

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/006 & ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	about 500 mg	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1700	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION			INTERMEDIATE PRECISION			CUMMULATIVE PRECISION
No. of preparation	Drug Release in %	Minimum	No. of preparation	Drug Release in %	Minimum	Average in %
Preparation-1	97.8	96.7	Preparation-1	98.6	98.1	98.12
Preparation-2	98.7		Preparation-2	98.4		
Preparation-3	98.3	Maximum	Preparation-3	98.2	Maximum	% RSD
Preparation-4	96.7		Preparation-4	98.2		
Preparation-5	97.6	98.7	Preparation-5	98.1	98.6	0.57
Preparation-6	98.7		Preparation-6	98.1		
Average	98.0	Not applicable	Average	98.3	Not applicable	
% RSD	0.78	Not applicable	% RSD	0.19	Not applicable	

Results:

- 1) % RSD for Assay of six preparations of Method precision
- 2) % RSD for Assay of six preparations of Intermediate precision
- 3) Cumulative %RSD for Assay of twelve preparations

0.78

0.19

0.57

Acceptance criteria:

- 1) % RSD for Assay of Six preparations should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

M.BHAVYASRI

Date :

14-09-2023

M.Bh
14/09/23

Checked by :

Date :

S.D.
14/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY 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
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Standard dilution :	about 60 mg	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION			INTERMEDIATE PRECISION			CUMMULATIVE PRECISION
No.of preparation	Drug Release in %	Minimum	No.of preparation	Drug Release in %	Minimum	Average in %
Preparation-1	99.5	96.7	Preparation-1	101.3	99.2	99.21
Preparation-2	100.1		Preparation-2	100.4		
Preparation-3	98.9	Maximum	Preparation-3	100.2	Maximum	% RSD
Preparation-4	96.7		Preparation-4	99.8		
Preparation-5	97.2	100.1	Preparation-5	99.6	101.3	1.40
Preparation-6	97.6		Preparation-6	99.2		
Average	98.3	Not applicable	Average	100.1	Not applicable	
% RSD	1.39	Not applicable	% RSD	0.73	Not applicable	

Results:

- 1) % RSD for Assay of six preparations of Method precision
- 2) % RSD for Assay of six preparations of Intermediate precision
- 3) Cumulative %RSD for Assay of twelve preparations

1.39

0.73

1.40

Acceptance criteria:

- 1) % RSD for Assay of Six preparations should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

M.BHAVYASRI

Date :

14-09-2023

M.Bh
14/09/23

Checked by :

Date :

A.A
14/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

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

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 500 mg
Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	500.64	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1001.28	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1004.144	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	500
Average weight :	970

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	695531	695673	695361	695538	695790	695579	162	0.023
Bracketing Std.	693225	693757				694982	1039	0.149

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	974.02	686342	492.94	98.6	98.3	0.18
Sample Preparation-2	974.16	684992	491.90	98.4		
Sample Preparation-3	974.20	683958	491.13	98.2		
Sample Preparation-4	974.14	683779	491.04	98.2		
Sample Preparation-5	974.07	683162	490.63	98.1		
Sample Preparation-6	974.32	683374	490.65	98.1		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by : M.BHAVYASRI
Date : 14-09-2023

M.Bh
14/09/23

Checked by :
Date : 14/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

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

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 500 mg
Gliclazide BP ----- 60 mg

ASSAY OF GLICLAZIDE

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
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Standard dilution :	58.05	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-116.1	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120.4973	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	60
Average weight :	970

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	287880	287403	286424	285572	285439	286544	1084	0.378
Bracketing Std.	279203	273341				283609	5364	1.891

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	974.02	301391	60.81	101.3	100.1	0.74
Sample Preparation-2	974.16	298536	60.22	100.4		
Sample Preparation-3	974.20	297936	60.10	100.2		
Sample Preparation-4	974.14	296962	59.90	99.8		
Sample Preparation-5	974.07	296186	59.75	99.6		
Sample Preparation-6	974.32	295096	59.52	99.2		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

M.BHAVYASRI

Date :

14-09-2023

H.Bh
14/09/23

Checked by :

Date :

S.A
14/09/23



GENERIC HEALTHCARE PVT. LTD.

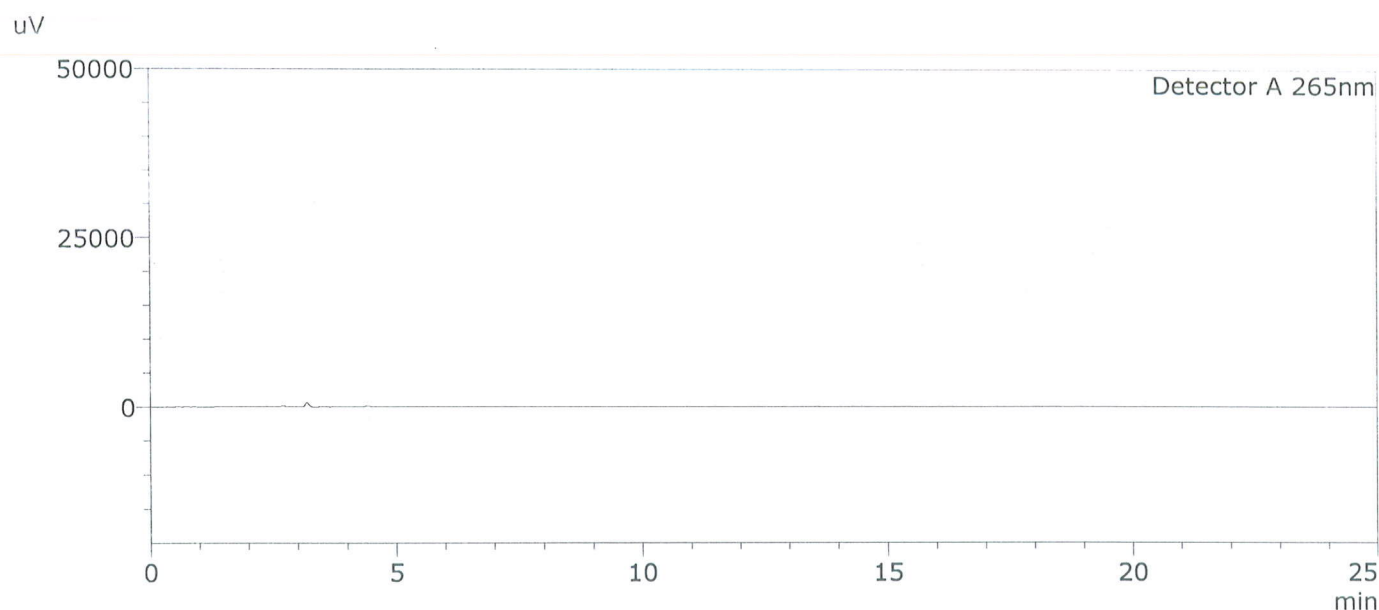
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : AS-BLANK
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-37
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 18:09:24
 Date Processed : 14-09-2023 10:09:50

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<Peak Table>

Detector A 265nm

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

M. Bh.
 14/09/23
 Analysed By

S. G.
 14/09/23
 Checked By


GENERIC HEALTHCARE PVT. LTD.

