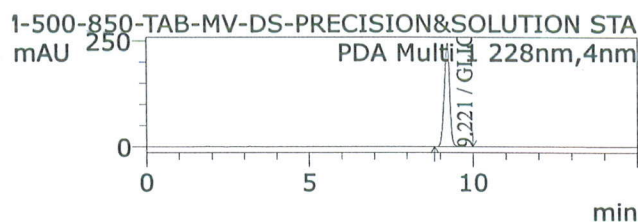
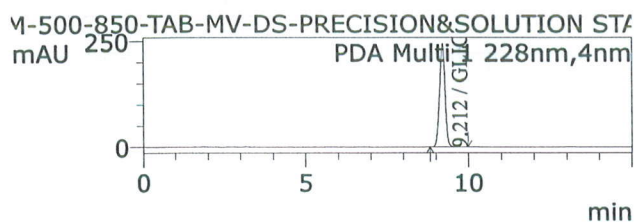
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-99
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 18:49:56
 Date Processed : 20-09-2023 10:23:28

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	TY-SPL-99.lcd	GLICLAZIDE-DS-STD-01	9.21	2831622	13483	0.92
3	Y-SPL-100.lcd	GLICLAZIDE-DS-STD-02	9.22	2830794	13522	0.92
3	Y-SPL-101.lcd	GLICLAZIDE-DS-STD-03	9.22	2829717	13523	0.92
3	Y-SPL-102.lcd	GLICLAZIDE-DS-STD-04	9.22	2829282	13494	0.92
3	Y-SPL-103.lcd	GLICLAZIDE-DS-STD-05	9.22	2828840	13516	0.92
	Average		9.22	2830051	13508	0.92
	%RSD		0.043	0.040	0.134	0.060

Analysed By

20/09/23

Checked By

21/09/23


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

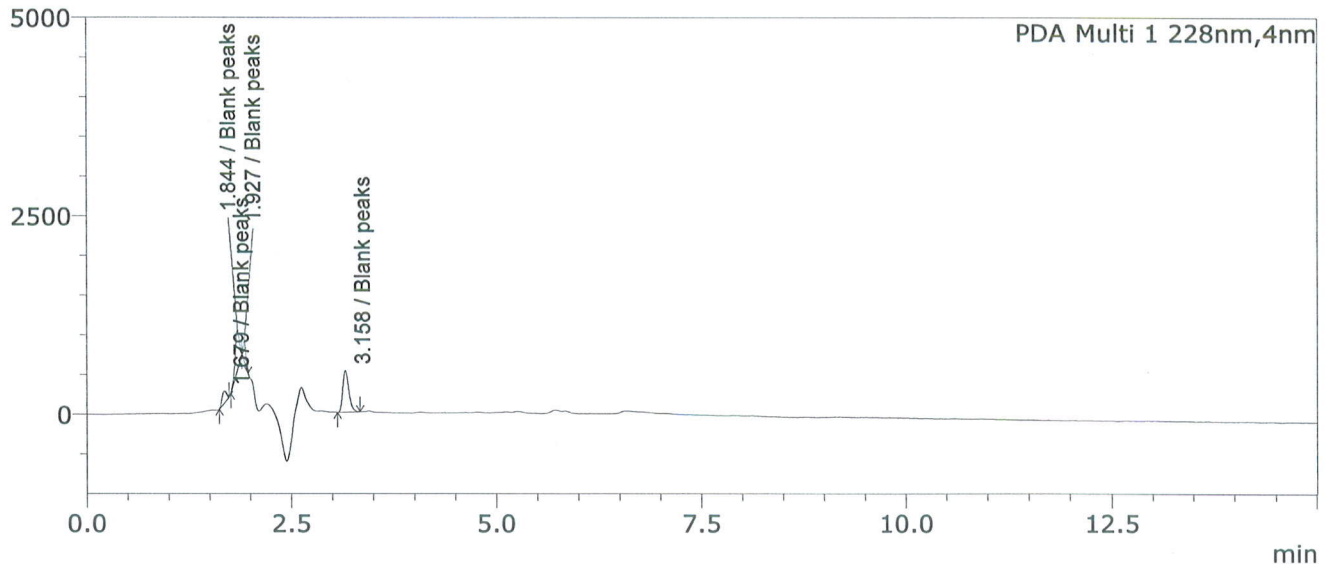
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-104.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 20:07:44
 Date Processed : 20-09-2023 10:10:11

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peaks	1.68	618	10.73	3838	1.011	--	--
2	Blank peaks	1.84	1966	34.13	4493	0.873	1.506	--
3	Blank peaks	1.93	476	8.26	16122	1.290	0.977	--
4	Blank peaks	3.16	2701	46.89	6591	1.329	11.377	--
Total			5761	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

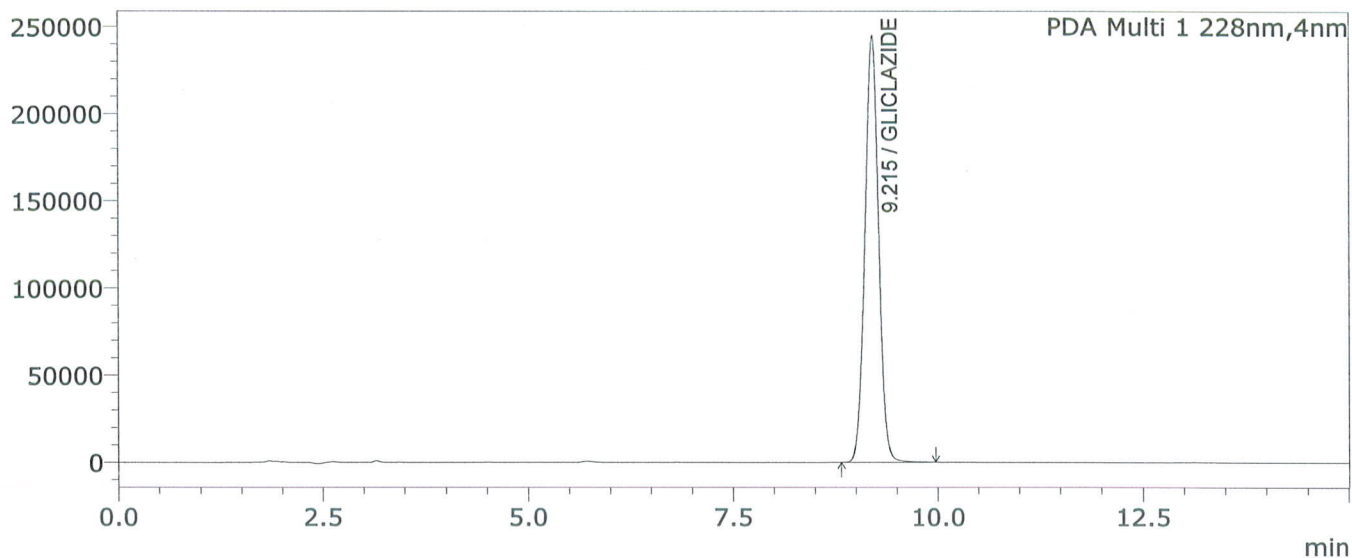
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE-API STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-105.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 20:23:18
 Date Processed : 20-09-2023 10:25:43

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU

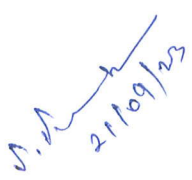


<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.21	2829758	100.00	13495	0.921	--	--
Total			2829758	100.00				


 20/09/23
 Analysed By


 21/09/23
 Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

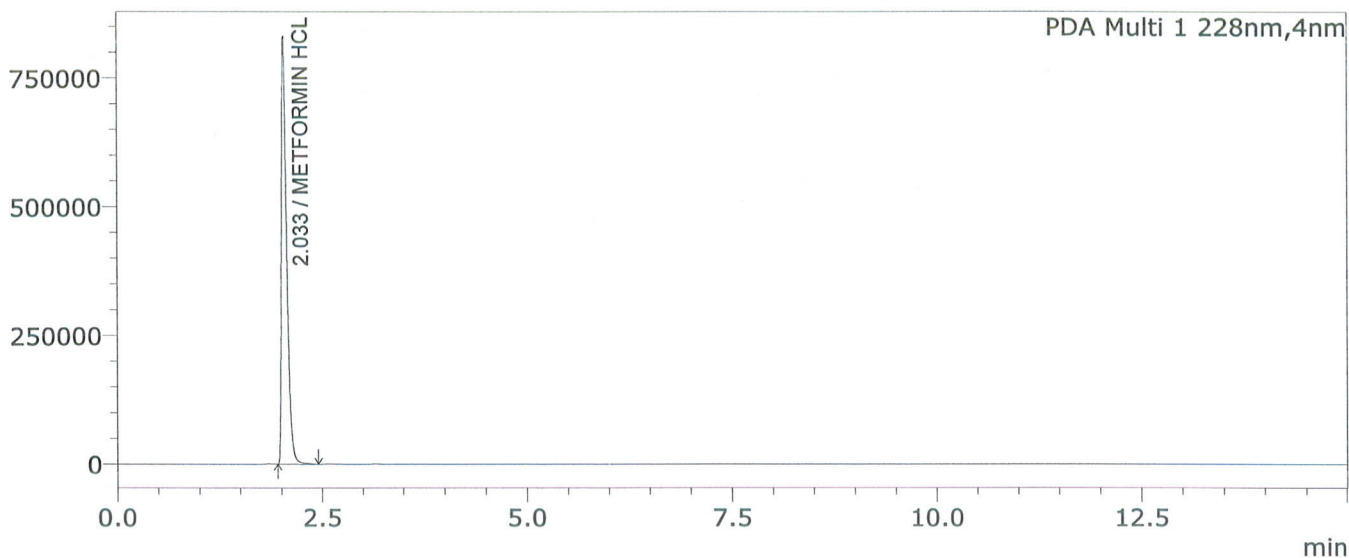
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : METFORMIN-API STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-106.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-5
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 20:38:53
 Date Processed : 20-09-2023 10:22:55

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	2.03	3775144	100.00	3780	1.499	--	--
Total			3775144	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

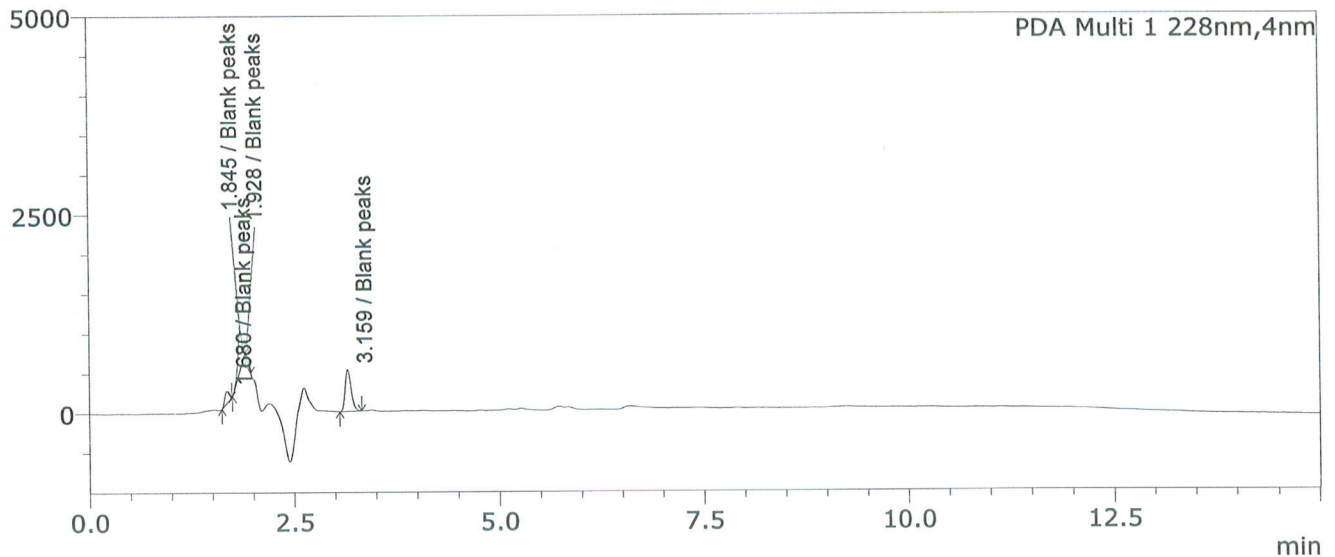
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-107.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 20:54:26
 Date Processed : 20-09-2023 10:28:48

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peaks	1.68	607	10.90	4186	1.008	--	--
2	Blank peaks	1.84	1910	34.31	4604	0.874	1.546	--
3	Blank peaks	1.93	356	6.40	17296	1.599	0.998	--
4	Blank peaks	3.16	2694	48.39	6645	1.314	11.517	--
Total			5567	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

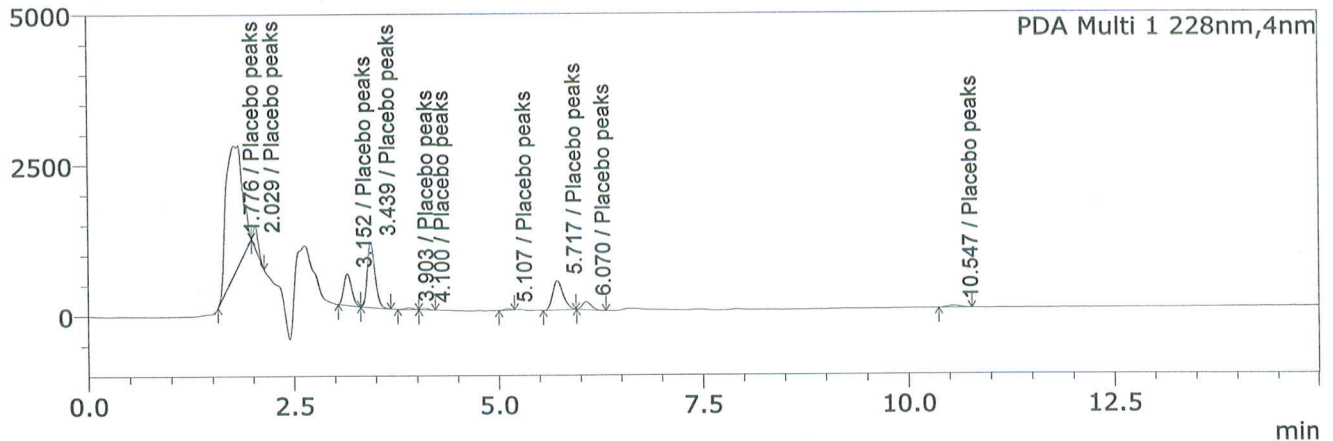
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO FOR GLIDE-M-60-500
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-108.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-6
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 21:10:01
 Date Processed : 20-09-2023 17:26:20

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Placebo peaks	1.78	29971	62.42	460	1.074	--	--
2	Placebo peaks	2.03	1293	2.69	4875	1.472	1.129	--
3	Placebo peaks	3.15	3531	7.35	4027	1.161	7.134	--
4	Placebo peaks	3.44	7036	14.66	5282	1.242	1.481	--
5	Placebo peaks	3.90	193	0.40	6476	0.975	2.421	--
6	Placebo peaks	4.10	139	0.29	8956	1.174	1.072	--
7	Placebo peaks	5.11	157	0.33	14273	0.913	5.850	--
8	Placebo peaks	5.72	4314	8.99	8476	1.223	2.911	--
9	Placebo peaks	6.07	1011	2.10	12284	1.244	1.509	--
10	Placebo peaks	10.55	367	0.77	19046	1.177	17.063	--
Total			48013	100.00				

Analysed By

20/09/23

Checked By

21/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

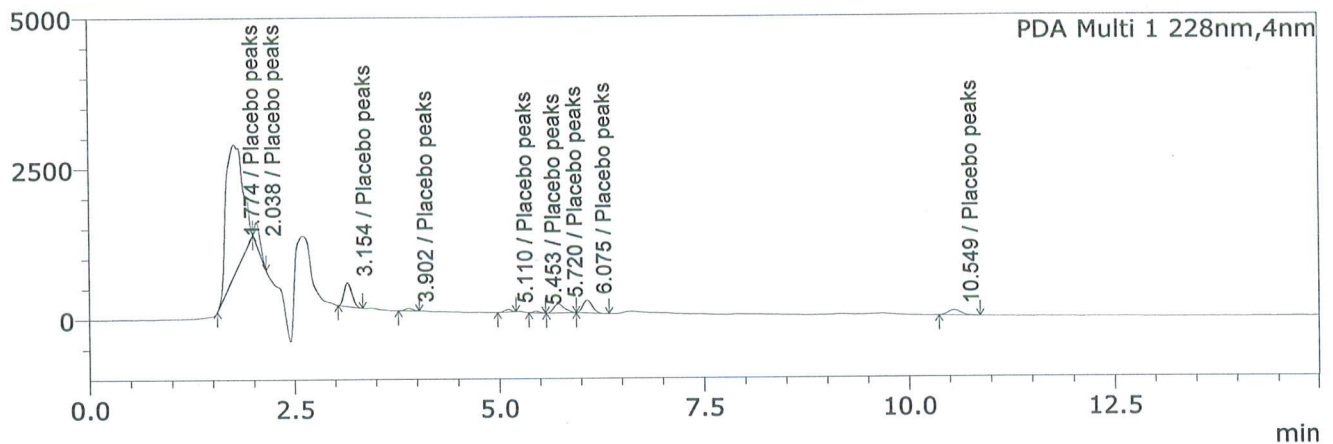
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO FOR GLIDE-M-60-850
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-109.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-7
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 21:25:35
 Date Processed : 20-09-2023 17:28:00

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Placebo peaks	1.77	31357	77.91	427	1.099	--	--
2	Placebo peaks	2.04	1655	4.11	3366	1.771	1.090	--
3	Placebo peaks	3.15	2650	6.58	4062	1.190	6.597	--
4	Placebo peaks	3.90	253	0.63	6383	1.017	3.805	--
5	Placebo peaks	5.11	237	0.59	14196	0.953	6.584	--
6	Placebo peaks	5.45	161	0.40	16102	1.100	1.996	--
7	Placebo peaks	5.72	1343	3.34	8241	1.290	1.258	--
8	Placebo peaks	6.08	1647	4.09	11567	1.187	1.486	--
9	Placebo peaks	10.55	948	2.36	19377	1.207	16.912	--
Total			40250	100.00				

Analysed By

[Signature]
20/09/23

Checked By

[Signature]
20/09/23


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

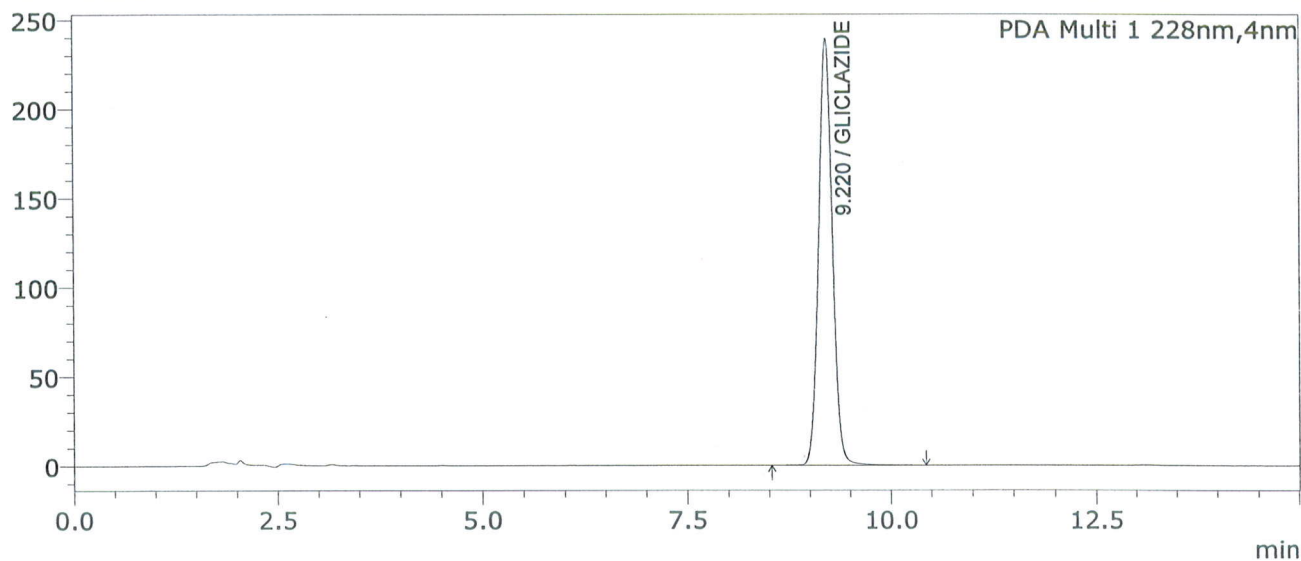
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO+GLICLAZIDE API
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-110.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-8
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 21:41:09
 Date Processed : 20-09-2023 17:34:12

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2818025	100.00	13246	0.933	--	--
Total			2818025	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

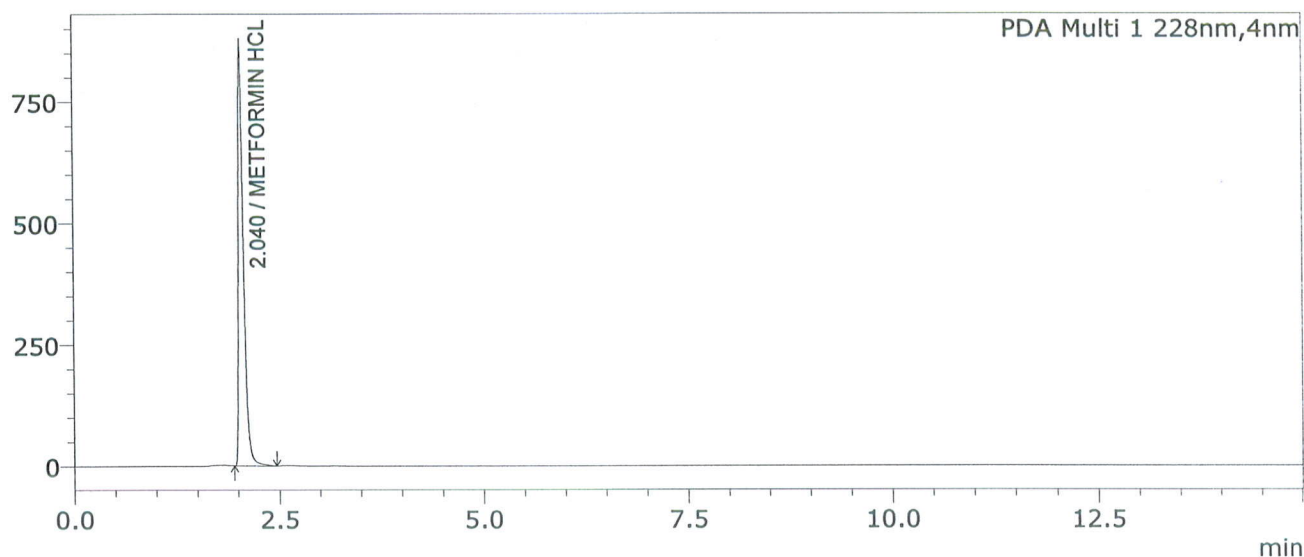
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO+METFORMIN API
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-111.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-9
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 21:56:44
 Date Processed : 20-09-2023 17:35:36

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	2.04	3751698	100.00	4097	1.533	--	--
Total			3751698	100.00				

20/09/23

Analysed By

21/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

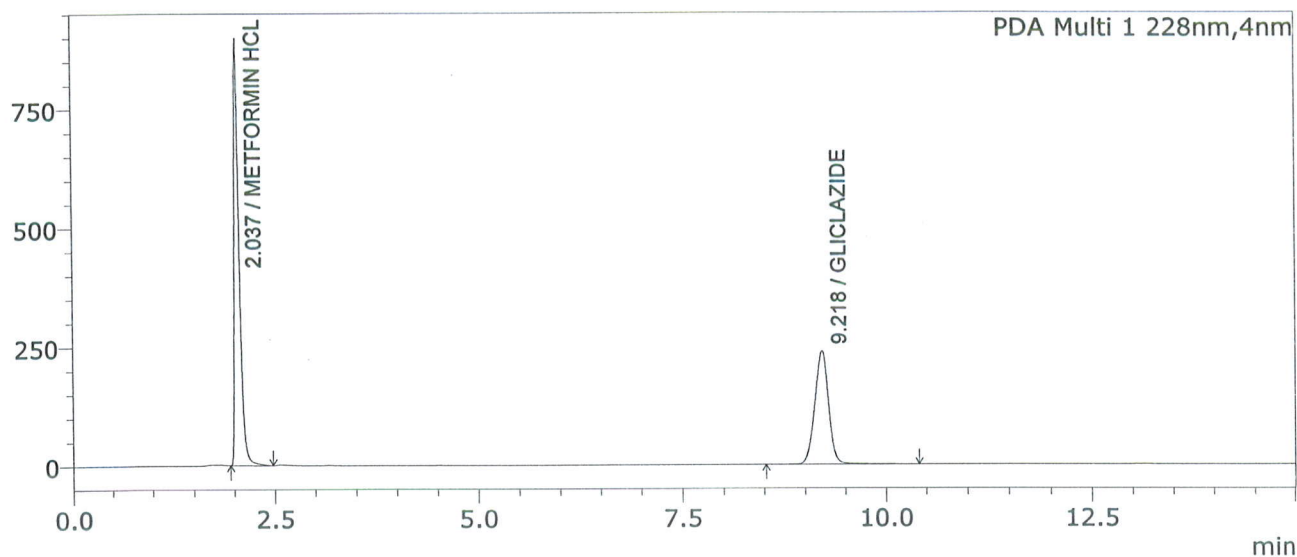
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO+METFORMIN+GLICLAZIDE
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-112.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-10
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 22:12:18
 Date Processed : 20-09-2023 17:36:53

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	2.04	3823144	57.67	4327	1.539	--	--
2	GLICLAZIDE	9.22	2805825	42.33	13286	0.933	32.368	--
Total			6628969	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

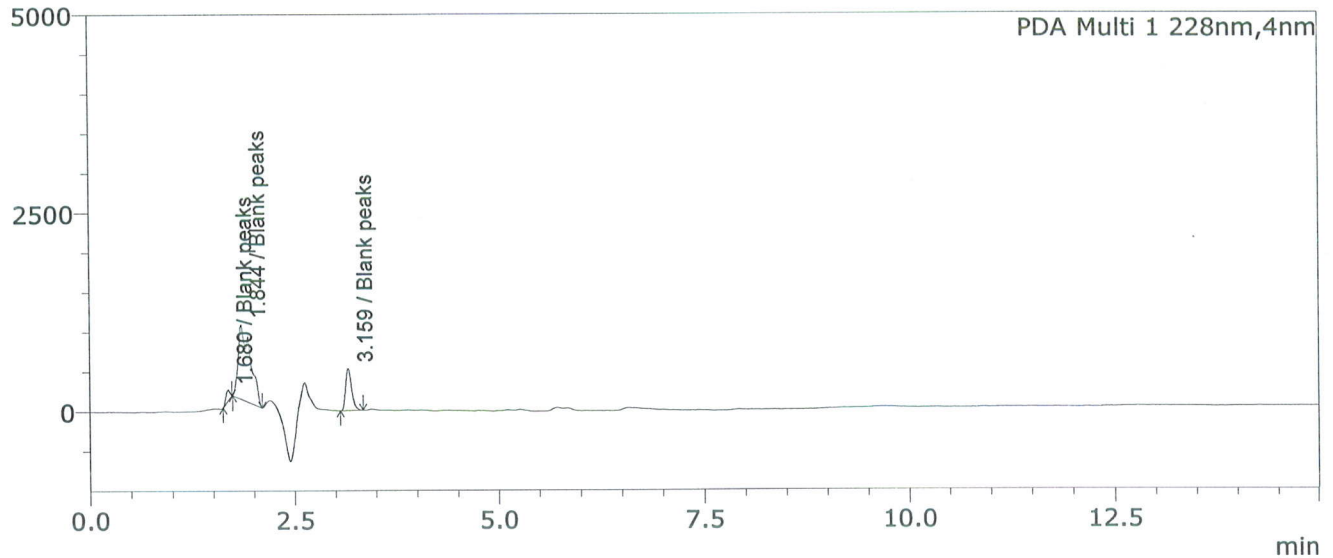
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-113.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 22:27:50
 Date Processed : 20-09-2023 11:02:13

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peaks	1.68	518	4.02	4666	0.938	--	--
2	Blank peaks	1.84	9678	75.05	713	1.794	0.876	--
3	Blank peaks	3.16	2700	20.94	6741	1.352	6.110	--
Total			12897	100.00				

Analysed By

20/09/23

Checked By

21/09/23

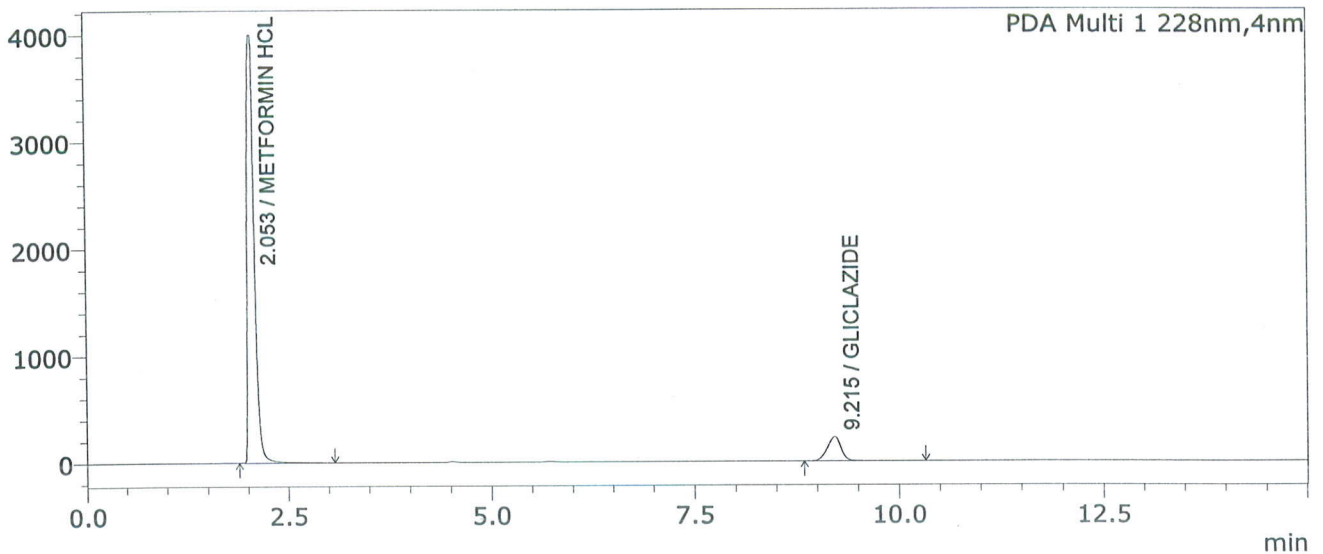

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLIDE-M-60-500-TAB-093-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-114.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-11
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 22:43:25
 Date Processed : 20-09-2023 17:38:11

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU


<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	2.05	24009307	90.16	2815	1.266	--	--
2	GLICLAZIDE	9.21	2621725	9.84	13591	0.932	30.412	--
Total			26631032	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

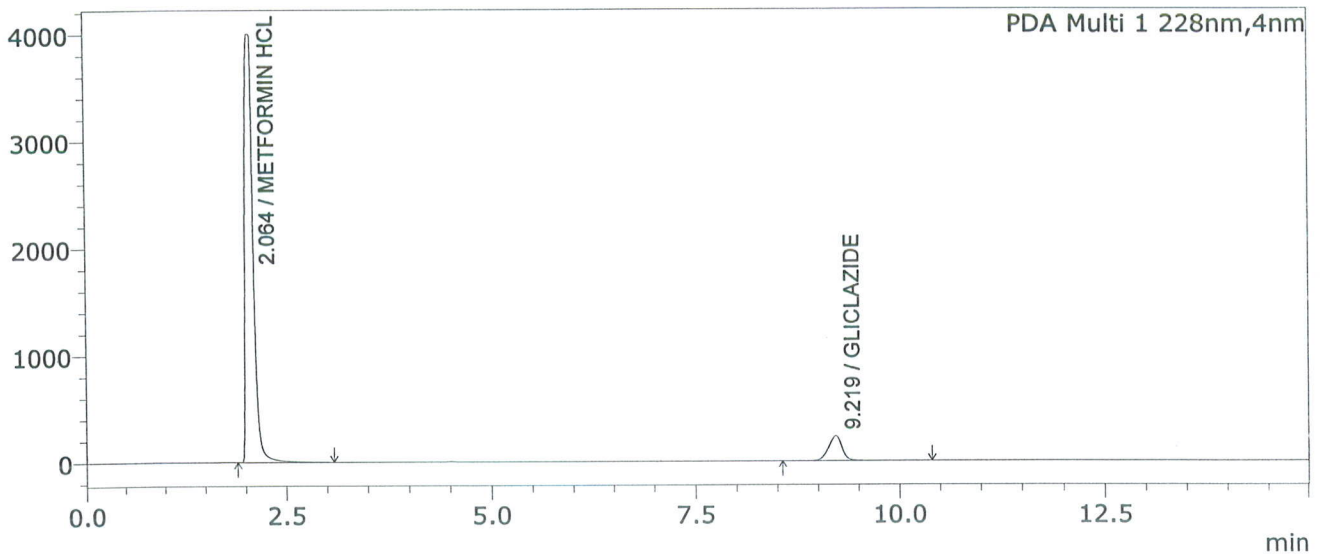
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLIDE-M-60-850-TAB-0801-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-115.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-12
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 22:58:58
 Date Processed : 20-09-2023 17:40:10

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	2.06	27977272	91.20	2297	1.218	--	--
2	GLICLAZIDE	9.22	2699841	8.80	13566	0.927	29.273	--
Total			30677113	100.00				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

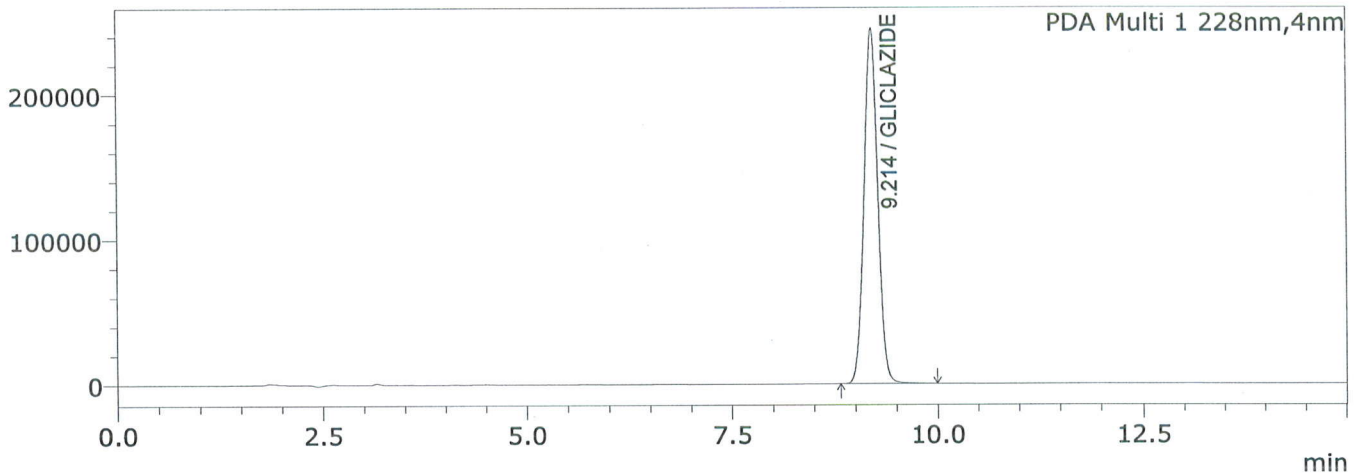
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE-DS-BKT-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-116.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 23:14:31
 Date Processed : 20-09-2023 09:57:05

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.21	2828210	100.00	13579	0.916	--	--
Total			2828210	100.00				

Analysed By

20/09/23

Checked By

20/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

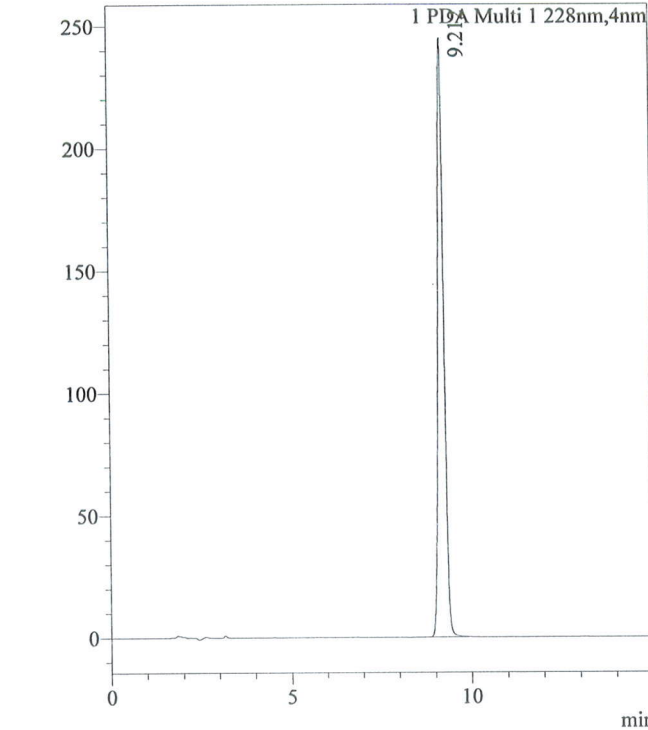
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-9
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 18:49:56
 Date Processed : 20-09-2023 10:23:28

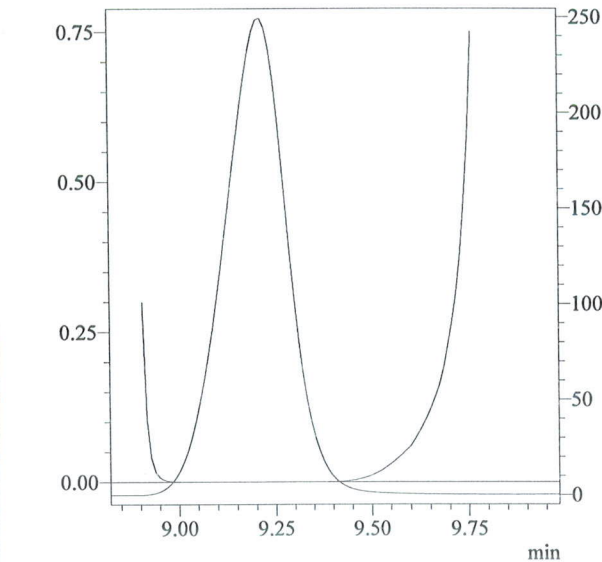
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 9.212 min
 Compound Name : GLICLAZIDE



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999997
 Minimum peak purity index : 2

PDA Ch1 228nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	9.212	1.000000	0.999997	GLICLAZIDE
Total				

20/09/23

Analysed By

21/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

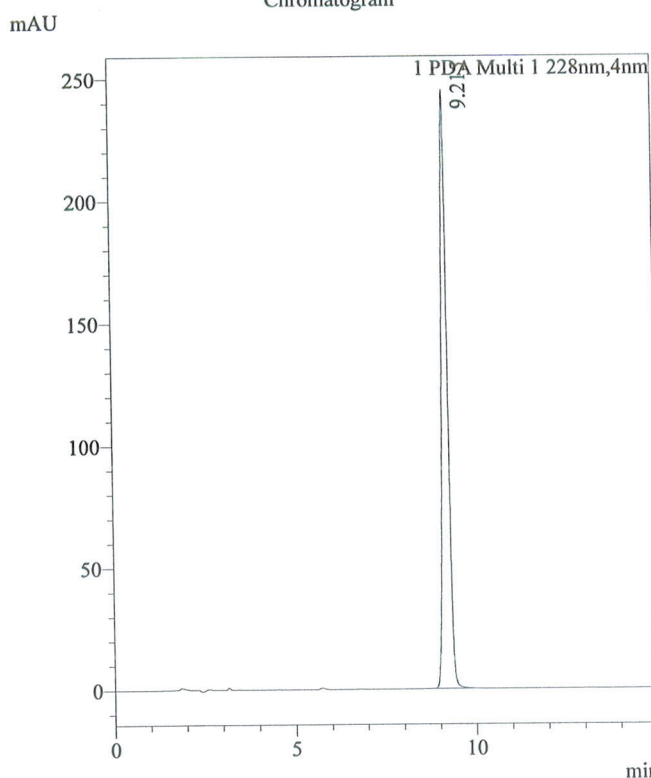
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE-API STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 20:23:18
 Date Processed : 20-09-2023 10:25:43

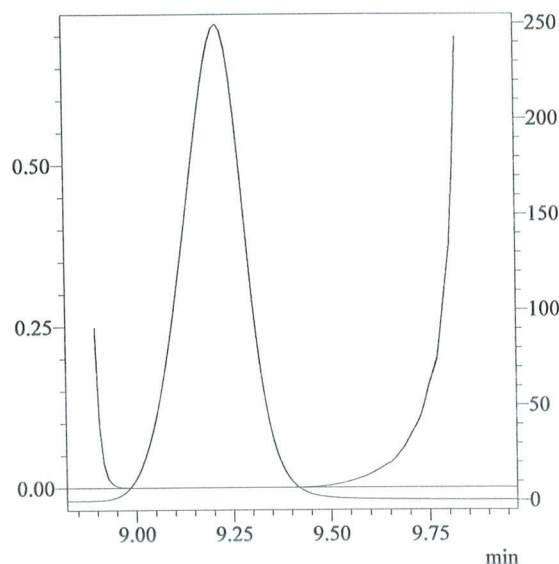
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 9.215 min
 Compound Name : GLICLAZIDE



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999999
 Minimum peak purity index : 0

Peak Table

PDA Ch1 228nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	9.215	1.000000	0.999999	GLICLAZIDE
Total				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

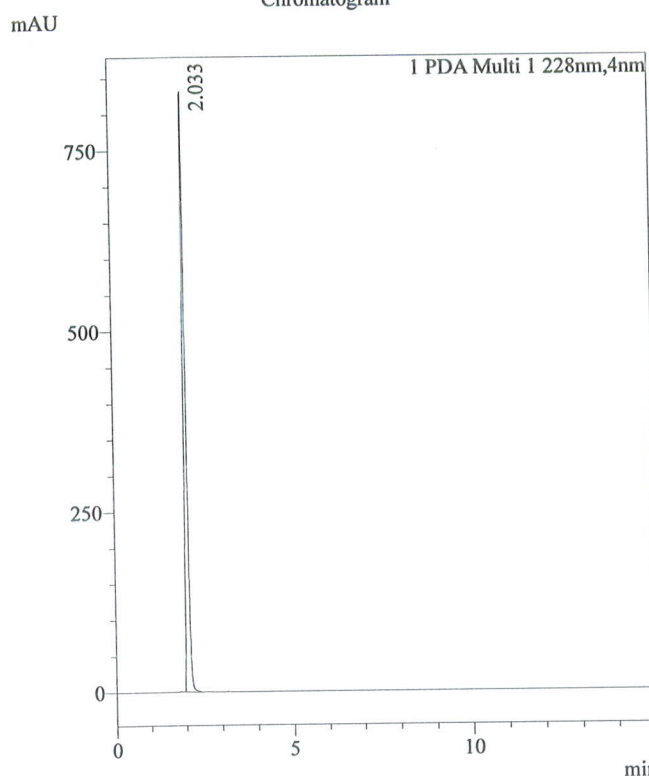
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : METFORMIN-API STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-5
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 20:38:53
 Date Processed : 20-09-2023 10:22:55

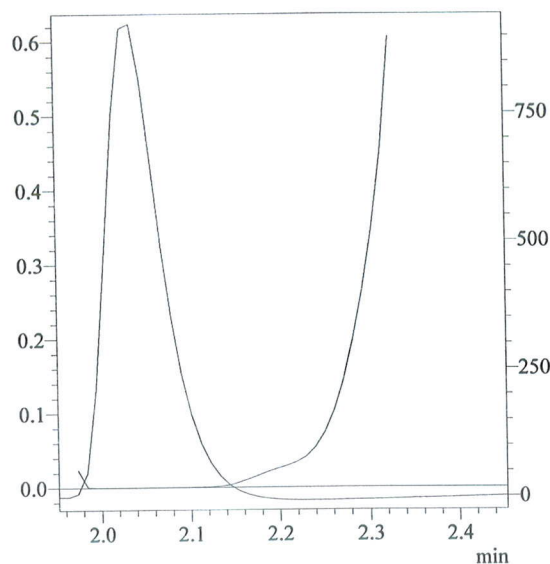
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 2.033 min
 Compound Name : METFORMIN HCL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999854
 Minimum peak purity index : 146

Peak Table

PDA Ch1 228nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.033	1.000000	0.999854	METFORMIN HCL
Total				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

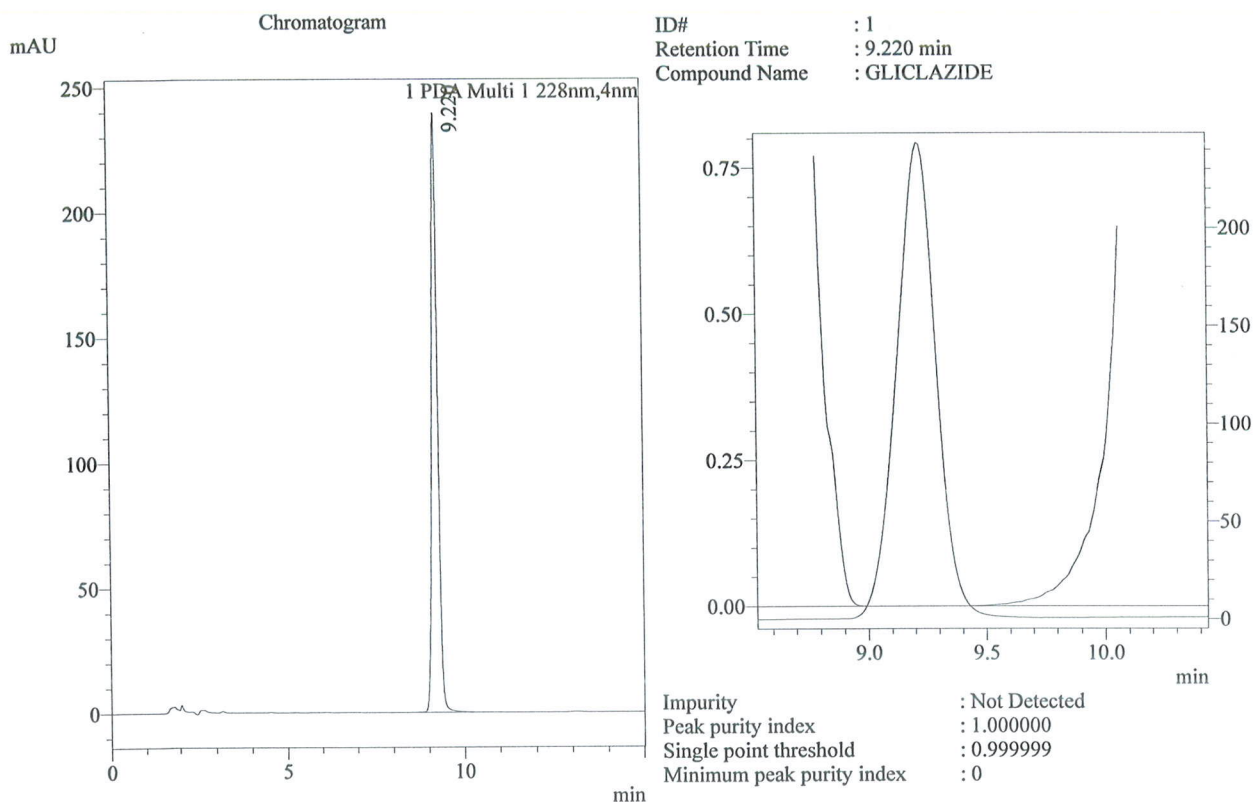
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO+GLICLAZIDE API
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-8
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 21:41:09
 Date Processed : 20-09-2023 17:34:12

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

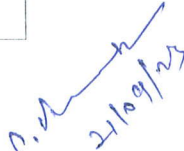


PDA Ch1 228nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	9.220	1.000000	0.999999	GLICLAZIDE
Total				


 20/09/23
 Analysed By


 21/09/23
 Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

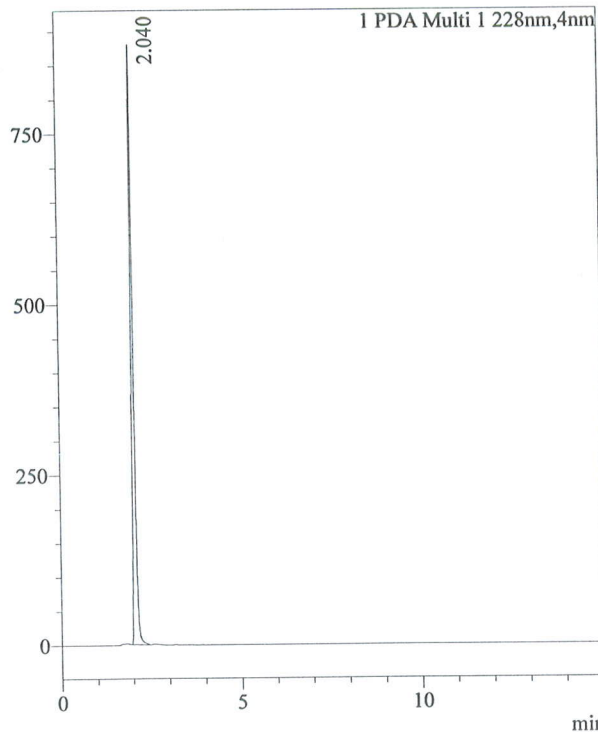
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : PLACEBO+METFORMIN API
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-9
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 21:56:44
 Date Processed : 20-09-2023 17:35:36