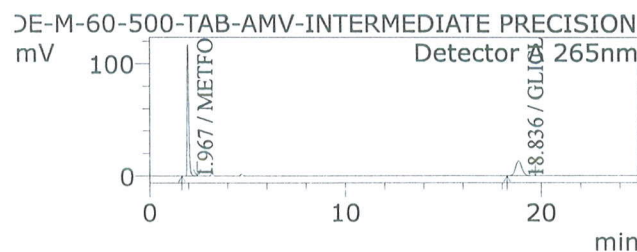
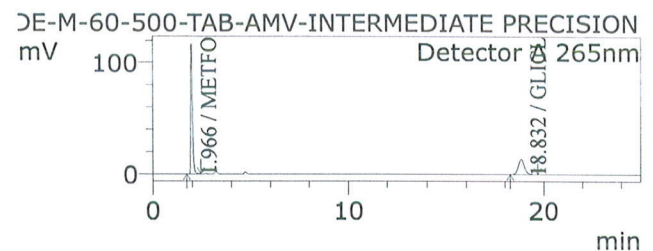
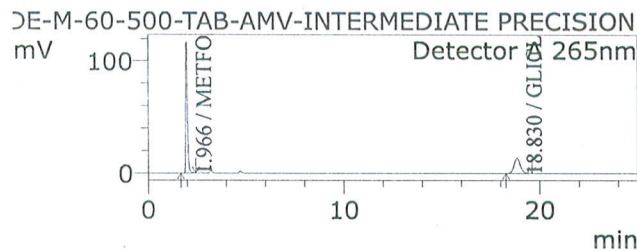
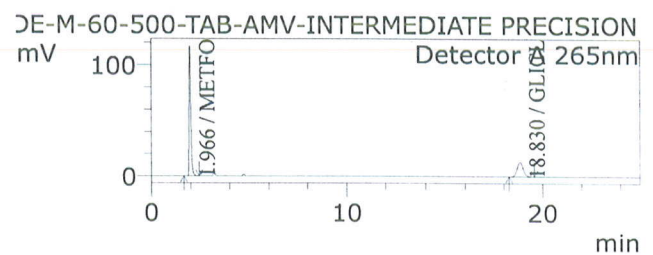
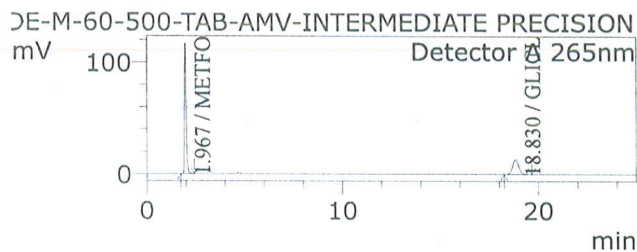
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-38
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 18:34:56
 Date Processed : 14-09-2023 10:10:05

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
38	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.97	695531	2253	1.49
38	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.97	695673	2247	1.49
38	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.97	695361	2244	1.49
38	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.97	695538	2247	1.49
38	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.97	695790	2251	1.49
	Average		1.97	695579	2248	1.49
	%RSD		0.020	0.023	0.158	0.116

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
38	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	18.83	287880	17818	1.12
38	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	18.83	287403	17814	1.12
38	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	18.83	286424	17801	1.12
38	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	18.83	285572	17823	1.12
38	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	18.84	285439	17775	1.12
	Average		18.83	286544	17806	1.12
	%RSD		0.014	0.378	0.109	0.059

M.Bh
19/09/23
Analysed By

Checked By

M.Bh
19/09/23



GENERIC HEALTHCARE PVT. LTD.

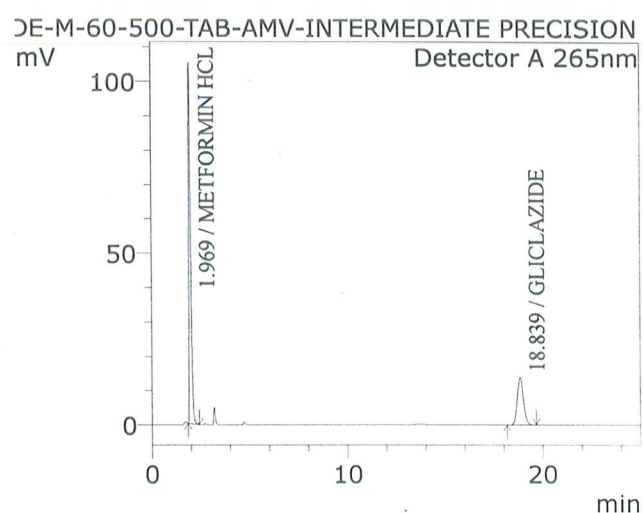
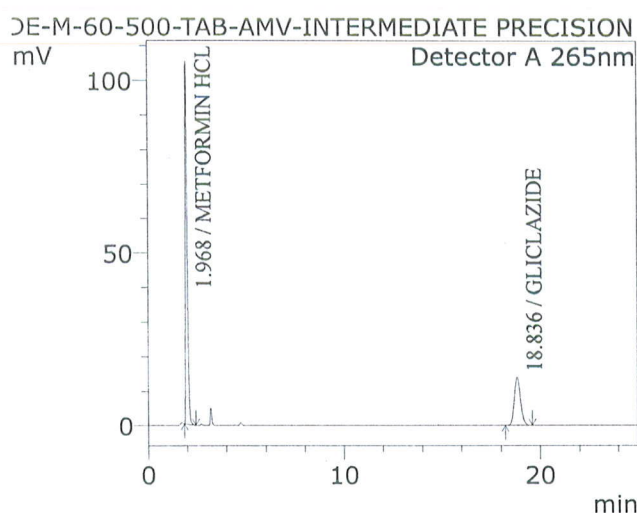
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-500-093-SET1-AS-SPL-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-07.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-39
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 20:42:39
 Date Processed : 14-09-2023 10:11:30

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
39	AS-SPL-07.lcd	GLIDEM-60-500-093-SET1-AS-SPL-1	1.97	687632	1883	1.48
39	AS-SPL-08.lcd	GLIDEM-60-500-093-SET1-AS-SPL-2	1.97	685052	1902	1.48
	Average		1.97	686342	1892	1.48
	%RSD		0.032	0.266	0.716	0.342

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
39	AS-SPL-07.lcd	GLIDEM-60-500-093-SET1-AS-SPL-1	18.84	302168	17431	1.13
39	AS-SPL-08.lcd	GLIDEM-60-500-093-SET1-AS-SPL-2	18.84	300614	17425	1.13
	Average		18.84	301391	17428	1.13
	%RSD		0.010	0.364	0.025	0.133

H.B.L.
 14/09/23
 Analysed By

14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

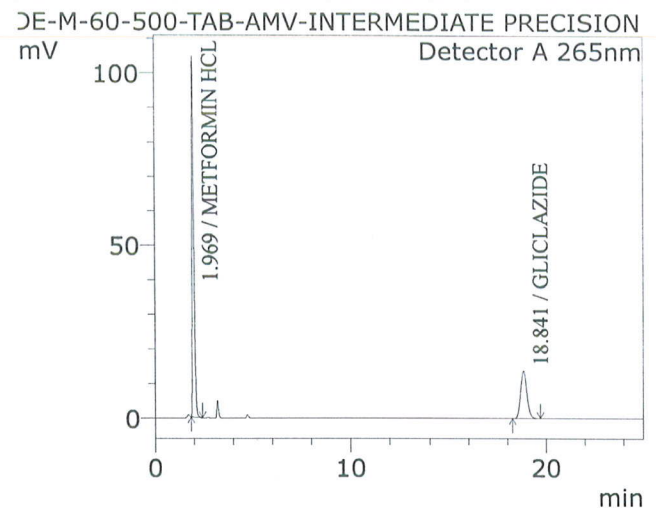
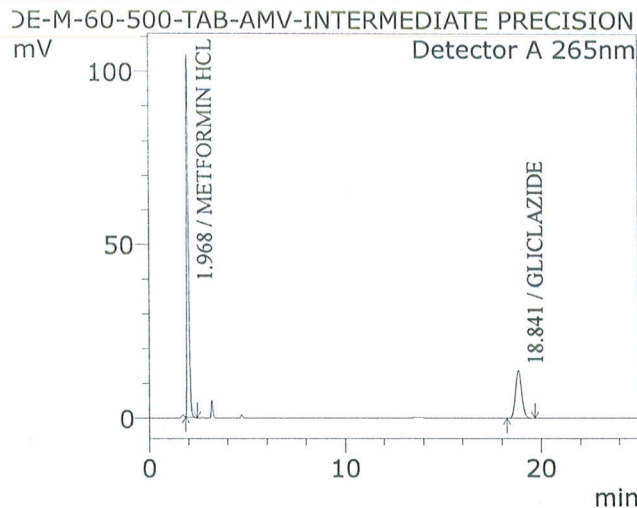
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-500-093-SET2-AS-SPL-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-09.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-40
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 21:33:44
 Date Processed : 14-09-2023 10:12:05

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
40	AS-SPL-09.lcd	GLIDEM-60-500-093-SET2-AS-SPL-1	1.97	684891	1886	1.48
40	AS-SPL-10.lcd	GLIDEM-60-500-093-SET2-AS-SPL-2	1.97	685093	1892	1.47
	Average		1.97	684992	1889	1.47
	%RSD		0.021	0.021	0.211	0.046

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
40	AS-SPL-09.lcd	GLIDEM-60-500-093-SET2-AS-SPL-1	18.84	298732	17418	1.13
40	AS-SPL-10.lcd	GLIDEM-60-500-093-SET2-AS-SPL-2	18.84	298340	17384	1.13
	Average		18.84	298536	17401	1.13
	%RSD		0.003	0.093	0.139	0.016

M. Bly
14/09/23

Analysed By

S. G. 14/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

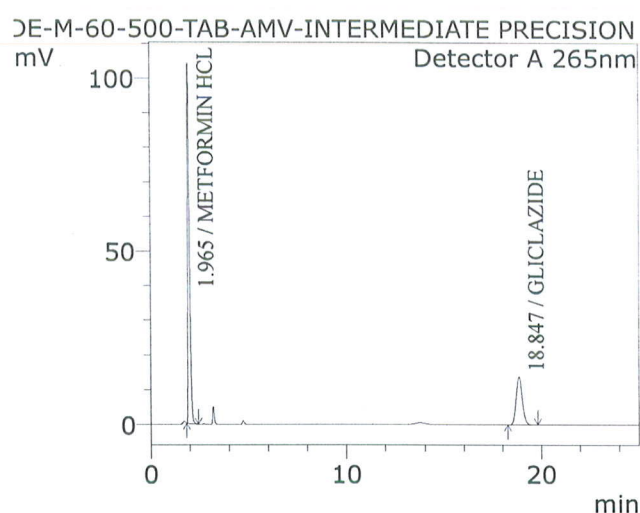
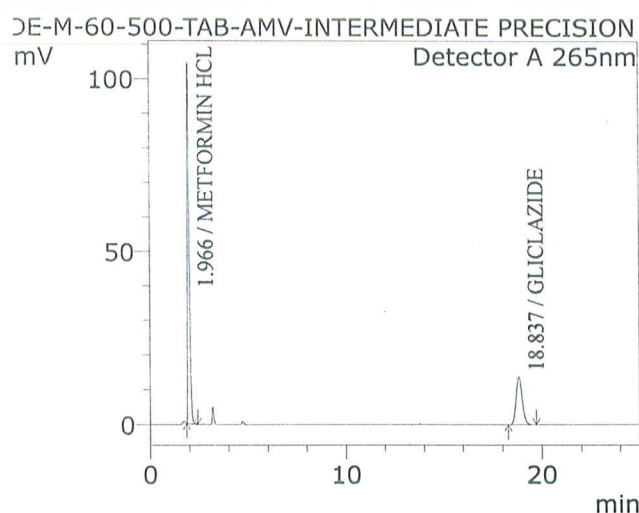
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-500-093-SET3-AS-SPL-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-11.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-41
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 22:24:49
 Date Processed : 14-09-2023 10:12:36

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
41	AS-SPL-11.lcd	GLIDEM-60-500-093-SET3-AS-SPL-1	1.97	684811	1873	1.48
41	AS-SPL-12.lcd	GLIDEM-60-500-093-SET3-AS-SPL-2	1.96	683106	1876	1.48
	Average		1.97	683958	1874	1.48
	%RSD		0.062	0.176	0.096	0.230

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
41	AS-SPL-11.lcd	GLIDEM-60-500-093-SET3-AS-SPL-1	18.84	298153	17465	1.13
41	AS-SPL-12.lcd	GLIDEM-60-500-093-SET3-AS-SPL-2	18.85	297719	17548	1.12
	Average		18.84	297936	17506	1.12
	%RSD		0.038	0.103	0.336	0.268

M. BL
 14/09/23
 Analysed By

S.G
 14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

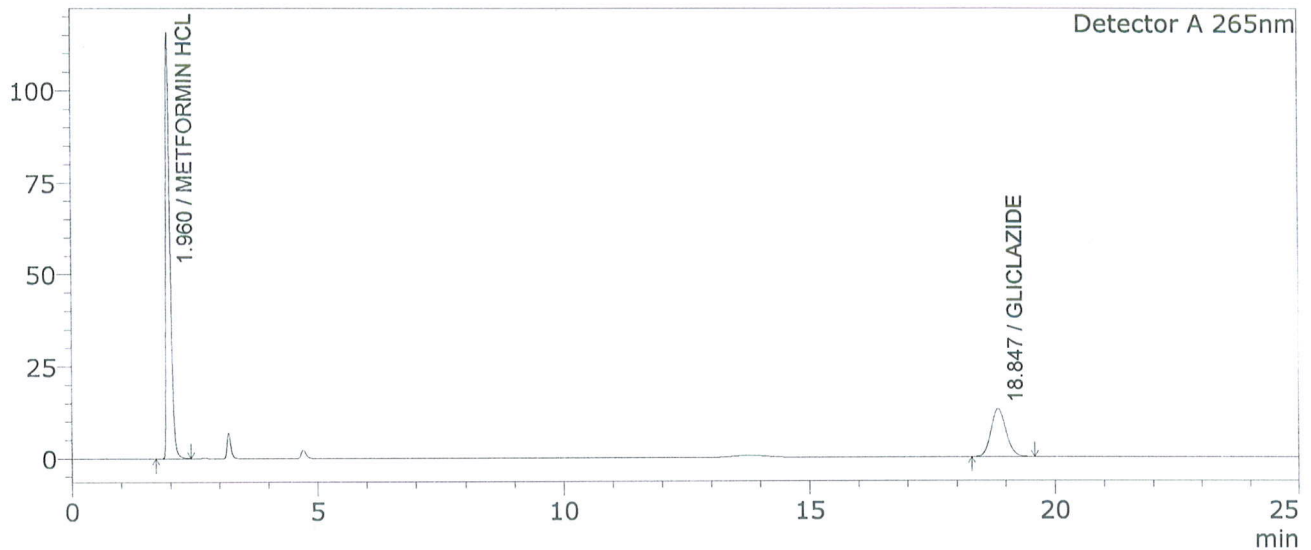
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Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-13.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-38
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 23:15:56
 Date Processed : 14-09-2023 10:13:06

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	693225	71.29	2230	1.501	--	--
2	GLICLAZIDE	18.85	279203	28.71	17864	1.108	46.258	--
Total			972428	100.00				

H.B.L.
 14/09/23
 Analysed By

S.G.
 14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

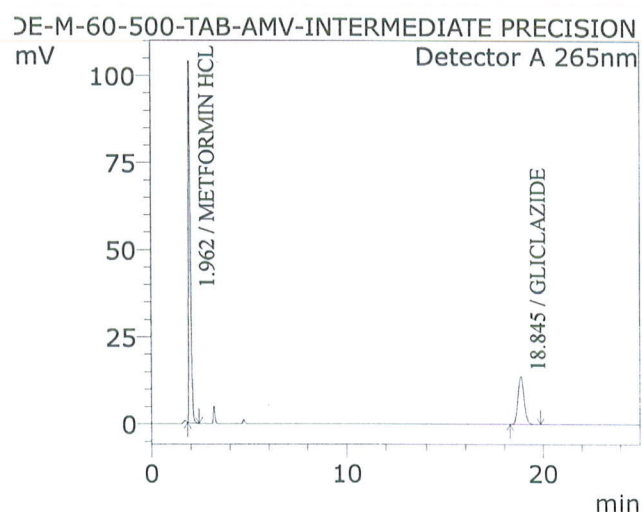
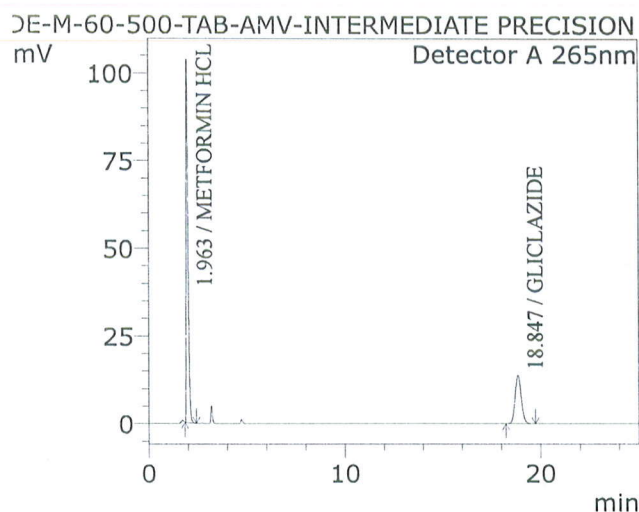
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-500-093-SET4-AS-SPL-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-14.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-42
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 23:41:29
 Date Processed : 14-09-2023 10:13:21