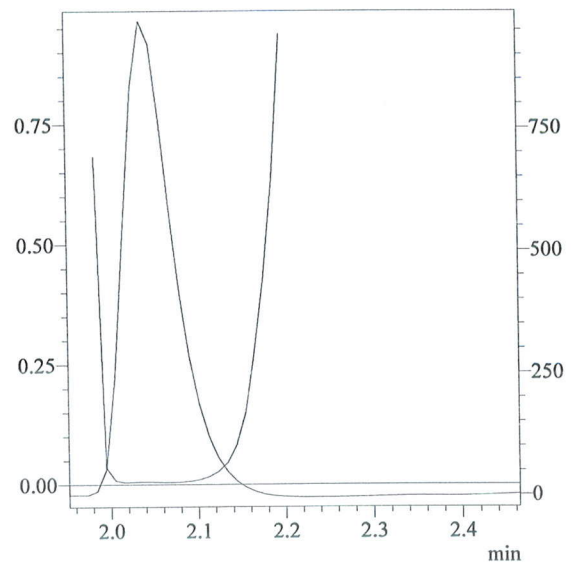
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram



ID# : 1
 Retention Time : 2.040 min
 Compound Name : METFORMIN HCL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.995295
 Minimum peak purity index : 4704

Peak Table

PDA Ch1 228nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.040	1.000000	0.995295	METFORMIN HCL
Total				

20/09/23
 Analysed By

21/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

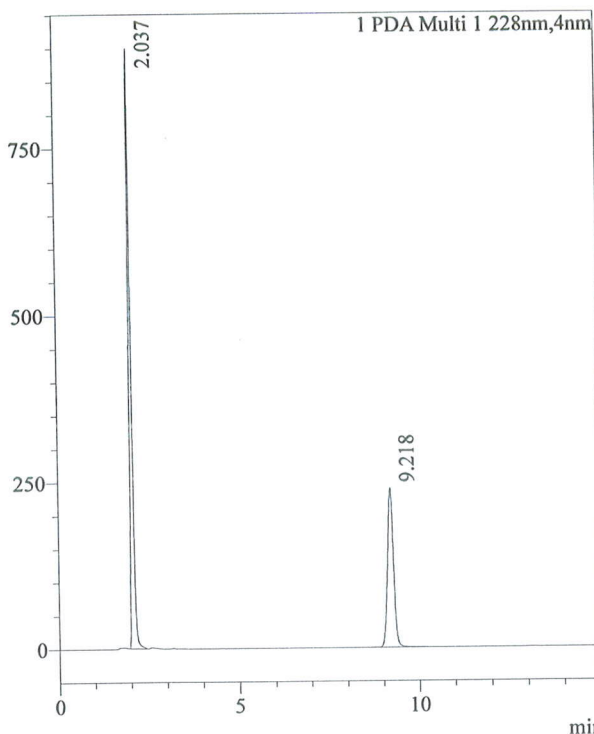
Analysis Report

<Sample Information>

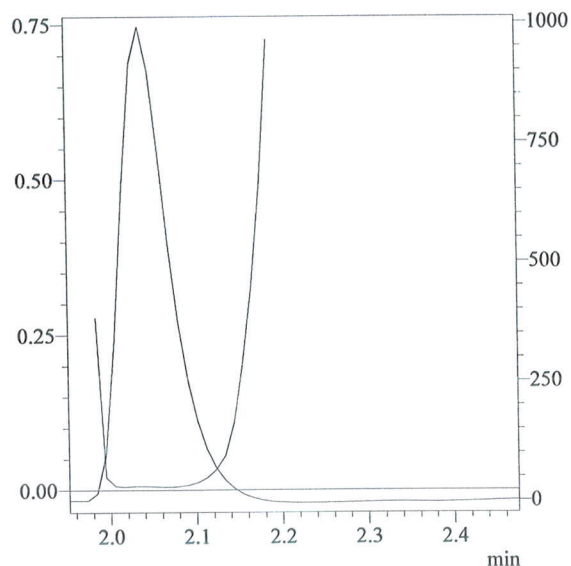
Sample Name	: SPECIFICITY	Acquired by	: E.MEENA
Sample ID	: PLACEBO+METFORMIN+GLICLAZIDE	Processed by	: C.K.SARAVANAN
Data Filename	: 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1		
Method Filename	: GLIDE-M 60-500-850-TAB-DS GLICLAZIDE.lcm		
Batch Filename	: 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb		
Vial #	: 2-10		
Injection Volume	: 20 uL		
Date Acquired	: 16-09-2023 22:12:18		
Date Processed	: 20-09-2023 17:36:53		

<Peak Purity>

mAU Chromatogram

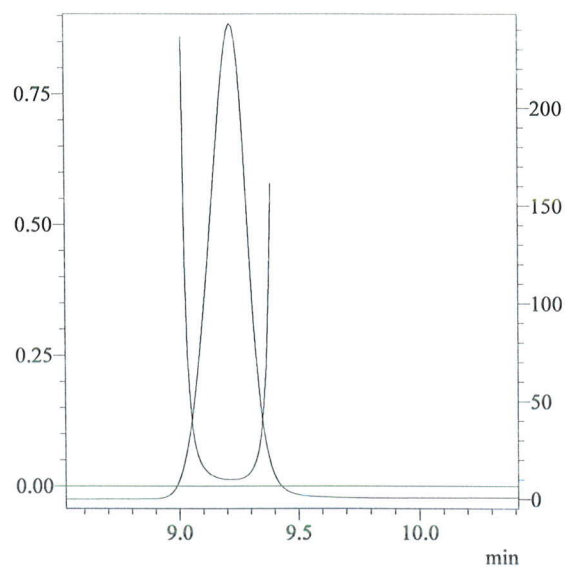


ID# : 1
Retention Time : 2.037 min
Compound Name : METFORMIN HCL



Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.994945
Minimum peak purity index : 5054

ID# : 2
 Retention Time : 9.218 min
 Compound Name : GLICLAZIDE



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.987116
 Minimum peak purity index : 12884

PDA Ch1 228nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.037	1.000000	0.994945	METFORMIN HCL
2	9.218	1.000000	0.987116	GLICLAZIDE
Total				

④ 20/09/23
Analysed By

21/09/23
Checked By



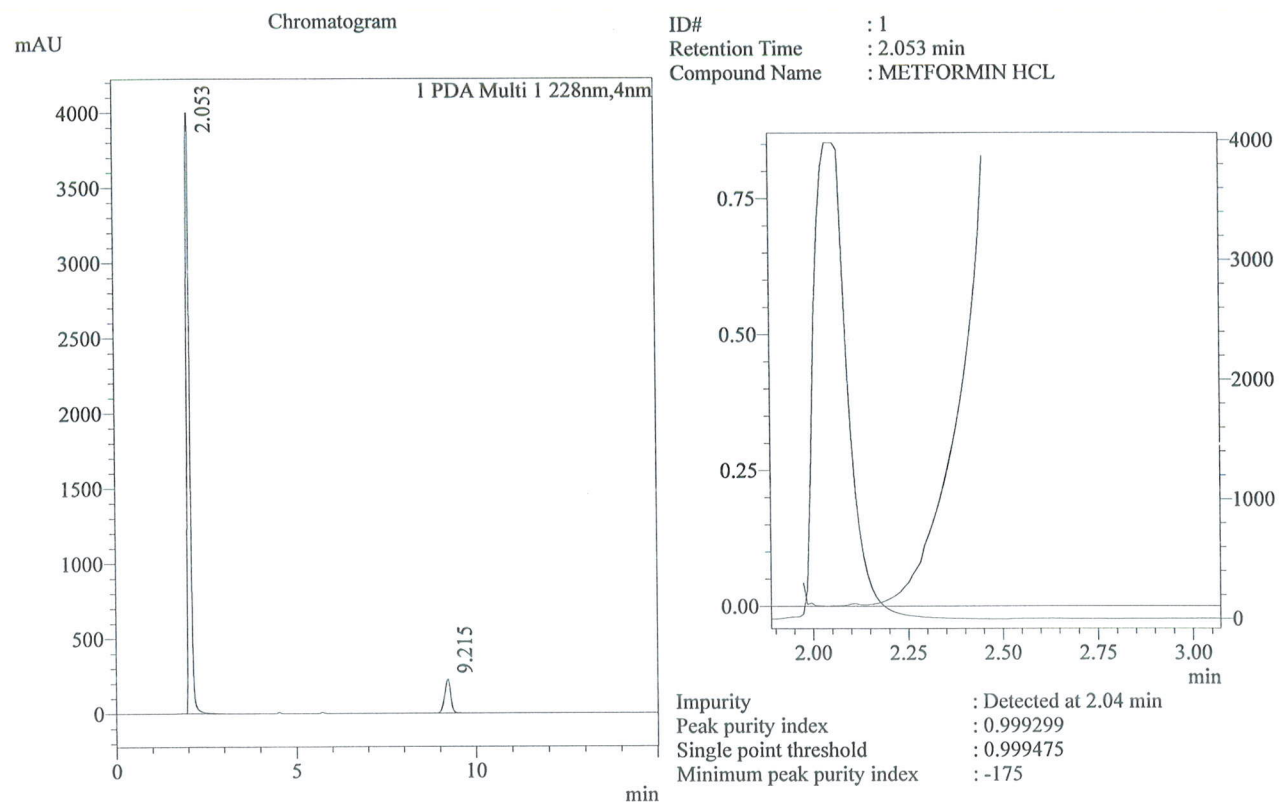
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

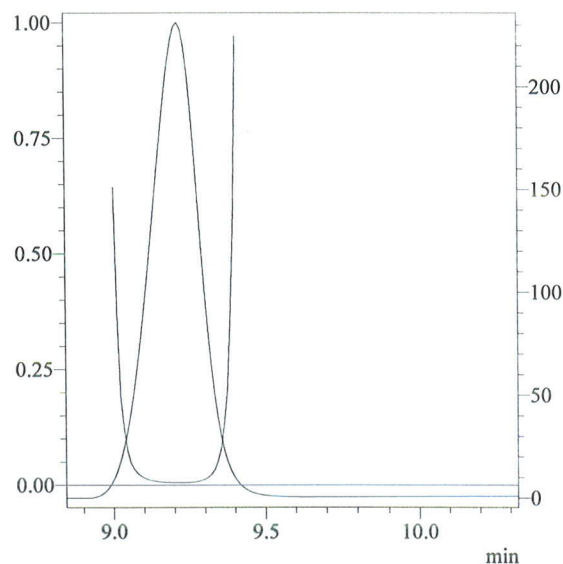
<Sample Information>

Sample Name : SPECIFICITY
Sample ID : GLIDE-M-60-500-TAB-093-DS-SPL
Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
Vial # : 2-11
Injection Volume : 20 uL
Date Acquired : 16-09-2023 22:43:25
Date Processed : 20-09-2023 17:38:11
Acquired by : E.MEENA
Processed by : C.K.SARAVANAN

<Peak Purity>



ID# : 2
 Retention Time : 9.215 min
 Compound Name : GLICLAZIDE



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.994460
 Minimum peak purity index : 5540

Peak Table

PDA Ch1 228nm

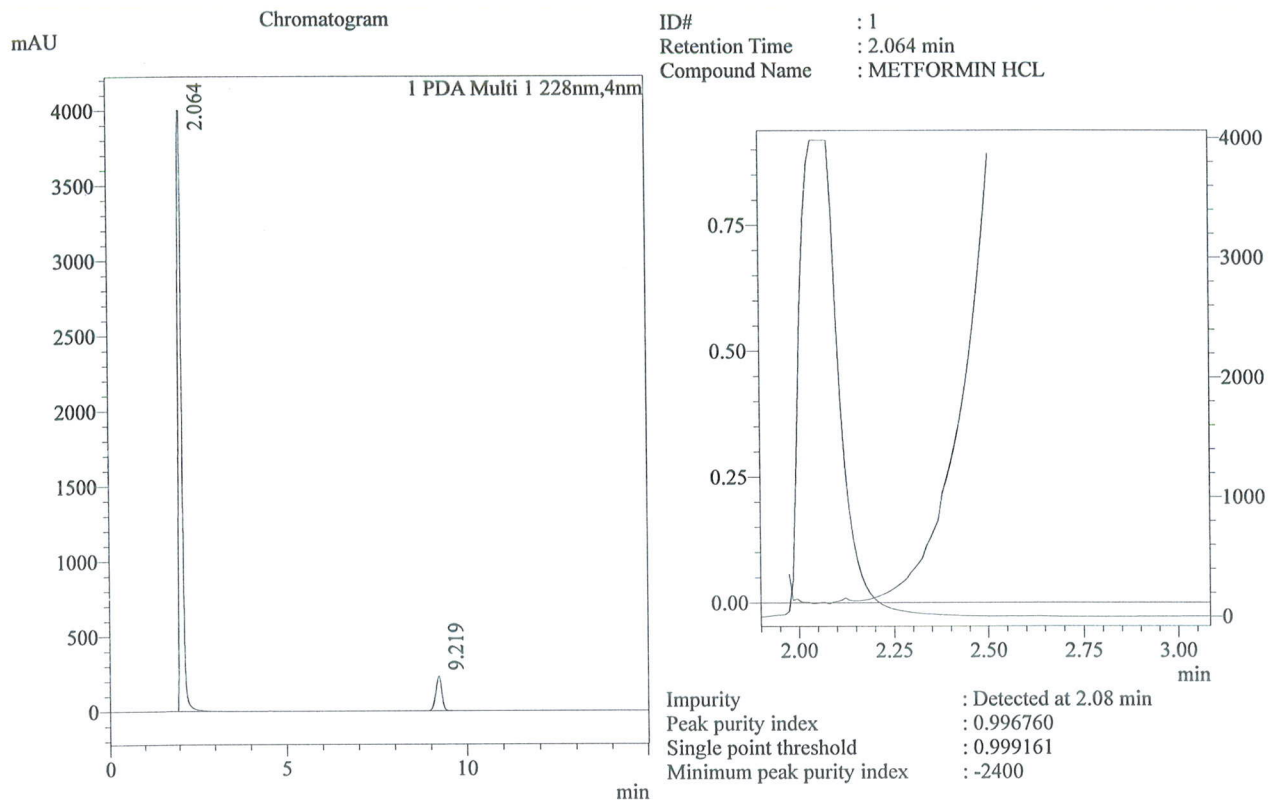
Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.053	0.999299	0.999475	METFORMIN HCL
2	9.215	1.000000	0.994460	GLICLAZIDE
Total				

W
 20/09/23
Analysed By

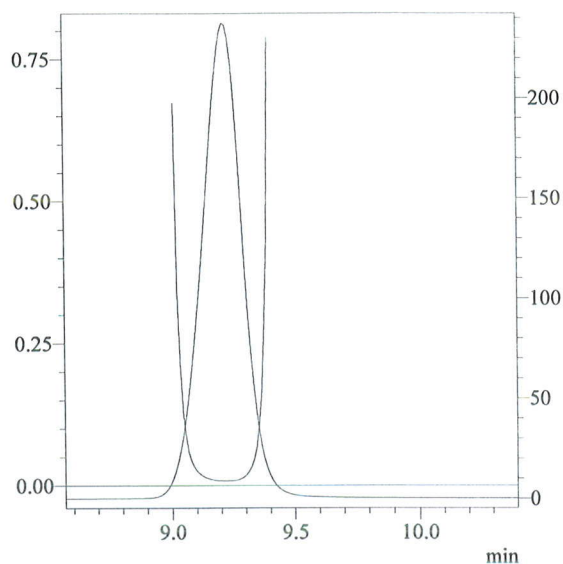
N.A
 20/09/23
Checked By

**GENERIC HEALTHCARE PVT. LTD.****Analysis Report****<Sample Information>**

Sample Name : SPECIFICITY
Sample ID : GLIDE-M-60-850-TAB-0801-DS-SPL
Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE.lcm
Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
Vial # : 2-12
Injection Volume : 20 uL
Date Acquired : 16-09-2023 22:58:58
Date Processed : 20-09-2023 17:40:10
Acquired by : E.MEENA
Processed by : C.K.SARAVANAN

<Peak Purity>

ID# : 2
 Retention Time : 9.219 min
 Compound Name : GLICLAZIDE



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.991661
 Minimum peak purity index : 8339

Peak Table

PDA Ch1 228nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.064	0.996760	0.999161	METFORMIN HCL
2	9.219	1.000000	0.991661	GLICLAZIDE
Total				

① 20/09/23
Analysed By

S.M. 20/09/23
Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

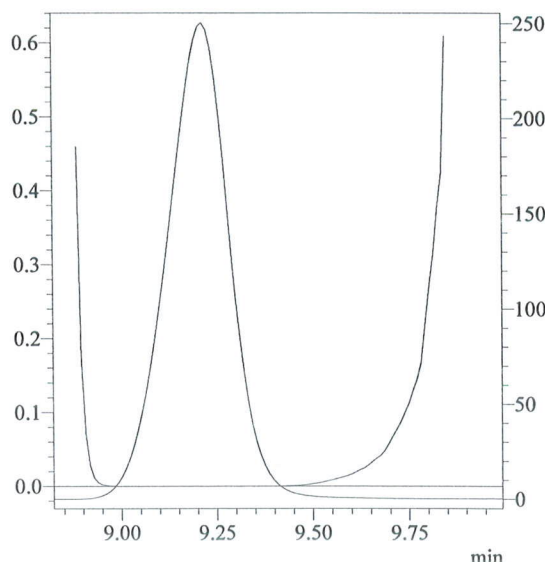
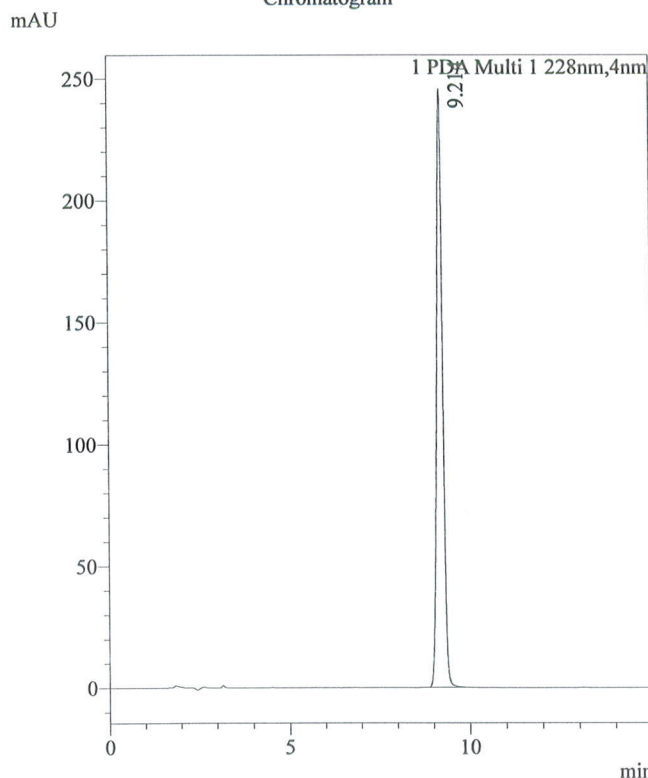
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE-DS-BKT-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-1
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 23:14:31
 Date Processed : 20-09-2023 18:42:58

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



Peak Table

PDA Ch1 228nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	9.214	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	ACCURACY STUDY(RECOVERY)	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006		Balance ID :	ST/QC/EQ/041		WS No.:	ST/WS/22/040	% Purity (aib)	100.0
Standard dilution :	66.02	mg to --->	100	ml to --->	5	ml to --->	50		
Std.conc (in ppm)-66.02	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 5% Dilution:	35.03	mg to --->	100	ml to --->	5	ml to --->	50		
Std.conc (in ppm)-3.503	5	ml to --->	50	ml to --->	1	ml to --->	1		
Recovery 50% Dilution:	33.01	mg to --->	100	ml to --->	5	ml to --->	50		
Std.conc (in ppm)-33.01	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 100% Dilution:	68.18	mg to --->	100	ml to --->	5	ml to --->	50		
Std.conc (in ppm)-68.18	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 150% Dilution:	99.08	mg to --->	100	ml to --->	5	ml to --->	50		
Std.conc (in ppm)-99.08	1	ml to --->	1	ml to --->	1	ml to --->	1		
System suitability	1	2	3	4	5	MEAN	S.D	RSD in %	
Gliclazide	2870361	2869993	2870329	2868997	2869948	2869926	552	0.019	
Standard con. in ppm.	66.02								

Level's	Injection No.	Observed area	Quantity added in ppm	Quantity Recovered in ppm	% Recovery
I(5%)	1	154116	3.503	3.55	101.21
	2	153867	3.503	3.54	101.04
	3	153942	3.503	3.54	101.09
				MEAN	101.11
				%RSD	0.083
II(50%)	1	1407032	33.010	32.37	98.05
	2	1407472	33.010	32.38	98.08
	3	1406592	33.010	32.36	98.02
				MEAN	98.05
				%RSD	0.031
III(100%)	1	2993182	68.180	68.86	100.99
	2	2993590	68.180	68.86	101.00
	3	2994811	68.180	68.89	101.05
				MEAN	101.01
				%RSD	0.028
III(150%)	1	4237201	99.080	97.47	98.38
	2	4237793	99.080	97.49	98.39
	3	4236835	99.080	97.46	98.37
				MEAN	98.38
				%RSD	0.011

Results:

The % recovery was complies at each levels.

Acceptance criteria:

The mean % recovery at each level should be 95.0 to 105.0.

CALCULATION FORMULA

Quantity added in ppm

$$\frac{\text{standard weight} \times \text{dilution} \times 1000}{100}$$

Quantity recovered in ppm

$$\frac{\text{Sample area} \times \text{std.conc in ppm}}{\text{Standard average area}}$$

% Recovery

$$\frac{\text{Quantity recovered in ppm} \times 100}{\text{Quantity added in ppm}}$$

Analysed by : E.MEENA
Date : 15-09-2023

15/09/23

Checked by :
Date : 15/09/23



GENERIC HEALTHCARE PVT. LTD.

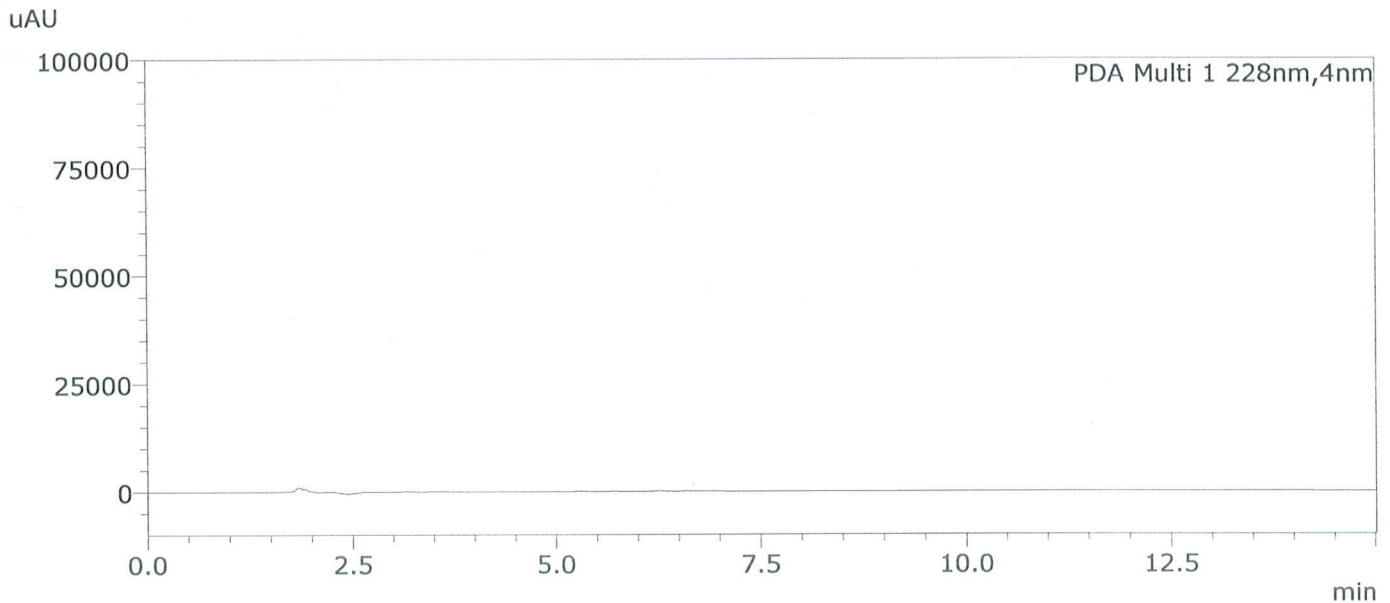
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-35.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-11
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 03:05:30
 Date Processed : 15-09-2023 09:16:46

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

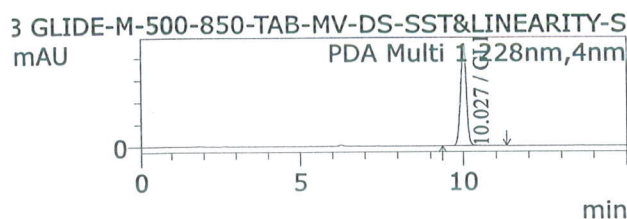
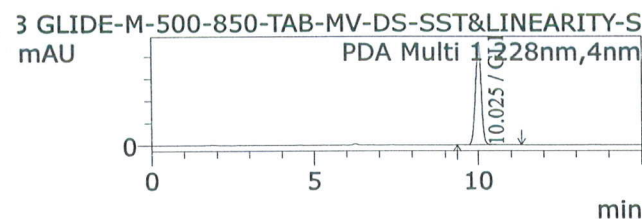
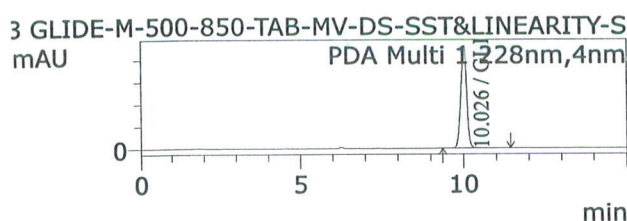
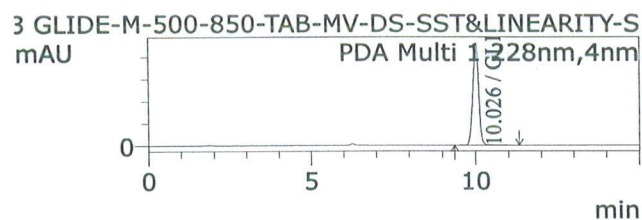
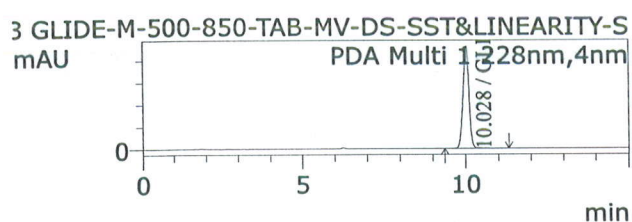
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : GLICLAZIDE-RECOVERY-DS-STD-01
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-36.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-12
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 03:21:02
 Date Processed : 15-09-2023 09:16:46

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	ITY-SPL-36.lcd	GLICLAZIDE-RECOVERY-DS-STD-01	10.03	2870361	14110	0.92
12	ITY-SPL-37.lcd	GLICLAZIDE-RECOVERY-DS-STD-02	10.03	2869993	14103	0.92
12	ITY-SPL-38.lcd	GLICLAZIDE-RECOVERY-DS-STD-03	10.03	2870329	14108	0.92
12	ITY-SPL-39.lcd	GLICLAZIDE-RECOVERY-DS-STD-04	10.02	2868997	14091	0.92
12	ITY-SPL-40.lcd	GLICLAZIDE-RECOVERY-DS-STD-05	10.03	2869948	14111	0.92
	Average		10.03	2869925	14105	0.92
	%RSD		0.010	0.019	0.057	0.025

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

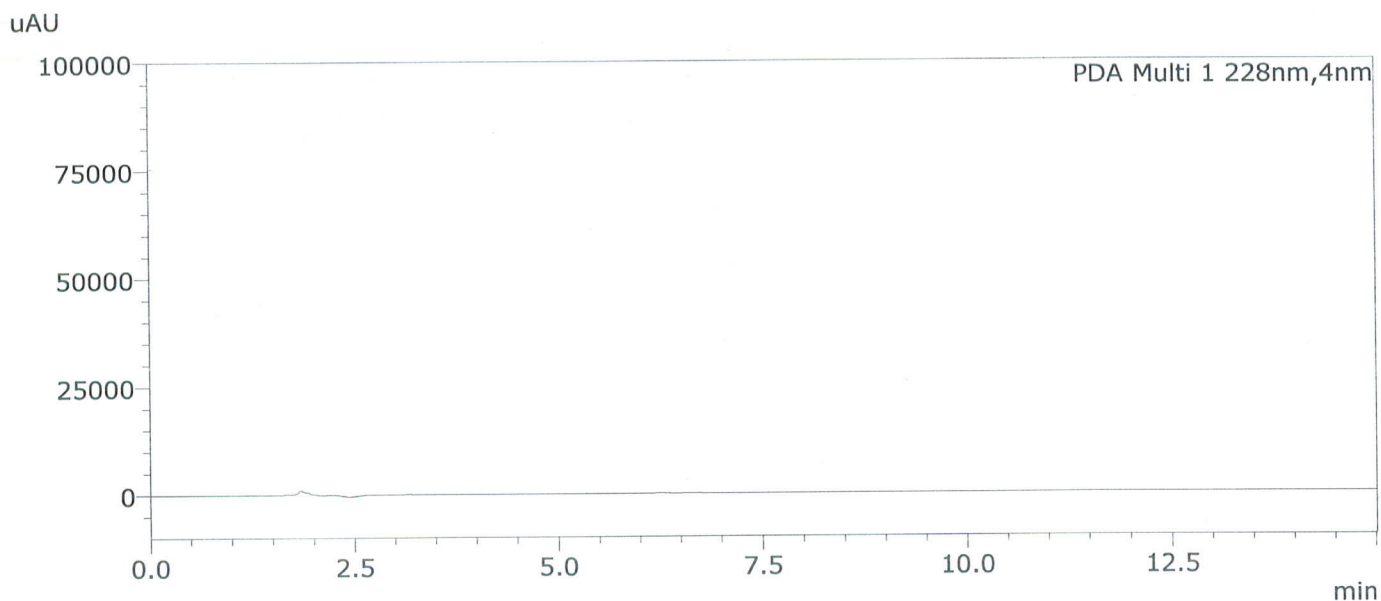
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-41.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-11
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 04:38:44
 Date Processed : 15-09-2023 09:16:48

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

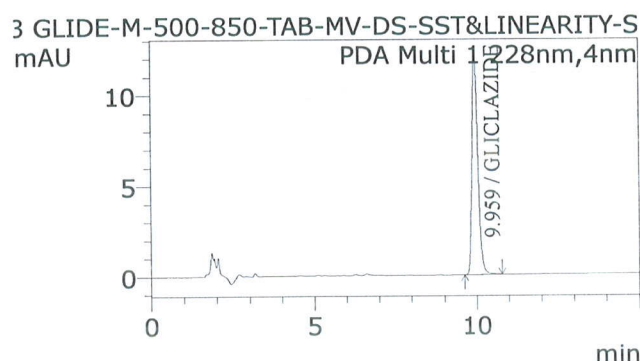
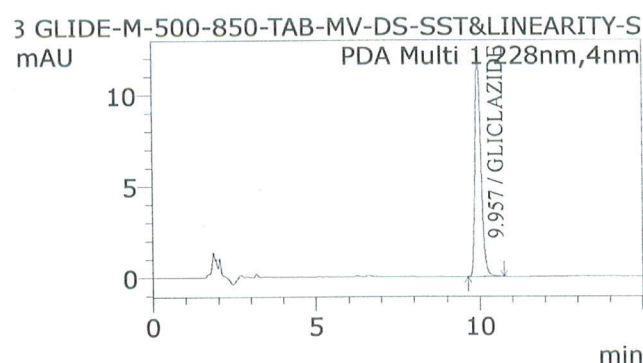
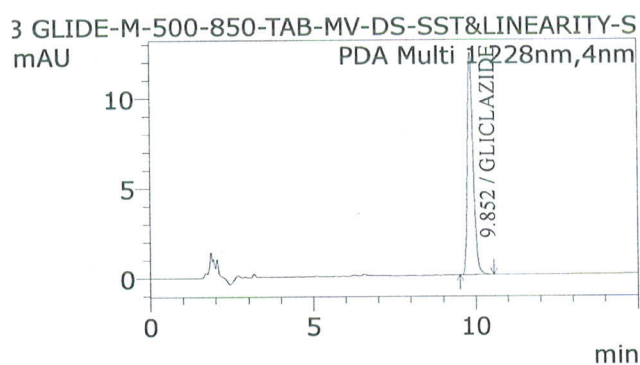
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : GLICLAZIDE-RECOVERY-5%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-42.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-13
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 04:54:30
 Date Processed : 15-09-2023 09:17:03

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	ITY-SPL-42.lcd	GLICLAZIDE-RECOVERY-5%-SPL-1	9.85	154116	13947	1.19
13	ITY-SPL-43.lcd	GLICLAZIDE-RECOVERY-5%-SPL-2	9.96	153867	14055	1.19
13	ITY-SPL-44.lcd	GLICLAZIDE-RECOVERY-5%-SPL-3	9.96	153942	14045	1.19
	Average		9.92	153975	14016	1.19
	%RSD		0.619	0.083	0.427	0.152

Analysed By

(Signature)
15/09/23

Checked By

(Signature)
15/09/23

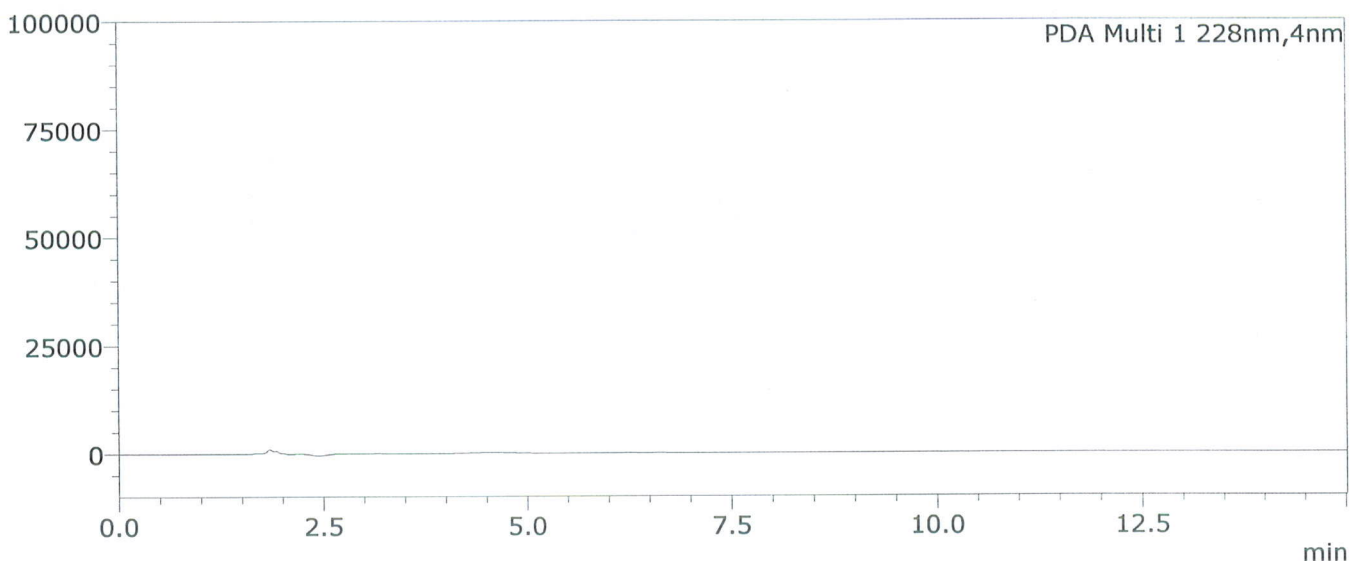

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-45.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-11
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 05:40:53
 Date Processed : 15-09-2023 09:16:49

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uAU


<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By
Checked By



GENERIC HEALTHCARE PVT. LTD.

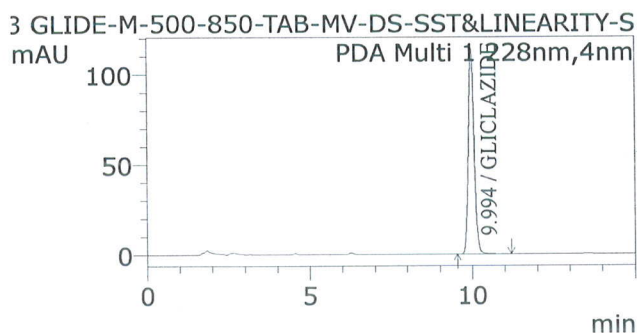
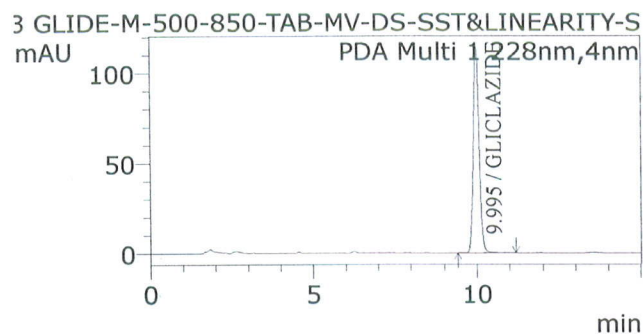
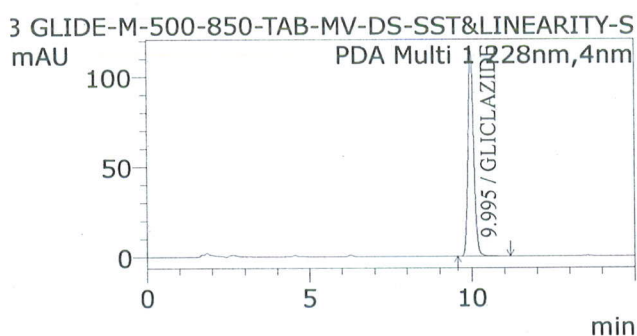
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : GLICLAZIDE-RECOVERY-50%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-46.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-14
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 05:56:26
 Date Processed : 15-09-2023 09:16:49

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	ITY-SPL-46.lcd	GLICLAZIDE-RECOVERY-50%-SPL-1	10.00	1407032	14357	1.03
14	ITY-SPL-47.lcd	GLICLAZIDE-RECOVERY-50%-SPL-2	9.99	1407472	14343	1.03
14	ITY-SPL-48.lcd	GLICLAZIDE-RECOVERY-50%-SPL-3	9.99	1406592	14328	1.03
	Average		9.99	1407032	14343	1.03
	%RSD		0.005	0.031	0.101	0.037

Analysed By

[Signature]
15/09/23

Checked By

[Signature]
15/09/23



GENERIC HEALTHCARE PVT. LTD.

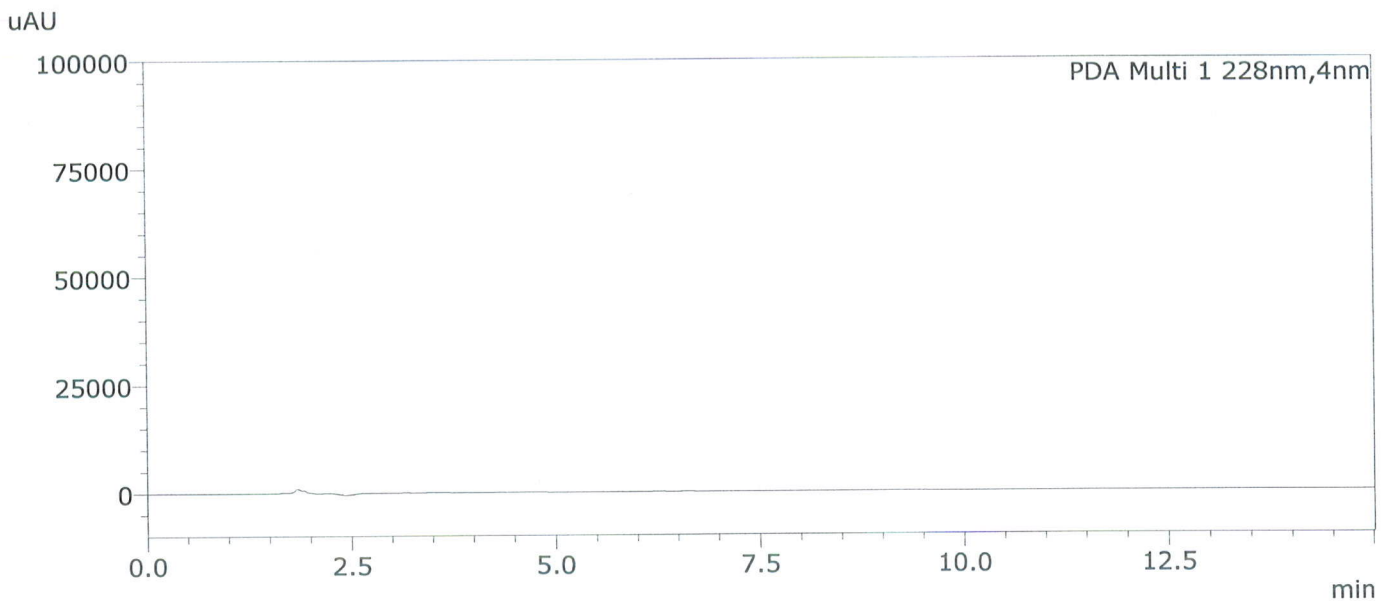
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-49.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-11
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 06:43:02
 Date Processed : 15-09-2023 09:16:50

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

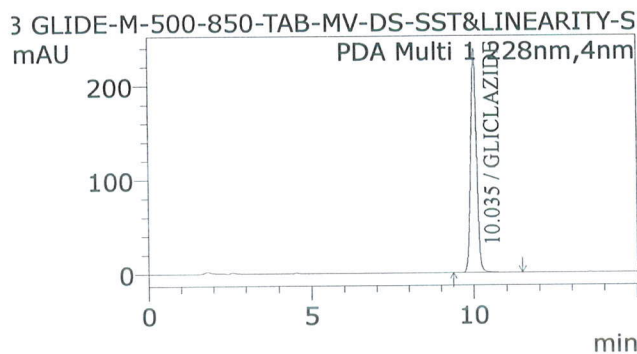
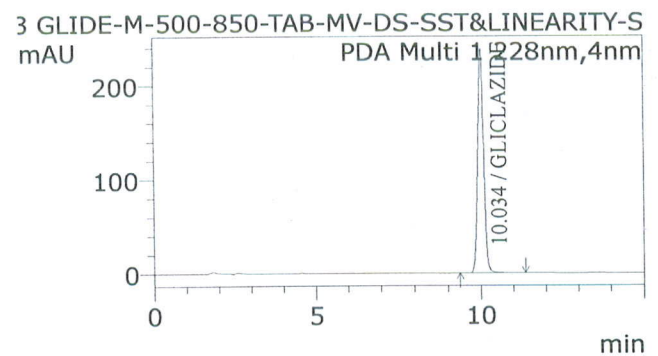
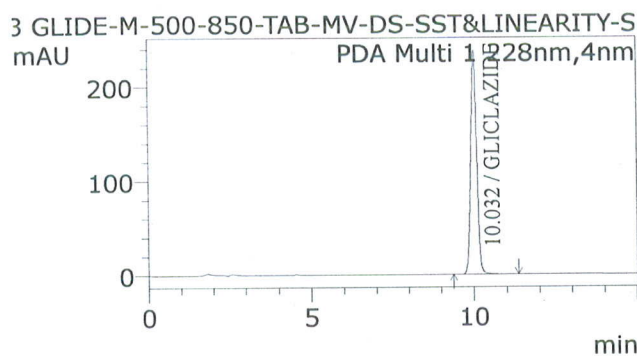
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : GLICLAZIDE-RECOVERY-100%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-50.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-15
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 06:58:35
 Date Processed : 15-09-2023 09:16:50

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	ITY-SPL-50.lcd	GLICLAZIDE-RECOVERY-100%-SPL-1	10.03	2993182	13848	0.93
15	ITY-SPL-51.lcd	GLICLAZIDE-RECOVERY-100%-SPL-2	10.03	2993590	13867	0.92
15	ITY-SPL-52.lcd	GLICLAZIDE-RECOVERY-100%-SPL-3	10.03	2994811	13872	0.92
	Average		10.03	2993861	13862	0.92
	%RSD		0.011	0.028	0.090	0.124

Analysed By

[Signature]
15/09/23

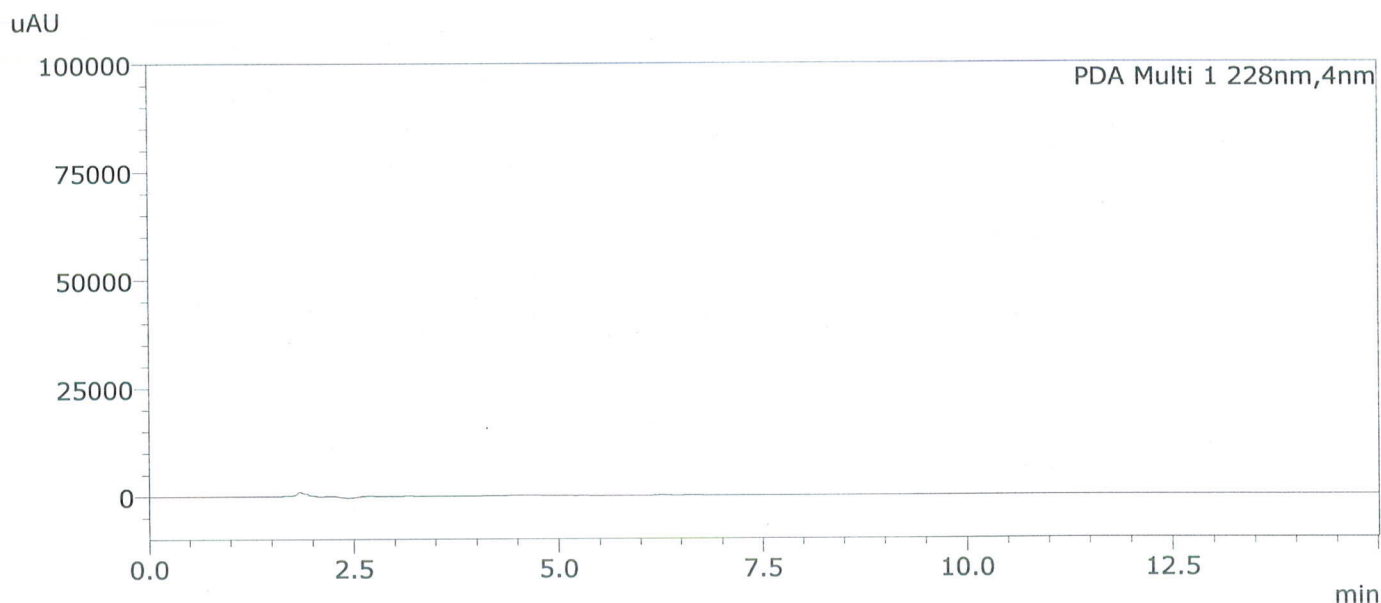
Checked By

[Signature]
15/09/23


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-53.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-11
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 07:45:11
 Date Processed : 15-09-2023 09:16:51

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

15/09/23

Analysed By

15/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

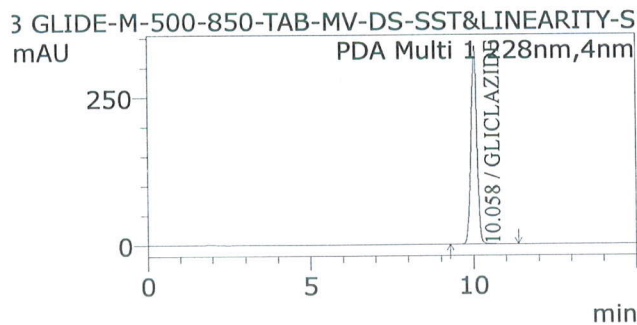
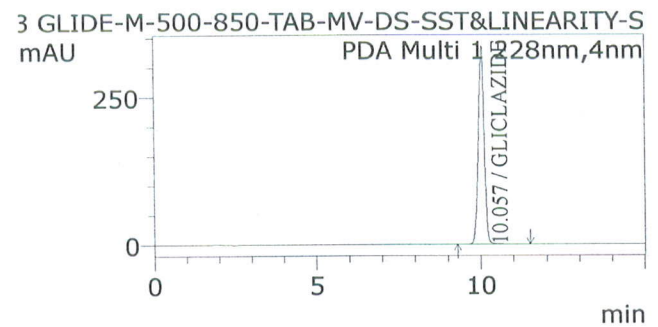
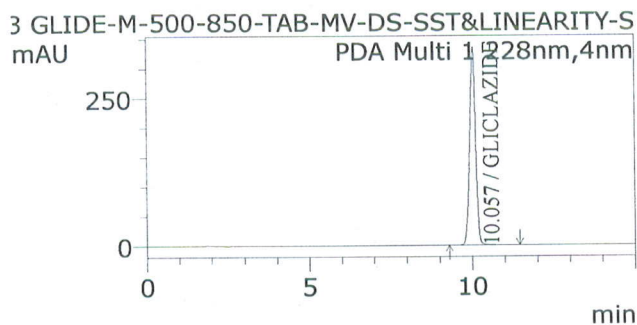
Analysis Report

<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : GLICLAZIDE-RECOVERY-150%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-54.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-16
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 07:59:42
 Date Processed : 15-09-2023 09:17:04

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
16	ITY-SPL-54.lcd	GLICLAZIDE-RECOVERY-150%-SPL-1	10.06	4237201	13411	0.85
16	ITY-SPL-55.lcd	GLICLAZIDE-RECOVERY-150%-SPL-2	10.06	4237793	13410	0.85
16	ITY-SPL-56.lcd	GLICLAZIDE-RECOVERY-150%-SPL-3	10.06	4236835	13414	0.85
	Average		10.06	4237276	13412	0.85
	%RSD		0.004	0.011	0.018	0.019

Analysed By

(Signature)
15/09/23

Checked By

(Signature)
15/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

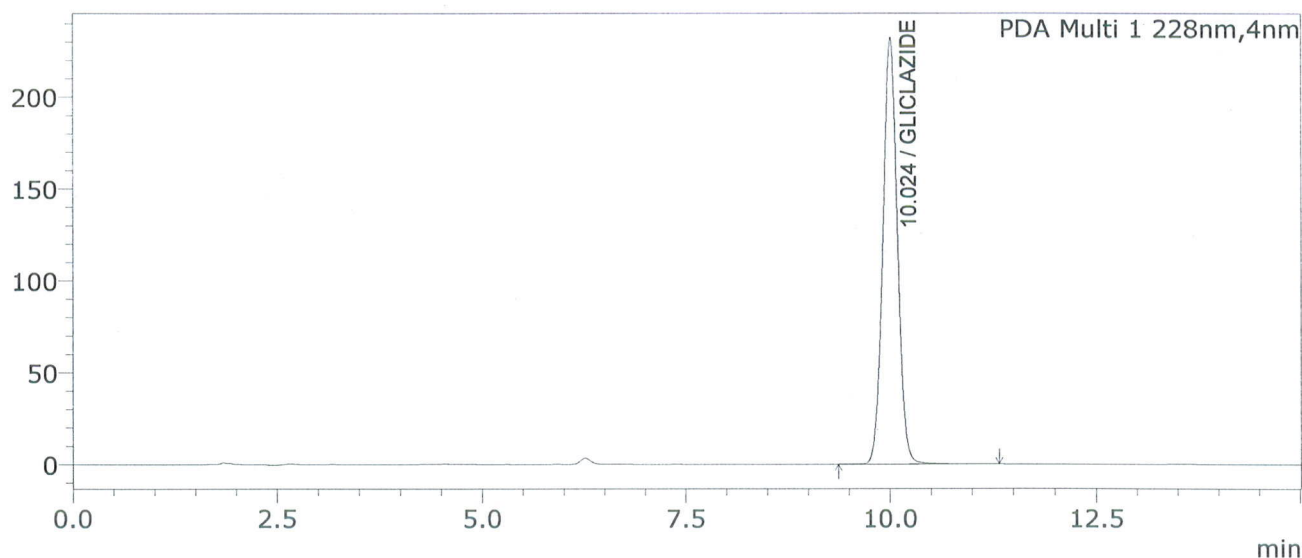
<Sample Information>

Sample Name : RECOVERY-DS
 Sample ID : GLICLAZIDE-RECOVERY-DS-STD-BKT
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-57.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-12
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 08:47:21
 Date Processed : 15-09-2023 09:16:52

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2870318	100.00	14167	0.920	--	--
Total			2870318	100.00				

15/09/23

Analysed By

15/09/23

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	LINEARITY and RANGE	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Linearity Level-I :	66.02	mg to ---	100	ml to ---	5	ml to ---	500
Std.conc (in ppm)-6.602	1	ml to ---	1	ml to ---	1	ml to ---	1

Linearity Level-II :	66.02	mg to ---	100	ml to ---	5	ml to ---	200
Std.conc (in ppm)-16.505	1	ml to ---	1	ml to ---	1	ml to ---	1

Linearity Level-III :	66.02	mg to ---	100	ml to ---	5	ml to ---	100
Std.conc (in ppm)-33.01	1	ml to ---	1	ml to ---	1	ml to ---	1

Linearity Level-IV :	66.02	mg to ---	100	ml to ---	7.5	ml to ---	100
Std.conc (in ppm)-49.515	1	ml to ---	1	ml to ---	1	ml to ---	1

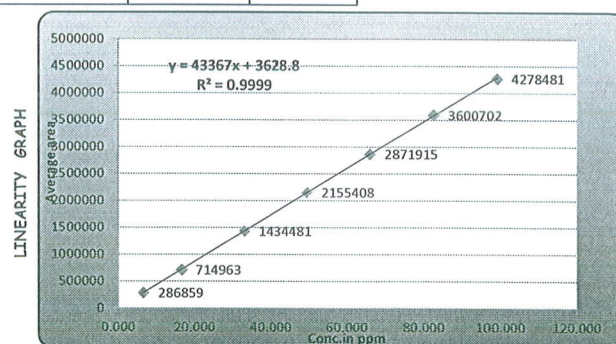
Linearity Level-V :	66.02	mg to ---	100	ml to ---	5	ml to ---	50
Std.conc (in ppm)-66.02	1	ml to ---	1	ml to ---	1	ml to ---	1

Linearity Level-VI :	66.02	mg to ---	100	ml to ---	2.5	ml to ---	20
Std.conc (in ppm)-82.525	1	ml to ---	1	ml to ---	1	ml to ---	1

Linearity Level-VII :	66.02	mg to ---	100	ml to ---	7.5	ml to ---	50
Std.conc (in ppm)-99.03	1	ml to ---	1	ml to ---	1	ml to ---	1

Level's	I	II	III	IV	V	VI	VII
No.of injections.	10%	25%	50%	75%	100%	125%	150%
1	286813	715159	1435643	2155560	2875177	3600822	4280316
2	286972	714764	1432671	2156139	2870381	3601424	4278007
3	286793	714966	1435129	2154524	2870186	3599860	4277121
Average	286859	714963	1434481	2155408	2871915	3600702	4278481
RSD%	0.034	0.028	0.111	0.038	0.098	0.022	0.039

LEVEL's	Conc.in ppm (X-axis)	Average area (Y-axis)
I	6.602	286859
II	16.505	714963
III	33.010	1434481
IV	49.515	2155408
V	66.020	2871915
VI	82.525	3600702
VII	99.030	4278481

**Results :**

- 1) Squared correlation coefficient of Gliclazide **1.000**
- 2) In Range , %RSD of areas at 10%,25%,50%, 75%, 100%, 125 & 150% levels within limits.