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
42	AS-SPL-14.lcd	GLIDEM-60-500-093-SET4-AS-SPL-1	1.96	684253	1861	1.47
42	AS-SPL-15.lcd	GLIDEM-60-500-093-SET4-AS-SPL-2	1.96	683305	1872	1.48
	Average		1.96	683779	1866	1.48
	%RSD		0.008	0.098	0.437	0.265

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
42	AS-SPL-14.lcd	GLIDEM-60-500-093-SET4-AS-SPL-1	18.85	296871	17632	1.12
42	AS-SPL-15.lcd	GLIDEM-60-500-093-SET4-AS-SPL-2	18.84	297053	17680	1.12
	Average		18.85	296962	17656	1.12
	%RSD		0.008	0.043	0.192	0.143

M. Bh
 14/09/23
 Analysed By

S. A
 14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

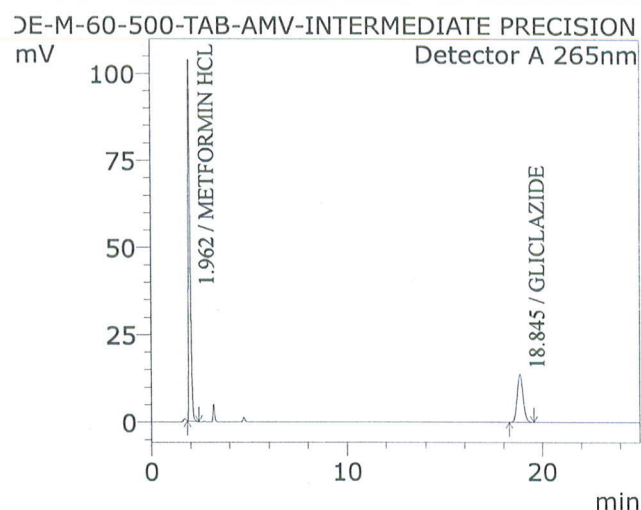
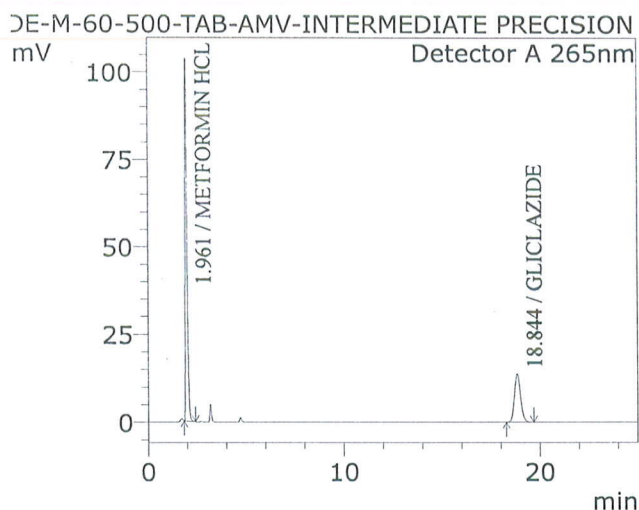
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-500-093-SET5-AS-SPL-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-16.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-43
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 00:32:36
 Date Processed : 14-09-2023 10:13:52

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
43	AS-SPL-16.lcd	GLIDEM-60-500-093-SET5-AS-SPL-1	1.96	683000	1855	1.47
43	AS-SPL-17.lcd	GLIDEM-60-500-093-SET5-AS-SPL-2	1.96	683324	1858	1.48
	Average		1.96	683162	1857	1.48
	%RSD		0.014	0.033	0.119	0.130

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
43	AS-SPL-16.lcd	GLIDEM-60-500-093-SET5-AS-SPL-1	18.84	297055	17617	1.12
43	AS-SPL-17.lcd	GLIDEM-60-500-093-SET5-AS-SPL-2	18.84	295318	17667	1.11
	Average		18.84	296186	17642	1.11
	%RSD		0.001	0.415	0.201	0.374

M. BLJ
 14/09/23
 Analysed By

S. S. S.
 14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

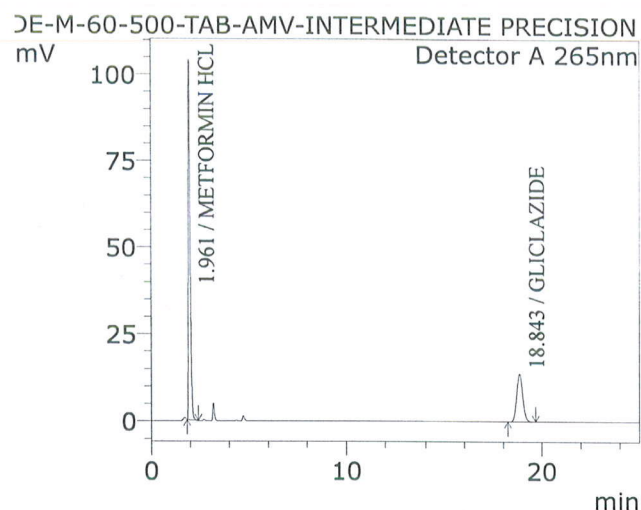
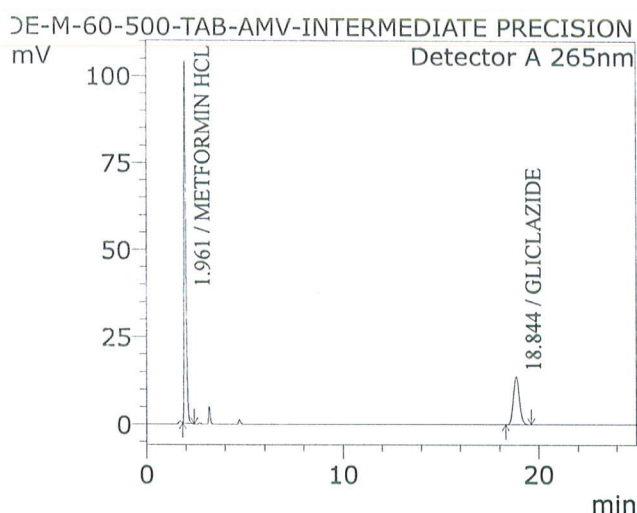
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-500-093-SET6-AS-SPL-1
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-18.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-44
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 01:23:42
 Date Processed : 14-09-2023 10:14:22

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
44	AS-SPL-18.lcd	GLIDEM-60-500-093-SET6-AS-SPL-1	1.96	683353	1859	1.48
44	AS-SPL-19.lcd	GLIDEM-60-500-093-SET6-AS-SPL-2	1.96	683395	1860	1.48
	Average		1.96	683374	1860	1.48
	%RSD		0.002	0.004	0.021	0.005

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
44	AS-SPL-18.lcd	GLIDEM-60-500-093-SET6-AS-SPL-1	18.84	294717	17748	1.11
44	AS-SPL-19.lcd	GLIDEM-60-500-093-SET6-AS-SPL-2	18.84	295474	17707	1.11
	Average		18.84	295096	17727	1.11
	%RSD		0.003	0.181	0.165	0.001