Acceptance criteria:

- 1) To conclude the linearity, the squared correlation coefficient (r^2) should be Not less than 0.995
- 2) To conclude the range , %RSD of areas at 10%,25%,50%, 75%, 100%, 125 & 150% levels should be Not more than 2.0.

Analysed by : E.MEENA
Date : 15-09-2023

Checked by :
Date :



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

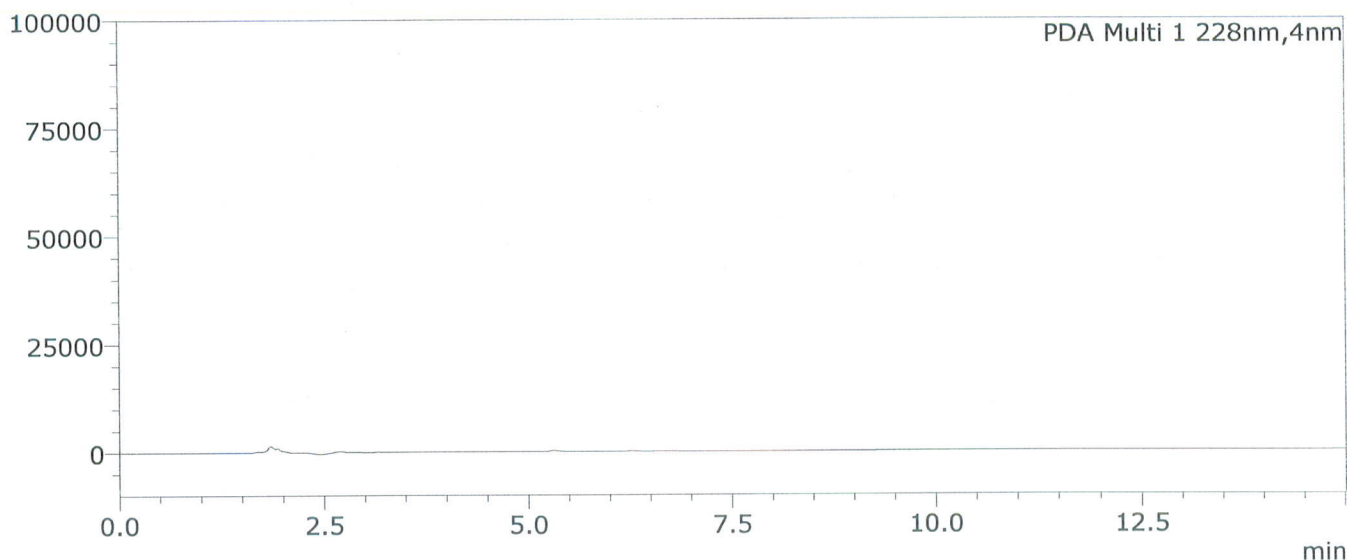
<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-07.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 19:50:21
 Date Processed : 15-09-2023 09:16:39

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

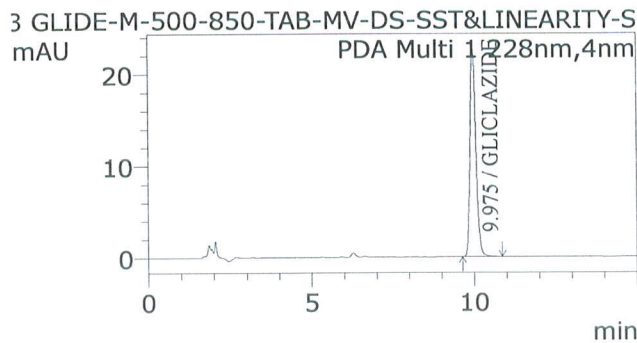
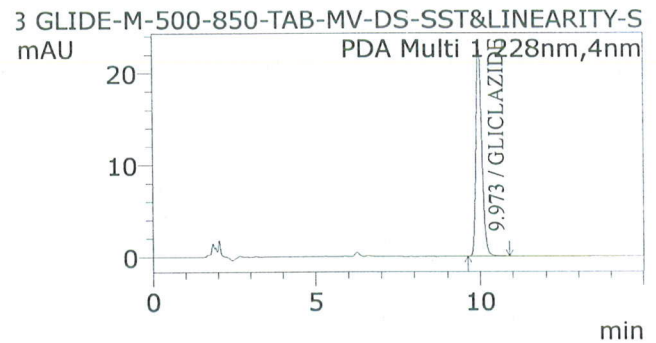
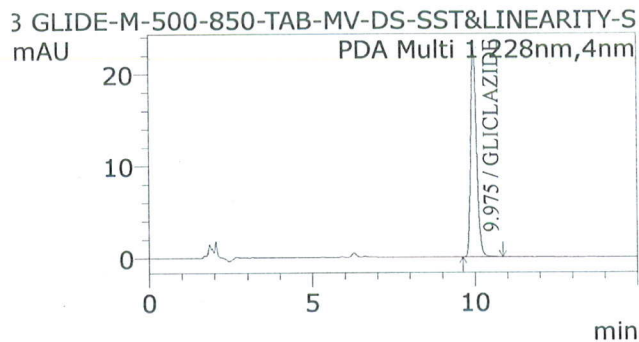
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-10%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-08.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-4
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 20:05:54
 Date Processed : 15-09-2023 09:16:39

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
4	ITY-SPL-08.lcd	GLICLAZIDE-LINEARITY-10%-SPL-1	9.97	286813	14149	1.15
4	ITY-SPL-09.lcd	GLICLAZIDE-LINEARITY-10%-SPL-2	9.97	286972	14146	1.15
4	ITY-SPL-10.lcd	GLICLAZIDE-LINEARITY-10%-SPL-3	9.98	286793	14165	1.15
	Average		9.97	286859	14154	1.15
	%RSD		0.011	0.034	0.072	0.054

Analysed By

15/09/23

Checked By

15/09/23



GENERIC HEALTHCARE PVT. LTD.

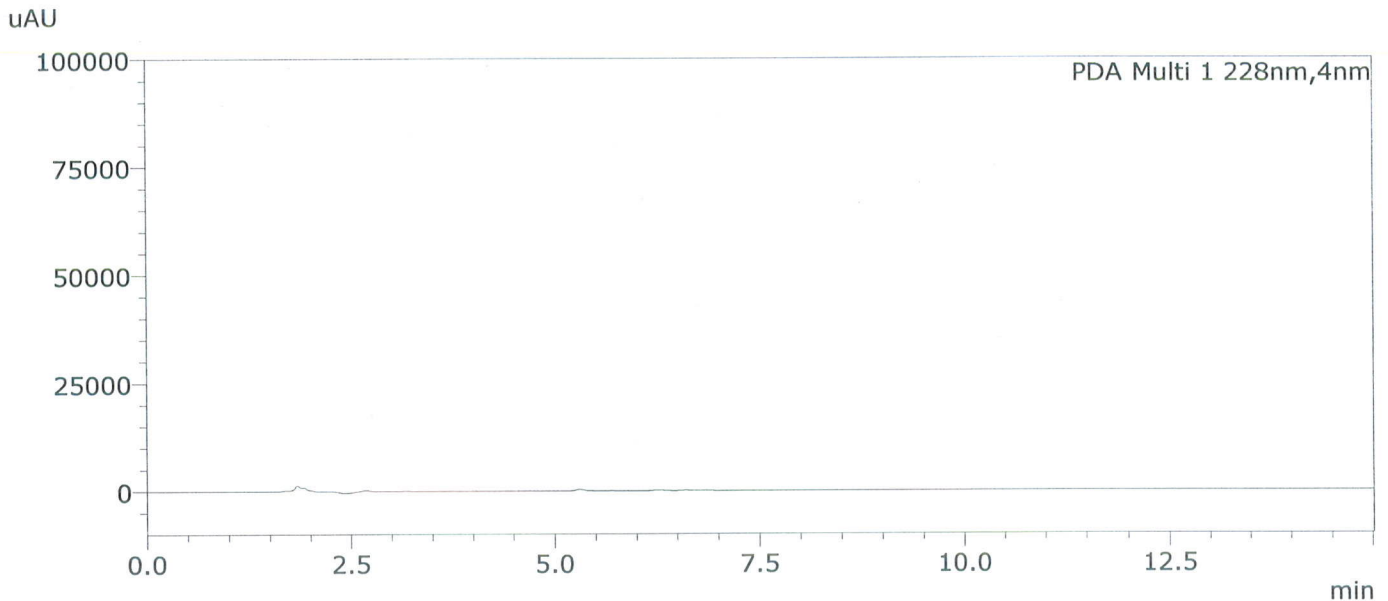
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-11.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 20:52:31
 Date Processed : 15-09-2023 09:16:40

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

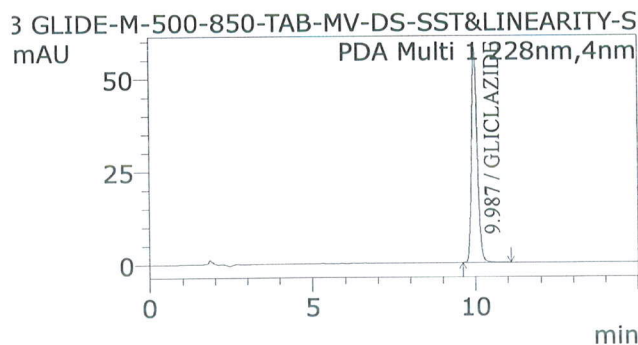
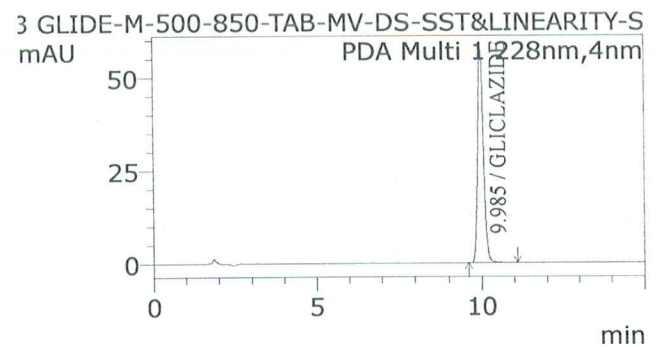
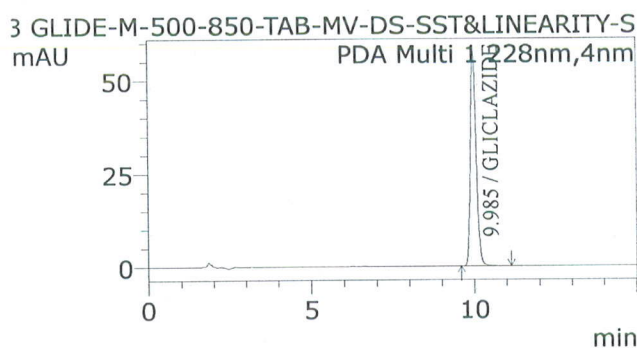
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-25%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-12.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-5
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 21:08:04
 Date Processed : 15-09-2023 09:16:41

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	ITY-SPL-12.lcd	GLICLAZIDE-LINEARITY-25%-SPL-1	9.99	715159	14342	1.09
5	ITY-SPL-13.lcd	GLICLAZIDE-LINEARITY-25%-SPL-2	9.99	714764	14339	1.09
5	ITY-SPL-14.lcd	GLICLAZIDE-LINEARITY-25%-SPL-3	9.99	714966	14345	1.09
	Average		9.99	714963	14342	1.09
	%RSD		0.011	0.028	0.018	0.021

Analysed By

(Signature)
15/09/23

Checked By

(Signature)
15/09/23



GENERIC HEALTHCARE PVT. LTD.

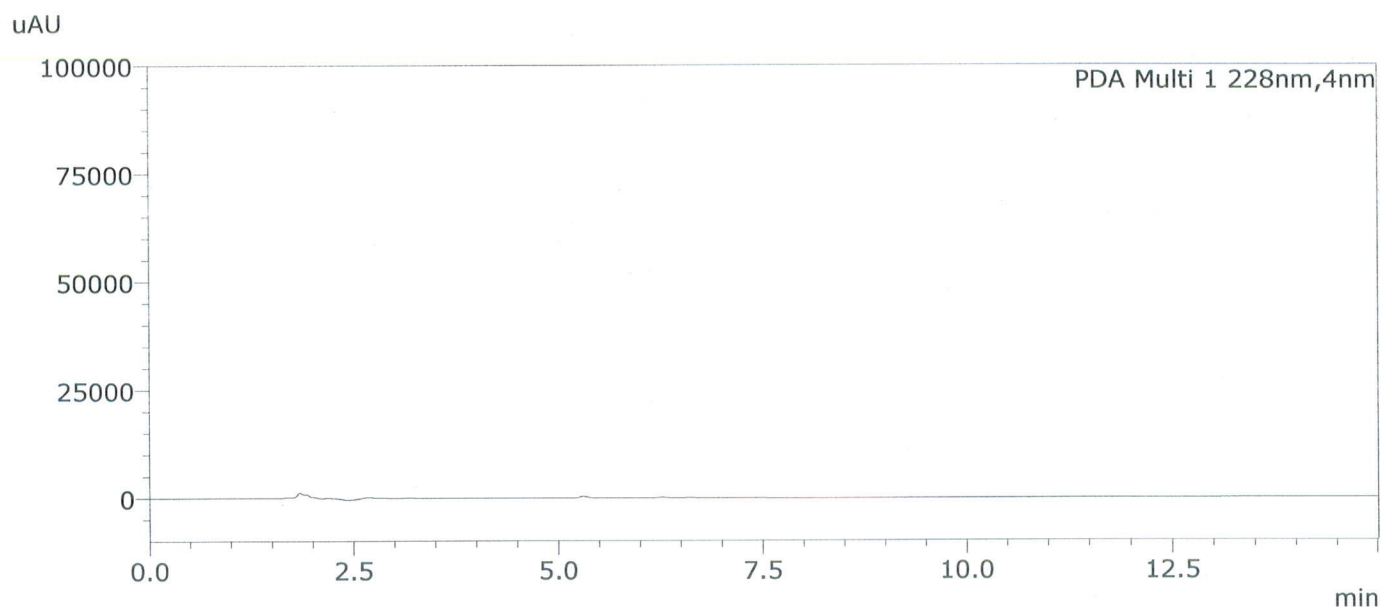
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-15.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 21:54:40
 Date Processed : 15-09-2023 09:16:41

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

15/09/23

Analysed By

15/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

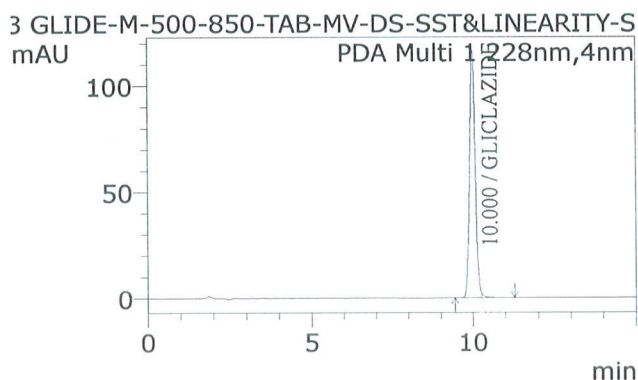
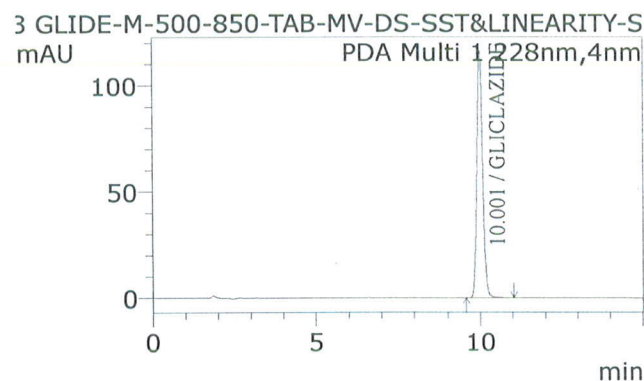
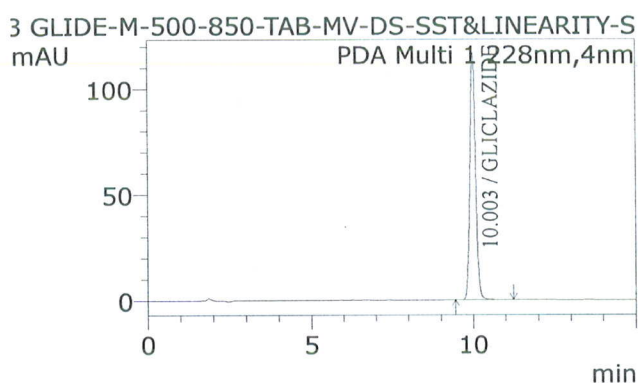
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-50%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-16.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-6
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 22:10:12
 Date Processed : 15-09-2023 09:16:41

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	ITY-SPL-16.lcd	GLICLAZIDE-LINEARITY-50%-SPL-1	10.00	1435643	14395	1.03
6	ITY-SPL-17.lcd	GLICLAZIDE-LINEARITY-50%-SPL-2	10.00	1432671	14401	1.03
6	ITY-SPL-18.lcd	GLICLAZIDE-LINEARITY-50%-SPL-3	10.00	1435129	14401	1.03
	Average		10.00	1434481	14399	1.03
	%RSD		0.016	0.111	0.023	0.072

Analysed By

15/09/23

Checked By

15/09/23



GENERIC HEALTHCARE PVT. LTD.

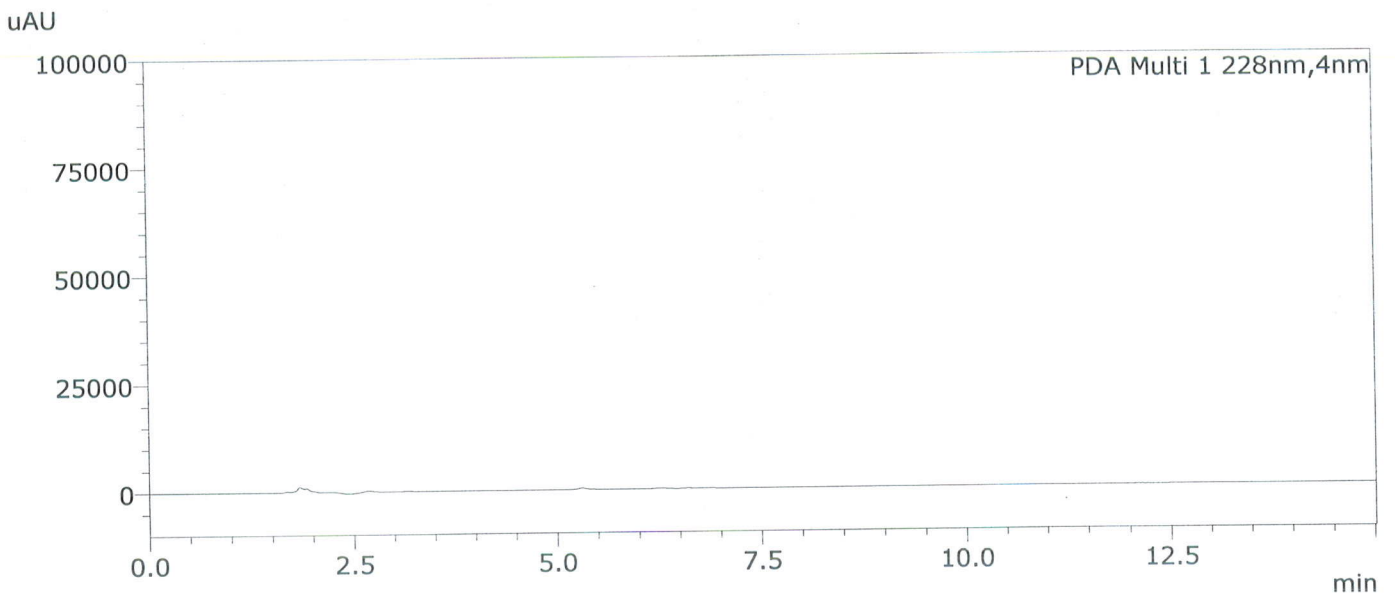
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-19.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 22:56:48
 Date Processed : 15-09-2023 09:16:42

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

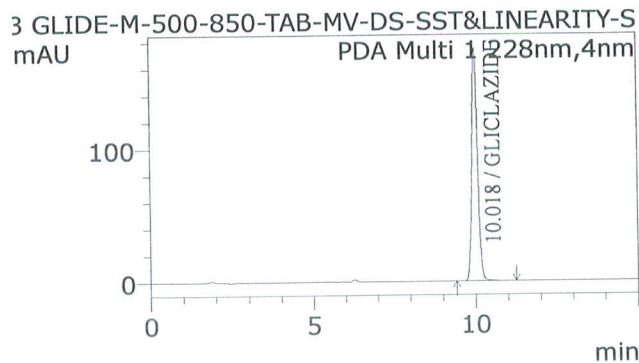
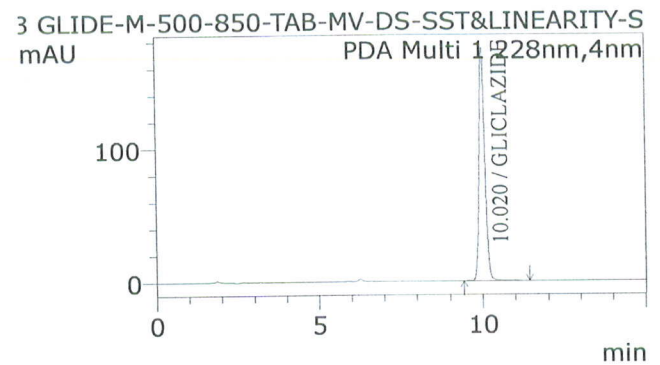
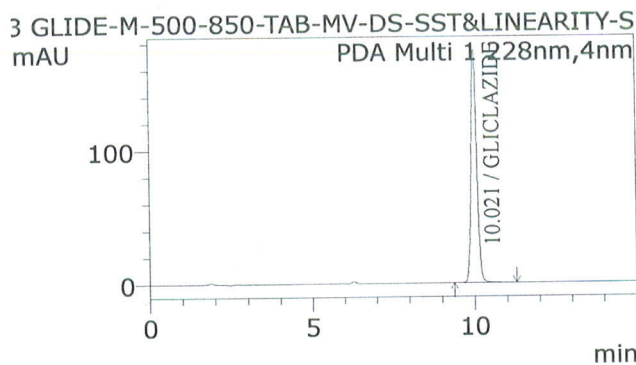
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-75%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-20.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-7
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 23:12:20
 Date Processed : 15-09-2023 09:16:42

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
7	ITY-SPL-20.lcd	GLICLAZIDE-LINEARITY-75%-SPL-1	10.02	2155560	14345	0.97
7	ITY-SPL-21.lcd	GLICLAZIDE-LINEARITY-75%-SPL-2	10.02	2156139	14333	0.97
7	ITY-SPL-22.lcd	GLICLAZIDE-LINEARITY-75%-SPL-3	10.02	2154524	14353	0.97
	Average		10.02	2155408	14344	0.97
	%RSD		0.020	0.038	0.070	0.083

Analysed By

15/09/23

Checked By

15/09/23

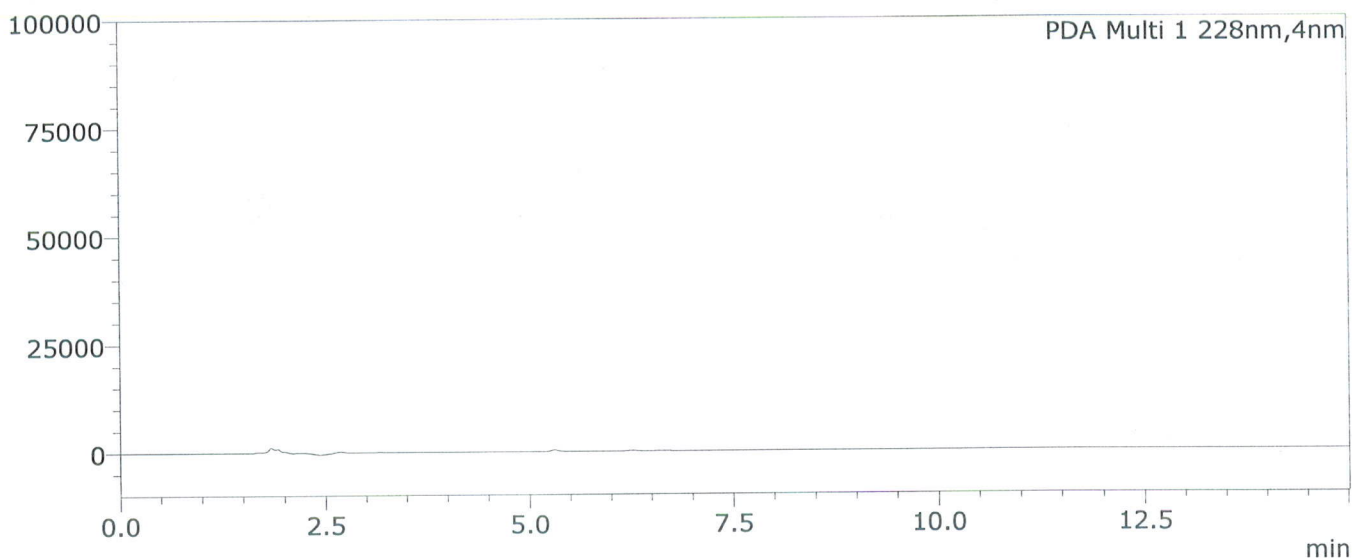

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-23.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 23:58:57
 Date Processed : 15-09-2023 09:16:43

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uAU


<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

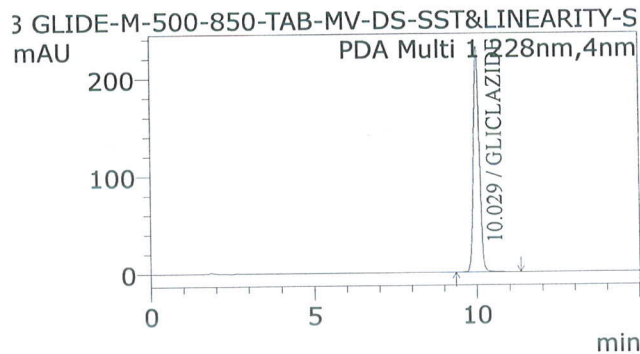
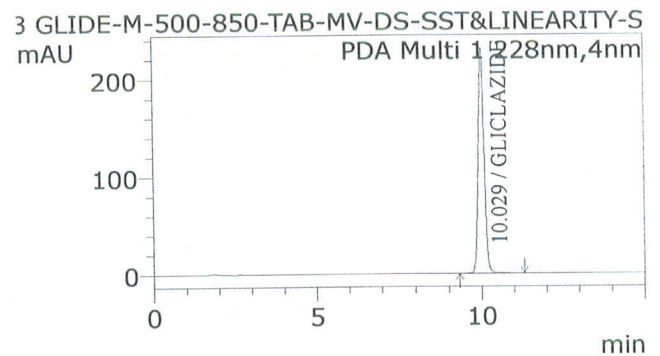
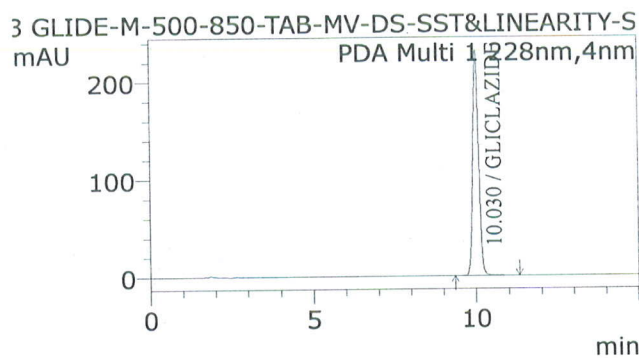
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-100%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-24.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-8
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 00:14:30
 Date Processed : 15-09-2023 09:16:43

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
8	ITY-SPL-24.lcd	GLICLAZIDE-LINEARITY-100%-SPL-1	10.03	2875177	14055	0.92
8	ITY-SPL-25.lcd	GLICLAZIDE-LINEARITY-100%-SPL-2	10.03	2870381	14092	0.92
8	ITY-SPL-26.lcd	GLICLAZIDE-LINEARITY-100%-SPL-3	10.03	2870186	14075	0.92
	Average		10.03	2871915	14074	0.92
	%RSD		0.004	0.098	0.135	0.027

Analysed By

15/09/23

Checked By

15/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

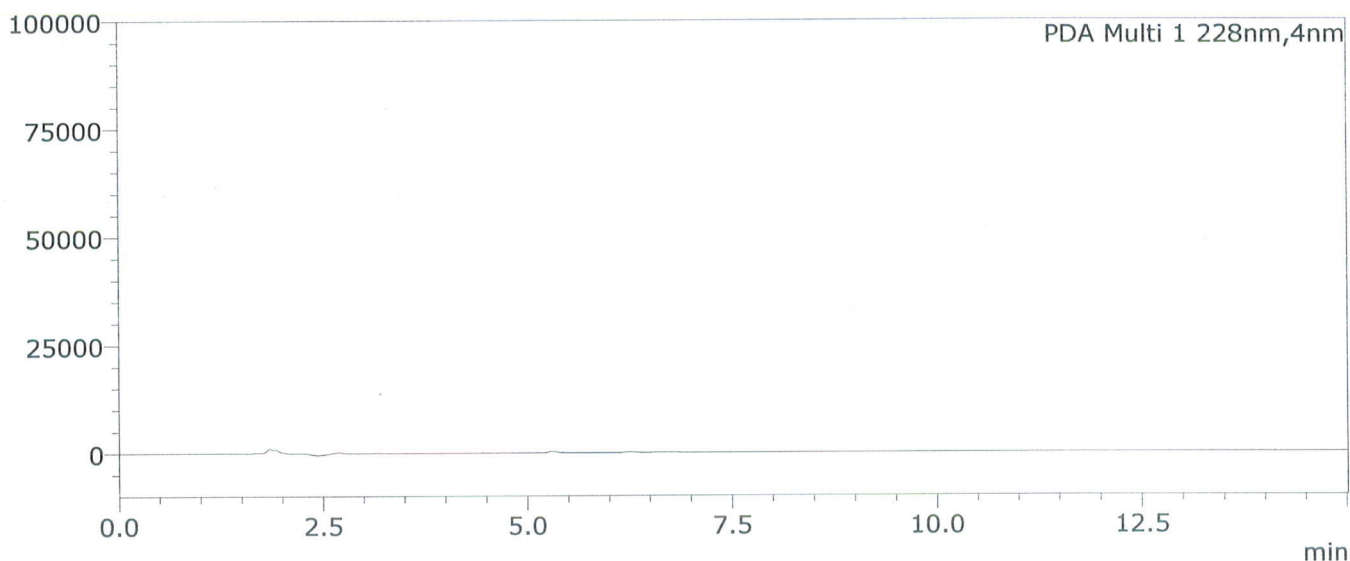
<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-27.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 01:01:08
 Date Processed : 15-09-2023 09:16:44

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

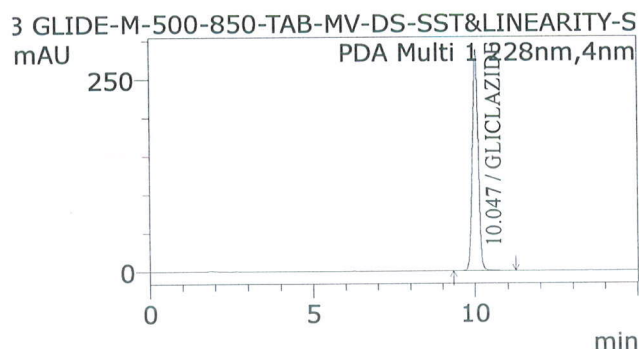
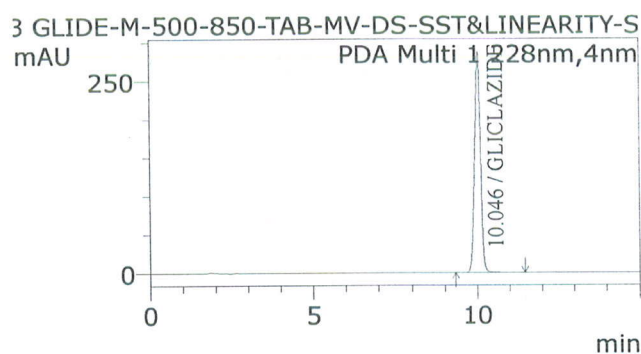
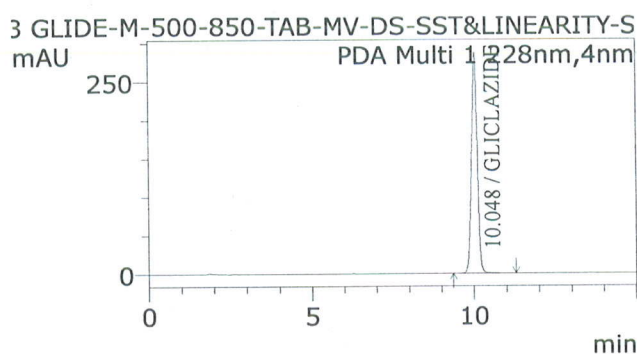
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-125%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-28.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-9
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 01:16:41
 Date Processed : 15-09-2023 09:16:45

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	ITY-SPL-28.lcd	GLICLAZIDE-LINEARITY-125%-SPL-1	10.05	3600822	13746	0.88
9	ITY-SPL-29.lcd	GLICLAZIDE-LINEARITY-125%-SPL-2	10.05	3601424	13755	0.88
9	ITY-SPL-30.lcd	GLICLAZIDE-LINEARITY-125%-SPL-3	10.05	3599860	13754	0.88
	Average		10.05	3600702	13752	0.88
	%RSD		0.009	0.022	0.038	0.023

Analysed By

15/09/23

Checked By

15/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

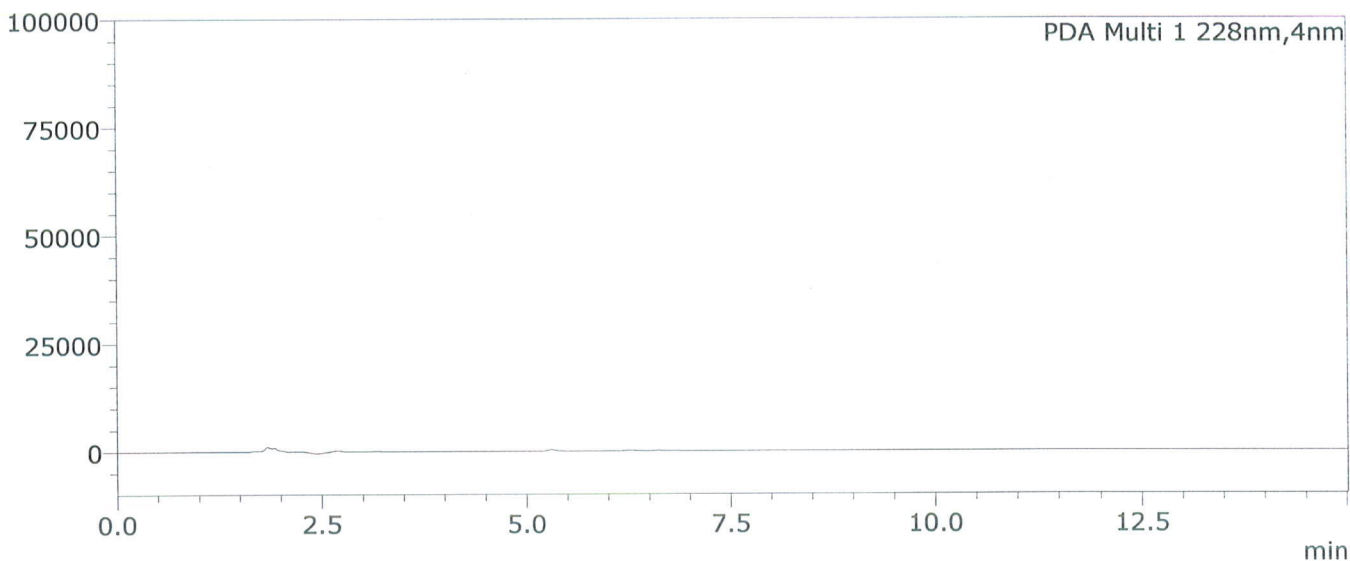
<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-31.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 02:03:20
 Date Processed : 15-09-2023 09:16:45

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

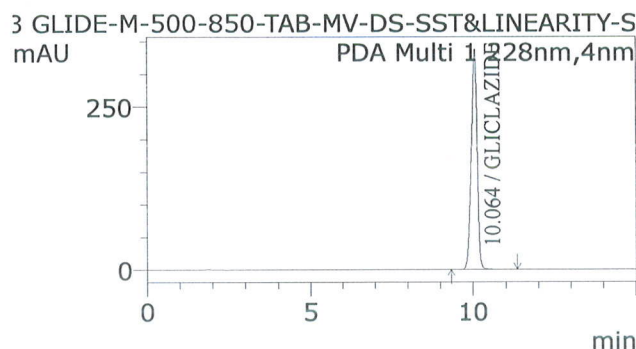
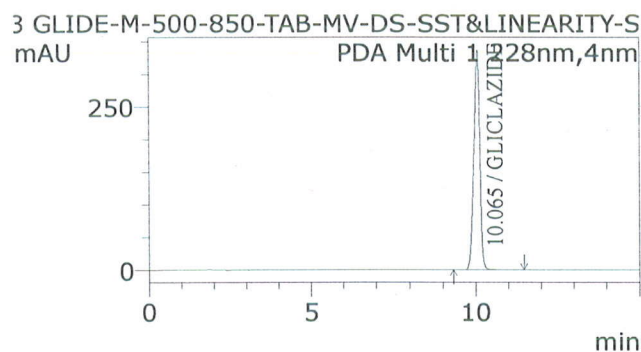
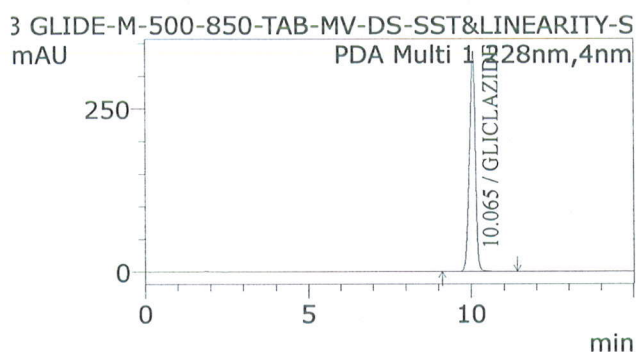
Analysis Report

<Sample Information>

Sample Name : LINEARITY-DS
 Sample ID : GLICLAZIDE-LINEARITY-150%-SPL-1
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-32.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-10
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 02:18:53
 Date Processed : 15-09-2023 09:16:46

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
10	ITY-SPL-32.lcd	GLICLAZIDE-LINEARITY-150%-SPL-1	10.07	4280316	13378	0.85
10	ITY-SPL-33.lcd	GLICLAZIDE-LINEARITY-150%-SPL-2	10.07	4278007	13377	0.85
10	ITY-SPL-34.lcd	GLICLAZIDE-LINEARITY-150%-SPL-3	10.06	4277121	13389	0.85
	Average		10.06	4278481	13381	0.85
	%RSD		0.009	0.039	0.052	0.022

Analysed By

W 15/09/23

Checked By

S.A 15/09/23

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	SYSTEM SUITABILITY	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	66.02	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.02	1	ml to --->	1	ml to --->	1	ml to --->	1

No.of injections	Retention time	Area	Theoretical plate	Tailing factor
1	10.034	2862162	14019	0.927
2	10.033	2861345	14030	0.927
3	10.031	2861167	14027	0.927
4	10.031	2861959	14026	0.927
5	10.031	2861262	14027	0.927
Average	10.030	2861579	14026	0.927
RSD %	0.015	0.016	Not applicable	Not applicable

Results :

- 1) % RSD of area of Gliclazide peak
- 2) Theoretical plate for Gliclazide peak
- 3) Tailing factor for Gliclazide peak

0.016

14026

0.927

Acceptance criteria:

- 1) % RSD of area of Gliclazide peak in five replicate Standard injections should not be more than 2.0.
- 2) Theoretical plate for Gliclazide peak in Standard injection should not be less than 2000.
- 3) Tailing factor for Gliclazide peak in Standard injection should not be more than 2.0.