M.B.L.
 14/09/23
 Analysed By

S.G.
 14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

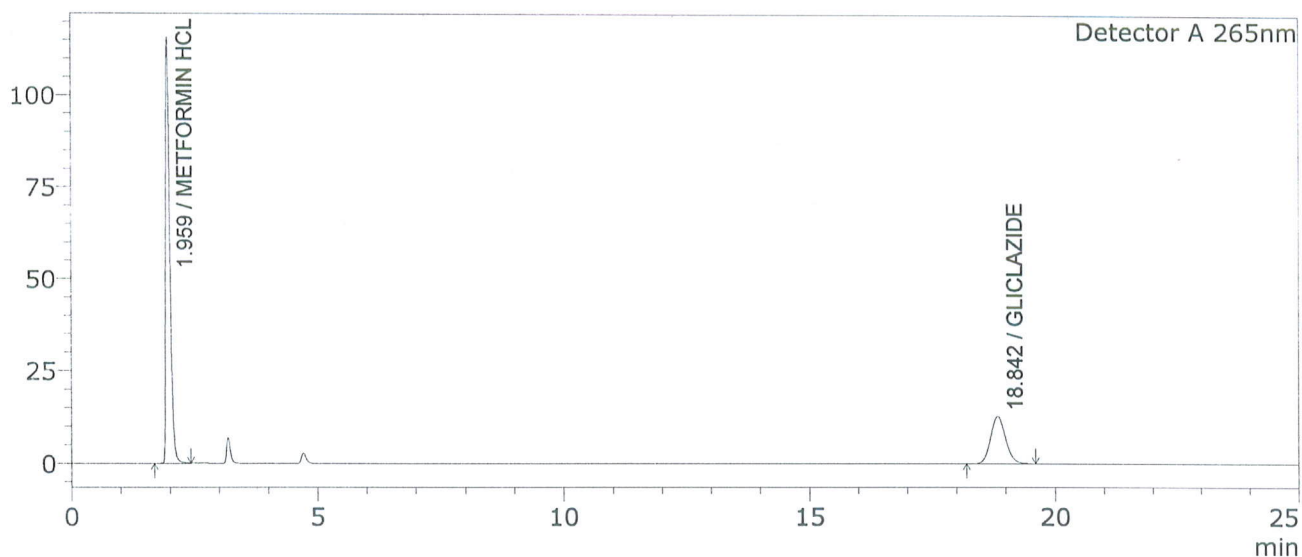
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Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-2
 Data Filename : 13092023 GLIDE-M-60-500-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-20.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 13092023 GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 2-38
 Injection Volume : 20 uL
 Date Acquired : 14-09-2023 02:14:47
 Date Processed : 14-09-2023 10:14:37

Acquired by : BHAVYASRI
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	693757	71.74	2204	1.511	--	--
2	GLICLAZIDE	18.84	273341	28.26	17981	1.106	46.322	--
Total			967097	100.00				

M. BL
 14/09/23
 Analysed By

S. G
 14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table_13092023_GLIDE-M-60-500-AMV-AS-INTERMEDIATE PRECISION.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
37	2	INTERMEDIATE PRECISION	AS-BLANK	50-500-850-TAB-AS.lcm	ISION-AS-SPL-01.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-02.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-03.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-3	50-500-850-TAB-AS.lcm	ISION-AS-SPL-04.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-4	50-500-850-TAB-AS.lcm	ISION-AS-SPL-05.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-5	50-500-850-TAB-AS.lcm	ISION-AS-SPL-06.lcd	20.0	QC/CL/23/041
39	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET1-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-07.lcd	20.0	QC/CL/23/041
39	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET1-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-08.lcd	20.0	QC/CL/23/041
40	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET2-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-09.lcd	20.0	QC/CL/23/041
40	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET2-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-10.lcd	20.0	QC/CL/23/041
41	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET3-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-11.lcd	20.0	QC/CL/23/041
41	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET3-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-12.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLA+METFORMIN-AS-STD-BKT-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-13.lcd	20.0	QC/CL/23/041
42	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET4-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-14.lcd	20.0	QC/CL/23/041
42	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET4-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-15.lcd	20.0	QC/CL/23/041
43	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET5-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-16.lcd	20.0	QC/CL/23/041
43	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET5-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-17.lcd	20.0	QC/CL/23/041
44	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET6-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
44	2	INTERMEDIATE PRECISION	GLIDEM-60-500-093-SET6-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-19.lcd	20.0	QC/CL/23/041
38	2	INTERMEDIATE PRECISION	GLICLA+METFORMIN-AS-STD-BKT-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-20.lcd	20.0	QC/CL/23/041
37	2	WASH	WASH	THOD-100%-WATER.lcm	ISION-AS-SPL-21.lcd	20.0	QC/CL/23/041
37	2	WASH	WASH	WASHING METHOD.lcm	ISION-AS-SPL-22.lcd	20.0	QC/CL/23/041
37	2	SHUTDOWN	SHUTDOWN	ETHOD\SHUTDOWN.lcm	ISION-AS-SPL-23.lcd	20.0	QC/CL/23/041

Analysed By

M. Bly
13/09/23

Checked By

M. Bly
13/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	850.24	mg to ---->	100	ml to ---->	5	ml to ---->	25
Std.conc (in ppm)-1700.48	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Sample dilution :	1360.54	mg to ---->	100	ml to ---->	5	ml to ---->	25
Test.conc (in ppm)-1700.67	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Conversion factor :	1.0000	
Labelled claim :	850	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	1123345	1121012	1123667	1124404	1122907	1123067	1272.2	0.113
With Bracketing std.	1127364					1123783	2090.9	0.186

Time interval	Metformin HCl Standard area	Absolute % difference of standard area	Metformin HCl Sample area	Absolute % difference of sample area	Assay in %	Absolute % difference of Assay preparation
Initial	1123067	Not applicable	1089282	Not applicable	97.17	Not applicable
4 Hours	1130787	-0.68	1098586	-0.85	98.00	-0.85
6 Hours	1124093	-0.09	1093160	-0.35	97.52	-0.35
8 Hours	1125768	-0.24	1095978	-0.61	97.77	-0.61
10 Hours	1128266	-0.46	1098486	-0.84	98.00	-0.84
12 Hours	1129120	-0.54	1099988	-0.97	98.13	-0.97
18 Hours	1141670	-1.63	1110065	-1.87	99.03	-1.87
24 Hours	1130787	-0.68	1107503	-1.65	98.80	-1.65
Average	1129195	-0.62	1099131	-1.02	98.1	-1.02
% RSD	0.515	Not applicable	0.628	Not applicable	0.628	Not applicable

Results :

Standard and Sample Solution Stability Study was performed upto 24 Hrs only.

Standard solution and Sample solution was Stable upto 24 hrs at room 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 : 09-09-2023Checked by :
Date : 09/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF GLICLAZIDE

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
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Standard dilution :	60.05	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.1	1	ml to --->	1	ml to --->	1	ml to --->	1

Sample dilution :	1360.54	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120.047	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	290502	291534	290256	290386	289976	290531	594.0	0.204
With Bracketing std.	292571					290871	987.9	0.340

Time interval	Gliclazide Standard area	Absolute % difference of standard area	Gliclazide Sample area	Absolute % difference of sample area	Assay in %	Absolute % difference of Assay preparation
Initial	290531	Not applicable	288061	Not applicable	99.19	Not applicable
4 Hours	290566	-0.01	287169	0.31	98.89	0.31
6 Hours	287769	0.96	285270	0.98	98.23	0.98
8 Hours	285302	1.83	283283	1.69	97.55	1.69
10 Hours	287356	1.10	284014	1.42	97.80	1.42
12 Hours	285718	1.68	283284	1.69	97.55	1.69
18 Hours	286425	1.43	284168	1.37	97.85	1.37
24 Hours	285934	1.61	283651	1.55	97.67	1.55
Average	287450	1.23	284863	1.29	98.1	1.29
% RSD	0.723	Not applicable	0.641	Not applicable	0.641	Not applicable

Results :

Standard and Sample Solution Stability Study was performed upto 24 Hrs only.
Standard solution and Sample solution was Stable upto 10 hrs at room 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 :

09-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

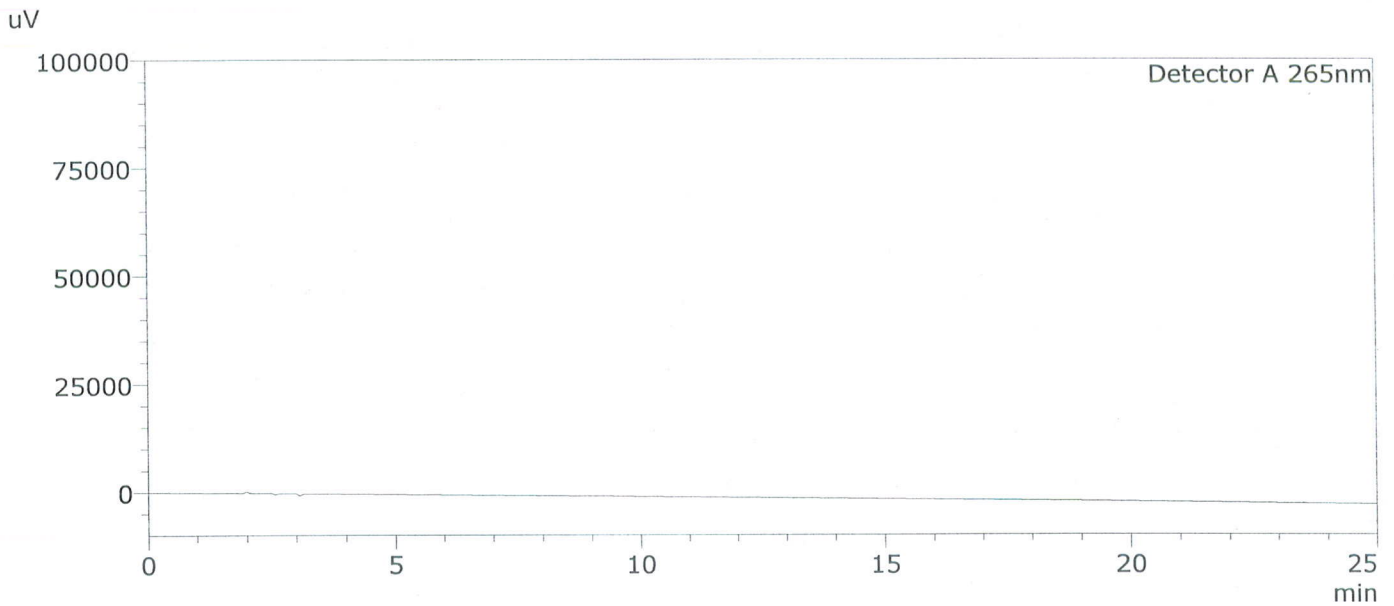
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 13:48:10
 Date Processed : 09-09-2023 10:29:35

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

(Signature)
09/09/23

Checked By

(Signature)
09/09/23



GENERIC HEALTHCARE PVT. LTD.

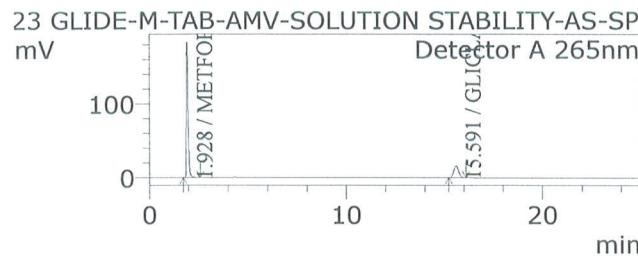
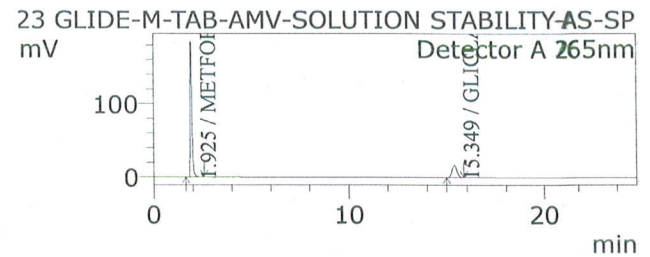
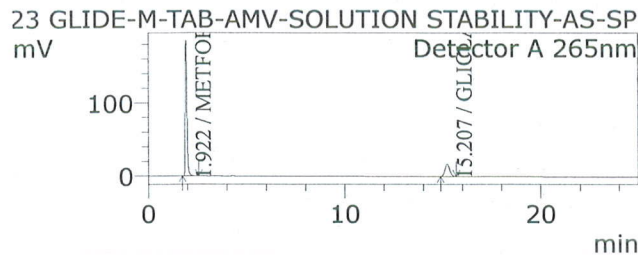
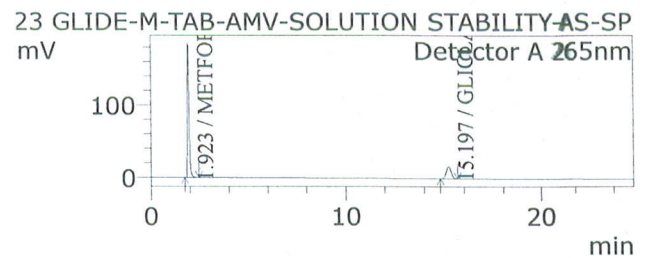
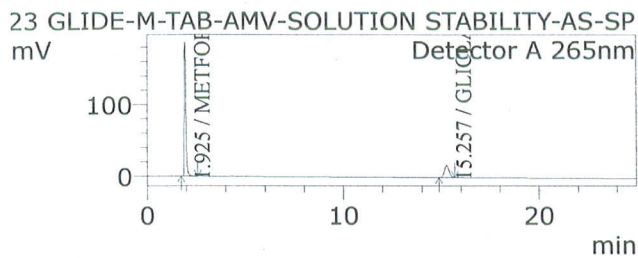
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 14:13:42
 Date Processed : 09-09-2023 16:19:32

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.93	1123345	2122	1.42
2	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.92	1121012	2125	1.43
2	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.92	1123667	2115	1.43
2	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.93	1124404	2078	1.42
2	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.93	1122907	2100	1.43
	Average		1.92	1123067	2108	1.43
	%RSD		0.108	0.113	0.918	0.265

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	15.26	290502	17651	1.09
2	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	15.20	291534	17585	1.10
2	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	15.21	290256	17553	1.11
2	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	15.35	290386	17495	1.11
2	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	15.59	289976	17537	1.11
	Average		15.32	290531	17564	1.10
	%RSD		1.062	0.204	0.333	1.043

Analysed By


09/09/23

Checked By


09/09/23



GENERIC HEALTHCARE PVT. LTD.

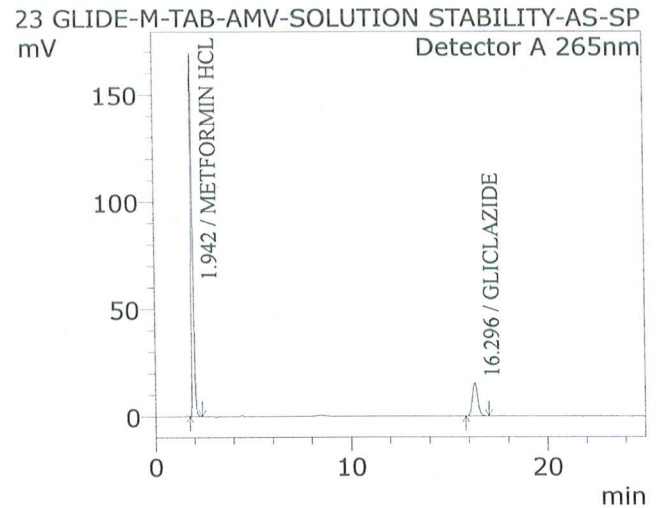
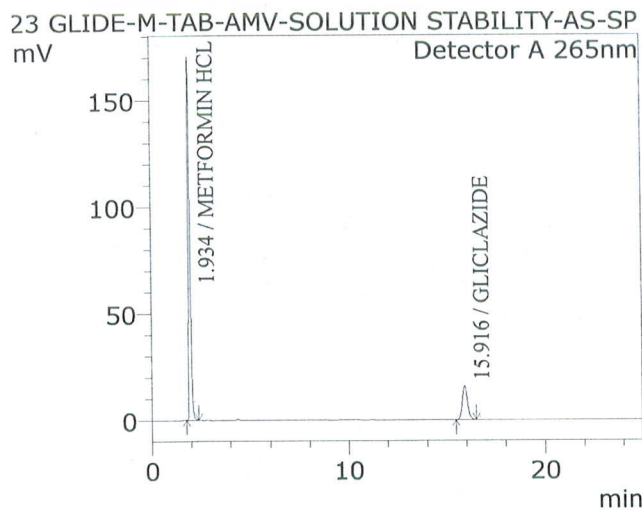
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLIDERM-60-850-801-INI-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-07.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 16:21:23
 Date Processed : 09-09-2023 16:00:25