Analysed by :

E.MEENA

Date :

15-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

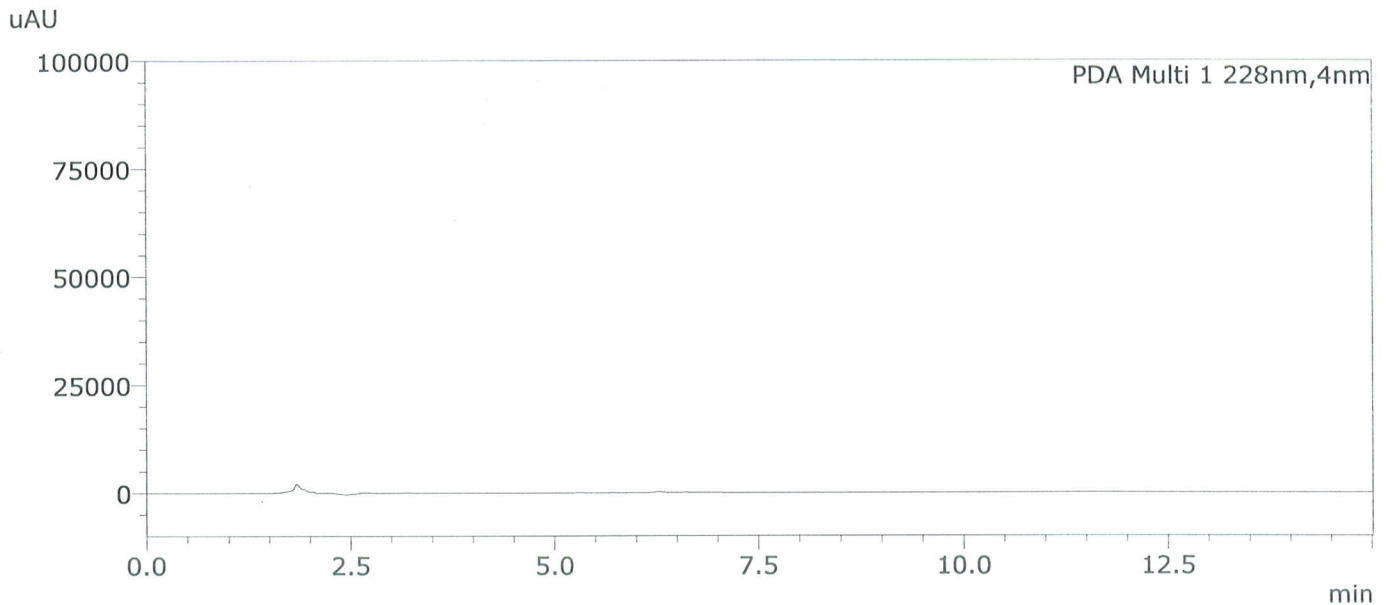
Analysis Report

<Sample Information>

Sample Name : SYSTEM SUITABILITY-DS
 Sample ID : BLANK-DS
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-01.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-1
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 18:17:09
 Date Processed : 15-09-2023 09:16:38

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

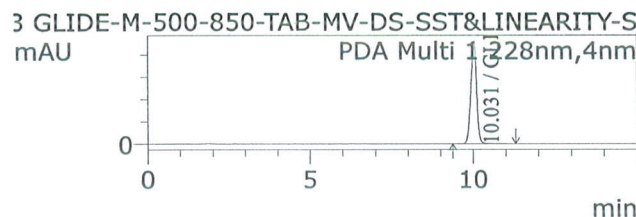
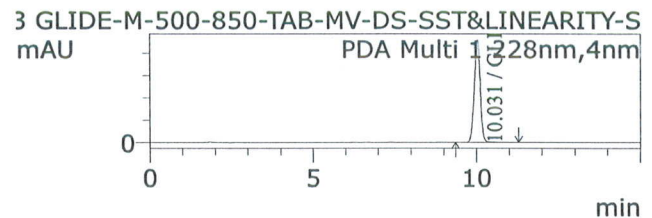
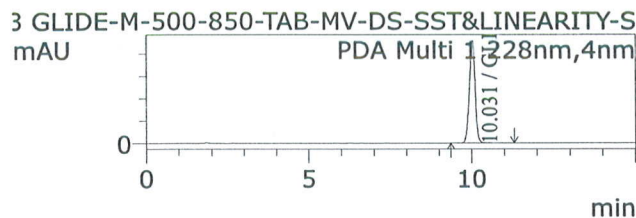
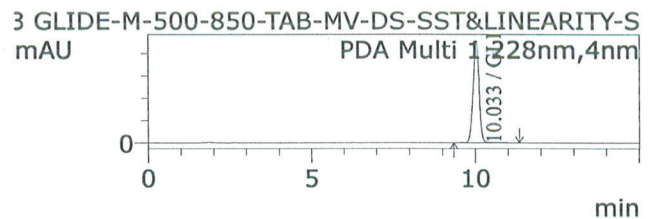
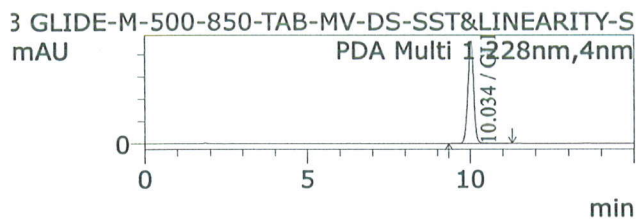
Analysis Report

<Sample Information>

Sample Name : SYSTEM SUITABILITY-DS
 Sample ID : GLICLAZIDE-SST-DS-STD-01
 Data Filename : 14092023 GLIDE-M-500-850-TAB-MV-DS-SST&LINEARITY-SPL-02.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 14092023 GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 18:32:41
 Date Processed : 15-09-2023 09:16:38

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	ITY-SPL-02.lcd	GLICLAZIDE-SST-DS-STD-01	10.03	2862162	14019	0.93
2	ITY-SPL-03.lcd	GLICLAZIDE-SST-DS-STD-02	10.03	2861345	14030	0.93
2	ITY-SPL-04.lcd	GLICLAZIDE-SST-DS-STD-03	10.03	2861167	14027	0.93
2	ITY-SPL-05.lcd	GLICLAZIDE-SST-DS-STD-04	10.03	2861959	14026	0.93
2	ITY-SPL-06.lcd	GLICLAZIDE-SST-DS-STD-05	10.03	2861262	14027	0.93
	Average		10.03	2861579	14026	0.93
	%RSD		0.015	0.016	0.029	0.010

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 14092023.GLIDE-M-60-500-850-TAB-MV-DS-SST&LINEARITY&RECOVERY.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	3	SYSTEM SUITABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-01.lcd	20.0	QC/CL/23/041
2	3	SYSTEM SUITABILITY-DS	GLICLAZIDE-SST-DS-STD-01	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-02.lcd	20.0	QC/CL/23/041
2	3	SYSTEM SUITABILITY-DS	GLICLAZIDE-SST-DS-STD-02	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-03.lcd	20.0	QC/CL/23/041
2	3	SYSTEM SUITABILITY-DS	GLICLAZIDE-SST-DS-STD-03	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-04.lcd	20.0	QC/CL/23/041
2	3	SYSTEM SUITABILITY-DS	GLICLAZIDE-SST-DS-STD-04	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-05.lcd	20.0	QC/CL/23/041
2	3	SYSTEM SUITABILITY-DS	GLICLAZIDE-SST-DS-STD-05	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-06.lcd	20.0	QC/CL/23/041
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-07.lcd	20.0	QC/CL/23/041
4	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-10%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-08.lcd	20.0	QC/CL/23/041
4	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-10%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-09.lcd	20.0	QC/CL/23/041
4	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-10%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-10.lcd	20.0	QC/CL/23/041
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-11.lcd	20.0	QC/CL/23/041
5	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-25%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-12.lcd	20.0	QC/CL/23/041
5	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-25%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-13.lcd	20.0	QC/CL/23/041
5	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-25%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-14.lcd	20.0	QC/CL/23/041
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-15.lcd	20.0	QC/CL/23/041
6	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-50%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-16.lcd	20.0	QC/CL/23/041
6	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-50%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-17.lcd	20.0	QC/CL/23/041
6	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-50%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-19.lcd	20.0	QC/CL/23/041
7	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-75%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-20.lcd	20.0	QC/CL/23/041
7	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-75%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-21.lcd	20.0	QC/CL/23/041
7	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-75%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-22.lcd	20.0	QC/CL/23/041
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-23.lcd	20.0	QC/CL/23/041
8	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-100%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-24.lcd	20.0	QC/CL/23/041
8	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-100%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-25.lcd	20.0	QC/CL/23/041
8	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-100%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-26.lcd	20.0	QC/CL/23/041
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-27.lcd	20.0	QC/CL/23/041
9	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-125%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-28.lcd	20.0	QC/CL/23/041
9	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-125%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-29.lcd	20.0	QC/CL/23/041
9	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-125%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-30.lcd	20.0	QC/CL/23/041
3	3	LINEARITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-31.lcd	20.0	QC/CL/23/041
10	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-150%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-32.lcd	20.0	QC/CL/23/041
10	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-150%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-33.lcd	20.0	QC/CL/23/041
10	3	LINEARITY-DS	GLICLAZIDE-LINEARITY-150%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-34.lcd	20.0	QC/CL/23/041
11	3	RECOVERY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-35.lcd	20.0	QC/CL/23/041
12	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-DS-STD-01	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-36.lcd	20.0	QC/CL/23/041
12	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-DS-STD-02	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-37.lcd	20.0	QC/CL/23/041
12	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-DS-STD-03	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-38.lcd	20.0	QC/CL/23/041
12	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-DS-STD-04	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-39.lcd	20.0	QC/CL/23/041
12	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-DS-STD-05	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-40.lcd	20.0	QC/CL/23/041
11	3	RECOVERY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-41.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
13	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-5%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-42.lcd	20.0	QC/CL/23/041
13	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-5%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-43.lcd	20.0	QC/CL/23/041
13	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-5%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-44.lcd	20.0	QC/CL/23/041
11	3	RECOVERY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-45.lcd	20.0	QC/CL/23/041
14	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-50%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-46.lcd	20.0	QC/CL/23/041
14	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-50%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-47.lcd	20.0	QC/CL/23/041
14	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-50%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-48.lcd	20.0	QC/CL/23/041
11	3	RECOVERY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-49.lcd	20.0	QC/CL/23/041
15	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-100%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-50.lcd	20.0	QC/CL/23/041
15	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-100%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-51.lcd	20.0	QC/CL/23/041
15	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-100%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-52.lcd	20.0	QC/CL/23/041
11	3	RECOVERY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-53.lcd	20.0	QC/CL/23/041
16	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-150%-SPL-1	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-54.lcd	20.0	QC/CL/23/041
16	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-150%-SPL-2	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-55.lcd	20.0	QC/CL/23/041
16	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-150%-SPL-3	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-56.lcd	20.0	QC/CL/23/041
12	3	RECOVERY-DS	GLICLAZIDE-RECOVERY-DS-STD-BKT	AB-DS_GLICLAZIDE.lcm	INEARITY-SPL-57.lcd	20.0	QC/CL/23/041
-1	3	RECOVERY-DS	WASH	IOD\WASH METHOD.lcm	INEARITY-SPL-58.lcd	20.0	QC/CL/23/041
-1	3	RECOVERY-DS	SHUTDOWN	HUTDOWN METHOD.lcm	INEARITY-SPL-59.lcd	20.0	QC/CL/23/041

14/09/23

Analysed By

14/09/23

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	STABILITY OF ANALYTICAL SOLUTION	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	66.20	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.2	1	ml to --->	1	ml to --->	1	ml to --->	1

Sample dilution :	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.666	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled claim :	60	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	2825740	2824897	2825555	2825902	2825032	2825425	440.7	0.016
With Bracketing std.						2825425	440.7	0.016

Time interval	Gliclazide Standard area	Absolute % difference of Standard area	Gliclazide Sample area	Absolute % difference of Sample area	Content in %	Absolute % difference of Content in %
Initial	2825425	Not applicable	2688105	Not applicable	94.47	Not applicable
2nd Hour	2823197	0.08	2688365	-0.01	94.48	-0.01
4th Hour	2823905	0.05	2688197	0.00	94.48	0.00
6th Hour	2822418	0.11	2685970	0.08	94.40	0.08
8th Hour	2821704	0.13	2686414	0.06	94.41	0.06
10th Hour	2820429	0.18	2685793	0.09	94.39	0.09
12th Hour	2819832	0.20	2684553	0.13	94.35	0.13
16th Hour	2817179	0.29	2681176	0.26	94.23	0.26
20th Hour	2817317	0.29	2683508	0.17	94.31	0.17
24th Hour	2816734	0.31	2682781	0.20	94.29	0.20
32th Hour	2790525	1.25	2663487	0.92	93.61	0.92
38th Hours	2776752	1.75	2659870	1.06	93.48	1.06
42nd Hours	2777427	1.73	2660384	1.04	93.50	1.04
48th Hours	2775155	1.81	2659946	1.06	93.48	1.06
Average	2809143	0.63	2678468	0.39	94.14	0.39
% RSD	0.698	Not applicable	0.438	Not applicable	0.44	Not applicable

Results :

Standard solution and Sample Solution was stable upto 48 hrs at ambient temperature.

Acceptance criteria:The Standard solution and Sample solution shall be considered stable for the final period till which the area difference between initial and next periodic interval should not be more than $\pm 2\%$.Analysed by : E.MEENA
Date : 20-09-2023Checked by :
Date :



GENERIC HEALTHCARE PVT. LTD.

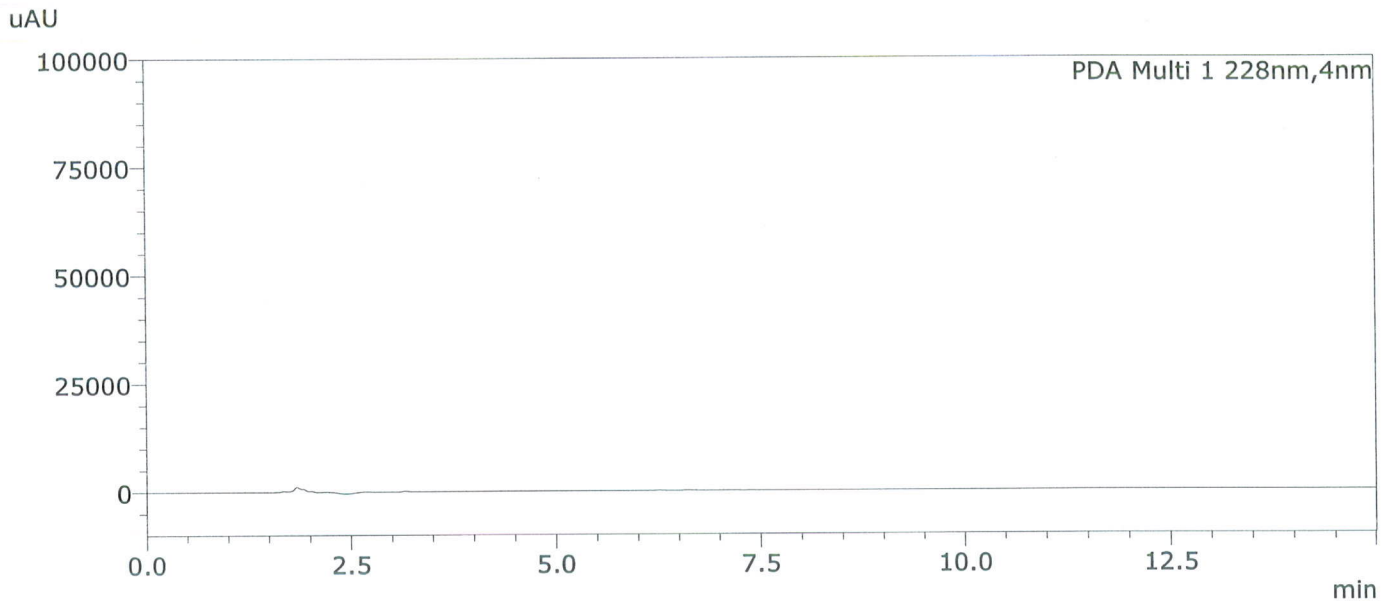
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-01.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 15:46:40
 Date Processed : 20-09-2023 09:57:01

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

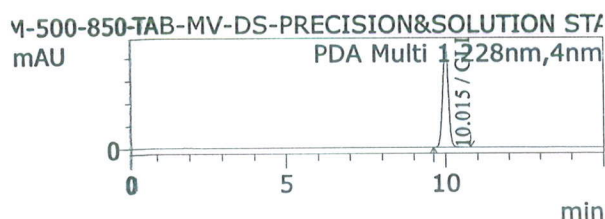
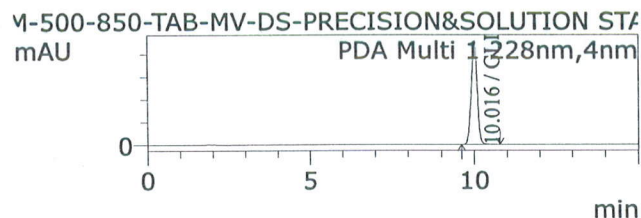
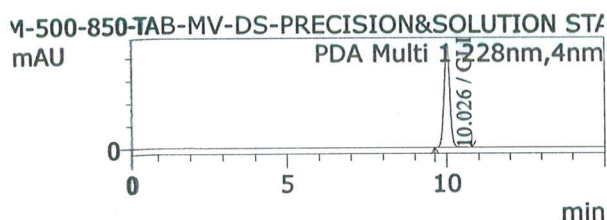
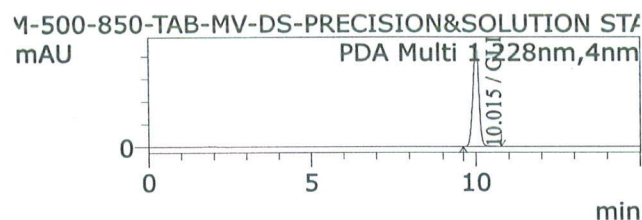
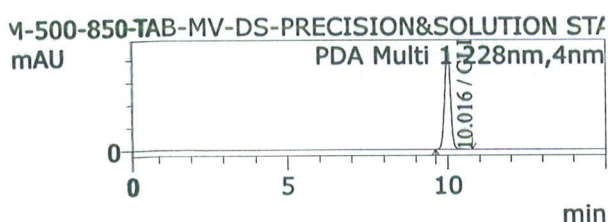
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-DS-STD-01
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-02
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 16:02:12
 Date Processed : 20-09-2023 09:57:01

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	ITY-SPL-02.lcd	GLICLAZIDE-SOL STB-DS-STD-01	10.02	2825740	14137	0.92
2	ITY-SPL-03.lcd	GLICLAZIDE-SOL STB-DS-STD-02	10.02	2824897	14143	0.92
2	ITY-SPL-04.lcd	GLICLAZIDE-SOL STB-DS-STD-03	10.03	2825555	14175	0.92
2	ITY-SPL-05.lcd	GLICLAZIDE-SOL STB-DS-STD-04	10.02	2825902	14143	0.92
2	ITY-SPL-06.lcd	GLICLAZIDE-SOL STB-DS-STD-05	10.01	2825032	14112	0.93
	Average		10.02	2825425	14142	0.92
	%RSD		0.048	0.016	0.158	0.012

Analysed By

20/09/23

Checked By

21/09/23

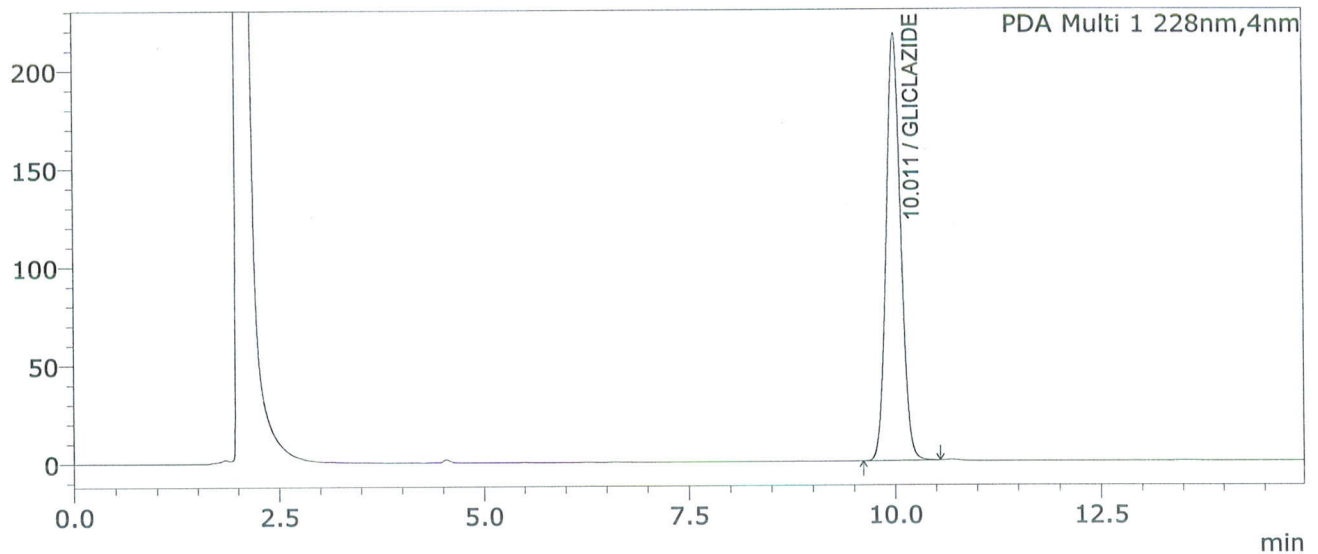

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : SOLUTION STABILITY-INI-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-07.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 17:19:55
 Date Processed : 20-09-2023 09:57:02

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU


<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2688105	100.00	14106	0.934	--	--
Total			2688105	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

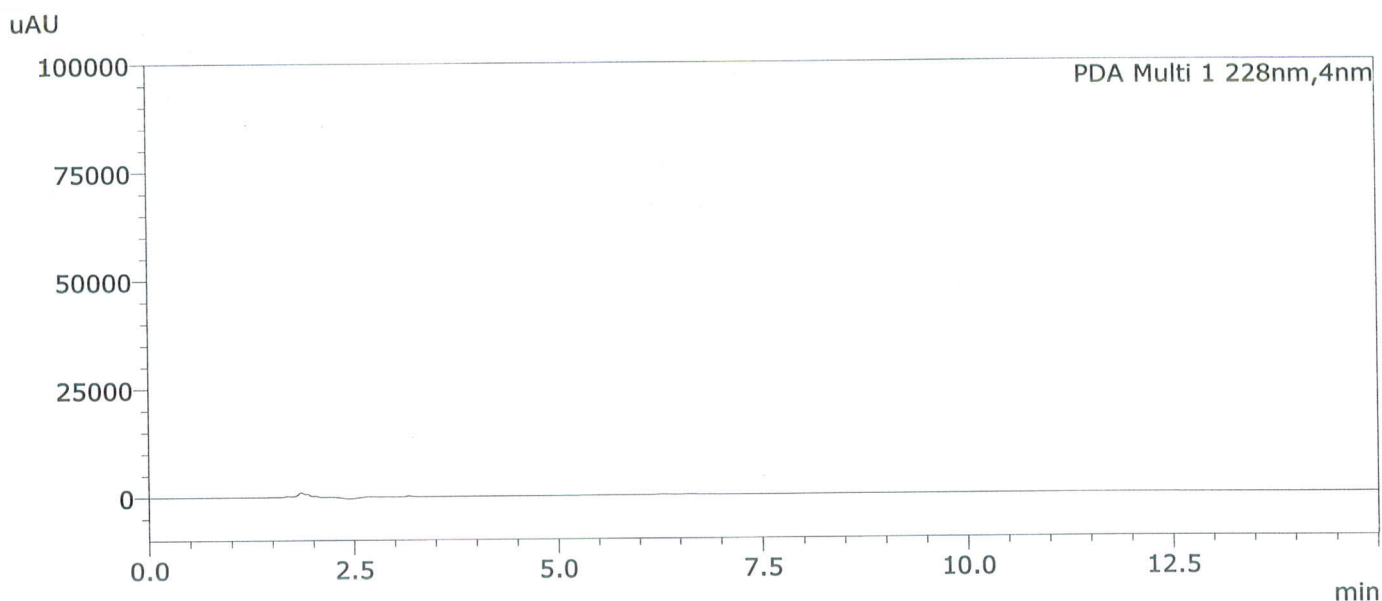
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-08.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 17:39:48
 Date Processed : 20-09-2023 09:57:02

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

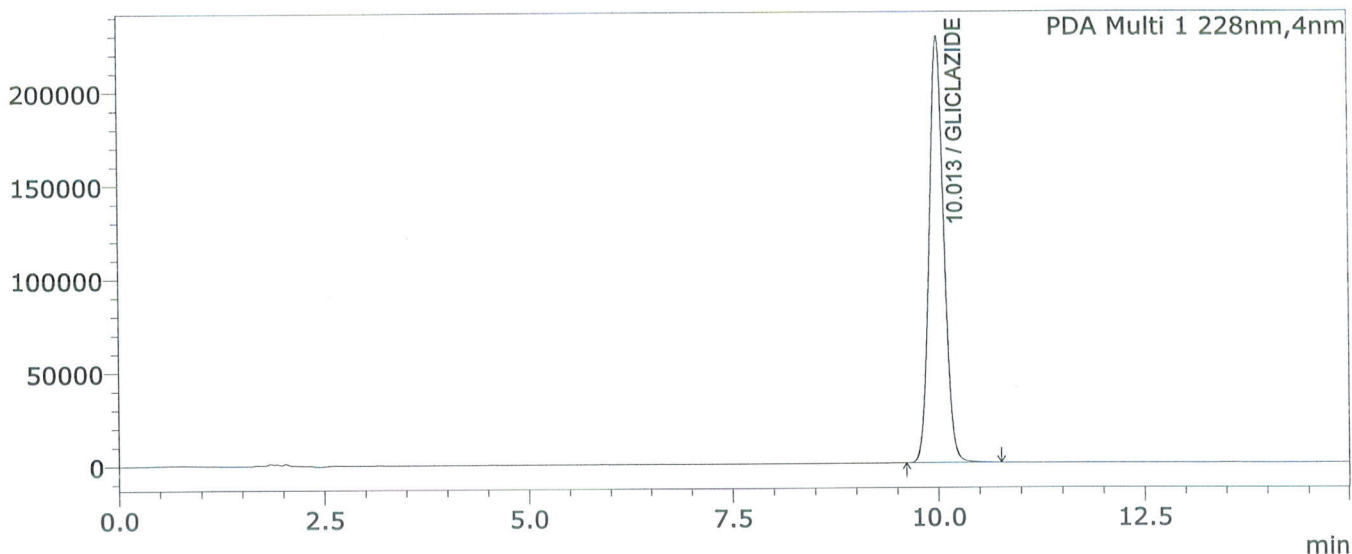
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-2H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-09.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 17:55:21
 Date Processed : 20-09-2023 09:57:02

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2823197	100.00	14104	0.927	--	--
Total			2823197	100.00				


 20/09/23
 Analysed By


 21/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

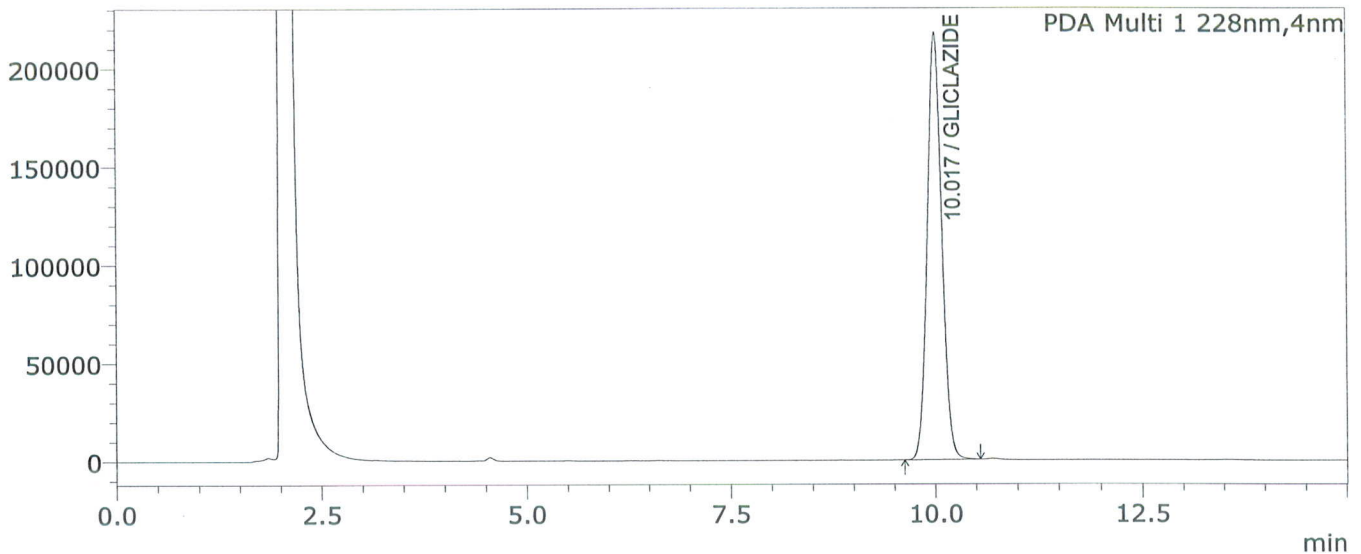
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-2H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-10.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 18:10:54
 Date Processed : 20-09-2023 09:57:03

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2688365	100.00	14098	0.936	--	--
Total			2688365	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

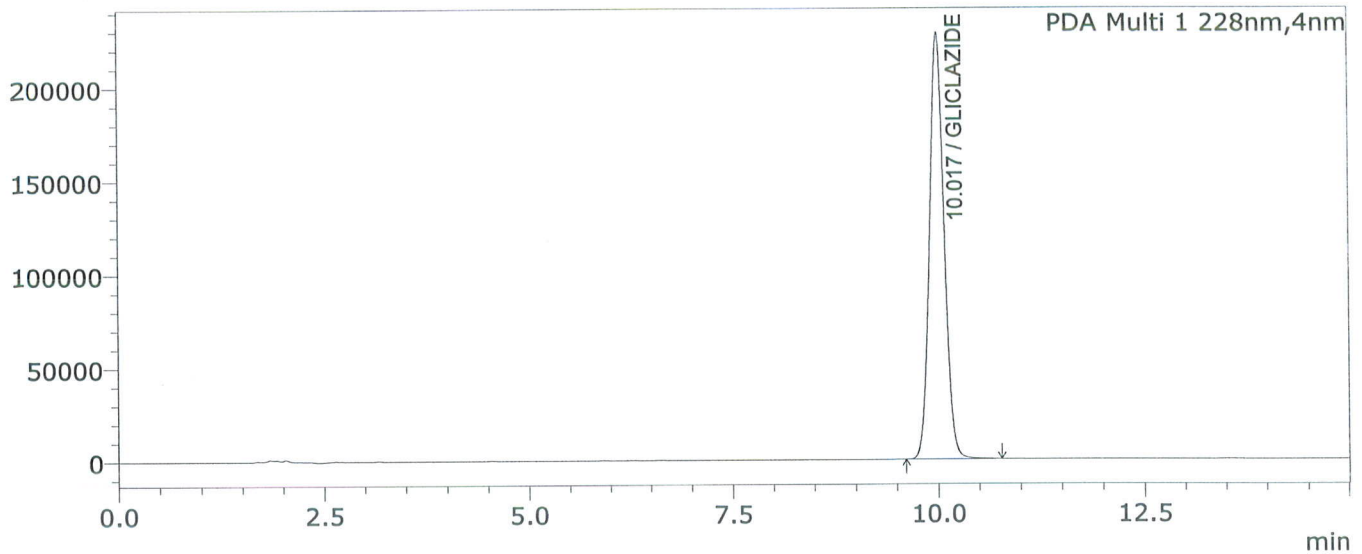
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-4H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-17.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 19:59:40
 Date Processed : 20-09-2023 09:57:08

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2823905	100.00	14120	0.926	--	--
Total			2823905	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

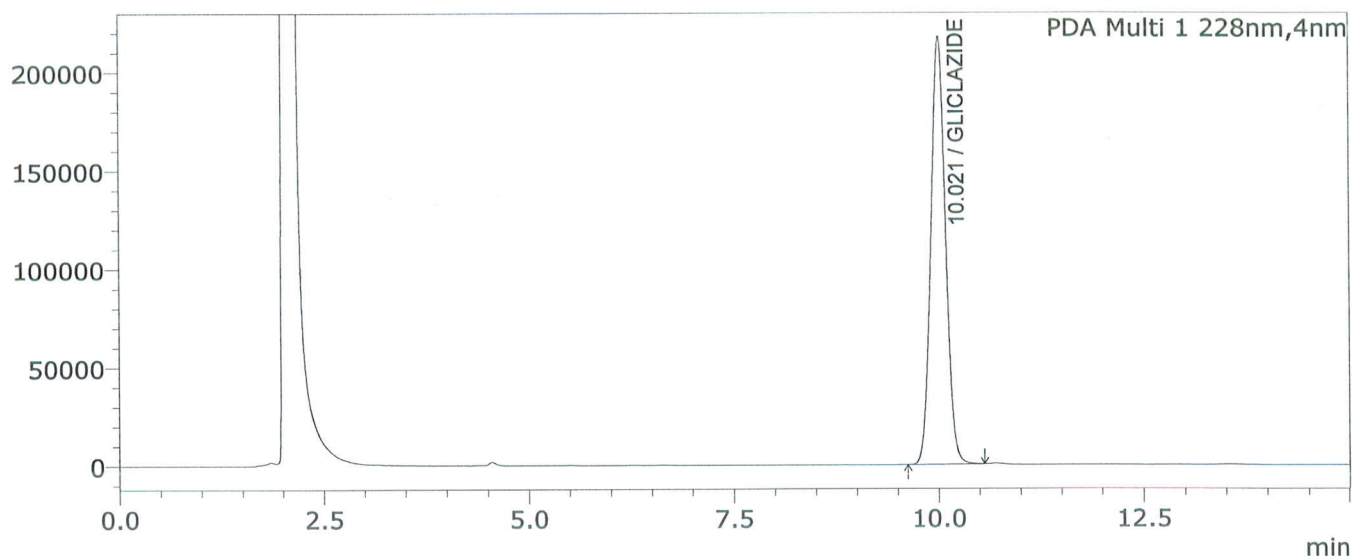
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-4H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-18.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 20:15:13
 Date Processed : 20-09-2023 09:57:09

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2688197	100.00	14103	0.935	--	--
Total			2688197	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

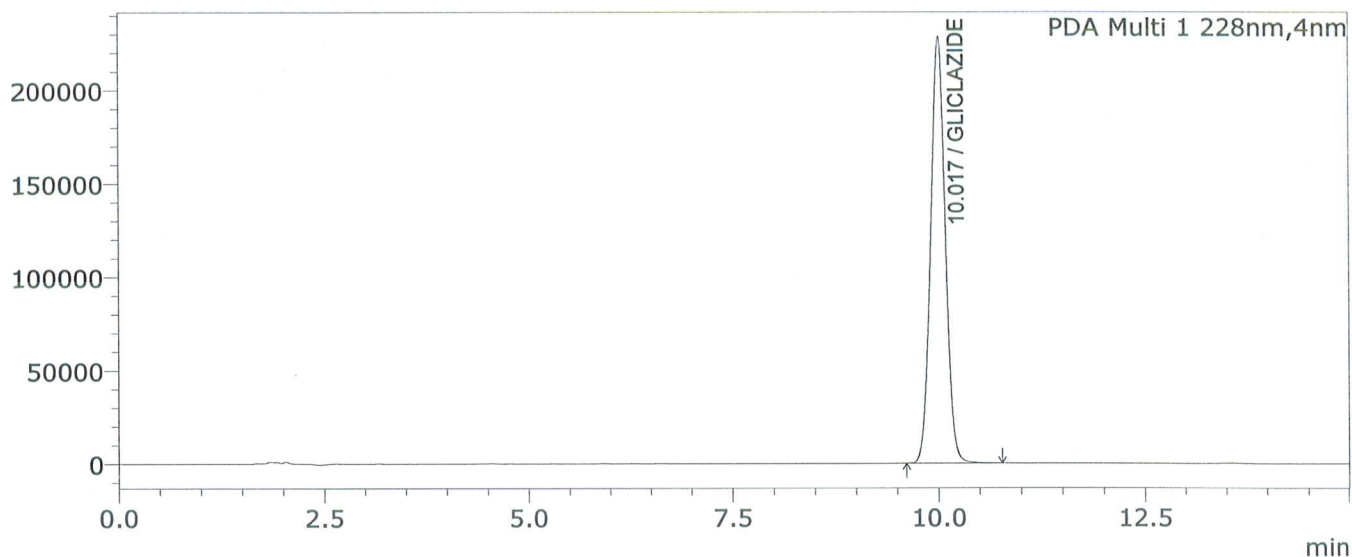
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-6H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-25.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 22:04:06
 Date Processed : 20-09-2023 09:57:11

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2822418	100.00	14129	0.925	--	--
Total			2822418	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

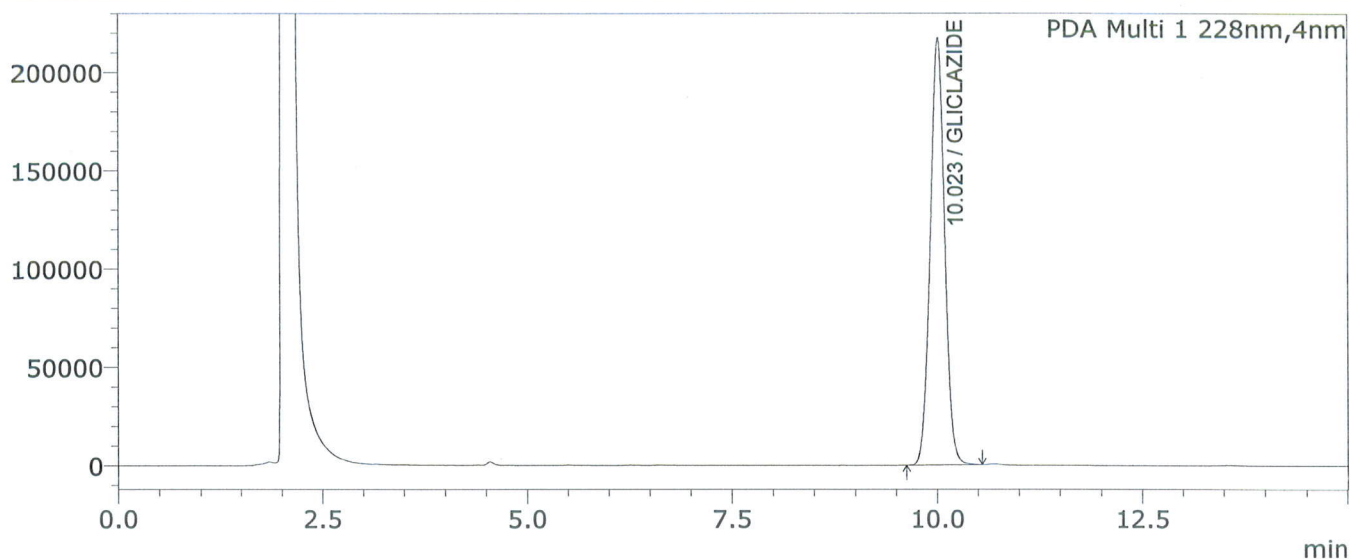
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-6H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-26.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 22:19:39
 Date Processed : 20-09-2023 09:57:11

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2685970	100.00	14121	0.934	--	--
Total			2685970	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

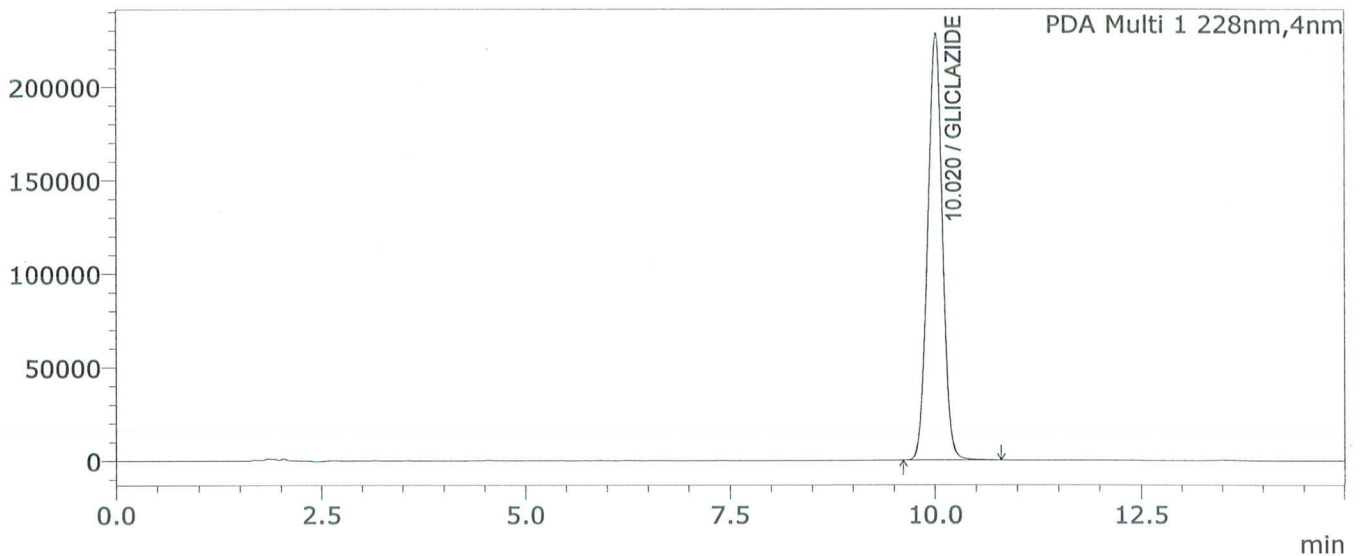
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-8H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-33.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 00:08:30
 Date Processed : 20-09-2023 09:57:14

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2821704	100.00	14133	0.924	--	--
Total			2821704	100.00				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

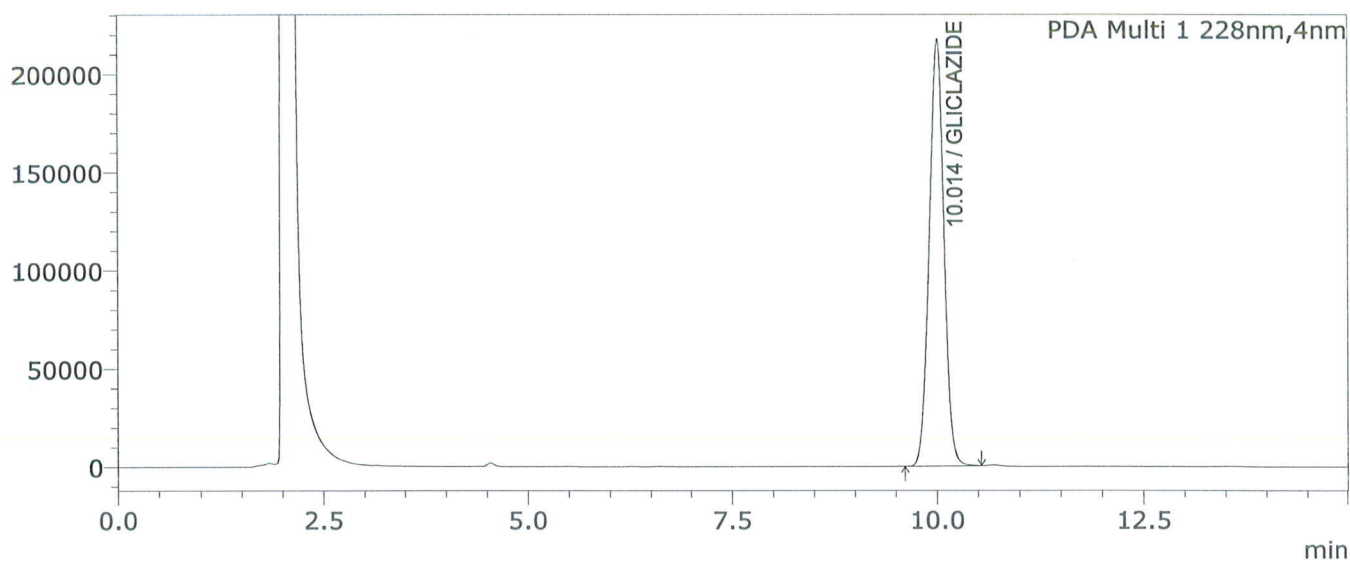
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-8H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-34.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 00:24:03
 Date Processed : 20-09-2023 09:57:15

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2686414	100.00	14088	0.934	--	--
Total			2686414	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

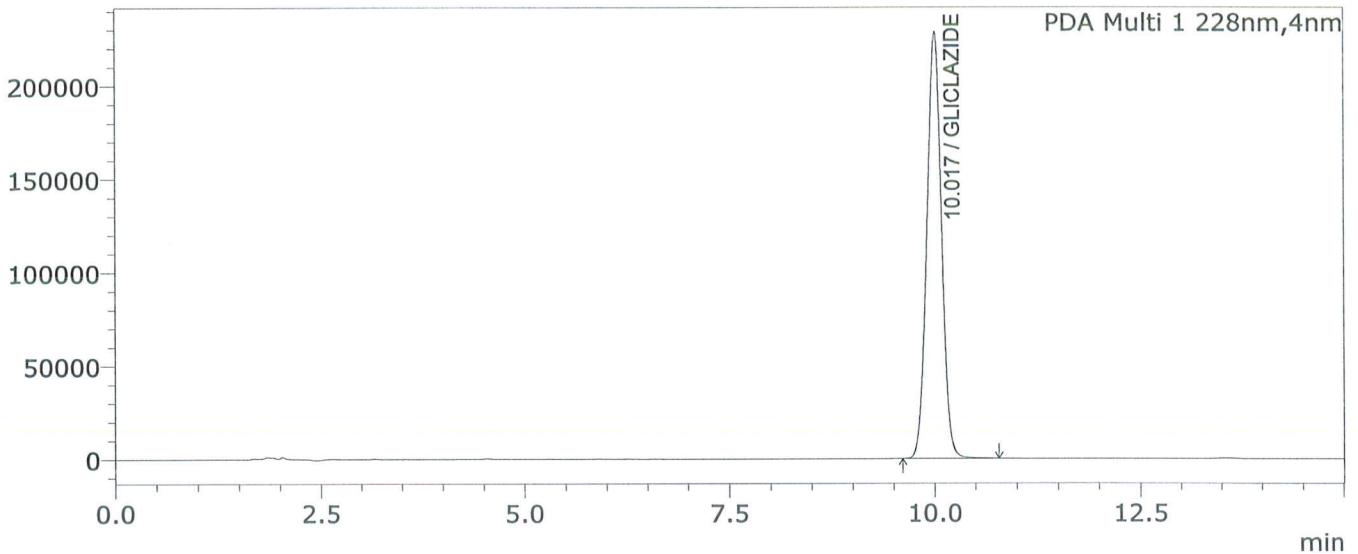
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-10H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-41.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 02:12:50
 Date Processed : 20-09-2023 09:57:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU

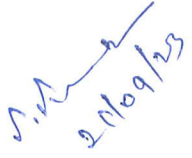


<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2820429	100.00	14152	0.924	--	--
Total			2820429	100.00				


 Analysed By


 Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

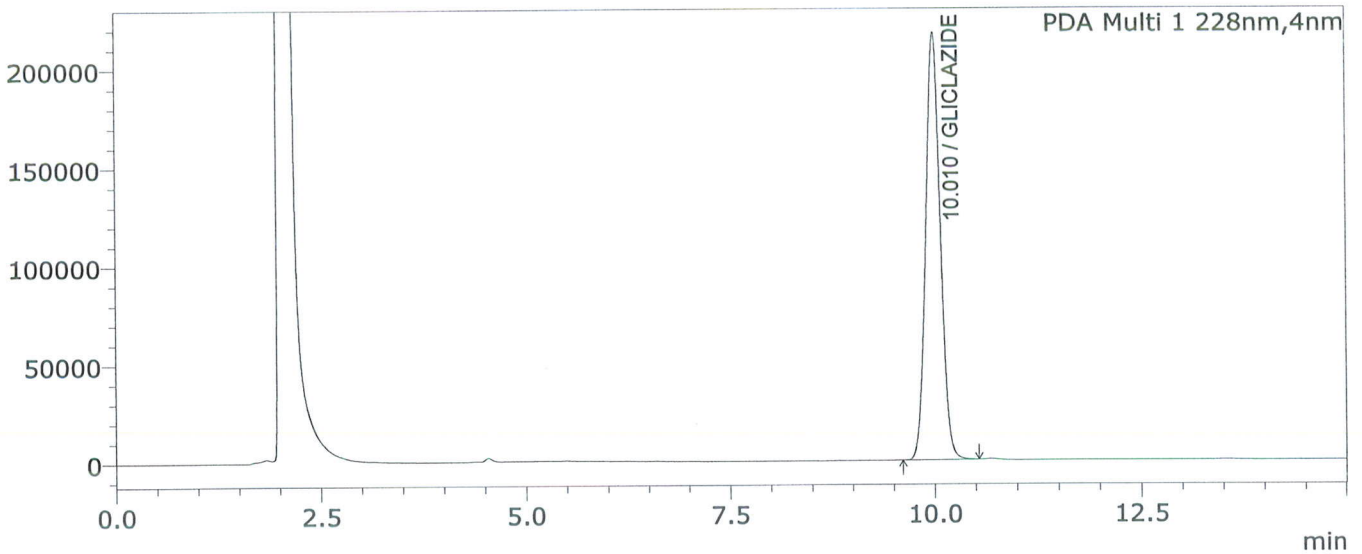
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-10H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-42.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 02:28:21
 Date Processed : 20-09-2023 09:57:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2685793	100.00	14091	0.934	--	--
Total			2685793	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

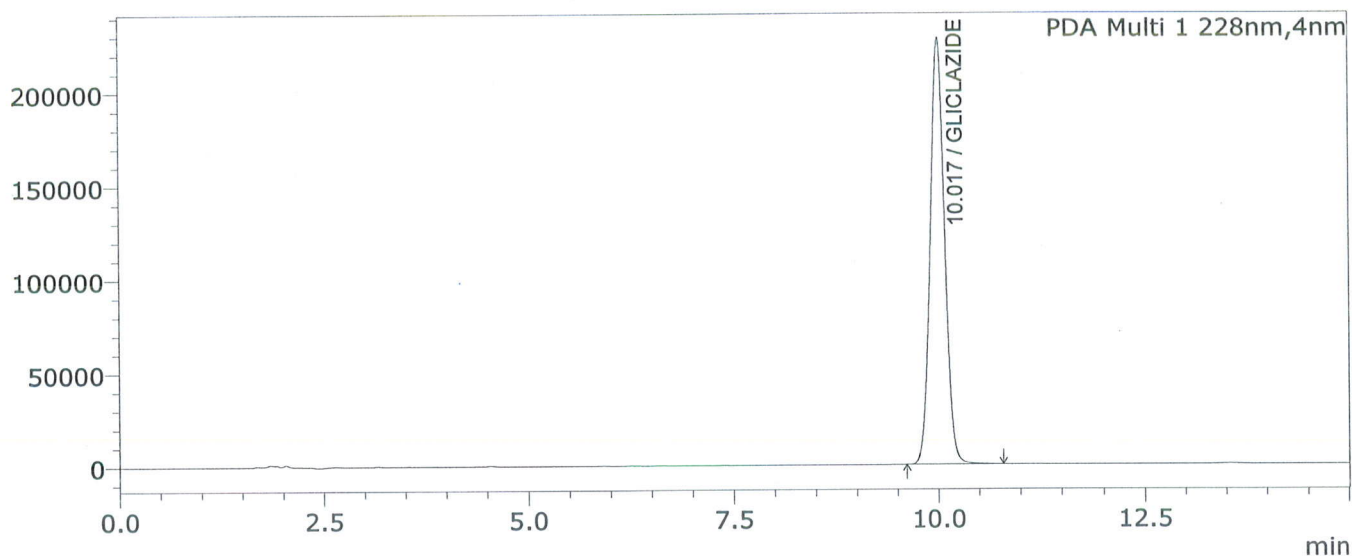
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-12H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-49.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 04:17:06
 Date Processed : 20-09-2023 09:57:20

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2819832	100.00	14147	0.924	--	--
Total			2819832	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

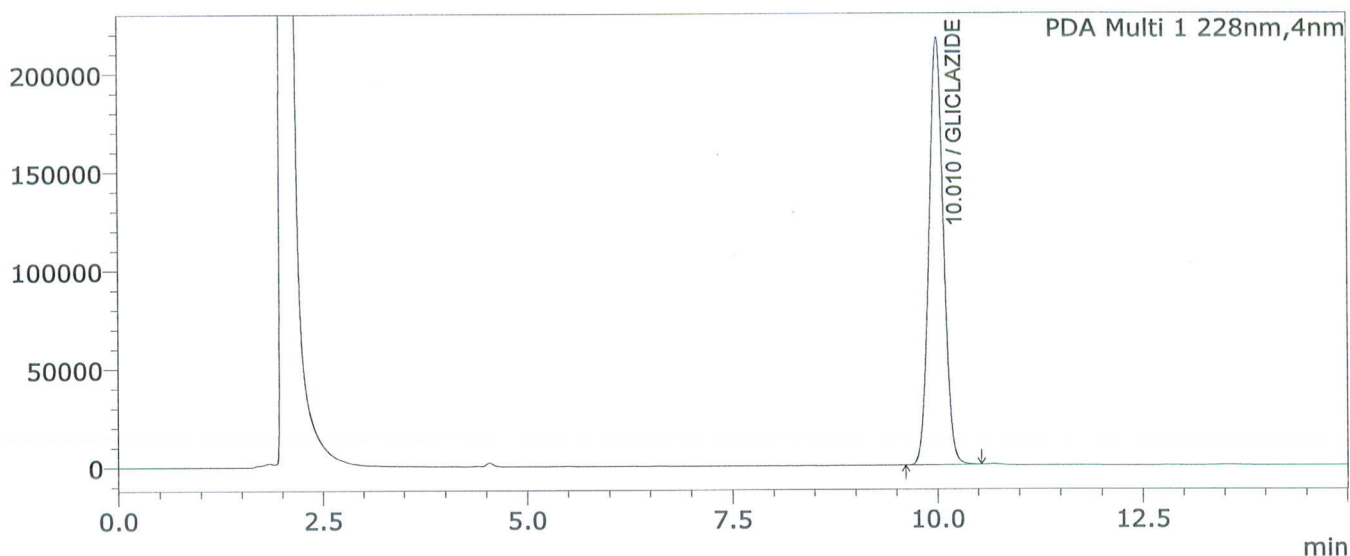
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-12H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-50.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 04:32:39
 Date Processed : 20-09-2023 09:57:20

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2684553	100.00	14097	0.933	--	--
Total			2684553	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

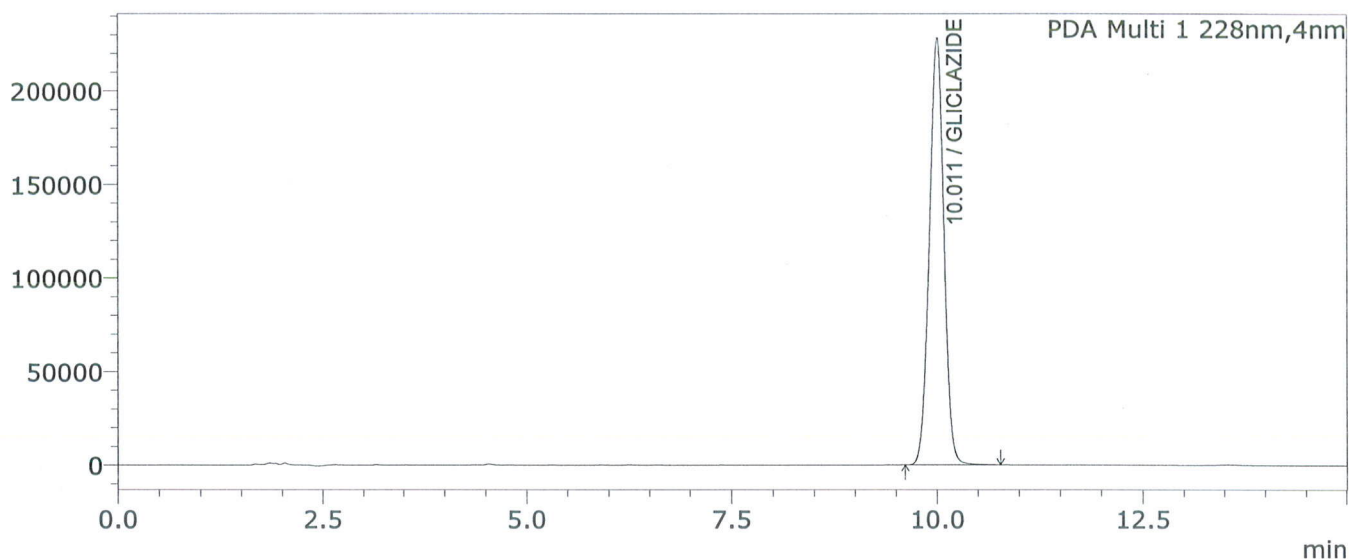
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-16H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-65.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 08:25:51
 Date Processed : 20-09-2023 09:57:25

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2817179	100.00	14151	0.923	--	--
Total			2817179	100.00				

20/09/23

Analysed By

21/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

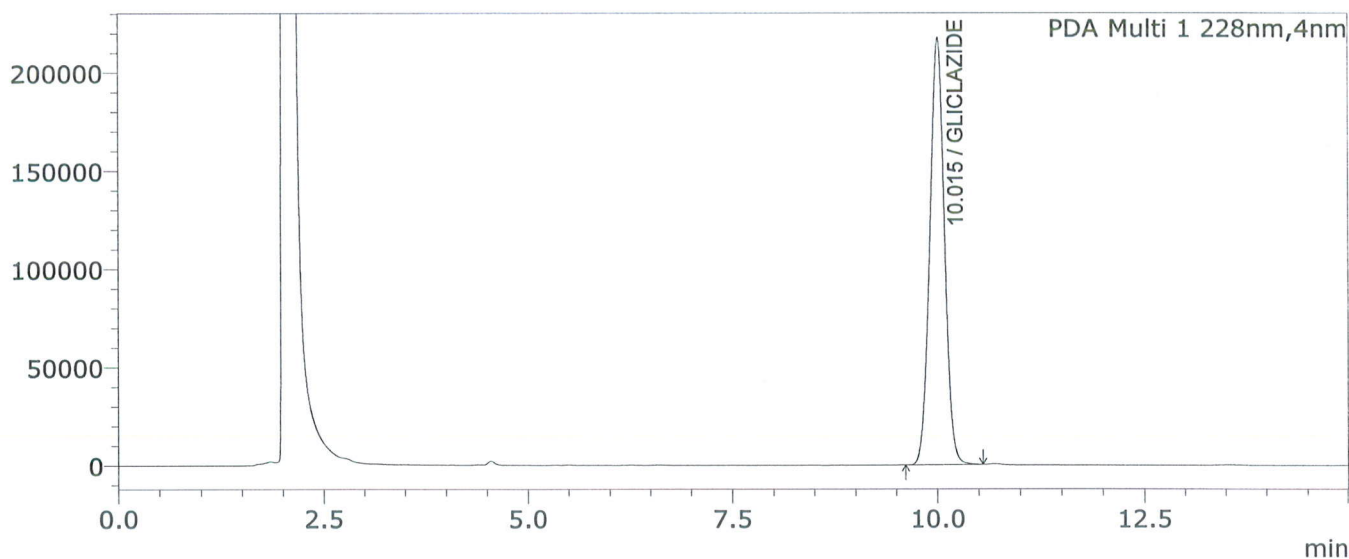
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-16H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-66.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 08:41:24
 Date Processed : 20-09-2023 09:57:26

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2681176	100.00	14127	0.933	--	--
Total			2681176	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

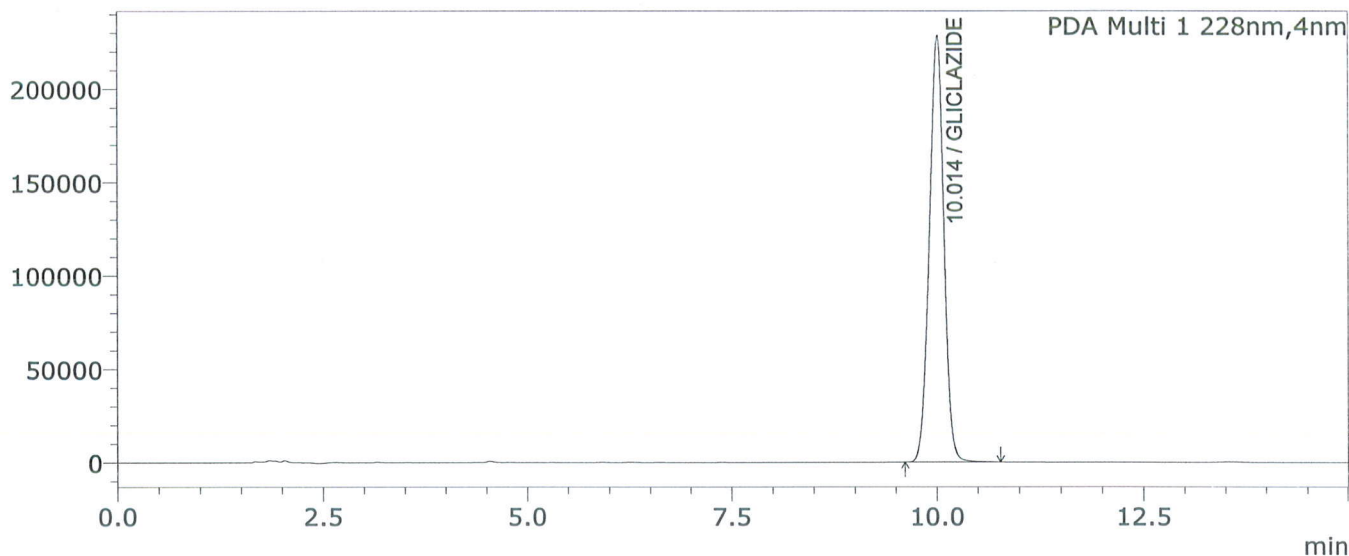
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-20H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-81.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 12:37:22
 Date Processed : 20-09-2023 09:57:30

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2817317	100.00	14150	0.923	--	--
Total			2817317	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

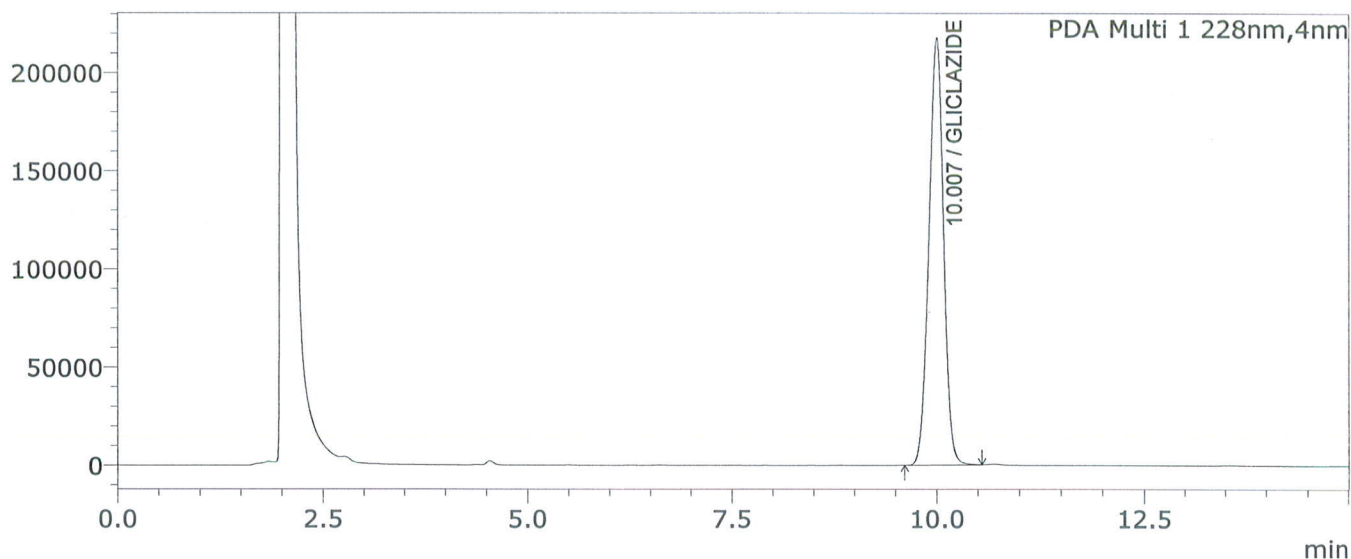
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-20H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-82.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 12:52:55
 Date Processed : 20-09-2023 09:57:31

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2683508	100.00	14115	0.932	--	--
Total			2683508	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

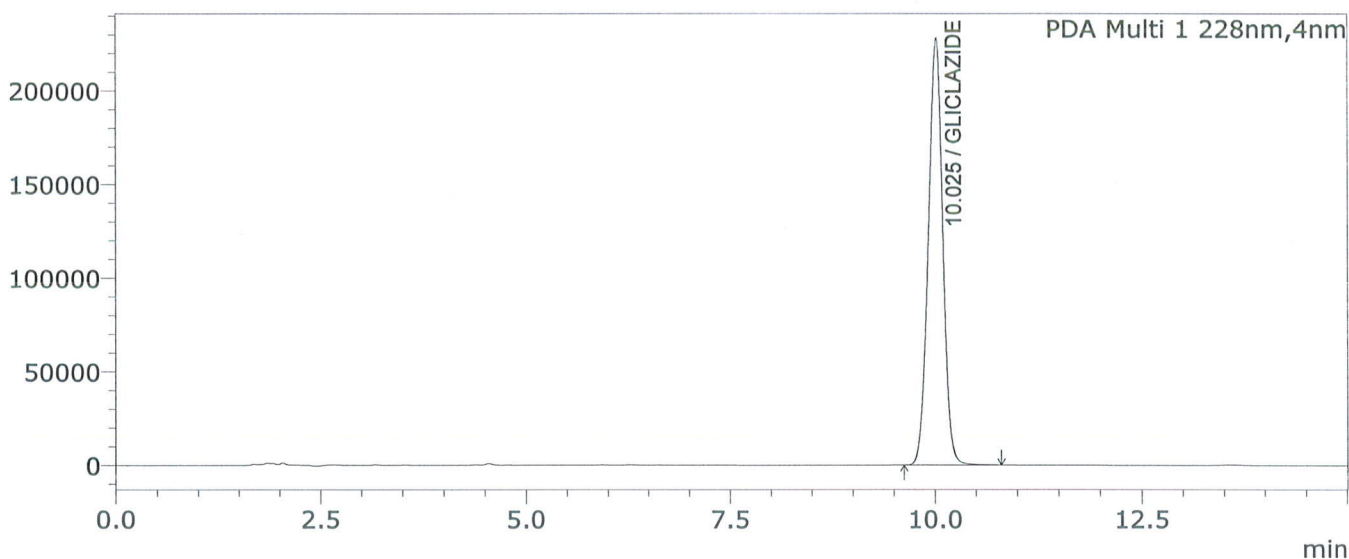
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-24H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-96.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 16:30:32
 Date Processed : 20-09-2023 09:57:35

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2816734	100.00	14139	0.925	--	--
Total			2816734	100.00				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

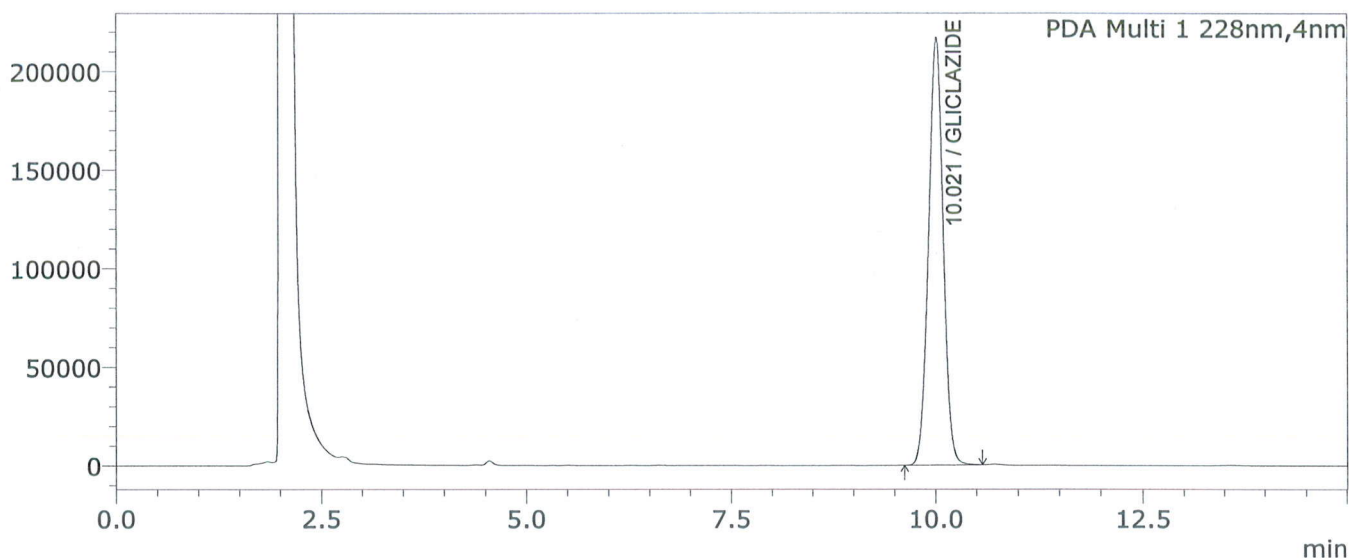
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-24H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-97.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 16:46:05
 Date Processed : 20-09-2023 09:57:35

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2682781	100.00	14107	0.934	--	--
Total			2682781	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

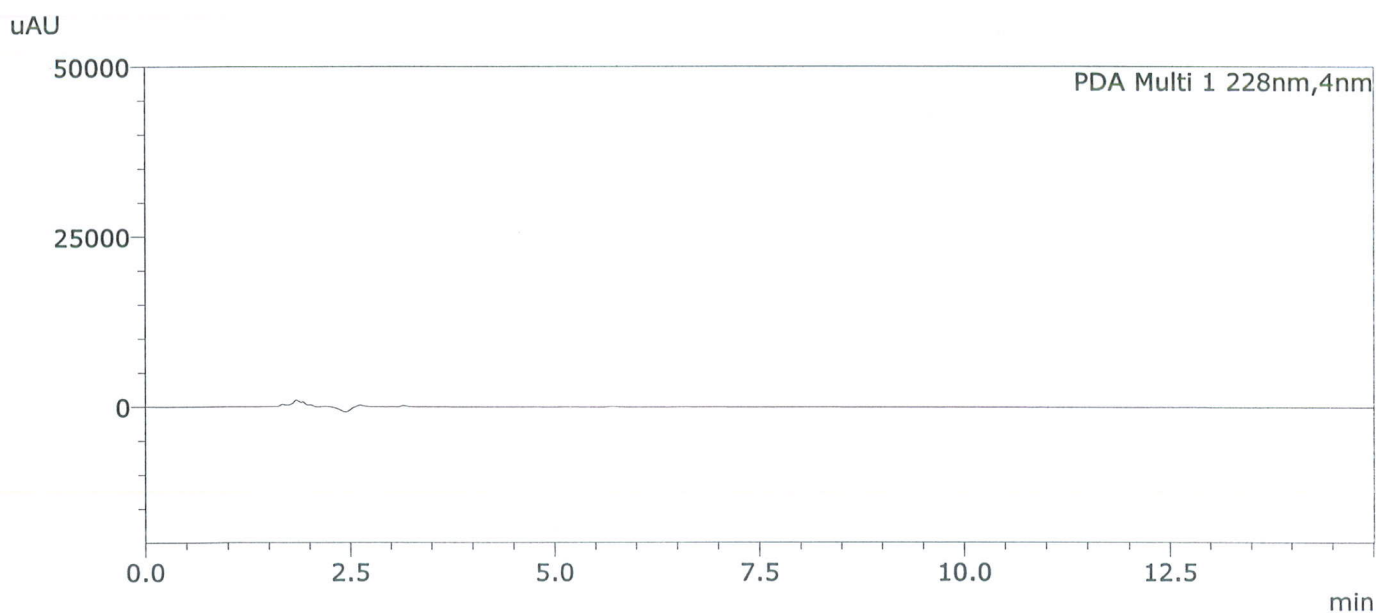
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-117.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 23:30:05
 Date Processed : 20-09-2023 09:57:05

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

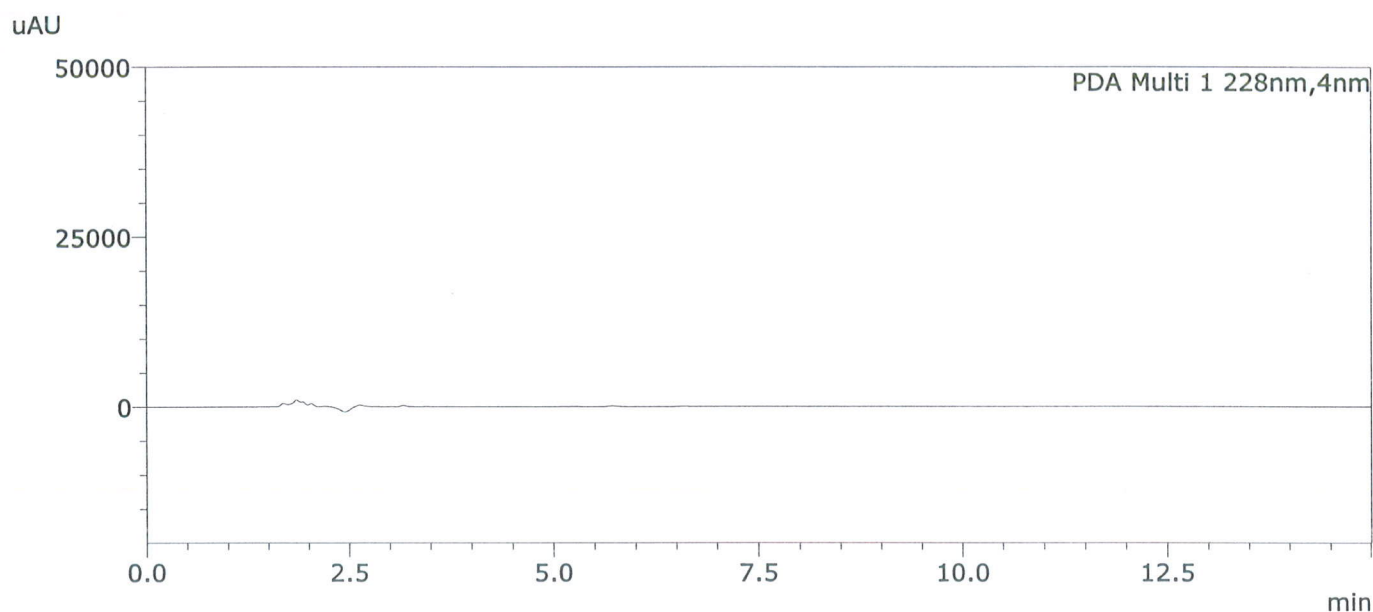
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-118.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 23:45:37
 Date Processed : 20-09-2023 09:57:06

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

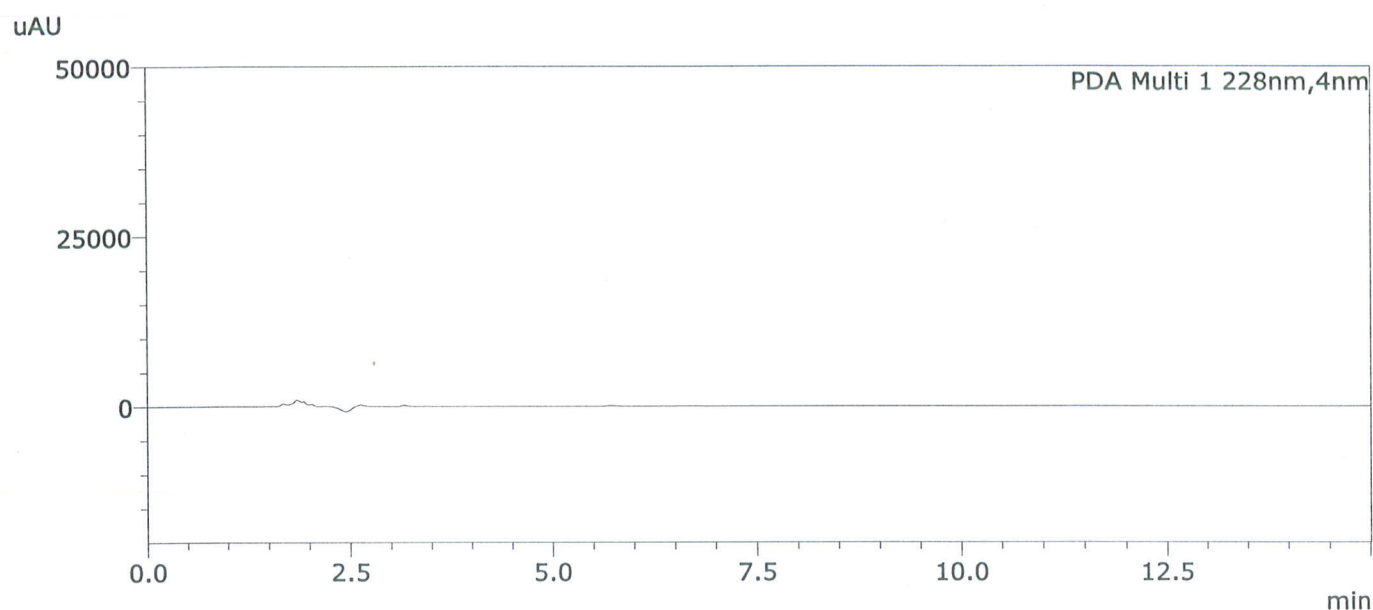
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-119.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 00:01:09
 Date Processed : 20-09-2023 09:57:06

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

20/09/23

Analysed By

21/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

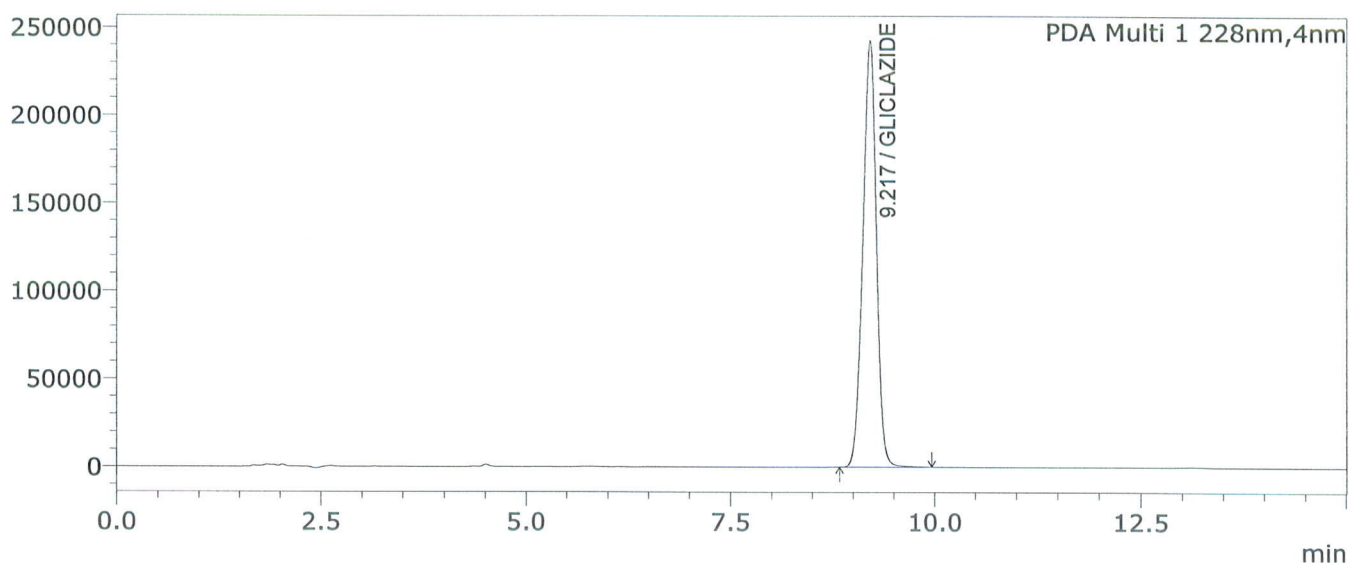
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-32H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-120.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 µL
 Date Acquired : 17-09-2023 00:16:41
 Date Processed : 20-09-2023 15:29:28

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2790525	100.00	13637	0.916	--	--
Total			2790525	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

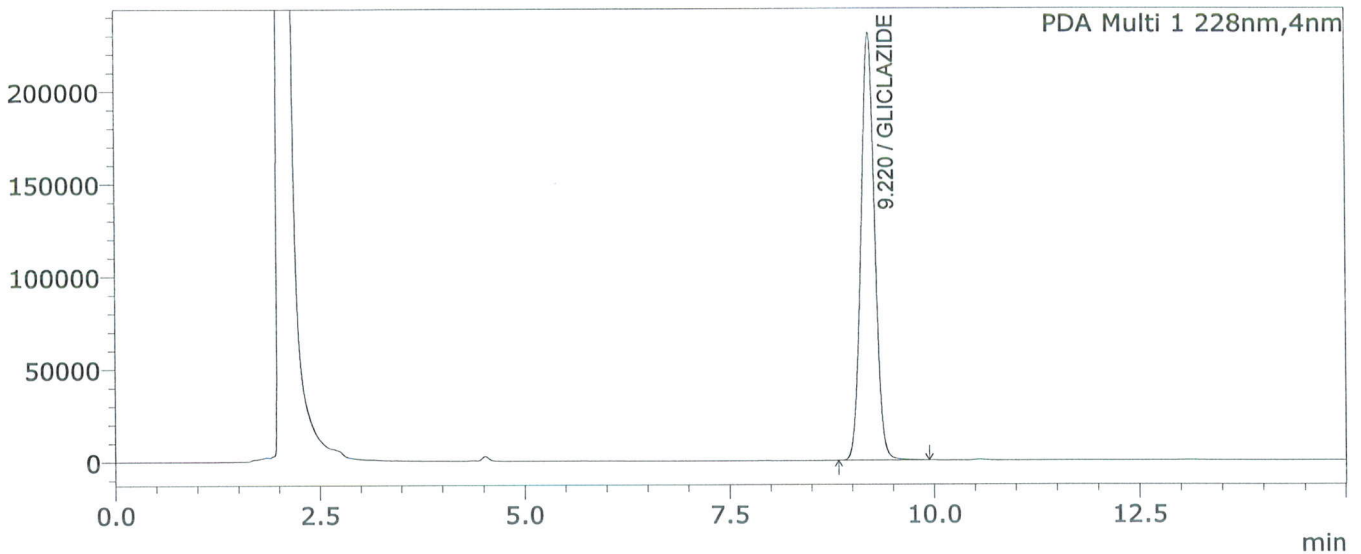
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-32H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-121.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 00:32:14
 Date Processed : 20-09-2023 15:29:54

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.22	2663487	100.00	13603	0.926	--	--
Total			2663487	100.00				

20/09/23
 Analysed By

21/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

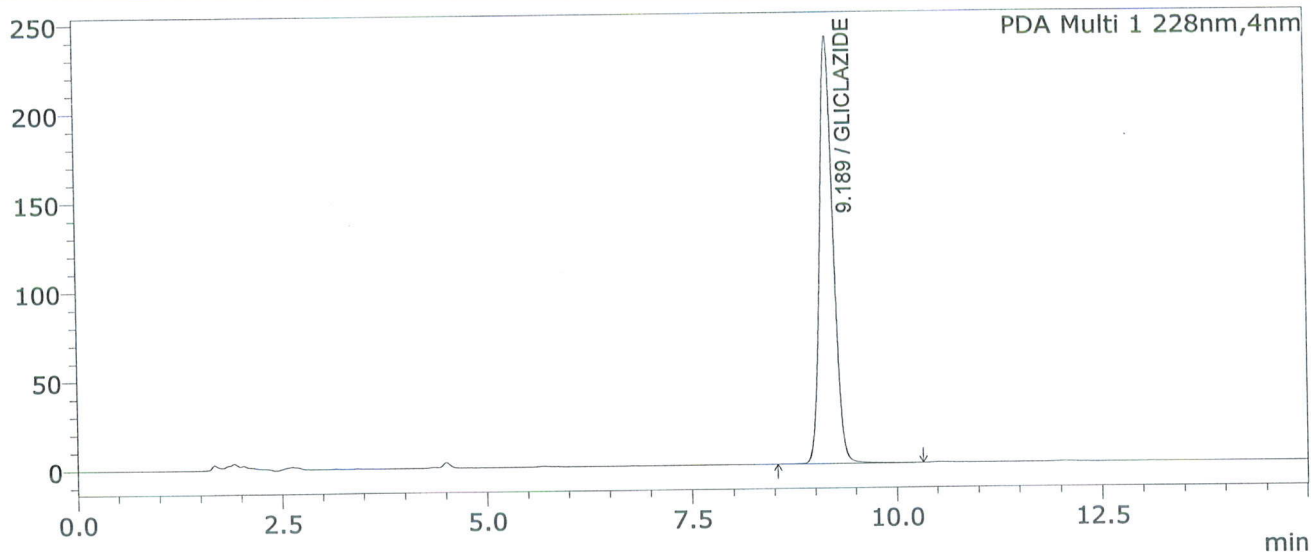
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-38H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-122.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 06:22:27
 Date Processed : 20-09-2023 18:03:01

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.19	2776752	100.00	13533	0.921	--	--
Total			2776752	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

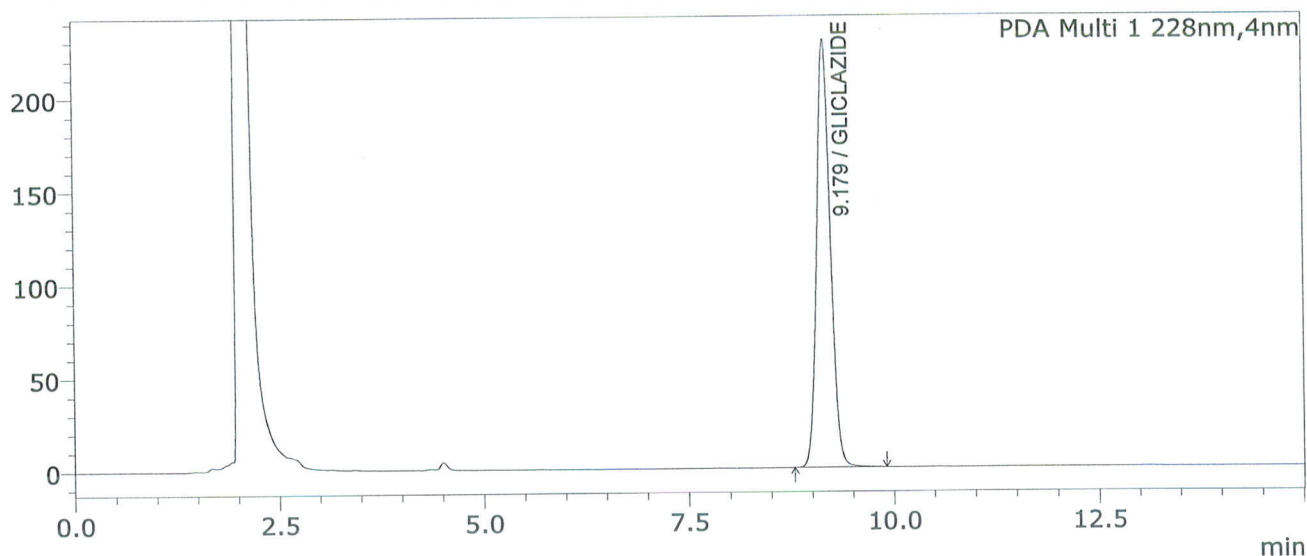
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-38H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-123.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 06:38:04
 Date Processed : 20-09-2023 17:58:40

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.18	2659870	100.00	13413	0.931	--	--
Total			2659870	100.00				

20/09/23

Analysed By

21/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

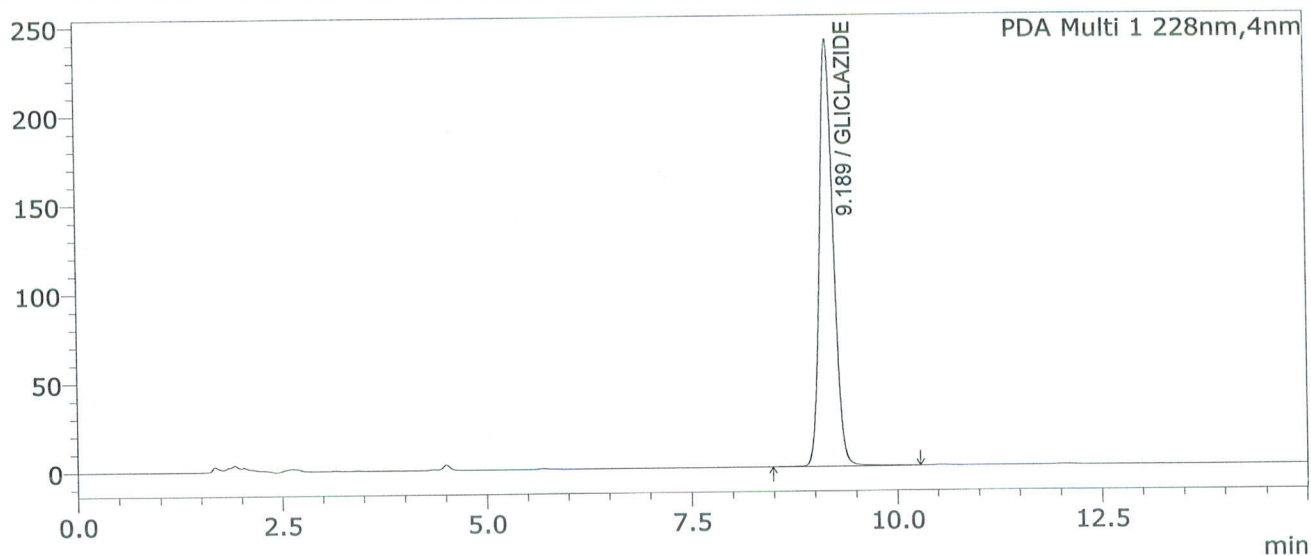
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-42H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-124.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 10:32:10
 Date Processed : 20-09-2023 18:04:11

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.19	2777427	100.00	13527	0.920	--	--
Total			2777427	100.00				

20/09/23
 Analysed By

21/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

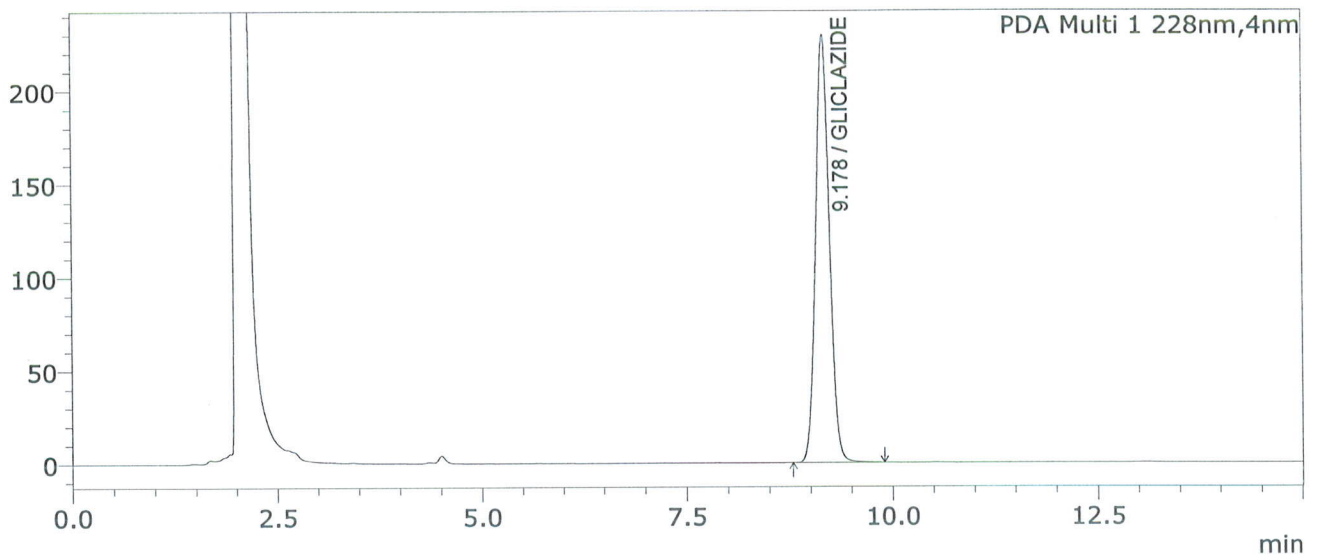
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-42H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-125.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 10:47:53
 Date Processed : 20-09-2023 17:58:40

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.18	2660384	100.00	13395	0.932	--	--
Total			2660384	100.00				

20/09/23

Analysed By

21/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

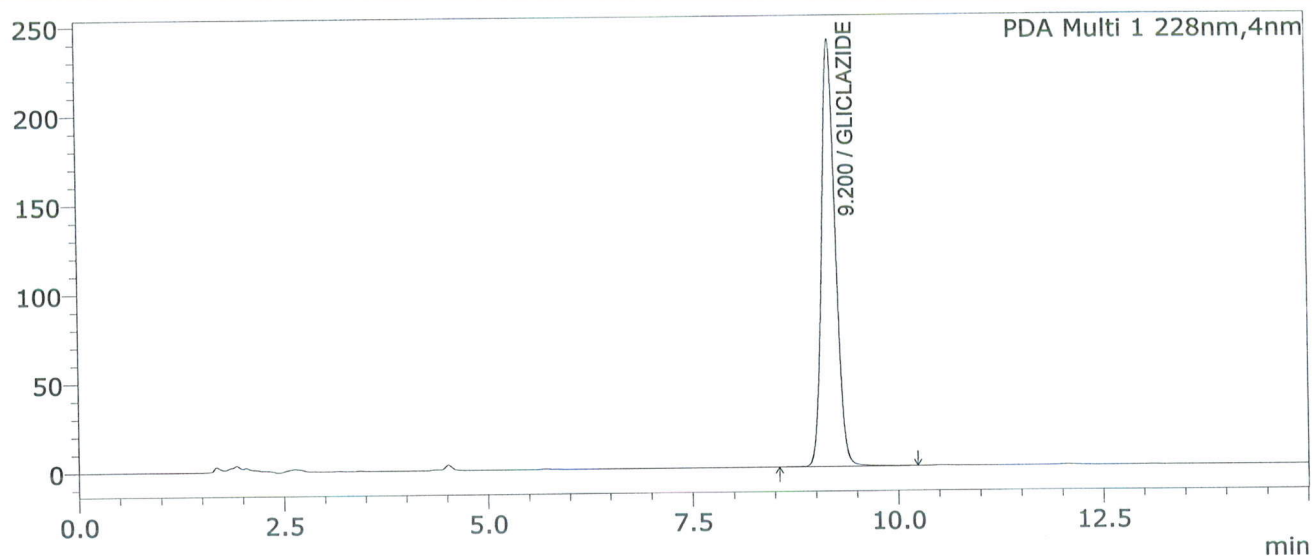
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-48H-DS-STD
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-126.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 16:34:58
 Date Processed : 20-09-2023 18:05:24

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.20	2775155	100.00	13556	0.921	--	--
Total			2775155	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

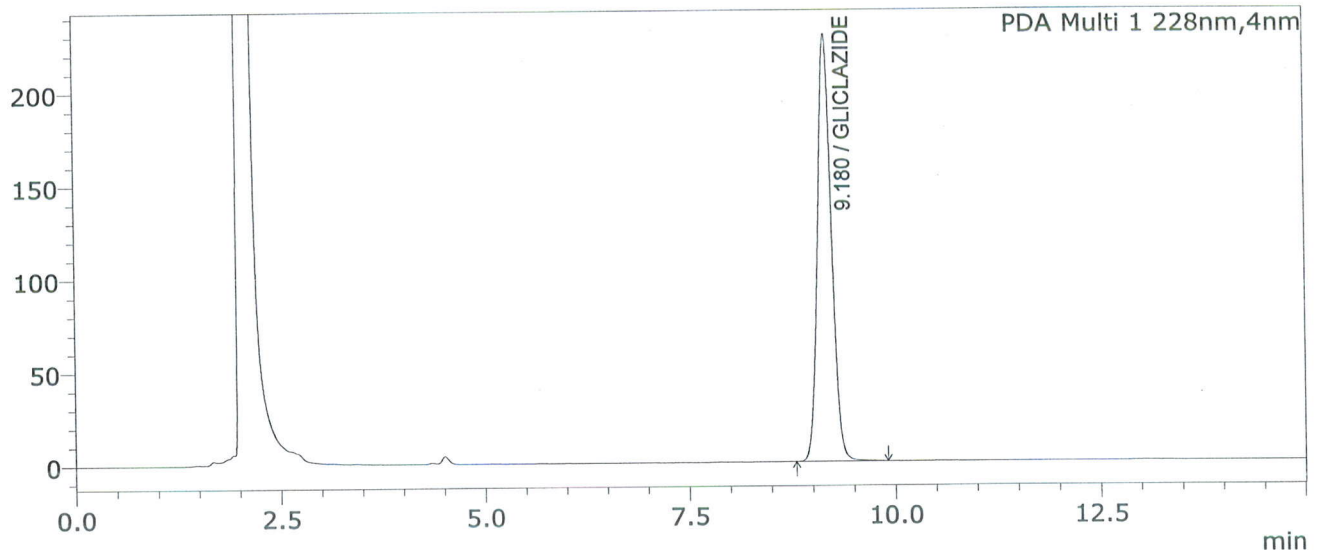
<Sample Information>

Sample Name : SOLUTION STABILITY-DS
 Sample ID : GLICLAZIDE-SOL STB-48H-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-127.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 17-09-2023 16:50:35
 Date Processed : 20-09-2023 17:58:41

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	9.18	2659946	100.00	13404	0.932	--	--
Total			2659946	100.00				


 20/09/23
 Analysed By


 21/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 15092023_GLIIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb

Vial #	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-01.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-02.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-03.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-04.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-05.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-06.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	SOLUTION STABILITY-INI-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-07.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-08.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-2H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-09.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-2H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-10.lcd	20.0	QC/CL/23/041
4	1	METHOD PRECISION	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-11.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-12.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-13.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-14.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-15.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-16.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-4H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-17.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-4H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
6	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-19.lcd	20.0	QC/CL/23/041
7	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-20.lcd	20.0	QC/CL/23/041
8	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-21.lcd	20.0	QC/CL/23/041
9	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-22.lcd	20.0	QC/CL/23/041
10	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-23.lcd	20.0	QC/CL/23/041
11	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-24.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-6H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-25.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-6H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-26.lcd	20.0	QC/CL/23/041
12	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-27.lcd	20.0	QC/CL/23/041
13	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-28.lcd	20.0	QC/CL/23/041
14	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-29.lcd	20.0	QC/CL/23/041
15	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-30.lcd	20.0	QC/CL/23/041
16	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-31.lcd	20.0	QC/CL/23/041
17	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-32.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-8H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-33.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-8H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-34.lcd	20.0	QC/CL/23/041
18	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-35.lcd	20.0	QC/CL/23/041
19	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-36.lcd	20.0	QC/CL/23/041
20	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-37.lcd	20.0	QC/CL/23/041
21	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-38.lcd	20.0	QC/CL/23/041
22	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-39.lcd	20.0	QC/CL/23/041
23	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-40.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-10H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-41.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-10H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-42.lcd	20.0	QC/CL/23/041
24	1	METHOD PRECISION	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-43.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-44.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-45.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-46.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-47.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-48.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-12H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-49.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-12H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-50.lcd	20.0	QC/CL/23/041
26	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-51.lcd	20.0	QC/CL/23/041
27	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-52.lcd	20.0	QC/CL/23/041
28	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-53.lcd	20.0	QC/CL/23/041
29	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-54.lcd	20.0	QC/CL/23/041
30	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-55.lcd	20.0	QC/CL/23/041
31	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-56.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-BKT-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-57.lcd	20.0	QC/CL/23/041
32	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-58.lcd	20.0	QC/CL/23/041
33	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-59.lcd	20.0	QC/CL/23/041
34	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-60.lcd	20.0	QC/CL/23/041
35	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-61.lcd	20.0	QC/CL/23/041
36	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-62.lcd	20.0	QC/CL/23/041
37	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-63.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-BKT-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-64.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-16H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-65.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-16H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-66.lcd	20.0	QC/CL/23/041
38	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-67.lcd	20.0	QC/CL/23/041
39	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-68.lcd	20.0	QC/CL/23/041
40	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-69.lcd	20.0	QC/CL/23/041
41	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-70.lcd	20.0	QC/CL/23/041
42	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-71.lcd	20.0	QC/CL/23/041
43	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-72.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-BKT-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-73.lcd	20.0	QC/CL/23/041
44	1	FILTER PAPER STUDY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-74.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-75.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-76.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-77.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-78.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-79.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-80.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-20H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-81.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-20H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-82.lcd	20.0	QC/CL/23/041
46	1	FILTER PAPER STUDY	GLIDE-M-60-850-CENTRIFUG-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-83.lcd	20.0	QC/CL/23/041
47	1	FILTER PAPER STUDY	GLIDE-M-60-850-NYLON-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-84.lcd	20.0	QC/CL/23/041
48	1	FILTER PAPER STUDY	GLIDE-M-60-850-NYLON-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-85.lcd	20.0	QC/CL/23/041
49	1	FILTER PAPER STUDY	GLIDE-M-60-850-NYLON-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-86.lcd	20.0	QC/CL/23/041
50	1	FILTER PAPER STUDY	GLIDE-M-60-850-PVDF-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-87.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
51	1	FILTER PAPER STUDY	GLIDE-M-60-850-PVDF-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-88.lcd	20.0	QC/CL/23/041
52	1	FILTER PAPER STUDY	GLIDE-M-60-850-PVDF-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-89.lcd	20.0	QC/CL/23/041
53	1	FILTER PAPER STUDY	GLIDE-M-60-850-WHATMAN-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-90.lcd	20.0	QC/CL/23/041
54	1	FILTER PAPER STUDY	GLIDE-M-60-850-WHATMAN-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-91.lcd	20.0	QC/CL/23/041
1	2	FILTER PAPER STUDY	GLIDE-M-60-850-WHATMAN-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-92.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-BKT-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-93.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-94.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-95.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-24H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-96.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-24H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-97.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-98.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-99.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-100.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-101.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-102.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-103.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-104.lcd	20.0	QC/CL/23/041
4	2	SPECIFICITY	GLICLAZIDE-API STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-105.lcd	20.0	QC/CL/23/041
5	2	SPECIFICITY	METFORMIN-API STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-106.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-107.lcd	20.0	QC/CL/23/041
6	2	SPECIFICITY	PLACEBO FOR GLIDE-M-60-500	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-108.lcd	20.0	QC/CL/23/041
7	2	SPECIFICITY	PLACEBO FOR GLIDE-M-60-850	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-109.lcd	20.0	QC/CL/23/041
8	2	SPECIFICITY	PLACEBO+GLICLAZIDE API	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-110.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
9	2	SPECIFICITY	PLACEBO+METFORMIN API	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-111.lcd	20.0	QC/CL/23/041
10	2	SPECIFICITY	PLACEBO+METFORMIN+GLICLAZIDE	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-112.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-113.lcd	20.0	QC/CL/23/041
11	2	SPECIFICITY	GLIDE-M-60-500-TAB-093-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-114.lcd	20.0	QC/CL/23/041
12	2	SPECIFICITY	GLIDE-M-60-850-TAB-0801-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-115.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-BKT-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-116.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-117.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-118.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-119.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-32H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-120.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-32H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-121.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-38H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-122.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-38H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-123.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-42H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-124.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-42H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-125.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-48H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-126.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-48H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-127.lcd	20.0	QC/CL/23/041
-1	1	SOLUTION STABILITY-DS	SHUTDOWN	HUTDOWN METHOD.lcm	TABILITY-SPL-128.lcd	20.0	QC/CL/23/041