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	AS-SPL-07.lcd	GLIDERM-60-850-801-INI-AS-SPL-1	1.93	1089282	1923	1.46
3	AS-SPL-08.lcd	GLIDERM-60-850-801-INI-AS-SPL-2	1.94	1090944	1919	1.47
	Average		1.94	1090113	1921	1.47
	%RSD		0.320	0.108	0.160	0.222

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	AS-SPL-07.lcd	GLIDERM-60-850-801-INI-AS-SPL-1	15.92	288581	17316	1.12
3	AS-SPL-08.lcd	GLIDERM-60-850-801-INI-AS-SPL-2	16.30	289541	17366	1.12
	Average		16.11	289061	17341	1.12
	%RSD		1.665	0.235	0.204	0.150

Analysed By

Checked By


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Analysis Report

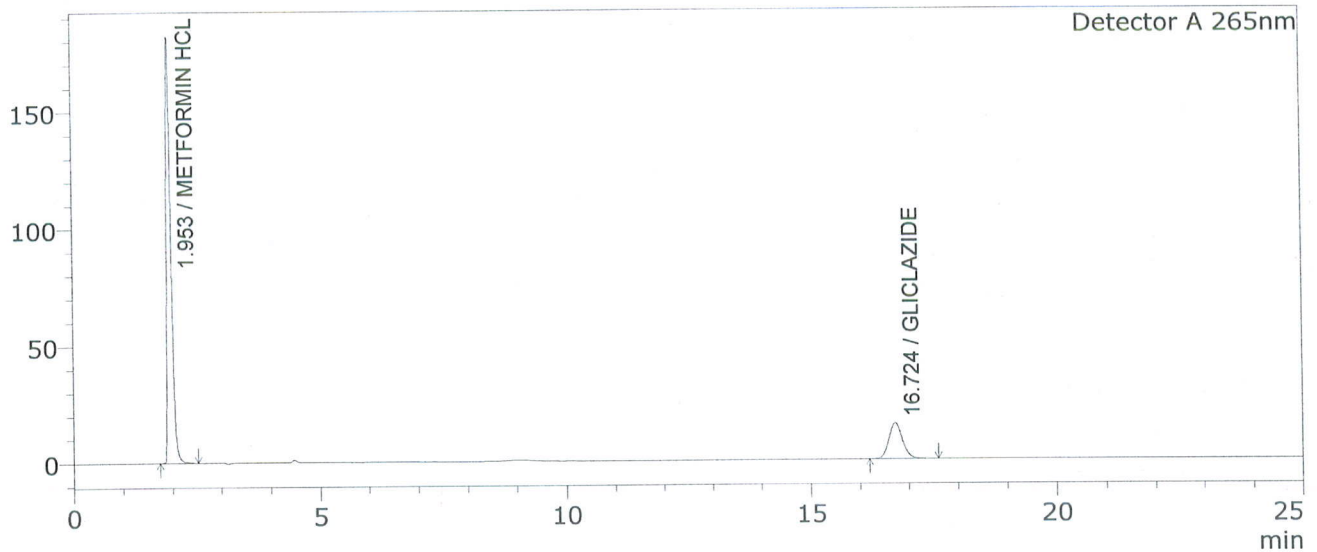
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Sample Name : SOLUTION STABILITY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-BKT
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-09.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 17:12:27
 Date Processed : 09-09-2023 10:29:37

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

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.95	1127364	79.40	2106	1.429	--	--
2	GLICLAZIDE	16.72	292571	20.60	17579	1.117	43.780	--
Total			1419936	100.00				

Analysed By

09/09/23

Checked By

09/09/23



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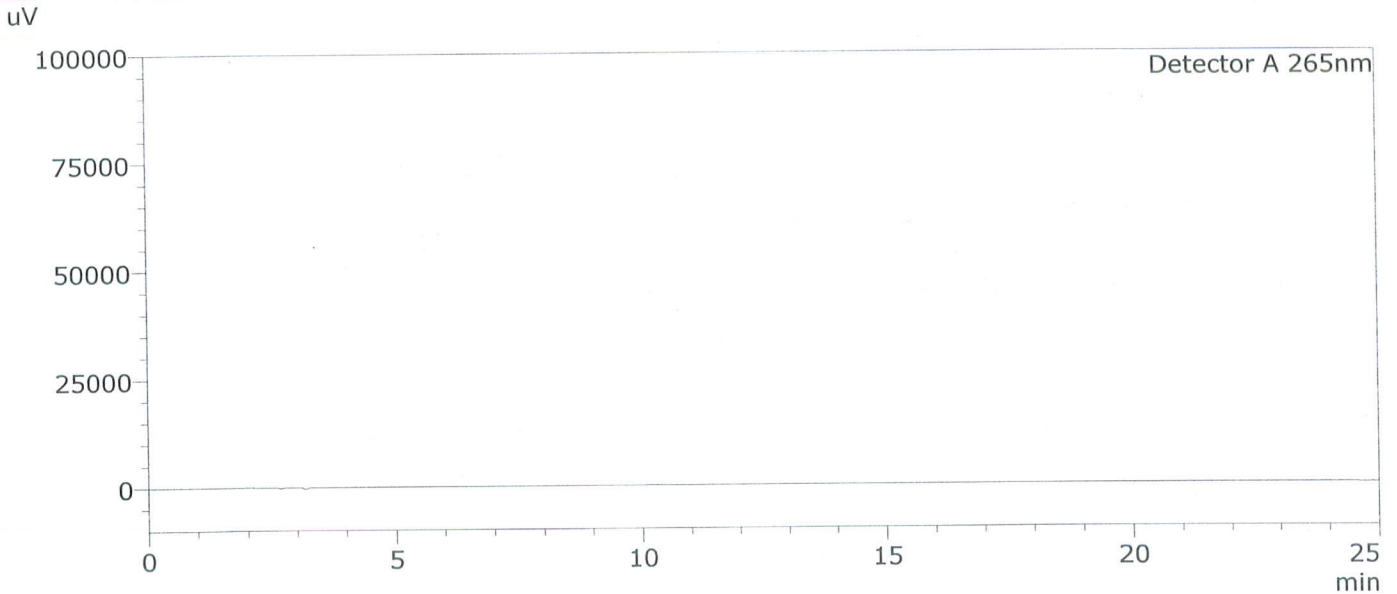
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-10.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 17:37:59
 Date Processed : 09-09-2023 10:29:37