15/09/23

Analysed By

Checked By

15/09/23

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number:	G17230801	Mfg.Date :	Aug-23
Stage:	METHOD PRECISION	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900
Speed	100 RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.20	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.2	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60

mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	2833082	2833290	2833957	2834148	2834203	2833736	516	0.018
With Bracketing std.						2833736	516	0.018

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	549621	11.56	19.26	0.21	19.1	15.4
Unit-2	619673	13.03	21.71	0.24		Maximum %
Unit-3	545649	11.47	19.12	0.21		
Unit-4	586698	12.34	20.56	0.23		
Unit-5	521670	10.97	18.28	0.20		
Unit-6	439733	9.25	15.41	0.17		21.7

5th Hour					Limit:Between 35.0-75.0%		
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Average %	Minimum %
Unit-1	1403677	29.51	49.19	0.547	49.40	48.3	44.3
Unit-2	1347659	28.33	47.22	0.525	47.47		Maximum%
Unit-3	1524820	32.06	53.43	0.594	53.65		
Unit-4	1302156	27.38	45.63	0.507	45.86		
Unit-5	1404010	29.52	49.20	0.547	49.40		53.6
Unit-6	1259601	26.48	44.14	0.490	44.31		

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2689660	56.55	94.25	95.01	94.0	90.4	2.6
Unit-2	2718421	57.16	95.26	96.03			
Unit-3	2558040	53.78	89.64	90.45		Maximum %	
Unit-4	2687928	56.51	94.19	94.93			
Unit-5	2717587	57.14	95.23	95.98		96.0	
Unit-6	2591685	54.49	90.82	91.48			

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor Standard area x sample dilution X 100
Correction factor	Drug release % in respective time point / 900 X 10

Drug release in %	Drug release in mg /tablet x 100 Labeled claim
-------------------	---

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by :

E.MEENA

Date :

20-09-2023

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

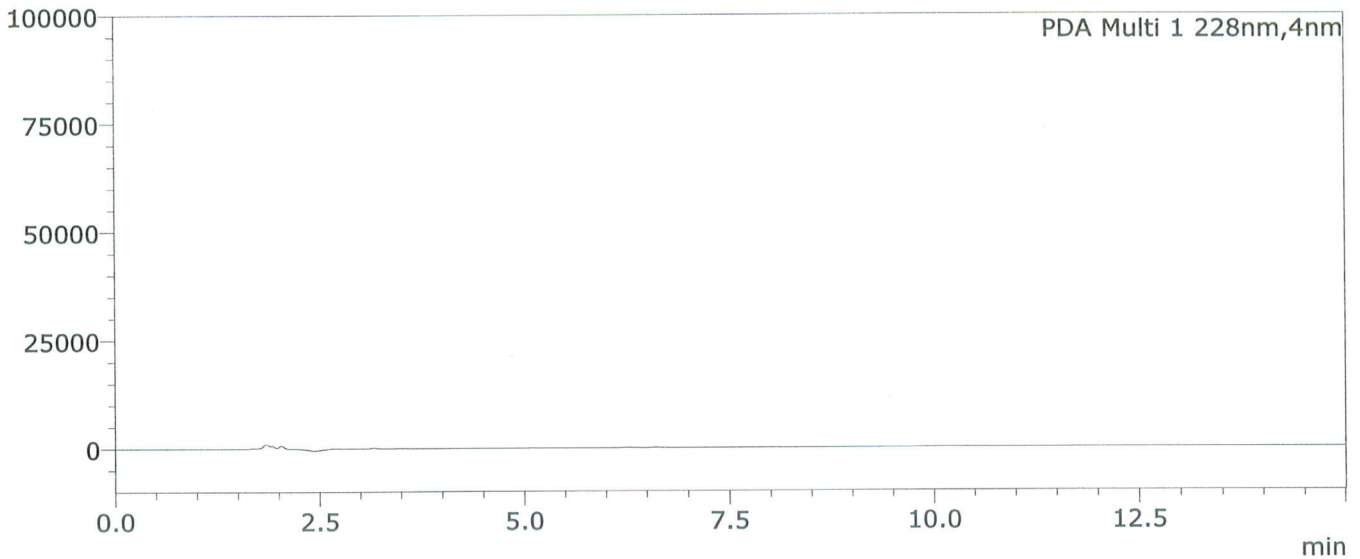
<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-11.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-4
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 18:26:26
 Date Processed : 20-09-2023 09:57:05

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

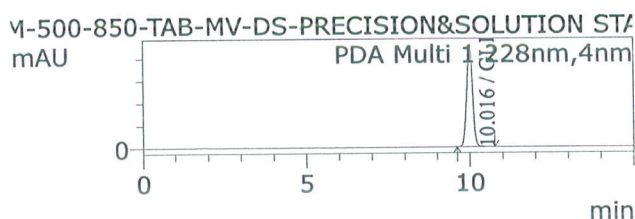
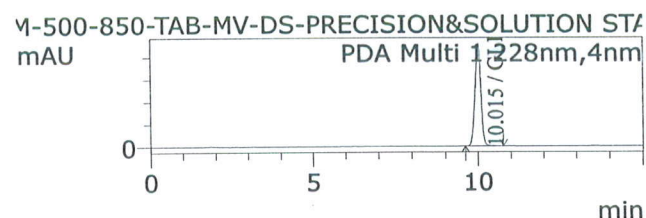
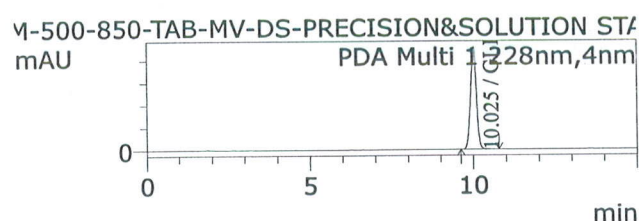
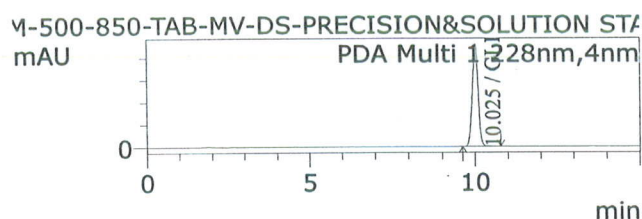
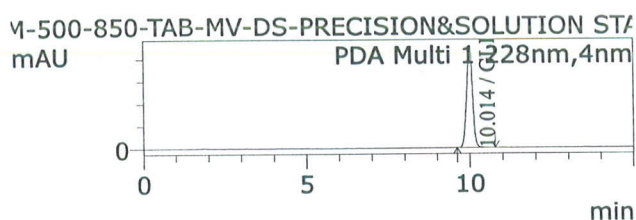
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-12
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 18:41:59
 Date Processed : 20-09-2023 09:57:07

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	ITY-SPL-12.lcd	GLICLAZIDE-DS-STD-01	10.01	2833082	14093	0.93
5	ITY-SPL-13.lcd	GLICLAZIDE-DS-STD-02	10.03	2833290	14118	0.93
5	ITY-SPL-14.lcd	GLICLAZIDE-DS-STD-03	10.02	2833957	14121	0.93
5	ITY-SPL-15.lcd	GLICLAZIDE-DS-STD-04	10.02	2834148	14082	0.93
5	ITY-SPL-16.lcd	GLICLAZIDE-DS-STD-05	10.02	2834203	14113	0.93
	Average		10.02	2833736	14105	0.93
	%RSD		0.054	0.018	0.120	0.012

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

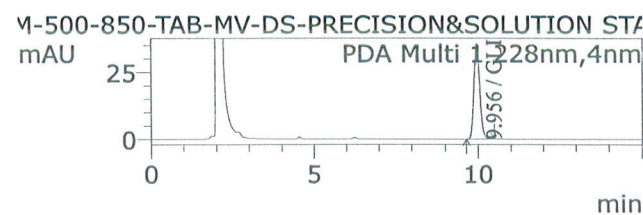
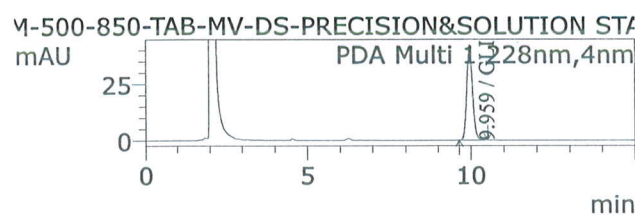
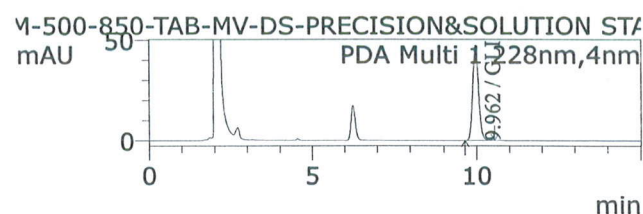
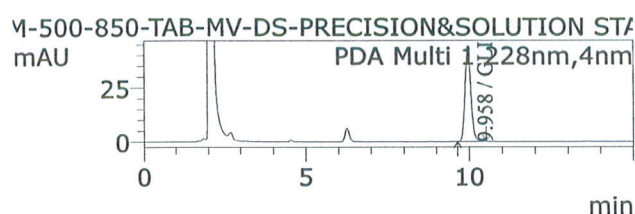
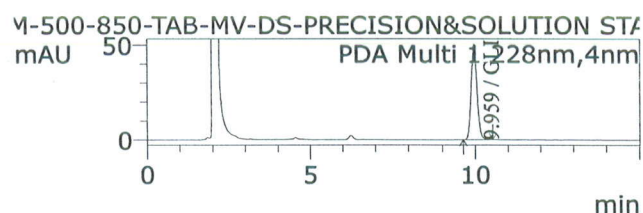
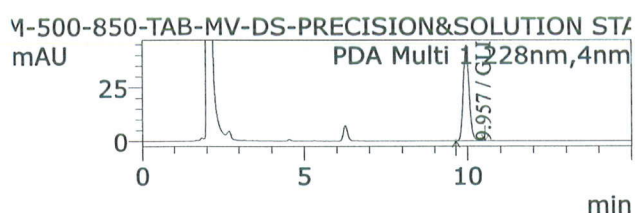
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDE-M-60-850-GLI-2HR-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-19
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-6
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 20:30:46
 Date Processed : 20-09-2023 09:57:09

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	ITY-SPL-19.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-1	9.96	549621	14243	1.12
7	ITY-SPL-20.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-2	9.96	619673	14299	1.11
8	ITY-SPL-21.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-3	9.96	545649	14252	1.12
9	ITY-SPL-22.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-4	9.96	586698	14290	1.11
10	ITY-SPL-23.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-5	9.96	521670	14281	1.12
11	ITY-SPL-24.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-6	9.96	439733	14253	1.13
	Average		9.96	543841	14269	1.12
	%RSD		0.022	11.321	0.163	0.679

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

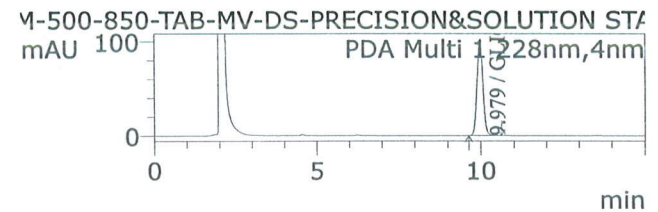
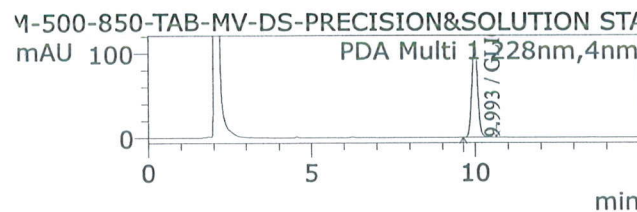
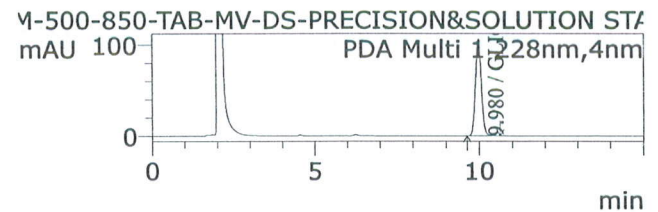
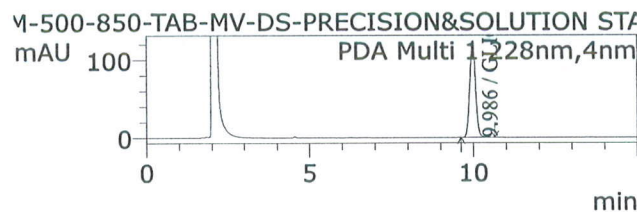
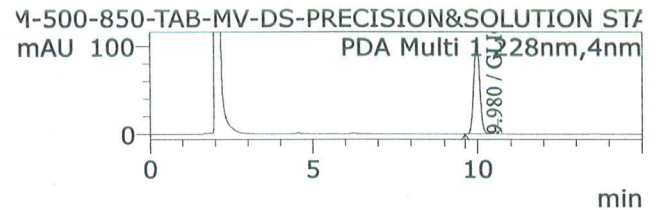
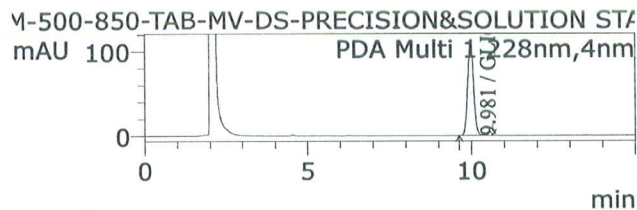
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDE-M-60-850-GLI-5HR-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-27
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-12
 Injection Volume : 20 uL
 Date Acquired : 15-09-2023 22:35:12
 Date Processed : 20-09-2023 09:57:12

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	ITY-SPL-27.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-1	9.98	1403677	14379	1.03
13	ITY-SPL-28.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-2	9.98	1347659	14373	1.03
14	ITY-SPL-29.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-3	9.99	1524820	14370	1.02
15	ITY-SPL-30.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-4	9.98	1302156	14368	1.04
16	ITY-SPL-31.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-5	9.99	1404010	14414	1.03
17	ITY-SPL-32.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-6	9.98	1259601	14379	1.04
	Average		9.98	1373654	14381	1.03
	%RSD		0.054	6.788	0.117	0.775

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

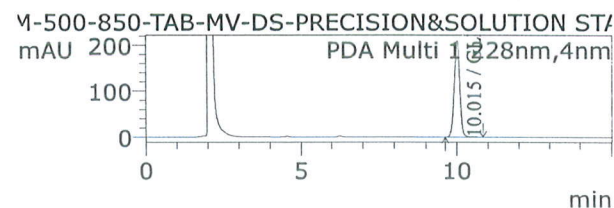
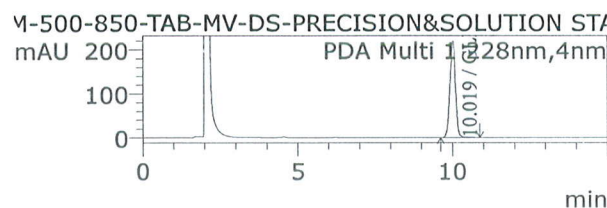
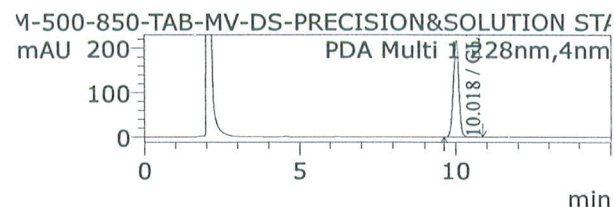
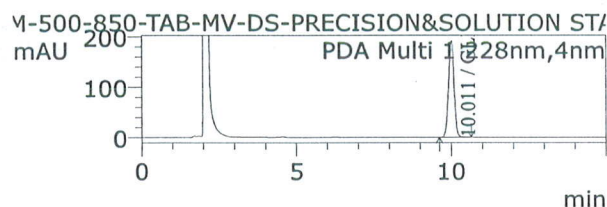
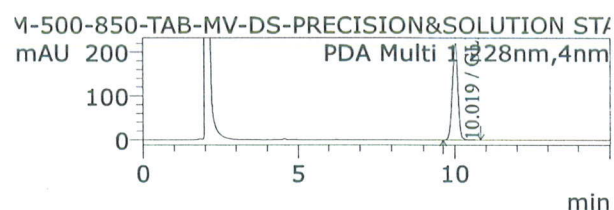
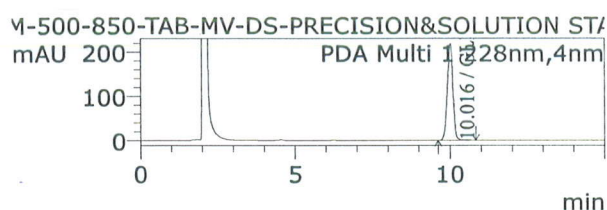
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDE-M-60-850-GLI-12H-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-35
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-18
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 00:39:35
 Date Processed : 20-09-2023 09:57:15

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
18	ITY-SPL-35.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-1	10.02	2689660	14095	0.94
19	ITY-SPL-36.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-2	10.02	2718421	14054	0.93
20	ITY-SPL-37.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-3	10.01	2558040	14215	0.96
21	ITY-SPL-38.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-4	10.02	2687928	14096	0.94
22	ITY-SPL-39.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-5	10.02	2717587	14069	0.93
23	ITY-SPL-40.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-6	10.01	2591685	14101	0.94
	Average		10.02	2660554	14105	0.94
	%RSD		0.030	2.574	0.403	0.905

Analysed By

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	FILTER PAPER STUDY	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution.:	66.20	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.2	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution.:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.666	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	60 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	2816390	2815017	2816170	2815978	2815052	2815721	644	0.023
With Bracketing std.	2822590					2816866	2863	0.102

S.No	Sample Name	Sample Area	Drug release in mg/tablet	Drug Release in %	% Difference from unfiltered sample
1	Unfiltered sample (Centrifuged)	2629956	55.65	92.7	Not applicable
2	Filter set-1 (0.45µ Nylon membrane)	2625549	55.56	92.6	0.17
3	Filter set-2 (0.45µ Nylon membrane)	2631670	55.69	92.8	-0.07
4	Filter set-3 (0.45µ Nylon membrane)	2627585	55.60	92.7	0.09
5	Filter set-1 (0.45µ PVDF membrane)	2643289	55.93	93.2	-0.50
6	Filter set-2 (0.45µ PVDF membrane)	2639776	55.86	93.1	-0.37
7	Filter set-3 (0.45µ PVDF membrane)	2647840	56.03	93.4	-0.68
8	Filter set-1 (Whatman membrane)	2625970	55.56	92.6	0.15
9	Filter set-2 (Whatman membrane)	2625494	55.55	92.6	0.17
10	Filter set-3 (Whatman membrane)	2639033	55.84	93.1	-0.34

Results :

The % difference on filtered sample (0.45µ PVDF membrane) within limit against that of unfiltered.

Acceptance criteria:The % difference on filter solution should not differ ± 2.0 against that of unfiltered.

Analysed by : E.MEENA
Date : 20-09-2023

Checked by :
Date :



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

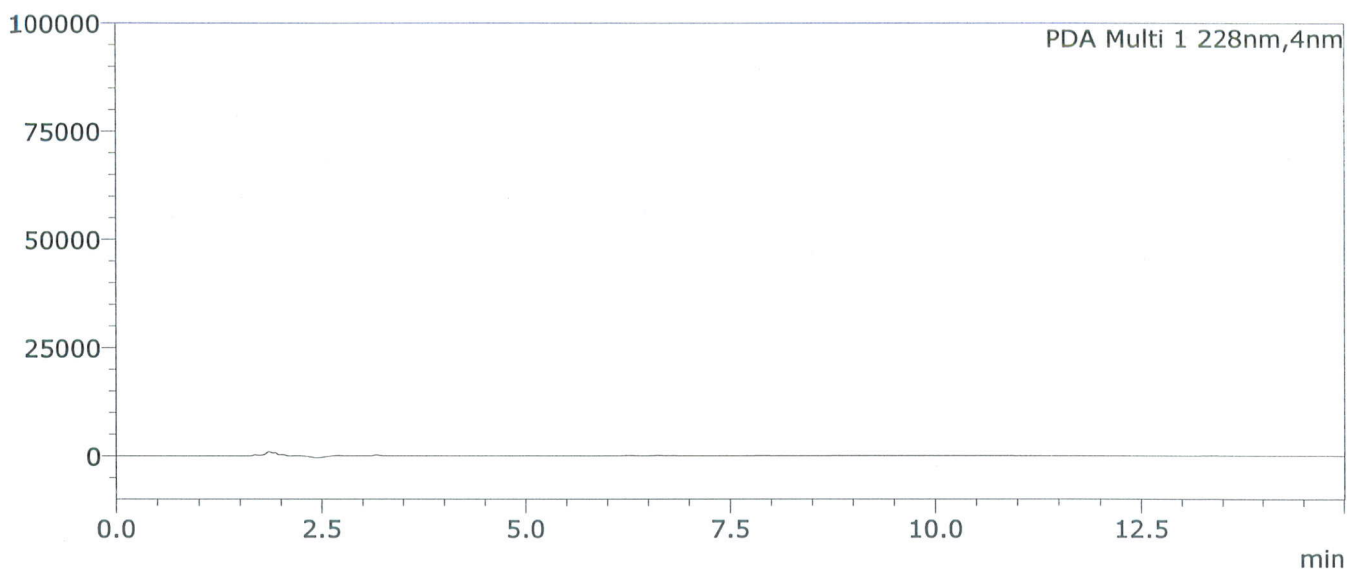
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-74.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-44
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 10:48:32
 Date Processed : 20-09-2023 09:57:28

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

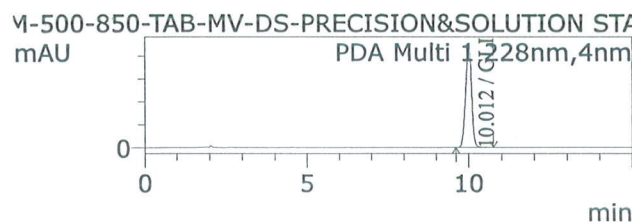
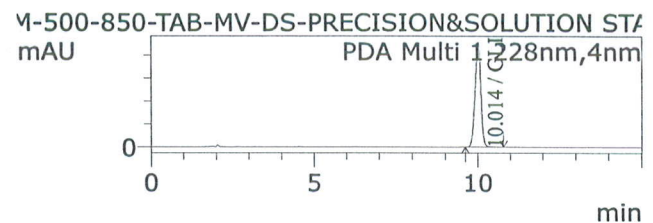
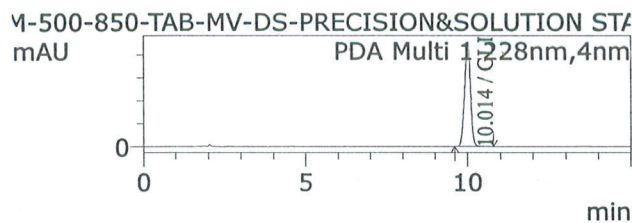
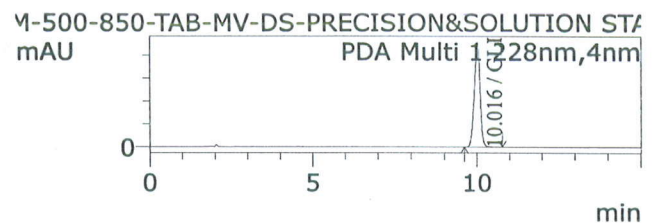
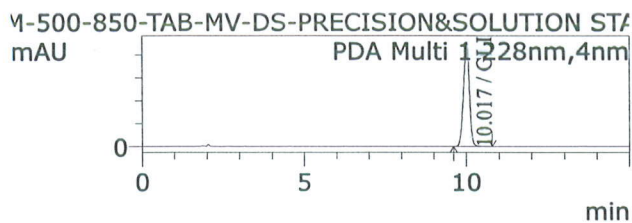
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-75
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-45
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 11:04:05
 Date Processed : 20-09-2023 09:57:28

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
45	ITY-SPL-75.lcd	GLICLAZIDE-DS-STD-01	10.02	2816390	14170	0.92
45	ITY-SPL-76.lcd	GLICLAZIDE-DS-STD-02	10.02	2815017	14167	0.92
45	ITY-SPL-77.lcd	GLICLAZIDE-DS-STD-03	10.01	2816170	14151	0.92
45	ITY-SPL-78.lcd	GLICLAZIDE-DS-STD-04	10.01	2815978	14150	0.92
45	ITY-SPL-79.lcd	GLICLAZIDE-DS-STD-05	10.01	2815052	14150	0.92
	Average		10.01	2815721	14158	0.92
	%RSD		0.022	0.023	0.069	0.037

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

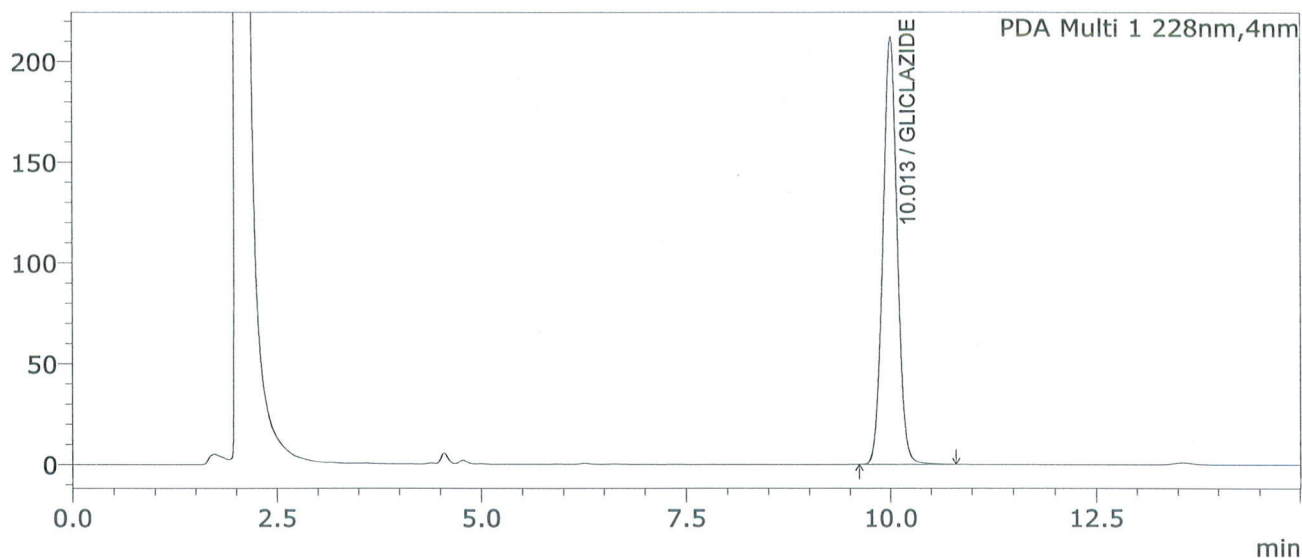
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-CENTRIFUG-DS-SPL
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-83.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-46
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 13:08:29
 Date Processed : 20-09-2023 09:57:31

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2629956	100.00	14107	0.941	--	--
Total			2629956	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

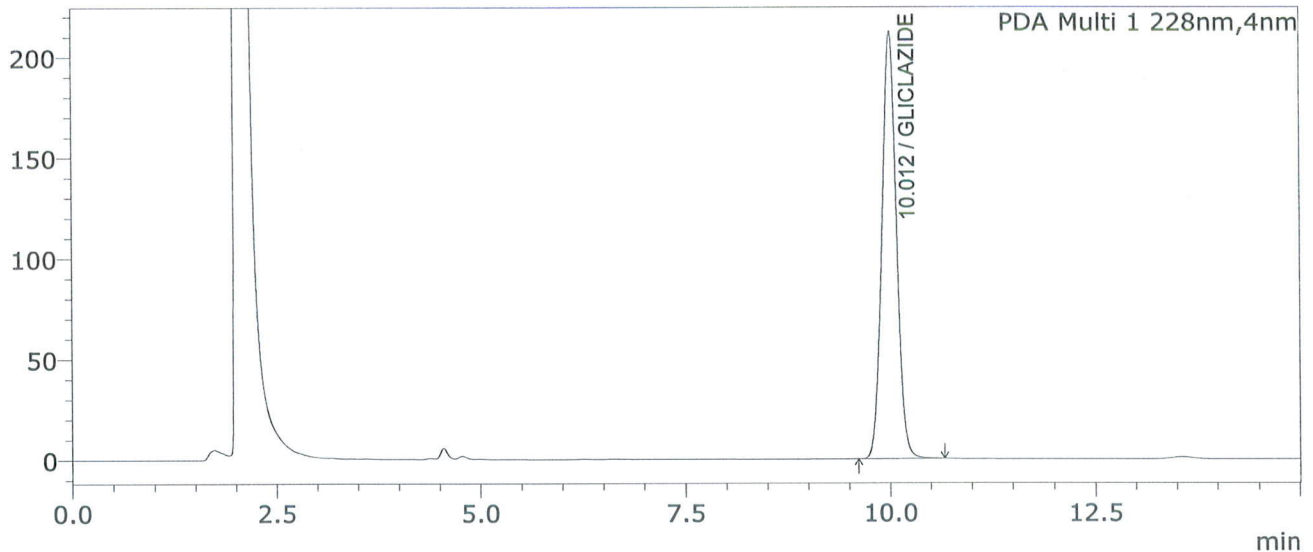
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-NYLON-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-84.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-47
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 13:24:01
 Date Processed : 20-09-2023 09:57:31

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2625549	100.00	14104	0.940	--	--
Total			2625549	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

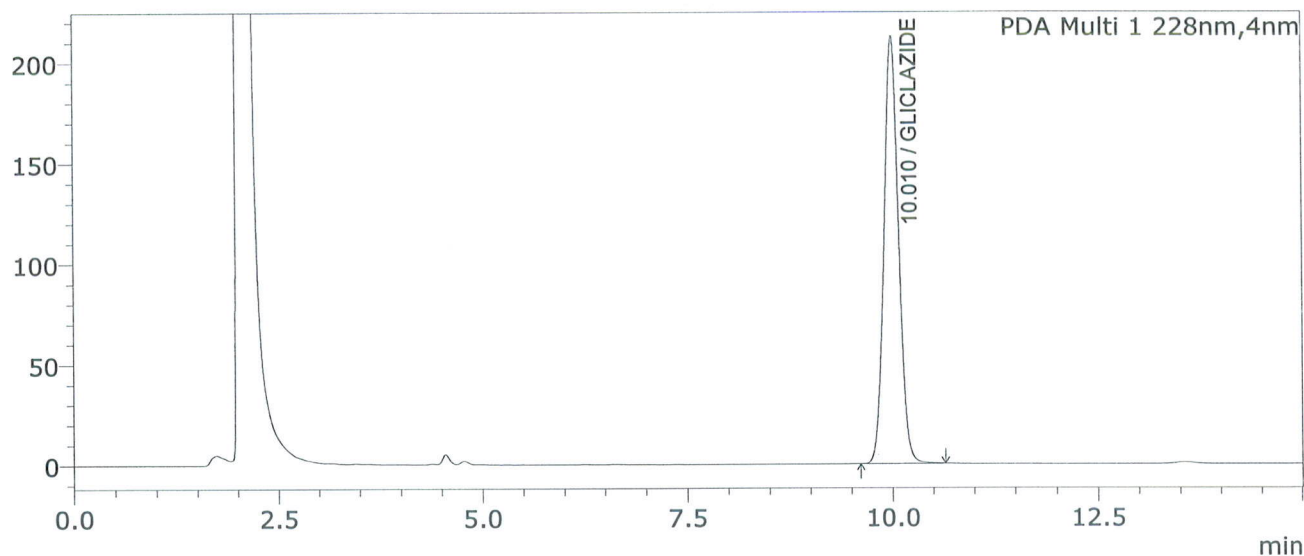
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-NYLON-DS-SPL-2
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-85.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-48
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 13:39:32
 Date Processed : 20-09-2023 09:57:32

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2631670	100.00	14090	0.939	--	--
Total			2631670	100.00				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

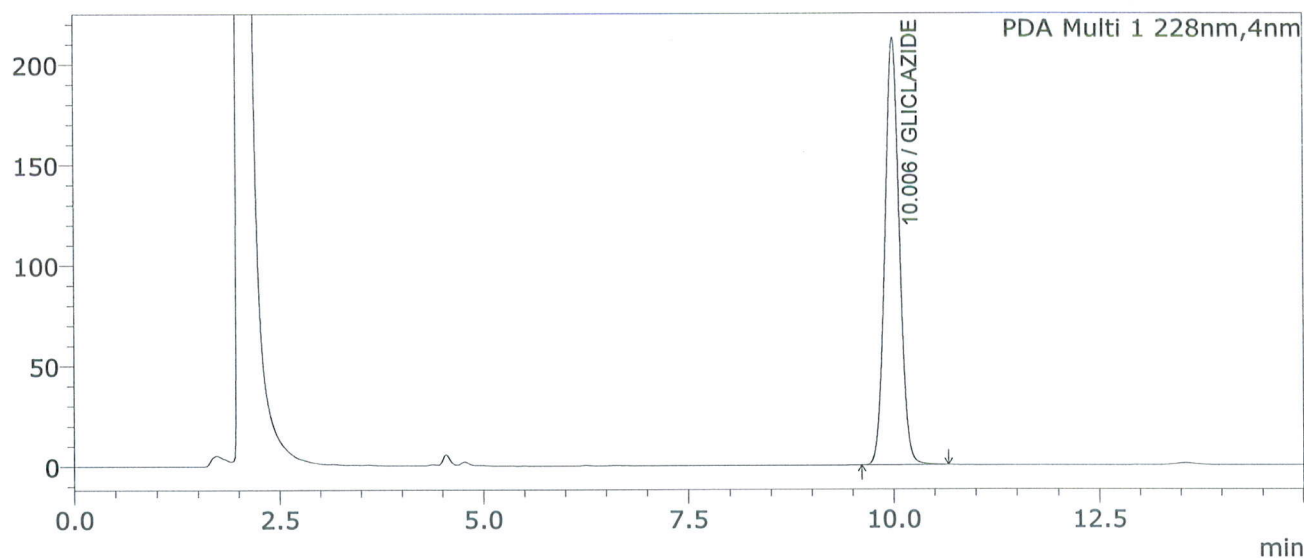
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-NYLON-DS-SPL-3
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-86.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-49
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 13:55:05
 Date Processed : 20-09-2023 09:57:32

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2627585	100.00	14095	0.940	--	--
Total			2627585	100.00				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

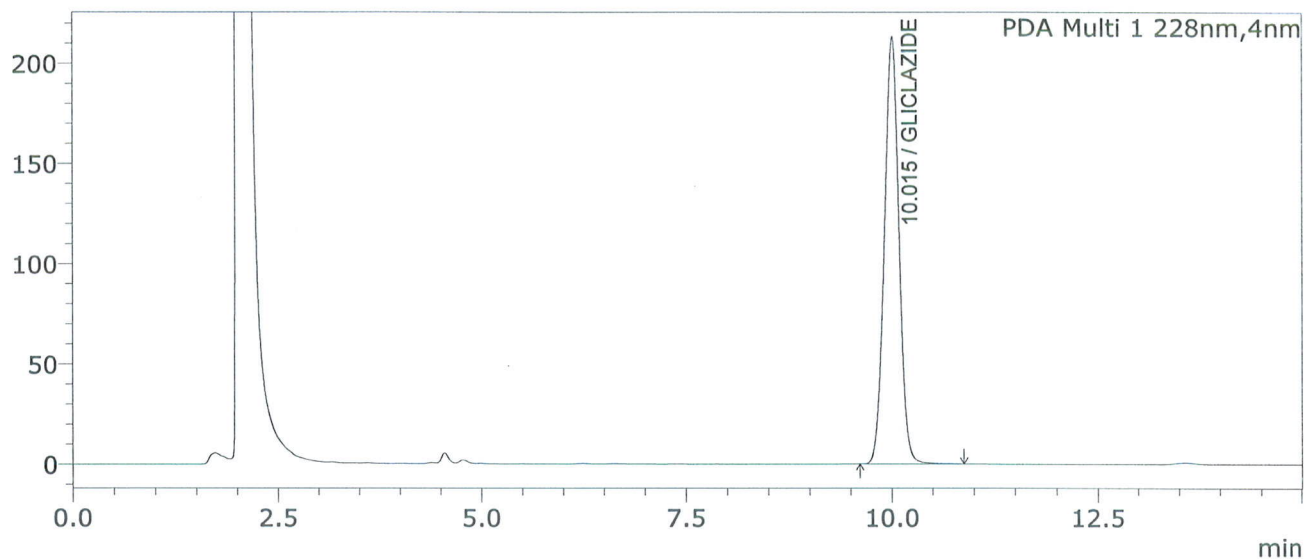
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-PVDF-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-87.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-50
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 14:10:38
 Date Processed : 20-09-2023 09:57:32

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2643289	100.00	14057	0.941	--	--
Total			2643289	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

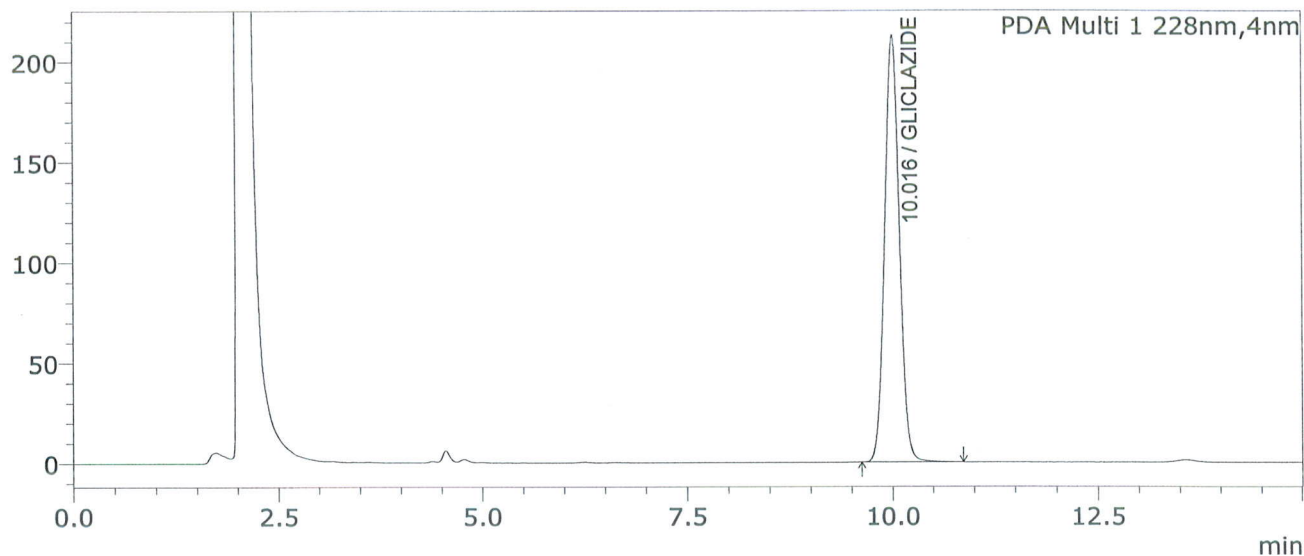
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-PVDF-DS-SPL-2
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-88.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-51
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 14:26:09
 Date Processed : 20-09-2023 09:57:33

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2639776	100.00	14076	0.942	--	--
Total			2639776	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

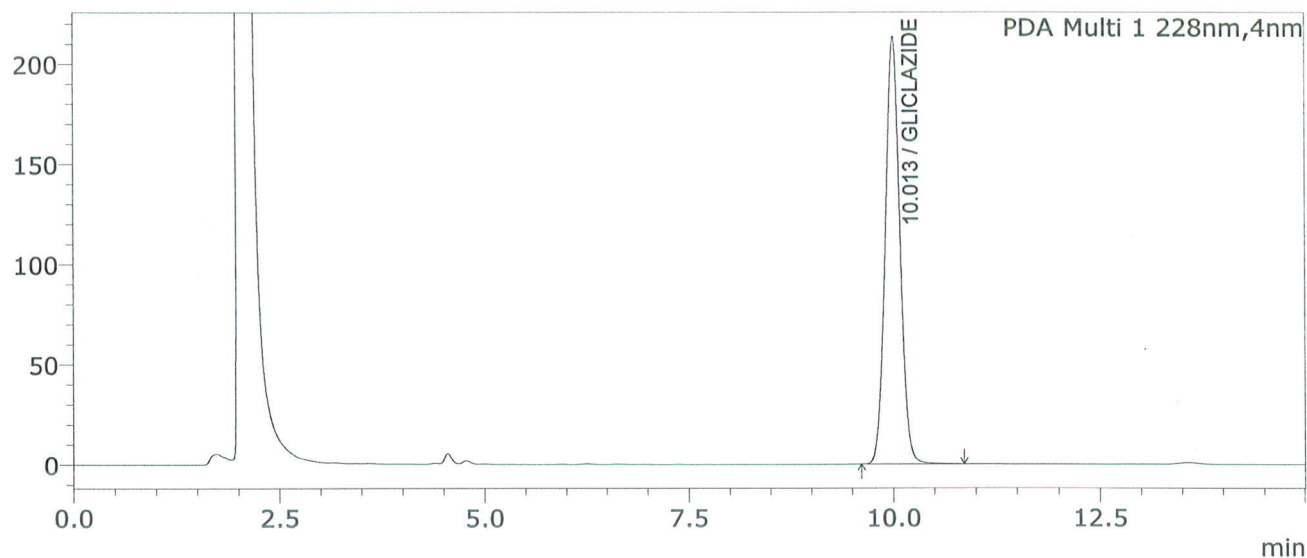
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-PVDF-DS-SPL-3
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-89.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-52
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 14:41:41
 Date Processed : 20-09-2023 09:57:33

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2647840	100.00	14060	0.943	--	--
Total			2647840	100.00				

20/09/23

Analysed By

20/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

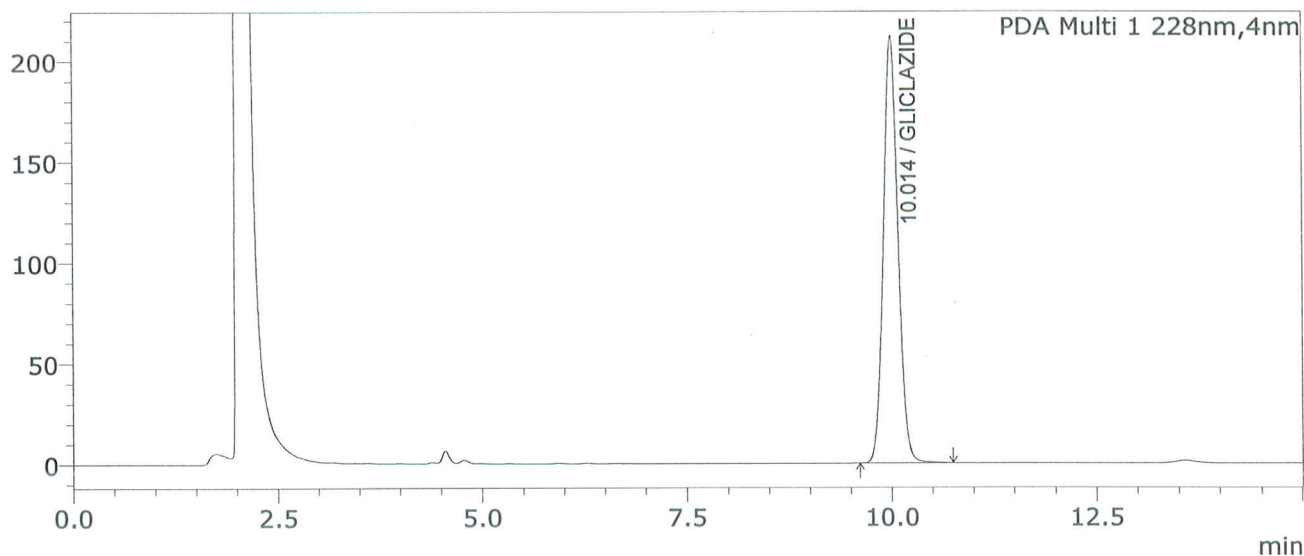
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-WHATMAN-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-90.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-53
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 14:57:14
 Date Processed : 20-09-2023 09:57:33

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2625970	100.00	14060	0.945	--	--
Total			2625970	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

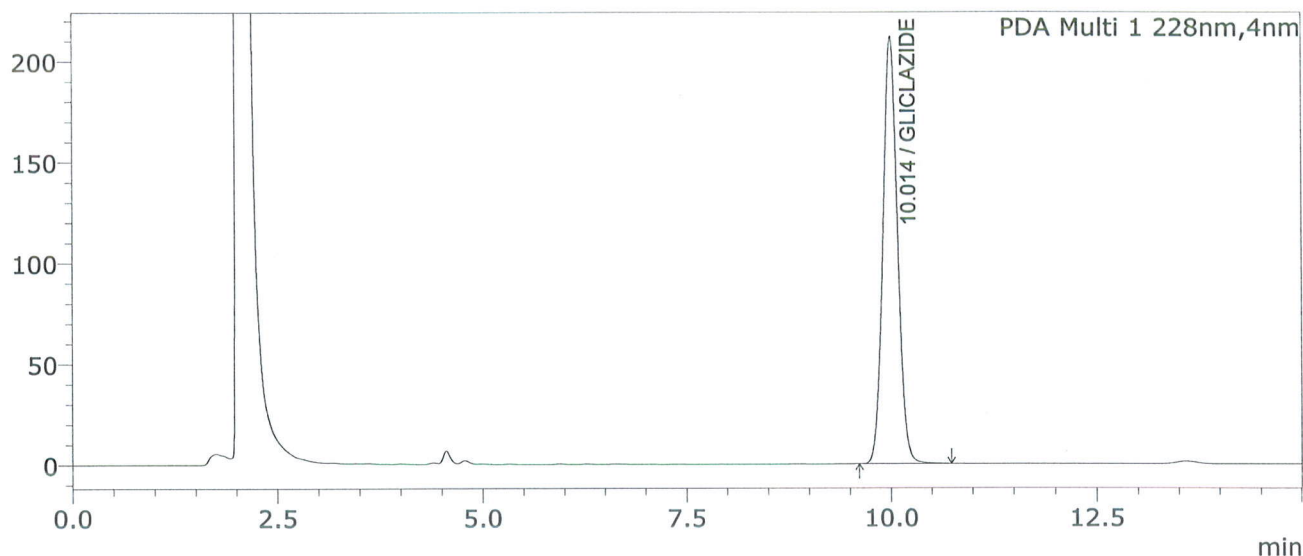
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-WHATMAN-DS-SPL-2
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-91.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-54
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 15:12:47
 Date Processed : 20-09-2023 09:57:34

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2625494	100.00	14045	0.946	--	--
Total			2625494	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

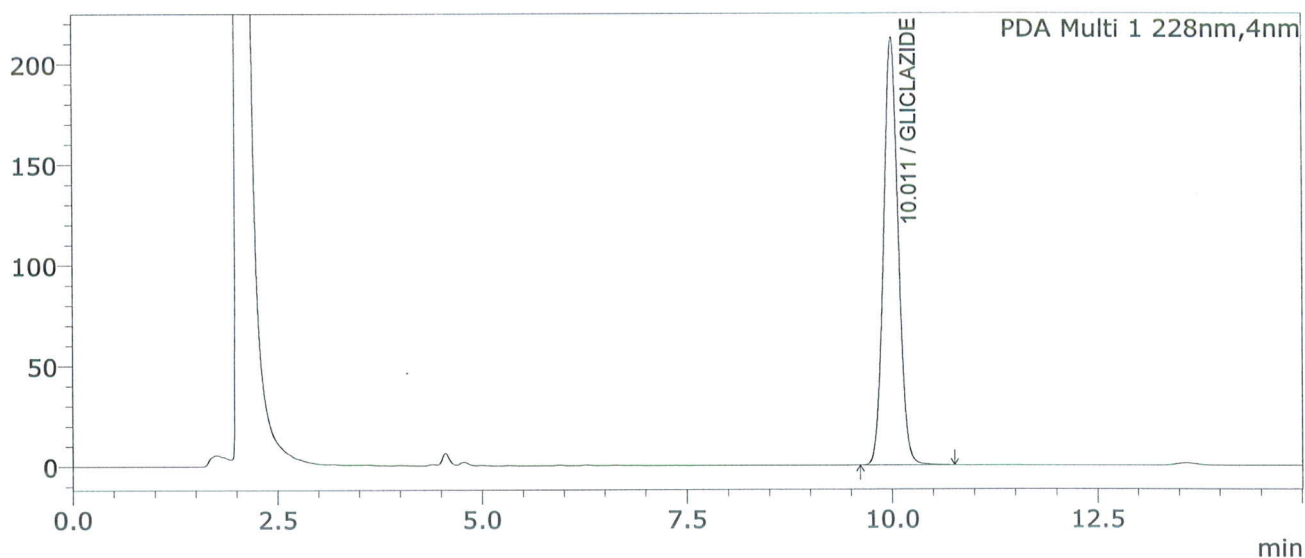
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDE-M-60-850-WHATMAN-DS-SPL-3
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-92.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 15:28:20
 Date Processed : 20-09-2023 09:57:34

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.01	2639033	100.00	14025	0.946	--	--
Total			2639033	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

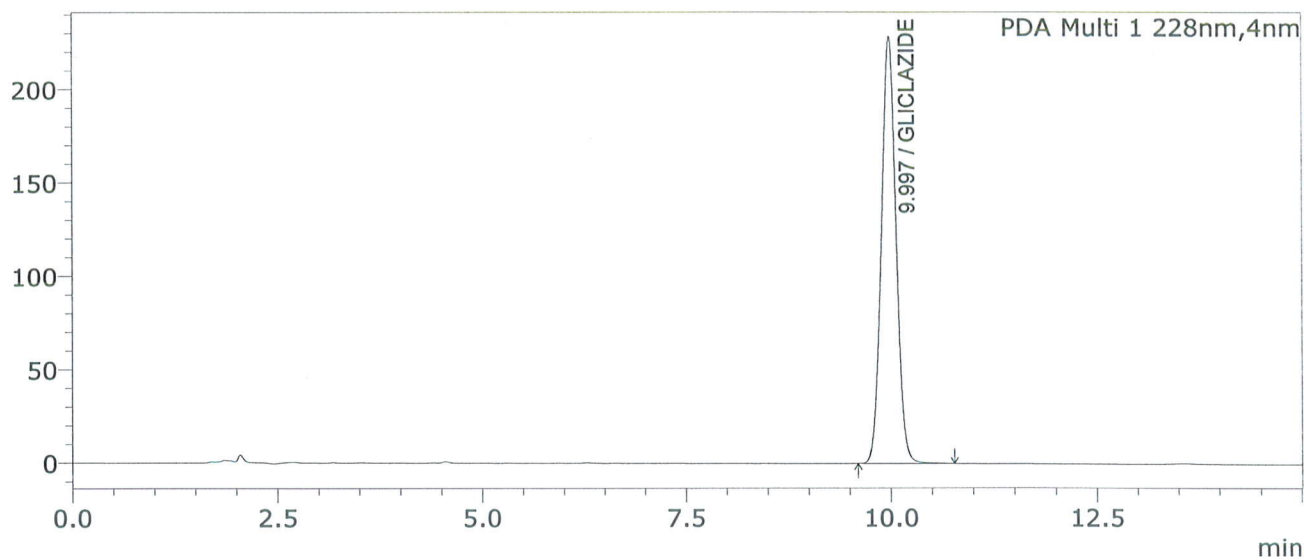
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLAZIDE-DS-STD-BKT-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-93.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-45
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 15:43:55
 Date Processed : 20-09-2023 09:57:34

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.00	2822590	100.00	14080	0.930	--	--
Total			2822590	100.00				

Analysed By

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	PRECISION (METHOD PRECISION and INTERMEDIATE PRECISION)	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006 & ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	---------------------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	66.23	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.23	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.666	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION (At final time point)			INTERMEDIATE PRECISION (At final time point)			CUMMULATIVE PRECISION
No.of preparation	Drug Release in %	Minimum	No.of preparation	Drug Release in %	Minimum	Average in %
Unit-1	95.01	90.5	Unit-1	93.34	89.1	93.06
Unit-2	96.03		Unit-2	94.27		
Unit-3	90.45	Maximum	Unit-3	92.58	Maximum	% RSD
Unit-4	94.93		Unit-4	90.47		
Unit-5	95.98	96.0	Unit-5	93.06	94.3	2.48
Unit-6	91.48		Unit-6	89.07		
Average	94.0	Not applicable	Average	92.1	Not applicable	
% RSD	2.56	Not applicable	% RSD	2.13	Not applicable	

Results:

- 1) % RSD for dissolution of six preparations of method precision
- 2) % RSD for dissolution of six preparations of Intermediate precision
- 3) Cumulative %RSD for dissolution of twelve preparations

2.56
2.13
2.48

Acceptance criteria:

- 1)% RSD for dissolution of six preparations should not be more than 10 at final interval.
- 2)Cumulative %RSD for dissolution of twelve preparations (of method and intermediate precision) should not be more than 10.0%

Analysed by : S.BHAVYASRI

Date : 23-09-2023

Checked by :

Date :

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name: GLIDE-M 60/850

Batch size :

Not applicable

Batch Number: G17230801

Mfg.Date :

Aug-23

Stage: INTERMEDIATE PRECISION

Exp.Date :

Jul-26

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID: ST/QCLC/009 Balance ID: ST/QC/EQ/041 WS No.: ST/WS/22/040 % Purity (aib) 100.0

Dissolution medium : Ph 7.4 Phosphate Buffer

Volume (ml) 900

Speed 100RPM

Time 2nd, 5th and 12th Hours

Standard dilution.:	66.23	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.23	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor 1.0000

Labelled claim 60 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	3066348	3066313	3066622	3067805	3067711	3066960	739	0.024
With Bracketing std.	3071134	3062199	3056061			3065524	4545	0.148

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	598301	11.63	19.38	0.22	19.9	18.3
Unit-2	660123	12.83	21.38	0.24		Maximum %
Unit-3	568935	11.06	18.43	0.20		
Unit-4	620653	12.06	20.10	0.22		
Unit-5	563667	10.95	18.26	0.20		
Unit-6	680337	13.22	22.04	0.24		22.0

5th Hour					Limit:Between 35.0-75.0%		
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Average %	Minimum %
Unit-1	1940659	37.72	62.86	0.698	63.08	50.1	44.1
Unit-2	1419782	27.59	45.99	0.511	46.23		Maximum%
Unit-3	1390528	27.03	45.04	0.500	45.25		
Unit-4	1503086	29.21	48.69	0.541	48.91		
Unit-5	1354702	26.33	43.88	0.488	44.08		63.1
Unit-6	1626005	31.60	52.67	0.585	52.91		

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2853464	55.46	92.43	93.34	92.1	89.1	2.1
Unit-2	2887160	56.11	93.52	94.27			
Unit-3	2836428	55.13	91.88	92.58		Maximum %	
Unit-4	2769326	53.82	89.70	90.47			
Unit-5	2851741	55.42	92.37	93.06			
Unit-6	2724216	52.95	88.24	89.07		94.3	

Calculation formula :

Drug release in mg / tablet = $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor}}{\text{Standard area} \times \text{sample dilution} \times 100}$ Drug release in % = $\frac{\text{Drug release in mg / tablet} \times 100}{\text{Labeled claim}}$ Correction factor = $\frac{\text{Drug release \% in respective time point}}{900 \times 10}$

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by : S.BHAVYASRI

Date : 23-09-2023

M.Bh
23/09/23

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

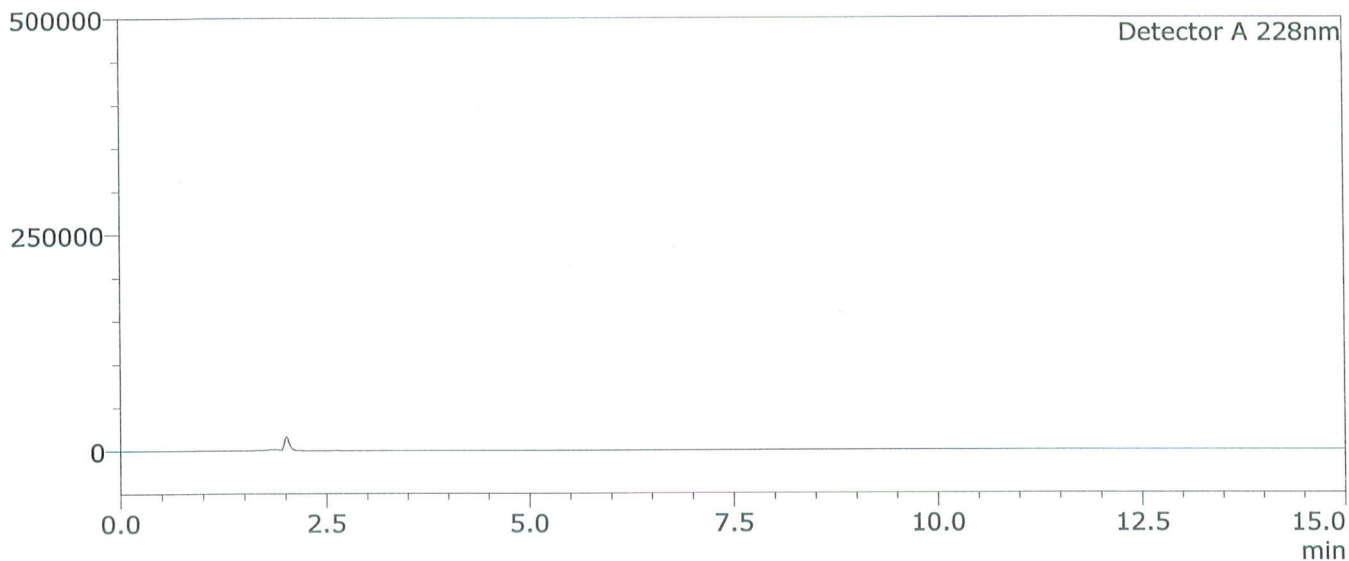
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : DS-BLANK
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-1
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 13:23:29
 Date Processed : 23-09-2023 09:02:27

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

H.Bh
 23/09/23
Analysed By

23/09/23
Checked By


GENERIC HEALTHCARE PVT. LTD.

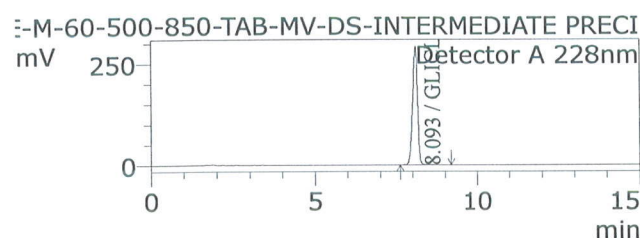
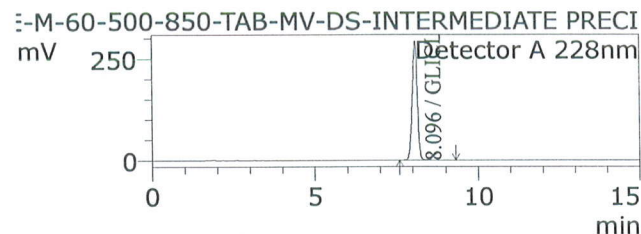
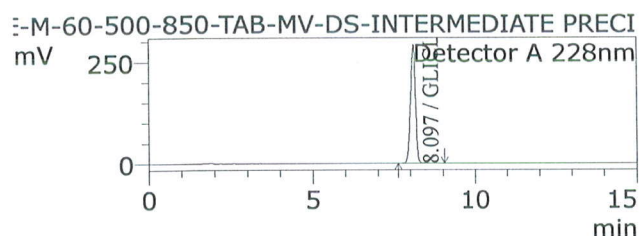
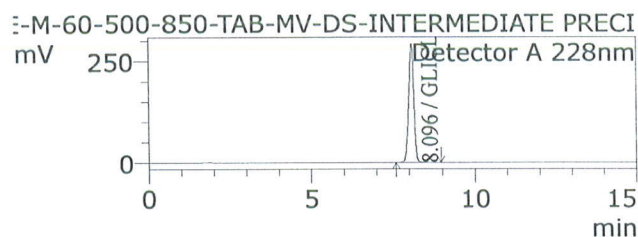
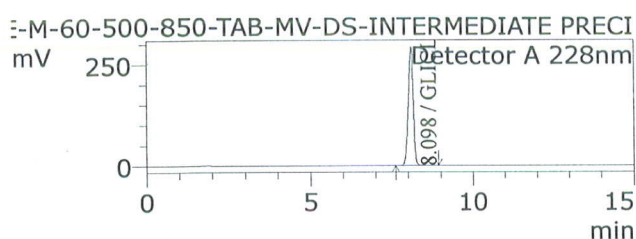
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 13:39:02
 Date Processed : 23-09-2023 09:02:27

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	ON-SPL-02.lcd	GLICLAZIDE-DS-STD-01	8.10	3066348	12763	0.87
2	ON-SPL-03.lcd	GLICLAZIDE-DS-STD-02	8.10	3066313	12747	0.87
2	ON-SPL-04.lcd	GLICLAZIDE-DS-STD-03	8.10	3066622	12713	0.87
2	ON-SPL-05.lcd	GLICLAZIDE-DS-STD-04	8.10	3067805	12751	0.87
2	ON-SPL-06.lcd	GLICLAZIDE-DS-STD-05	8.09	3067711	12788	0.87
	Average		8.10	3066960	12752	0.87
	%RSD		0.026	0.024	0.214	0.045

Analysed By

 H. Bly
23/09/23

Checked By

 H. Bly
23/09/23

 D:\ST-QCLC-009\DATA-2023\GLIDE-M-60-500-850-TAB-AMV-DS\22092023
 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-02.lcd



GENERIC HEALTHCARE PVT. LTD.

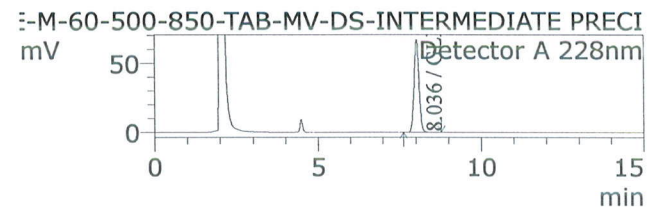
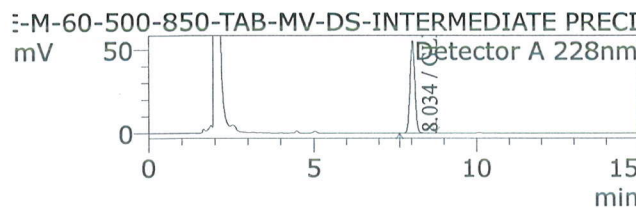
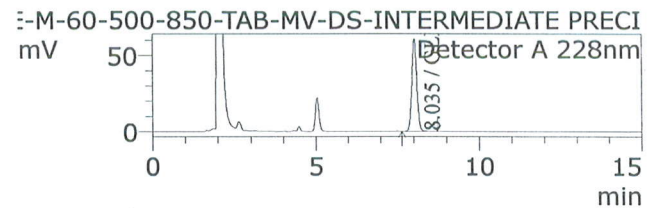
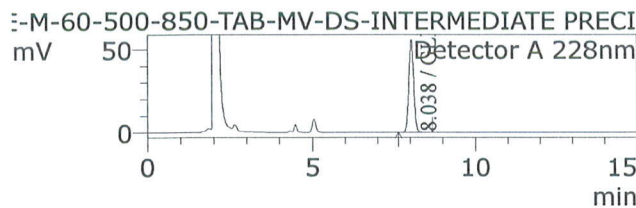
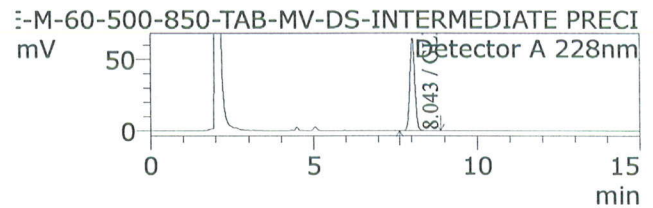
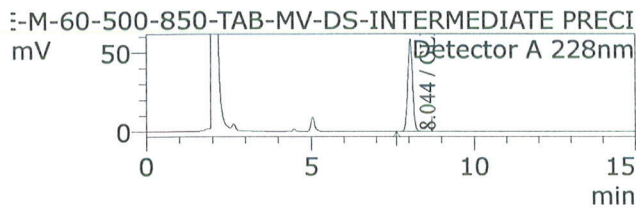
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDE-M-60-850-GLI-2HR-DS-SPL-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-07.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-3
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 15:35:14
 Date Processed : 23-09-2023 09:02:27

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	ON-SPL-07.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-1	8.04	598301	13439	1.01
4	ON-SPL-08.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-2	8.04	660123	13425	1.01
5	ON-SPL-09.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-3	8.04	568935	13515	1.01
6	ON-SPL-10.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-4	8.04	620653	13401	1.01
7	ON-SPL-11.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-5	8.03	563667	13438	1.01
8	ON-SPL-12.lcd	GLIDE-M-60-850-GLI-2HR-DS-SPL-6	8.04	680337	13542	1.01
	Average		8.04	615336	13460	1.01
	%RSD		0.051	7.750	0.411	0.315

Analysed By

M. B. L.
23/09/23

Checked By

C. K. Saravanan
23/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

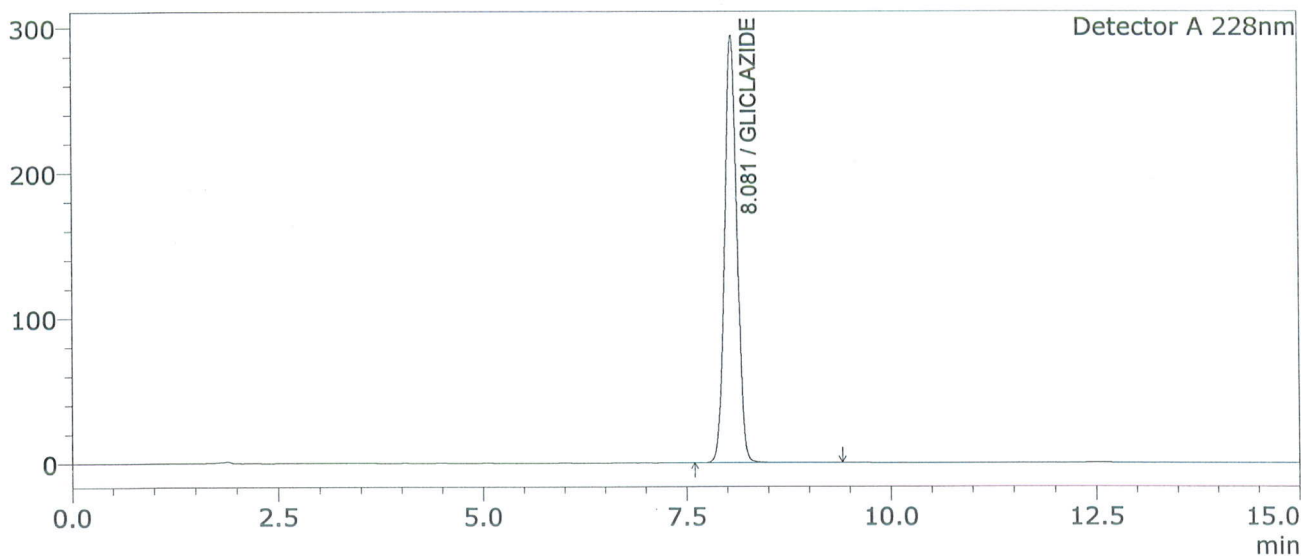
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-BKT-STD-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-13.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 17:08:26
 Date Processed : 23-09-2023 09:02:28

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.08	3071134	100.00	12800	0.867	--	--
Total			3071134	100.00				

M. Bly
23/09/23

Analysed By

S. A.
23/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

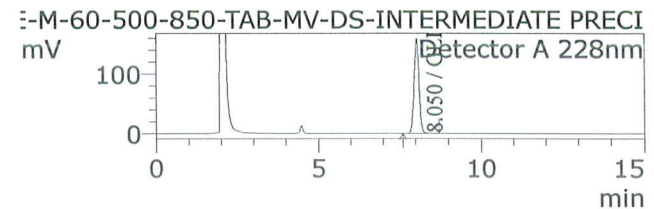
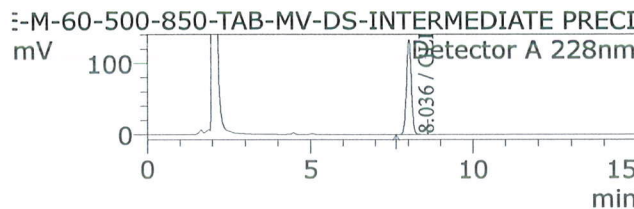
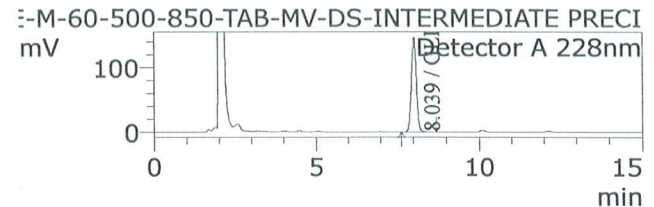
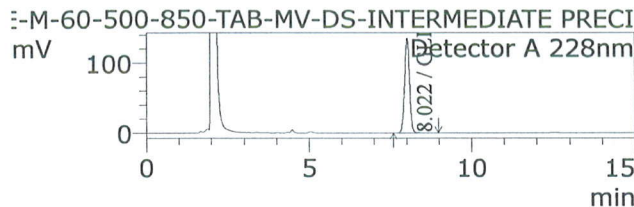
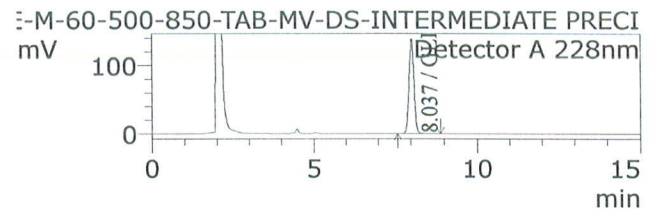
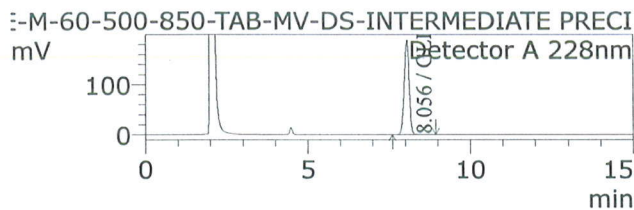
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDE-M-60-850-GLI-5HR-DS-SPL-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-14.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-9
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 17:24:00
 Date Processed : 23-09-2023 09:02:28

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	ON-SPL-14.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-1	8.06	1940659	13275	0.93
10	ON-SPL-15.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-2	8.04	1419782	13403	0.96
11	ON-SPL-16.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-3	8.02	1390528	13244	0.97
12	ON-SPL-17.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-4	8.04	1503086	13390	0.96
13	ON-SPL-18.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-5	8.04	1354702	13438	0.96
14	ON-SPL-19.lcd	GLIDE-M-60-850-GLI-5HR-DS-SPL-6	8.05	1626005	13366	0.95
	Average		8.04	1539127	13353	0.95
	%RSD		0.146	14.247	0.572	1.539

Analysed By

H. BL
23/09/23

Checked By

S. A
23/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

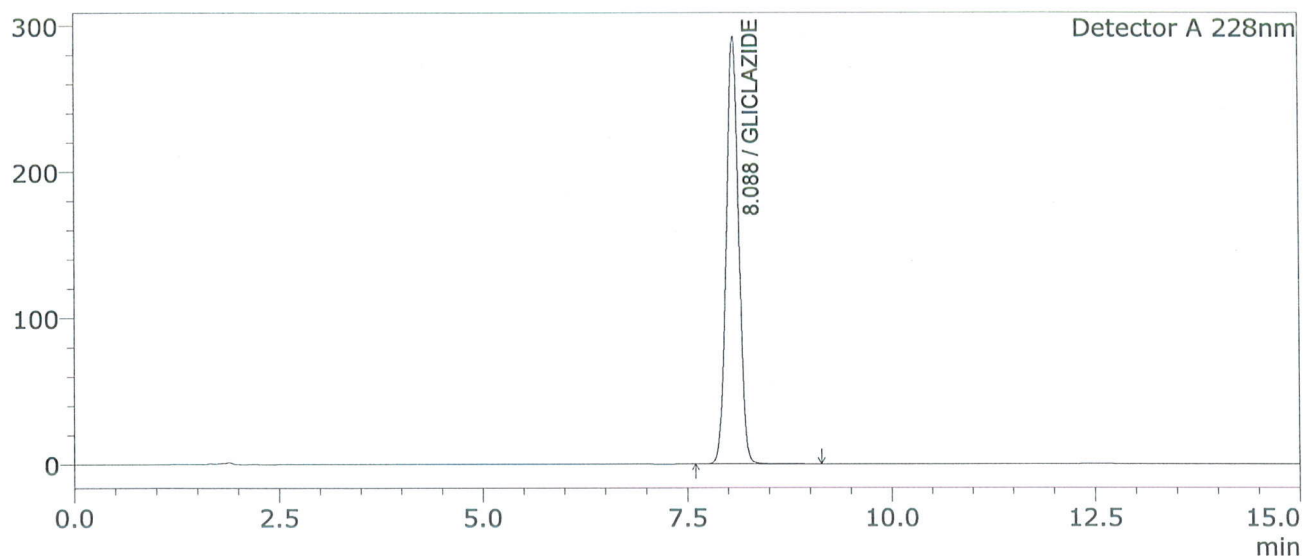
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-BKT-STD-2
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-20.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 20:16:57
 Date Processed : 23-09-2023 09:02:28

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.09	3062199	100.00	12776	0.867	--	--
Total			3062199	100.00				

M.Bh
23/09/23

Analysed By

23/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

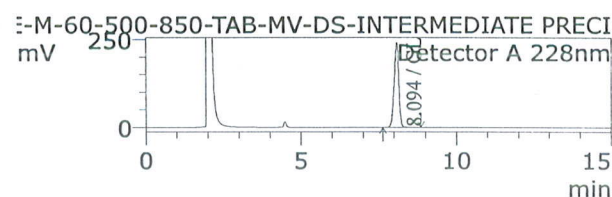
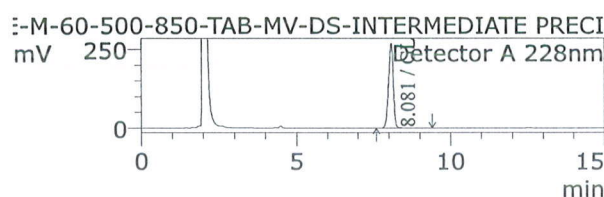
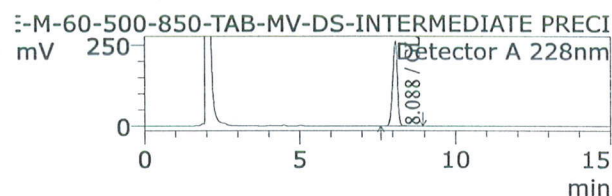
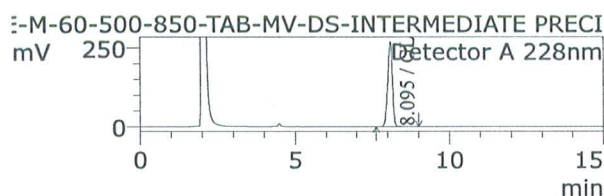
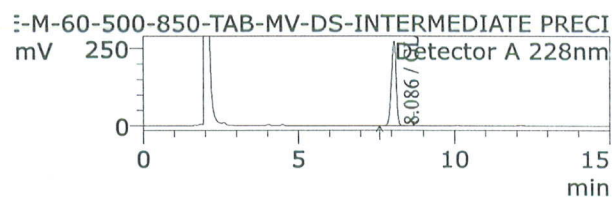
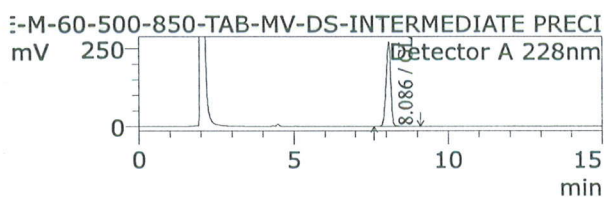
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDE-M-60-850-GLI-12H-DS-SPL-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-21.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-15
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 20:32:29
 Date Processed : 23-09-2023 09:02:28

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	ON-SPL-21.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-1	8.09	2853464	12794	0.88
16	ON-SPL-22.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-2	8.09	2887160	12649	0.88
17	ON-SPL-23.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-3	8.10	2836428	12736	0.88
18	ON-SPL-24.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-4	8.09	2769326	12651	0.88
19	ON-SPL-25.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-5	8.08	2851741	12537	0.88
20	ON-SPL-26.lcd	GLIDE-M-60-850-GLI-12H-DS-SPL-6	8.09	2724216	12889	0.89
	Average		8.09	2820389	12709	0.88
	%RSD		0.067	2.165	0.977	0.741

Analysed By *M.Bh*
23/09/23

Checked By *S.A*
23/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

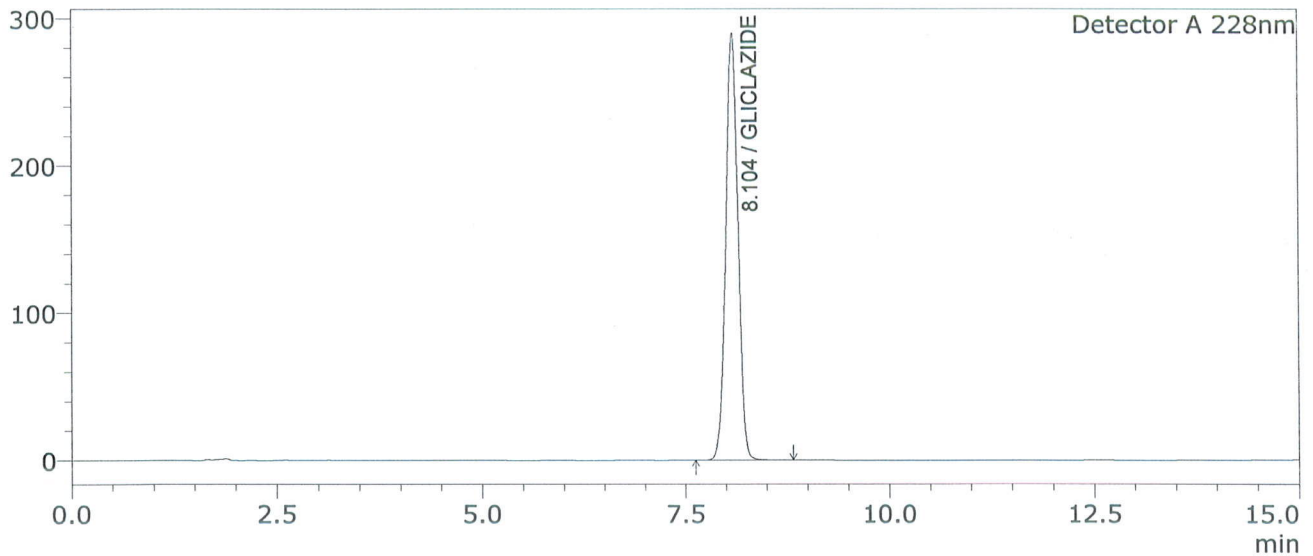
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-BKT-STD-3
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-27.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-2
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 22:05:40
 Date Processed : 23-09-2023 09:02:29

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.10	3056061	100.00	12688	0.866	--	--
Total			3056061	100.00				

M. Bh
 23/09/23
Analysed By

23/09/23
Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	INTERMEDIATE PRECISION	DS-BLANK	50-500-850-TAB-DS.lcm	RECISION-SPL-01.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-01	50-500-850-TAB-DS.lcm	RECISION-SPL-02.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-02	50-500-850-TAB-DS.lcm	RECISION-SPL-03.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-03	50-500-850-TAB-DS.lcm	RECISION-SPL-04.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-04	50-500-850-TAB-DS.lcm	RECISION-SPL-05.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-05	50-500-850-TAB-DS.lcm	RECISION-SPL-06.lcd	20.0	QC/CL/20/017
3	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-07.lcd	20.0	QC/CL/20/017
4	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-08.lcd	20.0	QC/CL/20/017
5	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-09.lcd	20.0	QC/CL/20/017
6	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-10.lcd	20.0	QC/CL/20/017
7	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-11.lcd	20.0	QC/CL/20/017
8	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-12.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-1	50-500-850-TAB-DS.lcm	RECISION-SPL-13.lcd	20.0	QC/CL/20/017
9	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-14.lcd	20.0	QC/CL/20/017
10	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-15.lcd	20.0	QC/CL/20/017
11	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-16.lcd	20.0	QC/CL/20/017
12	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-17.lcd	20.0	QC/CL/20/017
13	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-18.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
14	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-19.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-2	50-500-850-TAB-DS.lcm	RECISION-SPL-20.lcd	20.0	QC/CL/20/017
15	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-21.lcd	20.0	QC/CL/20/017
16	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-22.lcd	20.0	QC/CL/20/017
17	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-23.lcd	20.0	QC/CL/20/017
18	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-24.lcd	20.0	QC/CL/20/017
19	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-25.lcd	20.0	QC/CL/20/017
20	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-26.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-3	50-500-850-TAB-DS.lcm	RECISION-SPL-27.lcd	20.0	QC/CL/20/017
21	1	INTERMEDIATE PRECISION	DS-BLANK	50-500-850-TAB-DS.lcm	RECISION-SPL-28.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-01	50-500-850-TAB-DS.lcm	RECISION-SPL-29.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-02	50-500-850-TAB-DS.lcm	RECISION-SPL-30.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-03	50-500-850-TAB-DS.lcm	RECISION-SPL-31.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-04	50-500-850-TAB-DS.lcm	RECISION-SPL-32.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-05	50-500-850-TAB-DS.lcm	RECISION-SPL-33.lcd	20.0	QC/CL/20/017
23	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-34.lcd	20.0	QC/CL/20/017
24	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-35.lcd	20.0	QC/CL/20/017
25	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-36.lcd	20.0	QC/CL/20/017
26	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-37.lcd	20.0	QC/CL/20/017
27	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-38.lcd	20.0	QC/CL/20/017
28	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-39.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-1	50-500-850-TAB-DS.lcm	RECISION-SPL-40.lcd	20.0	QC/CL/20/017
29	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-41.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
30	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-42.lcd	20.0	QC/CL/20/017
31	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-43.lcd	20.0	QC/CL/20/017
32	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-44.lcd	20.0	QC/CL/20/017
33	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-45.lcd	20.0	QC/CL/20/017
34	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-46.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-2	50-500-850-TAB-DS.lcm	RECISION-SPL-47.lcd	20.0	QC/CL/20/017
35	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-48.lcd	20.0	QC/CL/20/017
36	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-49.lcd	20.0	QC/CL/20/017
37	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-50.lcd	20.0	QC/CL/20/017
38	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-51.lcd	20.0	QC/CL/20/017
39	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-52.lcd	20.0	QC/CL/20/017
40	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-53.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-3	50-500-850-TAB-DS.lcm	RECISION-SPL-54.lcd	20.0	QC/CL/20/017
-1	1	INTERMEDIATE PRECISION	WASH	HOD-100%-WATER.lcm	RECISION-SPL-55.lcd	20.0	QC/CL/20/017
-1	1	INTERMEDIATE PRECISION	WASH	WASHING METHOD.lcm	RECISION-SPL-56.lcd	20.0	QC/CL/20/017
-1	1	INTERMEDIATE PRECISION	SHUTDOWN	ETHOD\SHUTDOWN.lcm	RECISION-SPL-57.lcd	20.0	QC/CL/20/017

M.B.L.
22/09/23

Analysed By

23/09/23

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number:	G1722093	Mfg.Date :	Oct-22
Stage:	METHOD PRECISION	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900
Speed	100 RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.20	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.2	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	2821332	2821511	2820579	2820779	2821448	2821130	422	0.015
With Bracketing std.	2819670	2820300	2819943			2820695	700	0.025

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	617915	13.05	21.75	0.24	19.1	13.2
Unit-2	513335	10.84	18.07	0.20		Maximum %
Unit-3	374802	7.92	13.19	0.15		
Unit-4	560396	11.84	19.73	0.22		
Unit-5	600590	12.68	21.14	0.23		21.7
Unit-6	588201	12.42	20.70	0.23		

5th Hour					Limit:Between 35.0-75.0%		
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Average %	Minimum %
Unit-1	1713729	36.19	60.32	0.670	60.56	55.2	50.9
Unit-2	1464988	30.94	51.57	0.573	51.77		Maximum%
Unit-3	1696129	35.82	59.70	0.663	59.85		
Unit-4	1440639	30.43	50.71	0.563	50.93		
Unit-5	1579073	33.35	55.58	0.618	55.82		60.6
Unit-6	1471184	31.07	51.78	0.575	52.01		

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2601538	54.94	91.57	92.48	90.6	87.5	2.4
Unit-2	2526555	53.36	88.93	89.71			
Unit-3	2515842	53.13	88.55	89.36		Maximum %	
Unit-4	2462392	52.00	86.67	87.46			
Unit-5	2633739	55.62	92.70	93.56		93.6	
Unit-6	2571873	54.32	90.53	91.33			

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor Standard area x sample dilution X 100
-----------------------------	---

Drug release in %	Drug release in mg /tablet x 100 Labeled claim
-------------------	---

Correction factor	Drug release % in respective time point / 900 X 10
-------------------	--

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Fianl interval should not be more than 5.0.

Analysed by :

E.MEENA

Date :

20-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

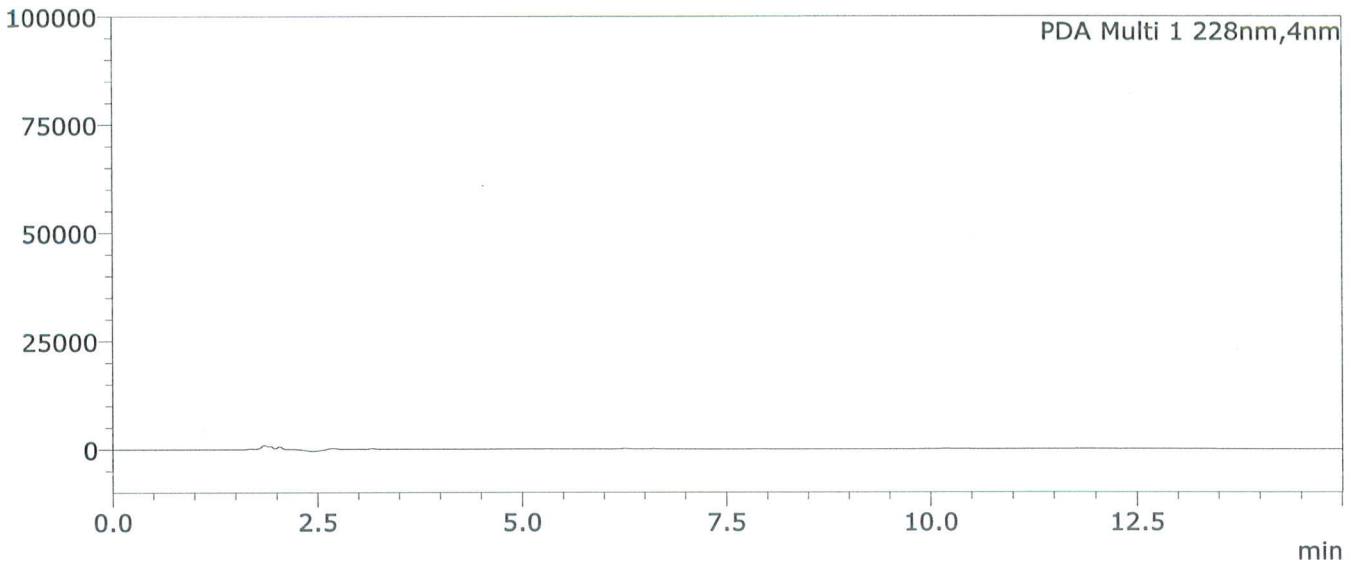
<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : BLANK-DS
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-43.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-24
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 02:43:53
 Date Processed : 20-09-2023 09:57:17

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

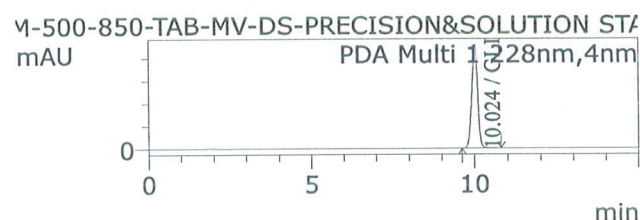
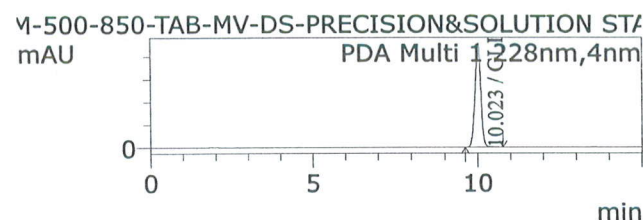
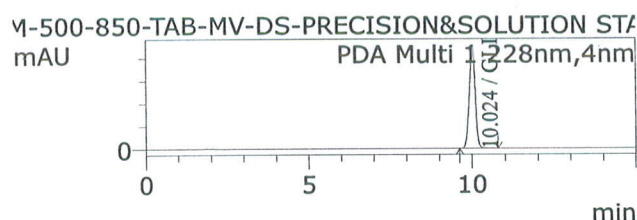
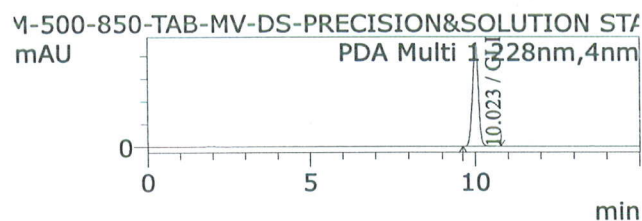
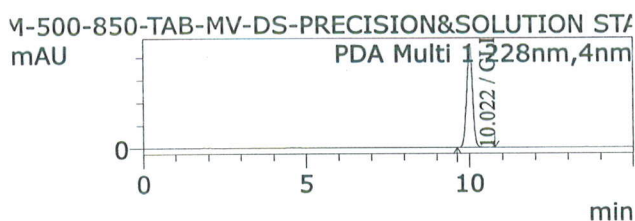
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-44
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-25
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 02:59:25
 Date Processed : 20-09-2023 09:57:18

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
25	ITY-SPL-44.lcd	GLICLAZIDE-DS-STD-01	10.02	2821332	14149	0.92
25	ITY-SPL-45.lcd	GLICLAZIDE-DS-STD-02	10.02	2821511	14157	0.92
25	ITY-SPL-46.lcd	GLICLAZIDE-DS-STD-03	10.02	2820579	14156	0.92
25	ITY-SPL-47.lcd	GLICLAZIDE-DS-STD-04	10.02	2820779	14157	0.92
25	ITY-SPL-48.lcd	GLICLAZIDE-DS-STD-05	10.02	2821448	14155	0.92
	Average		10.02	2821130	14155	0.92
	%RSD		0.009	0.015	0.024	0.011

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

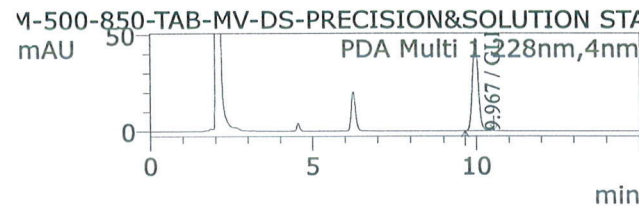
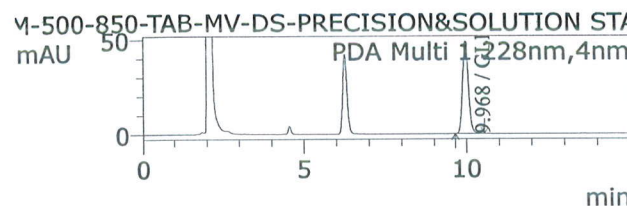
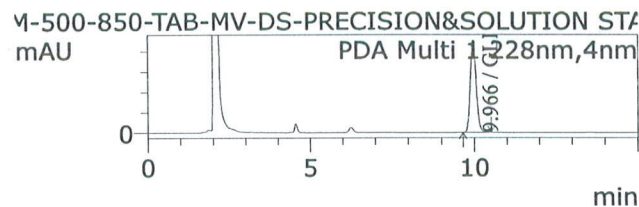
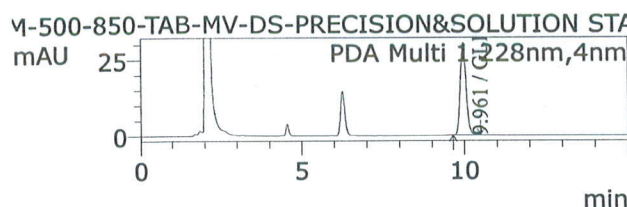
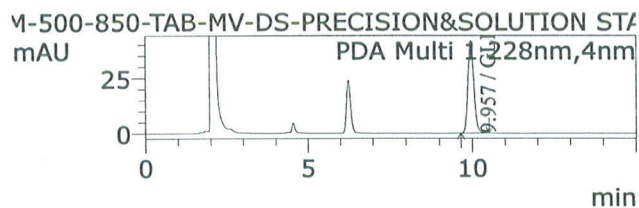
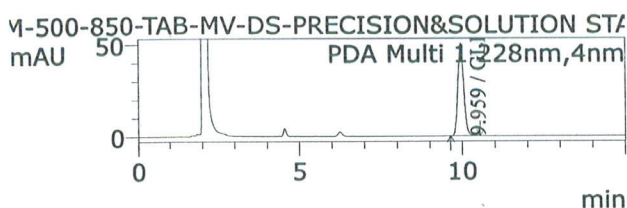
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDE-M-60-500-GLI-2HR-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-51
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-26
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 04:48:12
 Date Processed : 20-09-2023 09:57:21

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
26	ITY-SPL-51.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-1	9.96	617915	14328	1.11
27	ITY-SPL-52.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-2	9.96	513335	14313	1.12
28	ITY-SPL-53.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-3	9.96	374802	14270	1.14
29	ITY-SPL-54.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-4	9.97	560396	14378	1.11
30	ITY-SPL-55.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-5	9.97	600590	14385	1.11
31	ITY-SPL-56.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-6	9.97	588201	14386	1.11
	Average		9.96	542540	14343	1.11
	%RSD		0.044	16.577	0.329	1.047

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

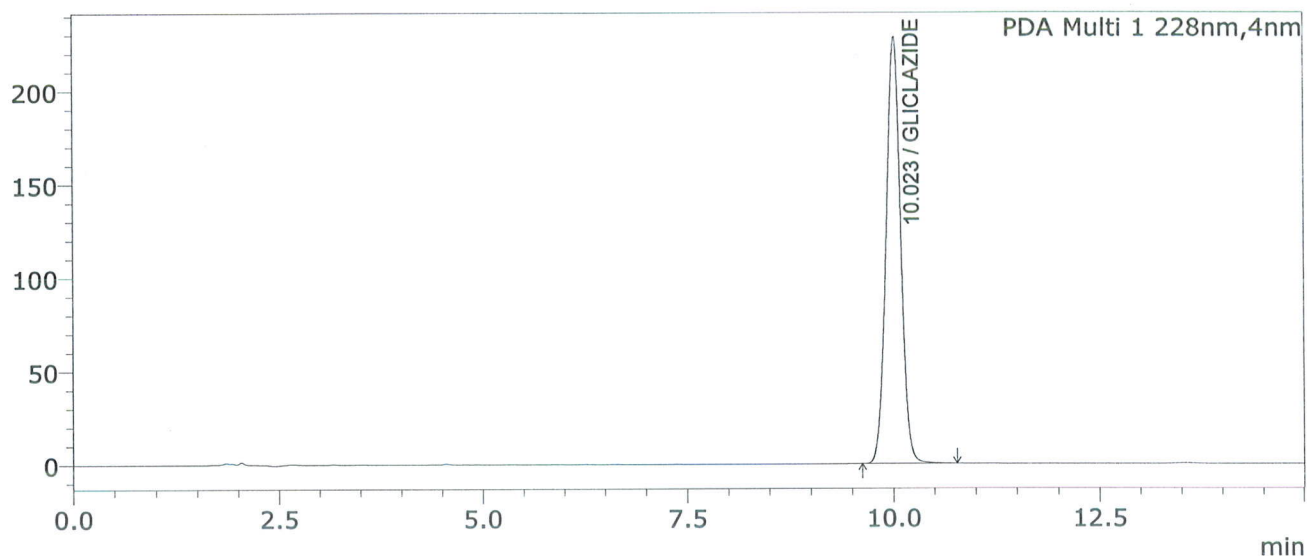
<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE-DS-STD-BKT-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-57.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-25
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 06:21:28
 Date Processed : 20-09-2023 09:57:23

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2819670	100.00	14170	0.923	--	--
Total			2819670	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

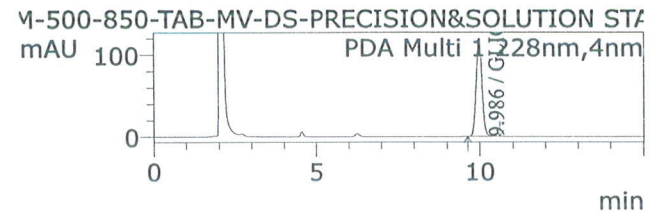
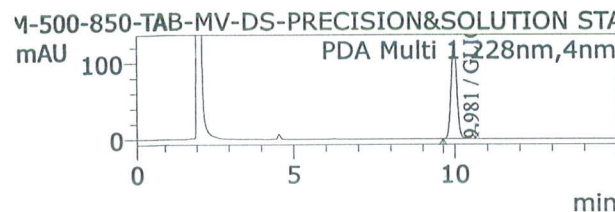
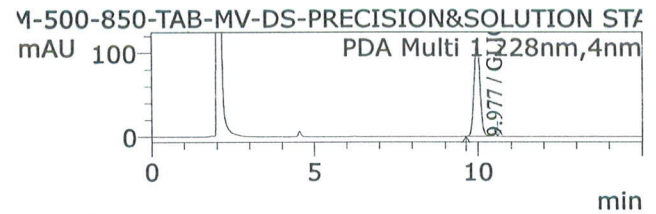
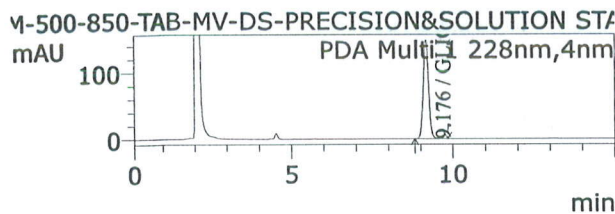
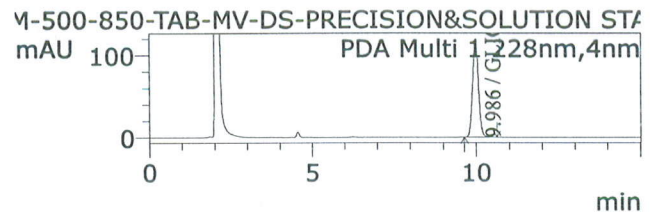
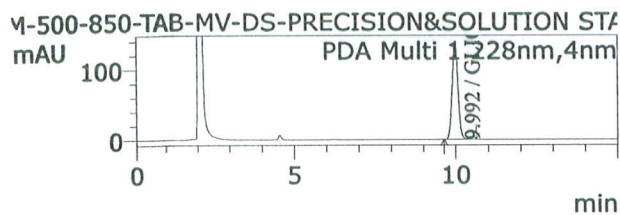
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDE-M-60-500-GLI-5HR-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-58
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-32
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 06:37:01
 Date Processed : 20-09-2023 09:57:23

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
32	ITY-SPL-58.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-1	9.99	1713729	14380	1.00
33	ITY-SPL-59.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-2	9.99	1464988	14448	1.02
34	ITY-SPL-60.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-3	9.18	1696129	13844	1.00
35	ITY-SPL-61.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-4	9.98	1440639	14429	1.02
36	ITY-SPL-62.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-5	9.98	1579073	14384	1.01
37	ITY-SPL-63.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-6	9.99	1471184	14438	1.02
	Average		9.85	1560957	14320	1.01
	%RSD		3.353	7.777	1.642	0.970

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

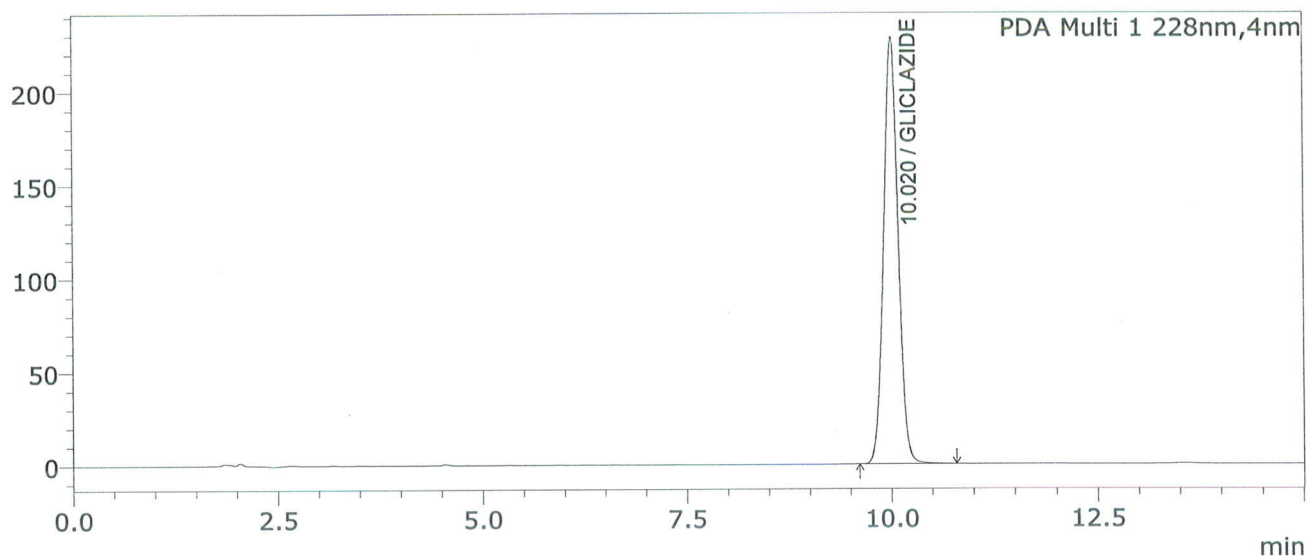
<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE-DS-STD-BKT-2
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-64.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-25
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 08:10:19
 Date Processed : 20-09-2023 12:07:04

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2820300	100.00	14160	0.923	--	--
Total			2820300	100.00				

Analysed By

Checked By



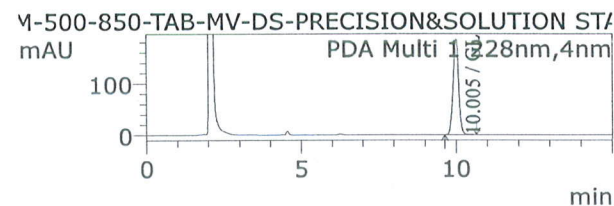
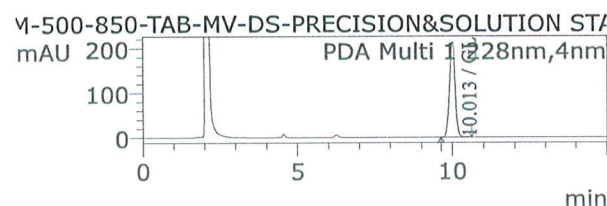
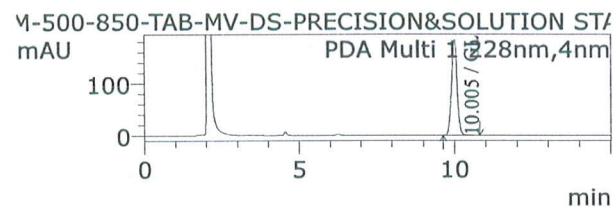
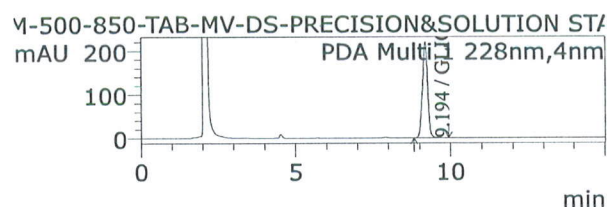
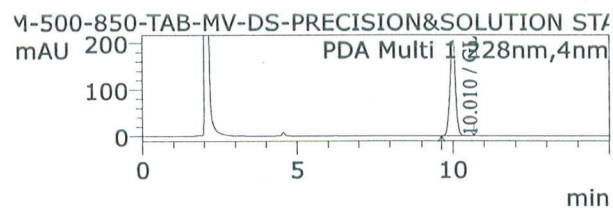
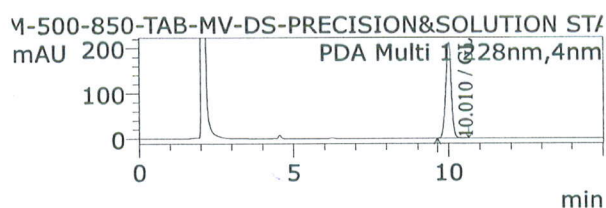
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDE-M-60-500-GLI-12H-DS-SPL-1
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-67
 Method Filename : GLIDE-M 60-500-850-TAB-DS GLICLAZIDE P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-38
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 08:56:56
 Date Processed : 20-09-2023 09:57:26
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
38	TY-SPL-67.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-1	10.01	2601538	14127	0.94
39	TY-SPL-68.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-2	10.01	2526555	14185	0.94
40	TY-SPL-69.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-3	9.19	2515842	13657	0.94
41	TY-SPL-70.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-4	10.01	2462392	14252	0.96
42	TY-SPL-71.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-5	10.01	2633739	14136	0.94
43	TY-SPL-72.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-6	10.00	2471873	14278	0.96
	Average		9.87	2535323	14106	0.95
	%RSD		3.368	2.725	1.615	1.199

Analysed By

20/09/23

Checked By

20/09/23



GENERIC HEALTHCARE PVT. LTD.

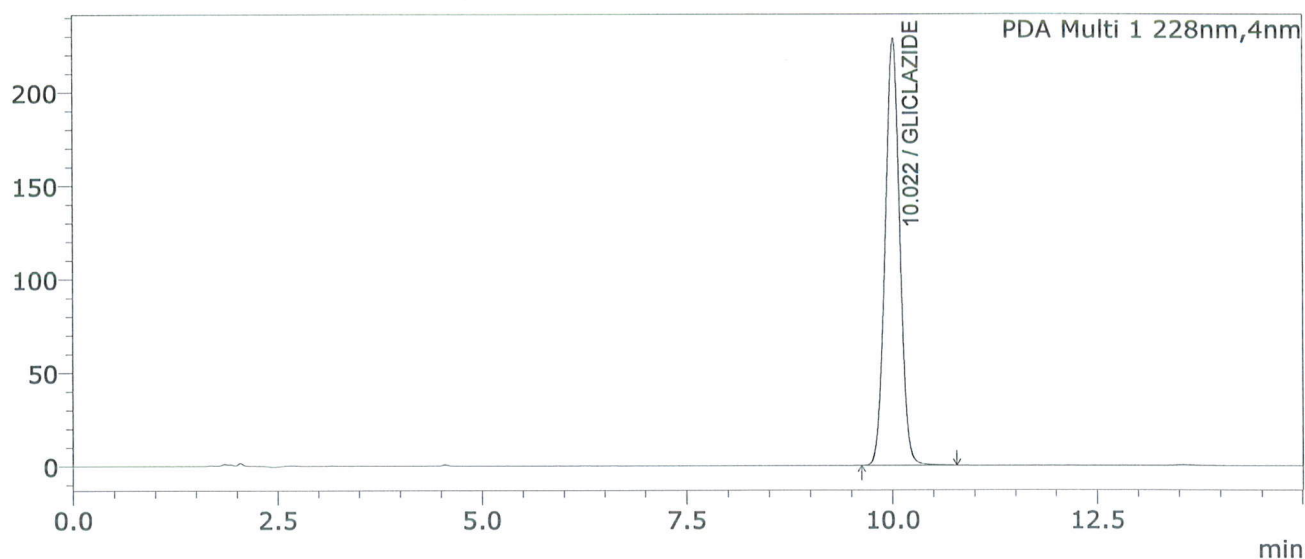
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE-DS-STD-BKT-3
 Data Filename : 15092023 GLIDE-M-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY-SPL-73.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-DS_GLICLAZIDE_P.lcm
 Batch Filename : 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb
 Vial # : 1-25
 Injection Volume : 20 uL
 Date Acquired : 16-09-2023 10:30:12
 Date Processed : 20-09-2023 12:19:02
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	10.02	2819943	100.00	14174	0.921	--	--
Total			2819943	100.00				

20/09/23

Analysed By

20/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 15092023 GLIDE-M-60-500-850-TAB-MV-DS-PRECISION&SOLUTION STABILITY.lcb

Vial #	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-01.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-02.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-03.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-04.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-05.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-06.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	SOLUTION STABILITY-DS-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-07.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-08.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-2H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-09.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-2H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-10.lcd	20.0	QC/CL/23/041
4	1	METHOD PRECISION	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-11.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-12.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-13.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-14.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-15.lcd	20.0	QC/CL/23/041
5	1	METHOD PRECISION	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-16.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-4H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-17.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-4H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
6	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-19.lcd	20.0	QC/CL/23/041
7	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-20.lcd	20.0	QC/CL/23/041
8	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-21.lcd	20.0	QC/CL/23/041
9	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-22.lcd	20.0	QC/CL/23/041
10	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-23.lcd	20.0	QC/CL/23/041
11	1	METHOD PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-24.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-6H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-25.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-6H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-26.lcd	20.0	QC/CL/23/041
12	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-27.lcd	20.0	QC/CL/23/041
13	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-28.lcd	20.0	QC/CL/23/041
14	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-29.lcd	20.0	QC/CL/23/041
15	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-30.lcd	20.0	QC/CL/23/041
16	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-31.lcd	20.0	QC/CL/23/041
17	1	METHOD PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-32.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-8H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-33.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-8H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-34.lcd	20.0	QC/CL/23/041
18	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-35.lcd	20.0	QC/CL/23/041
19	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-36.lcd	20.0	QC/CL/23/041
20	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-37.lcd	20.0	QC/CL/23/041
21	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-38.lcd	20.0	QC/CL/23/041
22	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-39.lcd	20.0	QC/CL/23/041
23	1	METHOD PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-40.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-10H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-41.lcd	20.0	QC/CL/23/041

Vial #	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-10H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-42.lcd	20.0	QC/CL/23/041
24	1	METHOD PRECISION	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-43.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-44.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-45.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-46.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-47.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-48.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-12H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-49.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-12H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-50.lcd	20.0	QC/CL/23/041
26	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-51.lcd	20.0	QC/CL/23/041
27	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-52.lcd	20.0	QC/CL/23/041
28	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-53.lcd	20.0	QC/CL/23/041
29	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-54.lcd	20.0	QC/CL/23/041
30	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-55.lcd	20.0	QC/CL/23/041
31	1	METHOD PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-56.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-BKT-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-57.lcd	20.0	QC/CL/23/041
32	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-58.lcd	20.0	QC/CL/23/041
33	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-59.lcd	20.0	QC/CL/23/041
34	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-60.lcd	20.0	QC/CL/23/041
35	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-61.lcd	20.0	QC/CL/23/041
36	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-62.lcd	20.0	QC/CL/23/041
37	1	METHOD PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-63.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-BKT-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-64.lcd	20.0	QC/CL/23/041

Vial #	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-16H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-65.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-16H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-66.lcd	20.0	QC/CL/23/041
38	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-67.lcd	20.0	QC/CL/23/041
39	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-68.lcd	20.0	QC/CL/23/041
40	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-69.lcd	20.0	QC/CL/23/041
41	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-4	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-70.lcd	20.0	QC/CL/23/041
42	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-5	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-71.lcd	20.0	QC/CL/23/041
43	1	METHOD PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-6	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-72.lcd	20.0	QC/CL/23/041
25	1	METHOD PRECISION	GLICLAZIDE-DS-STD-BKT-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-73.lcd	20.0	QC/CL/23/041
44	1	FILTER PAPER STUDY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-74.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-75.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-76.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-77.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-78.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-79.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-80.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-20H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-81.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-20H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-82.lcd	20.0	QC/CL/23/041
46	1	FILTER PAPER STUDY	GLIDE-M-60-850-CENTRIFUG-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-83.lcd	20.0	QC/CL/23/041
47	1	FILTER PAPER STUDY	GLIDE-M-60-850-NYLON-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-84.lcd	20.0	QC/CL/23/041
48	1	FILTER PAPER STUDY	GLIDE-M-60-850-NYLON-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-85.lcd	20.0	QC/CL/23/041
49	1	FILTER PAPER STUDY	GLIDE-M-60-850-NYLON-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-86.lcd	20.0	QC/CL/23/041
50	1	FILTER PAPER STUDY	GLIDE-M-60-850-PVDF-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-87.lcd	20.0	QC/CL/23/041

Vial #	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
51	1	FILTER PAPER STUDY	GLIDE-M-60-850-PVDF-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-88.lcd	20.0	QC/CL/23/041
52	1	FILTER PAPER STUDY	GLIDE-M-60-850-PVDF-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-89.lcd	20.0	QC/CL/23/041
53	1	FILTER PAPER STUDY	GLIDE-M-60-850-WHATMAN-DS-SPL-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-90.lcd	20.0	QC/CL/23/041
54	1	FILTER PAPER STUDY	GLIDE-M-60-850-WHATMAN-DS-SPL-2	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-91.lcd	20.0	QC/CL/23/041
1	2	FILTER PAPER STUDY	GLIDE-M-60-850-WHATMAN-DS-SPL-3	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-92.lcd	20.0	QC/CL/23/041
45	1	FILTER PAPER STUDY	GLICLAZIDE-DS-STD-BKT-1	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-93.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-94.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-95.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-24H-DS-STD	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-96.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-24H-DS-SPL	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-97.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-98.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-01	AB-DS_GLICLAZIDE.lcm	STABILITY-SPL-99.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-02	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-100.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-03	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-101.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-04	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-102.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-STD-05	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-103.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-104.lcd	20.0	QC/CL/23/041
4	2	SPECIFICITY	GLICLAZIDE-API STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-105.lcd	20.0	QC/CL/23/041
5	2	SPECIFICITY	METFORMIN-API STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-106.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-107.lcd	20.0	QC/CL/23/041
6	2	SPECIFICITY	PLACEBO FOR GLIDE-M-60-500	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-108.lcd	20.0	QC/CL/23/041
7	2	SPECIFICITY	PLACEBO FOR GLIDE-M-60-850	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-109.lcd	20.0	QC/CL/23/041
8	2	SPECIFICITY	PLACEBO+GLICLAZIDE API	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-110.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
9	2	SPECIFICITY	PLACEBO+METFORMIN API	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-111.lcd	20.0	QC/CL/23/041
10	2	SPECIFICITY	PLACEBO+METFORMIN+GLICLAZIDE	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-112.lcd	20.0	QC/CL/23/041
2	2	SPECIFICITY	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-113.lcd	20.0	QC/CL/23/041
11	2	SPECIFICITY	GLIDE-M-60-500-TAB-093-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-114.lcd	20.0	QC/CL/23/041
12	2	SPECIFICITY	GLIDE-M-60-850-TAB-0801-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-115.lcd	20.0	QC/CL/23/041
3	2	SPECIFICITY	GLICLAZIDE-DS-BKT-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-116.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-117.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-118.lcd	20.0	QC/CL/23/041
1	1	SOLUTION STABILITY-DS	BLANK-DS	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-119.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-32H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-120.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-32H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-121.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-38H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-122.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-38H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-123.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-42H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-124.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-42H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-125.lcd	20.0	QC/CL/23/041
2	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-48H-DS-STD	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-126.lcd	20.0	QC/CL/23/041
3	1	SOLUTION STABILITY-DS	GLICLAZIDE-SOL STB-48H-DS-SPL	AB-DS_GLICLAZIDE.lcm	TABILITY-SPL-127.lcd	20.0	QC/CL/23/041
-1	1	SOLUTION STABILITY-DS	SHUTDOWN	SHUTDOWN METHOD.lcm	TABILITY-SPL-128.lcd	20.0	QC/CL/23/041

15/09/23

Analysed By

Checked By

15/09/23

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number :	G1722093	Mfg.Date :	Oct-22
Parameter :	PRECISION (METHOD PRECISION and INTERMEDIATE PRECISION)	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/006 & ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	---------------------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	66.23	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.23	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.6666	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION (At final time point)			INTERMEDIATE PRECISION (At final time point)			CUMMULATIVE PRECISION
No. of preparation	Drug Release in %	Minimum	No. of preparation	Drug Release in %	Minimum	Average in %
Unit-1	92.48	87.5	Unit-1	92.29	92.3	93.29
Unit-2	89.71		Unit-2	94.40		
Unit-3	89.36	Maximum	Unit-3	100.81	Maximum	% RSD
Unit-4	87.46		Unit-4	92.49		
Unit-5	93.56	93.6	Unit-5	96.50	100.8	4.22
Unit-6	91.33		Unit-6	99.12		
Average	90.7	Not applicable	Average	95.9	Not applicable	
% RSD	2.47	Not applicable	% RSD	3.66	Not applicable	

Results:

- 1) % RSD for dissolution of six preparations of method precision
- 2) % RSD for dissolution of six preparations of Intermediate precision
- 3) Cumulative %RSD for dissolution of twelve preparations

2.47
3.66
4.22

Acceptance criteria:

- 1)% RSD for dissolution of six preparations should not be more than 10 at final interval.
- 2)Cumulative %RSD for dissolution of twelve preparations (of method and intermediate precision) should not be more than 10.0%

Analysed by : S.BHAVYASRI
Date : 23-09-2023

M.B.L.
23/09/23

Checked by :
Date :

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

DISSOLUTION OF GLICLAZIDE IN METFORMIN AND GLICLAZIDE SUSTAINED RELEASE TABLETS

Product Name:	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number:	G1722093	Mfg.Date :	Oct-22
Stage:	INTERMEDIATE PRECISION	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	Ph 7.4 Phosphate Buffer
Volume (ml)	900
Speed	100RPM
Time	2nd,5th and 12th Hours

Standard dilution.:	66.23	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66.23	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60

mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	3061277	3058895	3060185	3058876	3061212	3060089	1181	0.039
With Bracketing std.	3058652	3056009	3056850			3058995	1897	0.062

2nd Hour					Limit:NMT 30.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D2)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	788096	15.35	25.59	0.28	24.0	20.2
Unit-2	752071	14.65	24.42	0.27		Maximum %
Unit-3	848389	16.53	27.54	0.31		
Unit-4	710074	13.83	23.05	0.26		
Unit-5	718714	14.00	23.33	0.26		
Unit-6	622835	12.13	20.22	0.22		27.5

5th Hour					Limit:Between 35.0-75.0%	
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D5)	Correction Factor (CF2)	Cumulative % (D5+CF1)	Minimum %
Unit-1	1831096	35.67	59.45	0.661	59.73	52.0
Unit-2	2038645	39.71	66.18	0.735	66.46	
Unit-3	1868472	36.40	60.66	0.674	60.97	
Unit-4	2263683	44.09	73.49	0.817	73.75	
Unit-5	1885093	36.72	61.20	0.680	61.46	
Unit-6	1594253	31.05	51.76	0.575	51.98	

12th Hour					Limit: Not less than 70.0%		NMT 5.0%
Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D12+CF1+CF2)	Average %	Minimum %	RSD %
Unit-1	2813665	54.81	91.34	92.29	95.9	92.3	3.7
Unit-2	2876664	56.03	93.39	94.40			
Unit-3	3075170	59.90	99.83	100.81			
Unit-4	2815774	54.85	91.41	92.49		Maximum %	
Unit-5	2943462	57.34	95.56	96.50			
Unit-6	3028382	58.99	98.32	99.12		100.8	

Calculation formula :

Drug release in mg / tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor
	Standard area x sample dilution X 100
Correction factor	Drug release % in respective time point / 900 X 10

Drug release in %	Drug release in mg /tablet x 100
	Labeled claim

Acceptance criteria:

% RSD for Dissolution of six sample preparations for Final interval should not be more than 5.0.

Analysed by : S.BHAVYASRI

Date : 23-09-2023

M.Bh
23/09/23

Checked by :

Date :

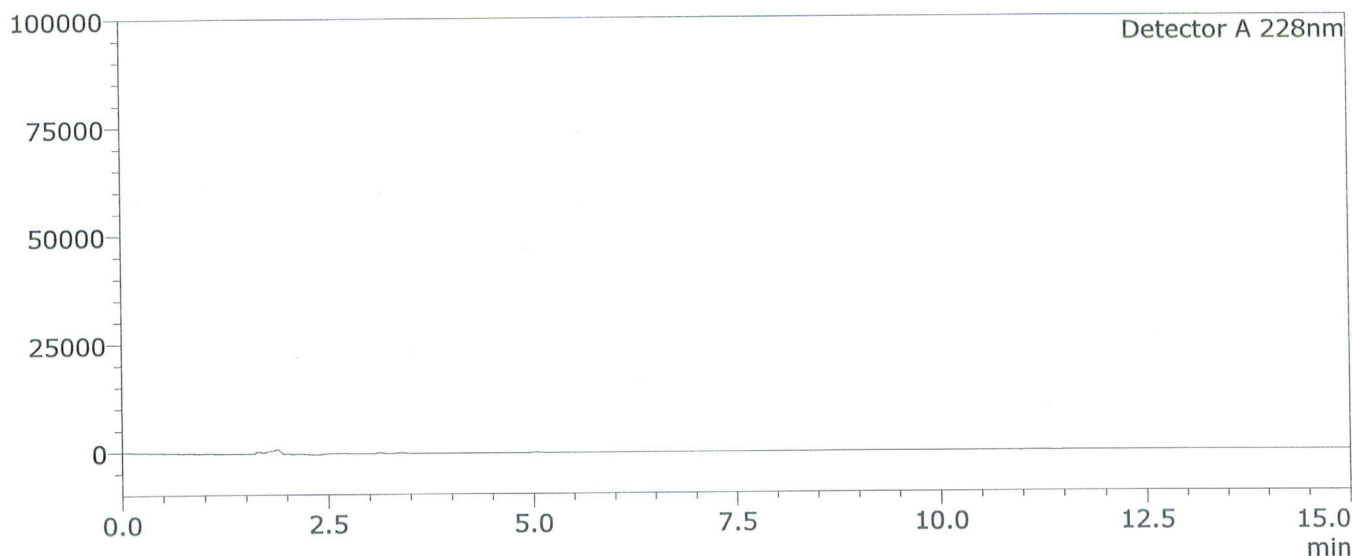

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : DS-BLANK
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-28.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-21
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 22:21:11
 Date Processed : 23-09-2023 09:02:29

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV


<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
Total								

M. Bhj
 23/09/23
Analysed By

23/09/23
Checked By



GENERIC HEALTHCARE PVT. LTD.

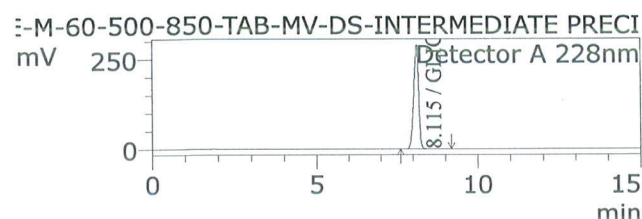
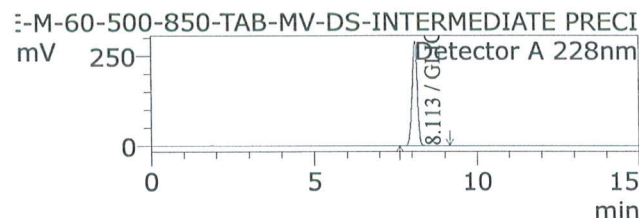
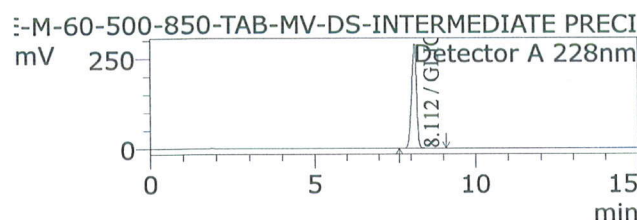
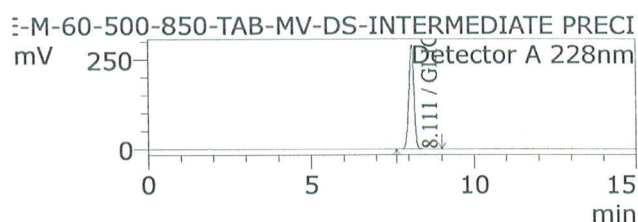
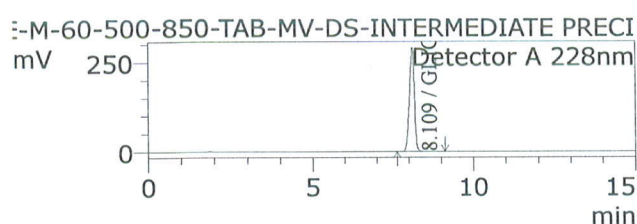
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-STD-01
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-29.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-22
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 22:36:43
 Date Processed : 23-09-2023 09:02:29

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
22	ON-SPL-29.lcd	GLICLAZIDE-DS-STD-01	8.11	3061277	12698	0.87
22	ON-SPL-30.lcd	GLICLAZIDE-DS-STD-02	8.11	3058895	12704	0.87
22	ON-SPL-31.lcd	GLICLAZIDE-DS-STD-03	8.11	3060185	12686	0.86
22	ON-SPL-32.lcd	GLICLAZIDE-DS-STD-04	8.11	3058876	12671	0.86
22	ON-SPL-33.lcd	GLICLAZIDE-DS-STD-05	8.11	3061212	12639	0.86
	Average		8.11	3060089	12680	0.86
	%RSD		0.028	0.039	0.204	0.039

Analysed By

M. Biji
23/09/23

Checked By

S. V. A.
23/09/23



GENERIC HEALTHCARE PVT. LTD.

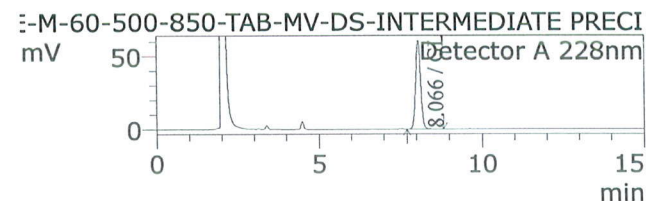
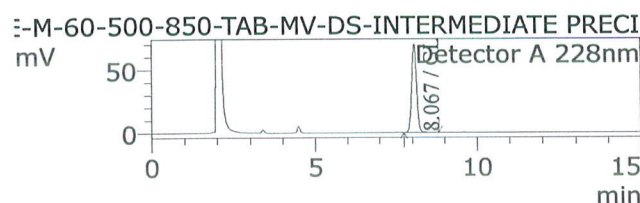
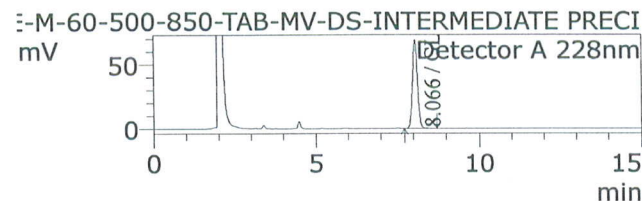
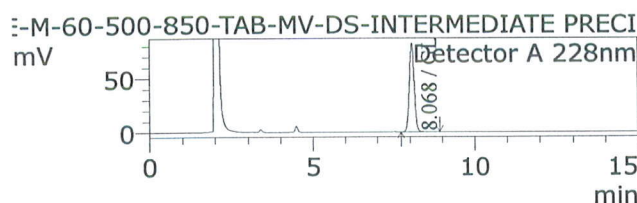
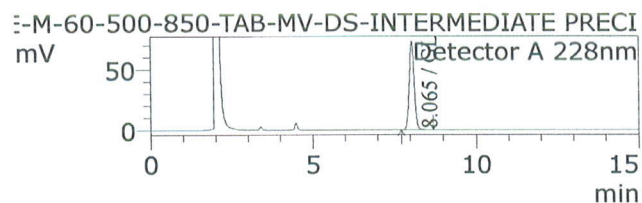
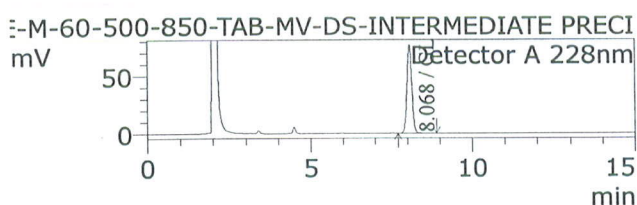
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDE-M-60-500-GLI-2HR-DS-SPL-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-34.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-23
 Injection Volume : 20 uL
 Date Acquired : 22-09-2023 23:54:20
 Date Processed : 23-09-2023 09:02:29

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
23	ON-SPL-34.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-1	8.07	788096	13358	1.00
24	ON-SPL-35.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-2	8.07	752071	13418	1.00
25	ON-SPL-36.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-3	8.07	848389	13349	0.99
26	ON-SPL-37.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-4	8.07	710074	13420	1.00
27	ON-SPL-38.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-5	8.07	718714	13371	1.00
28	ON-SPL-39.lcd	GLIDE-M-60-500-GLI-2HR-DS-SPL-6	8.07	622835	13420	1.01
	Average		8.07	740030	13389	1.00
	%RSD		0.018	10.341	0.251	0.564

Analysed By

H. Bly
23/09/23

Checked By

S. A.
23/09/23


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

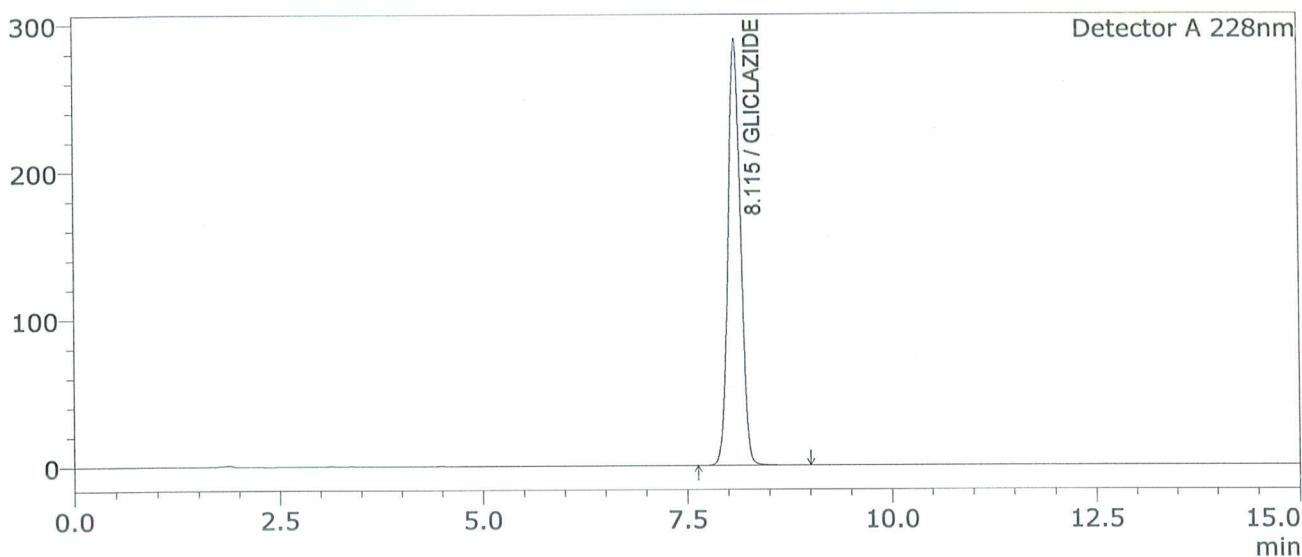
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-BKT-STD-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-40.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-22
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 01:27:30
 Date Processed : 23-09-2023 09:02:29

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.12	3058652	100.00	12677	0.865	--	--
Total			3058652	100.00				

M.Bh
 23/09/23
Analysed By

23/09/23
Checked By


GENERIC HEALTHCARE PVT. LTD.

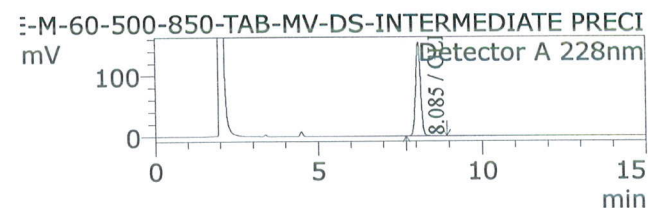
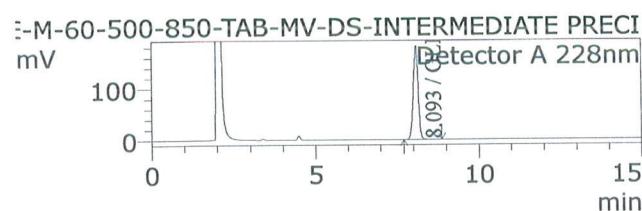
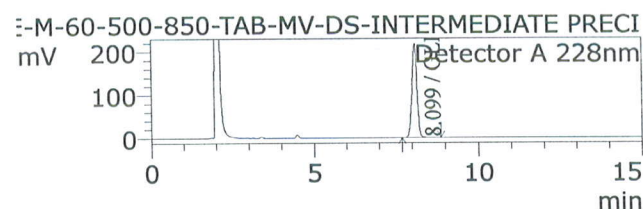
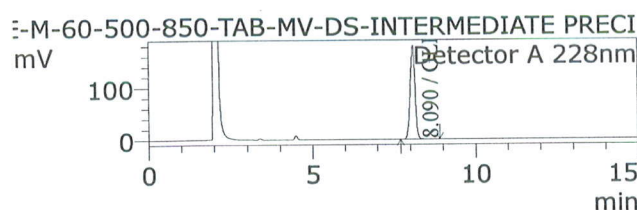
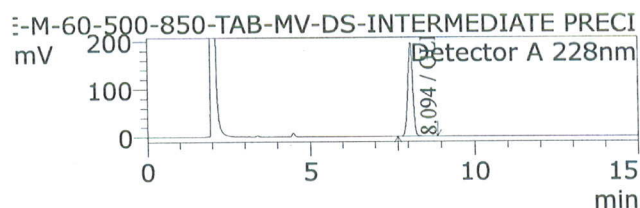
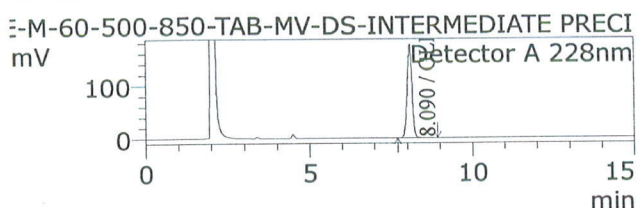
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDE-M-60-500-GLI-5HR-DS-SPL-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-41.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-29
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 01:43:02
 Date Processed : 23-09-2023 09:02:30

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
29	ON-SPL-41.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-1	8.09	1831096	13193	0.93
30	ON-SPL-42.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-2	8.09	2038645	13095	0.92
31	ON-SPL-43.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-3	8.09	1868472	13186	0.93
32	ON-SPL-44.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-4	8.10	2263683	13028	0.91
33	ON-SPL-45.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-5	8.09	1885093	13178	0.93
34	ON-SPL-46.lcd	GLIDE-M-60-500-GLI-5HR-DS-SPL-6	8.09	1594253	13239	0.94
	Average		8.09	1913541	13153	0.92
	%RSD		0.058	11.682	0.586	1.341

Analysed By

 M. B. J.
23/09/23

Checked By

 A. V. J.
23/09/23

 D:\ST-QCLC-009\DATA-2023\GLIDE-M-60-500-850-TAB-AMV-DS\22092023
 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-41.lcd



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

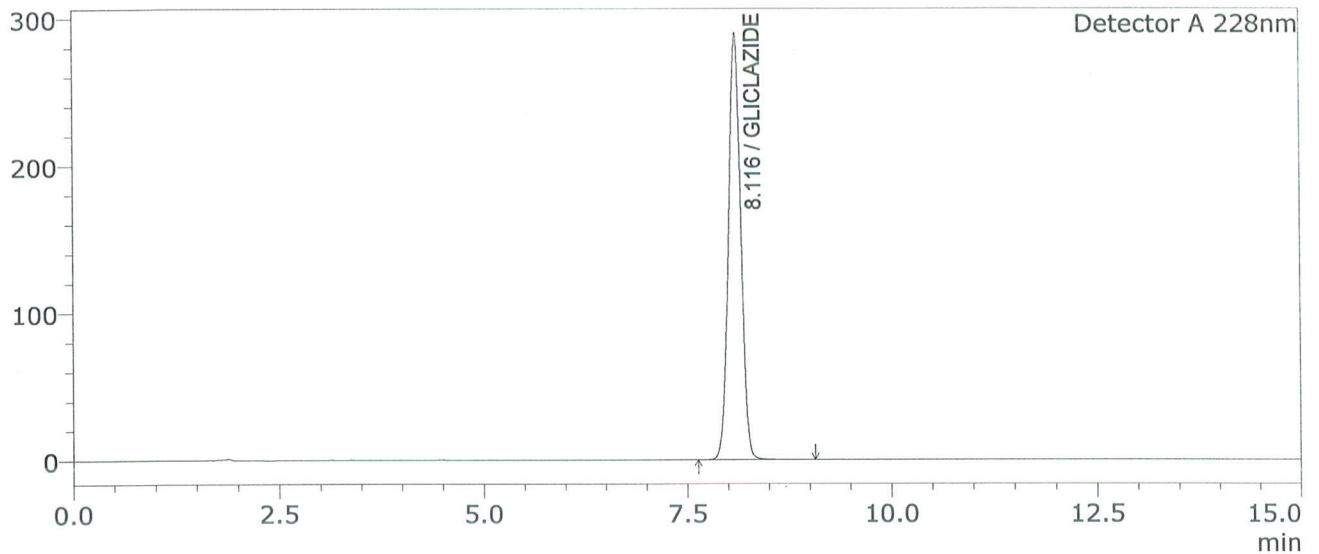
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-BKT-STD-2
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-47.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-22
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 03:16:10
 Date Processed : 23-09-2023 09:02:30

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.12	3056009	100.00	12701	0.866	--	--
Total			3056009	100.00				

M. B. J.
23/09/23

Analysed By

S. N.
23/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

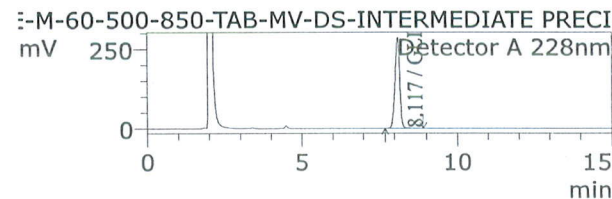
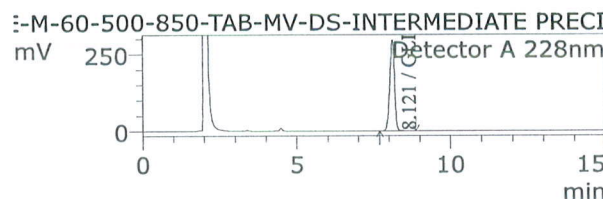
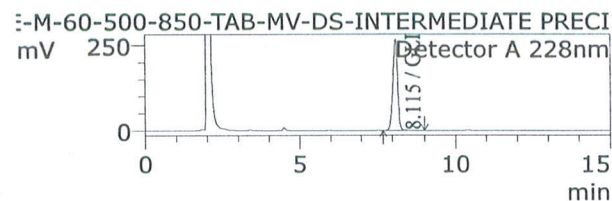
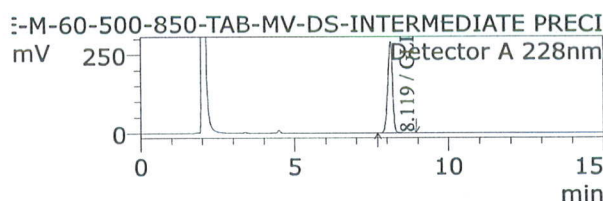
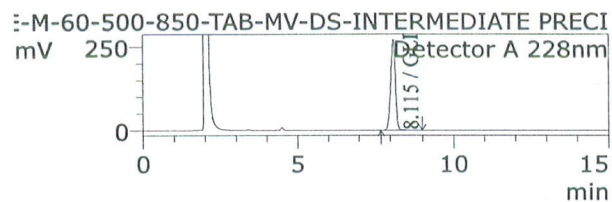
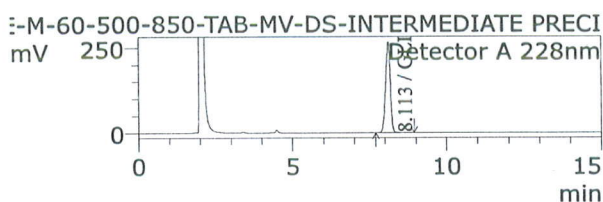
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDE-M-60-500-GLI-12H-DS-SPL-1
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-48.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-35
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 03:31:42
 Date Processed : 23-09-2023 09:02:30

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
35	ON-SPL-48.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-1	8.11	2813665	12695	0.88
36	ON-SPL-49.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-2	8.12	2876664	12656	0.88
37	ON-SPL-50.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-3	8.12	3075170	12580	0.87
38	ON-SPL-51.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-4	8.12	2815774	12717	0.88
39	ON-SPL-52.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-5	8.12	2943462	12504	0.87
40	ON-SPL-53.lcd	GLIDE-M-60-500-GLI-12H-DS-SPL-6	8.12	3028382	12606	0.87
	Average		8.12	2925520	12626	0.88
	%RSD		0.037	3.752	0.628	0.653

Analysed By
M.Bh
23/09/23

Checked By
S.V
23/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

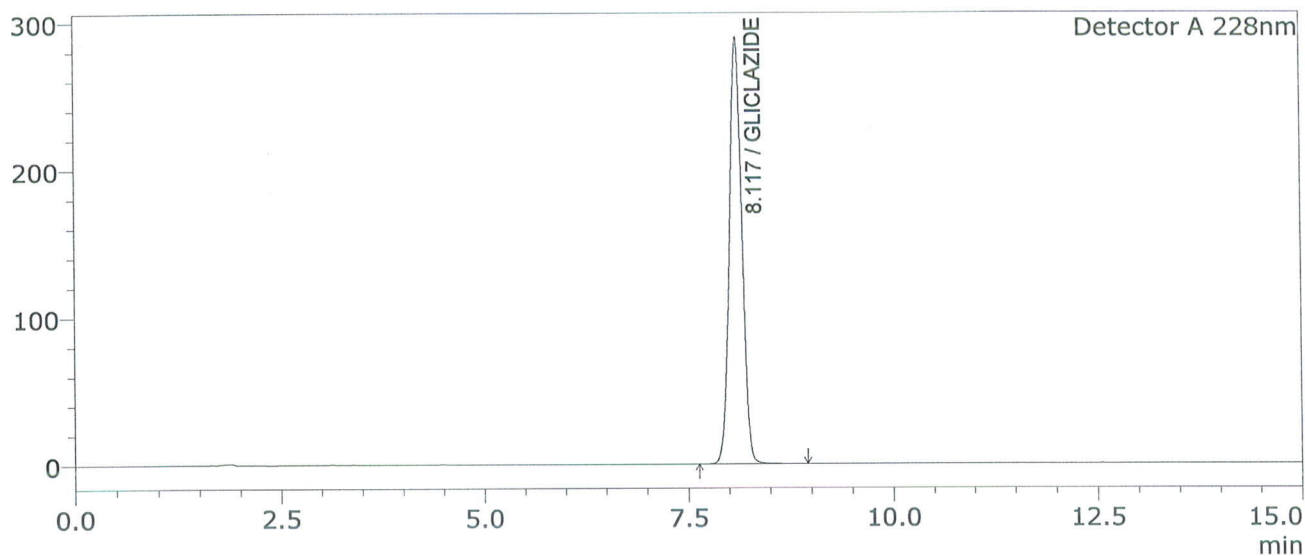
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE-DS-BKT-STD-3
 Data Filename : 22092023 GLIDE-M-60-500-850-TAB-MV-DS-INTERMEDIATE PRECISION-SPL-54.lcd
 Method Filename : GLIDE M60-500-850-TAB-DS_P.lcm
 Batch Filename : 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-22
 Injection Volume : 20 uL
 Date Acquired : 23-09-2023 05:04:53
 Date Processed : 23-09-2023 09:02:30

Acquired by : BHAVYASRI
 Processed by : C.K.SARAVANAN.

<Chromatogram>

mV



<Peak Table>

Detector A 228nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	8.12	3056850	100.00	12695	0.867	--	--
Total			3056850	100.00				

H. BL
 23/09/23
 Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 22092023 GLIDE-M-60-500-AMV-GLICLAZIDE-DS-INTERMEDIATE PRECISION.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	INTERMEDIATE PRECISION	DS-BLANK	50-500-850-TAB-DS.lcm	RECISION-SPL-01.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-01	50-500-850-TAB-DS.lcm	RECISION-SPL-02.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-02	50-500-850-TAB-DS.lcm	RECISION-SPL-03.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-03	50-500-850-TAB-DS.lcm	RECISION-SPL-04.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-04	50-500-850-TAB-DS.lcm	RECISION-SPL-05.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-05	50-500-850-TAB-DS.lcm	RECISION-SPL-06.lcd	20.0	QC/CL/20/017
3	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-07.lcd	20.0	QC/CL/20/017
4	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-08.lcd	20.0	QC/CL/20/017
5	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-09.lcd	20.0	QC/CL/20/017
6	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-10.lcd	20.0	QC/CL/20/017
7	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-11.lcd	20.0	QC/CL/20/017
8	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-2HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-12.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-1	50-500-850-TAB-DS.lcm	RECISION-SPL-13.lcd	20.0	QC/CL/20/017
9	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-14.lcd	20.0	QC/CL/20/017
10	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-15.lcd	20.0	QC/CL/20/017
11	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-16.lcd	20.0	QC/CL/20/017
12	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-17.lcd	20.0	QC/CL/20/017
13	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-18.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
14	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-5HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-19.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-2	50-500-850-TAB-DS.lcm	RECISION-SPL-20.lcd	20.0	QC/CL/20/017
15	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-21.lcd	20.0	QC/CL/20/017
16	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-22.lcd	20.0	QC/CL/20/017
17	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-23.lcd	20.0	QC/CL/20/017
18	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-24.lcd	20.0	QC/CL/20/017
19	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-25.lcd	20.0	QC/CL/20/017
20	1	INTERMEDIATE PRECISION	GLIDE-M-60-850-GLI-12H-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-26.lcd	20.0	QC/CL/20/017
2	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-3	50-500-850-TAB-DS.lcm	RECISION-SPL-27.lcd	20.0	QC/CL/20/017
21	1	INTERMEDIATE PRECISION	DS-BLANK	50-500-850-TAB-DS.lcm	RECISION-SPL-28.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-01	50-500-850-TAB-DS.lcm	RECISION-SPL-29.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-02	50-500-850-TAB-DS.lcm	RECISION-SPL-30.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-03	50-500-850-TAB-DS.lcm	RECISION-SPL-31.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-04	50-500-850-TAB-DS.lcm	RECISION-SPL-32.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-STD-05	50-500-850-TAB-DS.lcm	RECISION-SPL-33.lcd	20.0	QC/CL/20/017
23	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-34.lcd	20.0	QC/CL/20/017
24	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-35.lcd	20.0	QC/CL/20/017
25	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-36.lcd	20.0	QC/CL/20/017
26	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-37.lcd	20.0	QC/CL/20/017
27	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-38.lcd	20.0	QC/CL/20/017
28	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-2HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-39.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-1	50-500-850-TAB-DS.lcm	RECISION-SPL-40.lcd	20.0	QC/CL/20/017
29	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-41.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
30	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-42.lcd	20.0	QC/CL/20/017
31	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-43.lcd	20.0	QC/CL/20/017
32	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-44.lcd	20.0	QC/CL/20/017
33	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-45.lcd	20.0	QC/CL/20/017
34	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-5HR-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-46.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-2	50-500-850-TAB-DS.lcm	RECISION-SPL-47.lcd	20.0	QC/CL/20/017
35	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-1	50-500-850-TAB-DS.lcm	RECISION-SPL-48.lcd	20.0	QC/CL/20/017
36	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-2	50-500-850-TAB-DS.lcm	RECISION-SPL-49.lcd	20.0	QC/CL/20/017
37	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-3	50-500-850-TAB-DS.lcm	RECISION-SPL-50.lcd	20.0	QC/CL/20/017
38	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-4	50-500-850-TAB-DS.lcm	RECISION-SPL-51.lcd	20.0	QC/CL/20/017
39	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-5	50-500-850-TAB-DS.lcm	RECISION-SPL-52.lcd	20.0	QC/CL/20/017
40	1	INTERMEDIATE PRECISION	GLIDE-M-60-500-GLI-12H-DS-SPL-6	50-500-850-TAB-DS.lcm	RECISION-SPL-53.lcd	20.0	QC/CL/20/017
22	1	INTERMEDIATE PRECISION	GLICLAZIDE-DS-BKT-STD-3	50-500-850-TAB-DS.lcm	RECISION-SPL-54.lcd	20.0	QC/CL/20/017
-1	1	INTERMEDIATE PRECISION	WASH	THOD-100%-WATER.lcm	RECISION-SPL-55.lcd	20.0	QC/CL/20/017
-1	1	INTERMEDIATE PRECISION	WASH	WASHING METHOD.lcm	RECISION-SPL-56.lcd	20.0	QC/CL/20/017
-1	1	INTERMEDIATE PRECISION	SHUTDOWN	ETHOD\SHUTDOWN.lcm	RECISION-SPL-57.lcd	20.0	QC/CL/20/017

Analysed By

M. Blj
22/09/23A. Dush
22/09/23
Checked By