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

[Signature]
09/09/23

Checked By

[Signature]
09/09/23



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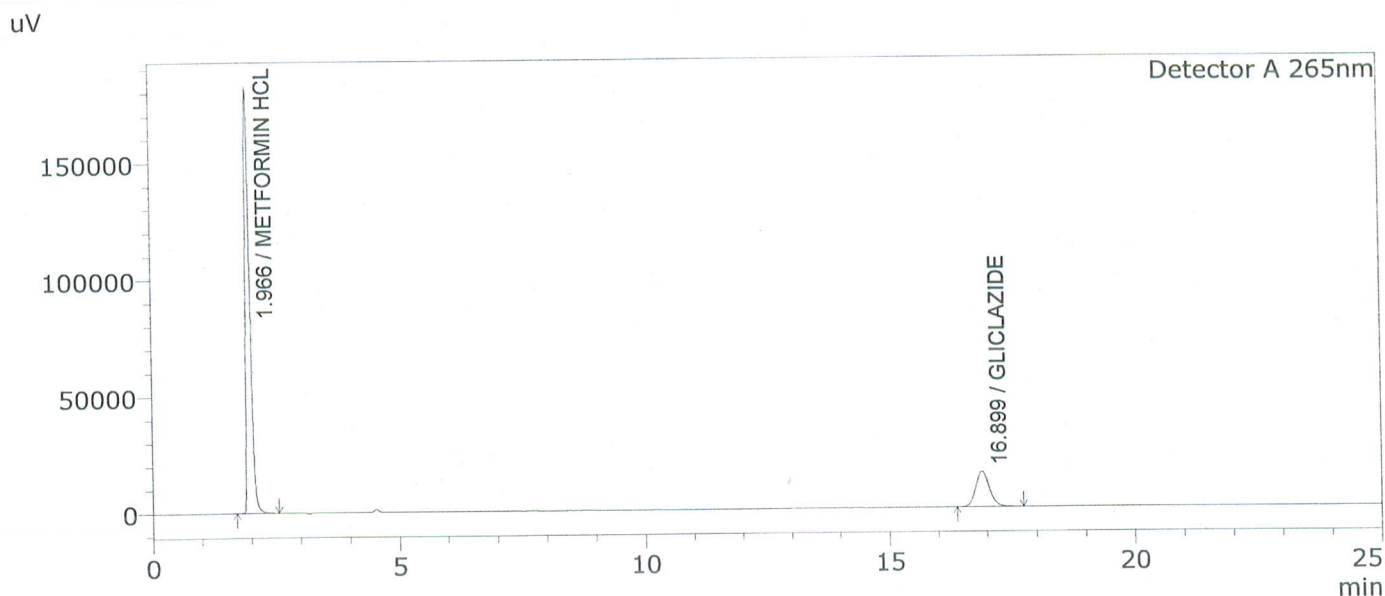
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-4H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-11.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 18:03:31
 Date Processed : 09-09-2023 10:29:38

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

<Chromatogram>



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.97	1130787	79.56	2136	1.423	--	--
2	GLICLAZIDE	16.90	290566	20.44	17858	1.118	44.185	--
Total			1421354	100.00				

Analysed By

09/09/23

Checked By

09/09/23

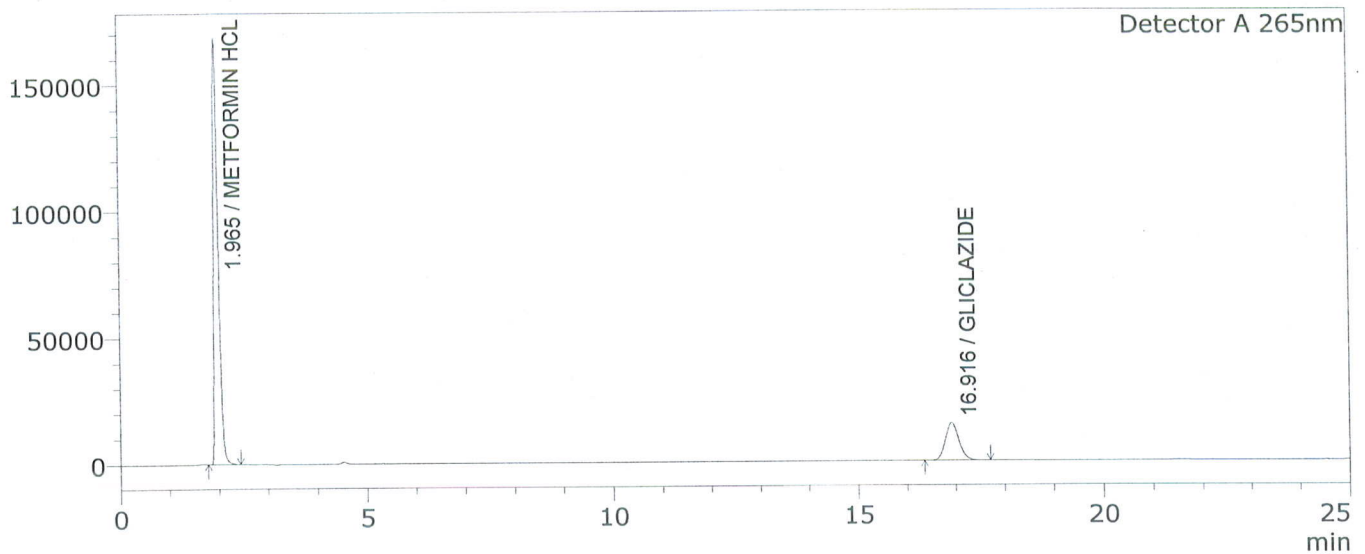

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-4H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-12.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 18:29:04
 Date Processed : 09-09-2023 10:29:38

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

<Chromatogram>

uV


<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.97	1098586	79.28	1916	1.461	--	--
2	GLICLAZIDE	16.92	287169	20.72	17624	1.125	43.383	--
Total			1385755	100.00				

Analysed By

09/09/23

Checked By

09/09/23



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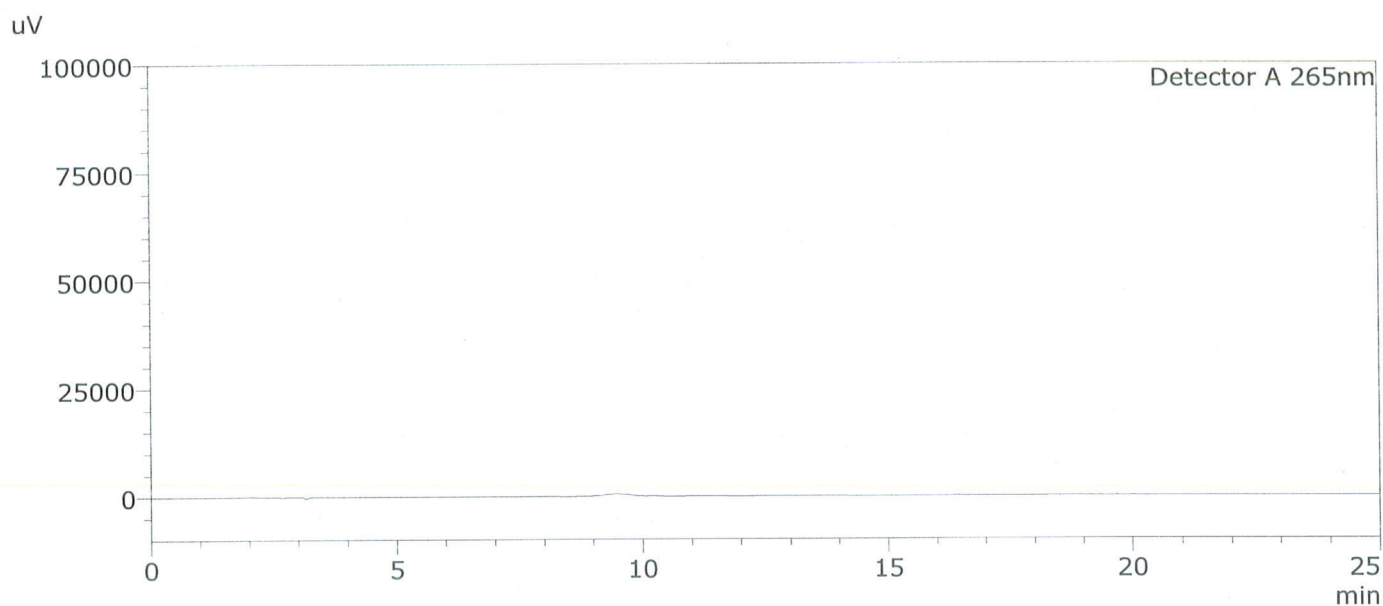
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-13.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 18:54:36
 Date Processed : 09-09-2023 10:29:38

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

(Signature)
09/09/23

Checked By

(Signature)
09/09/23



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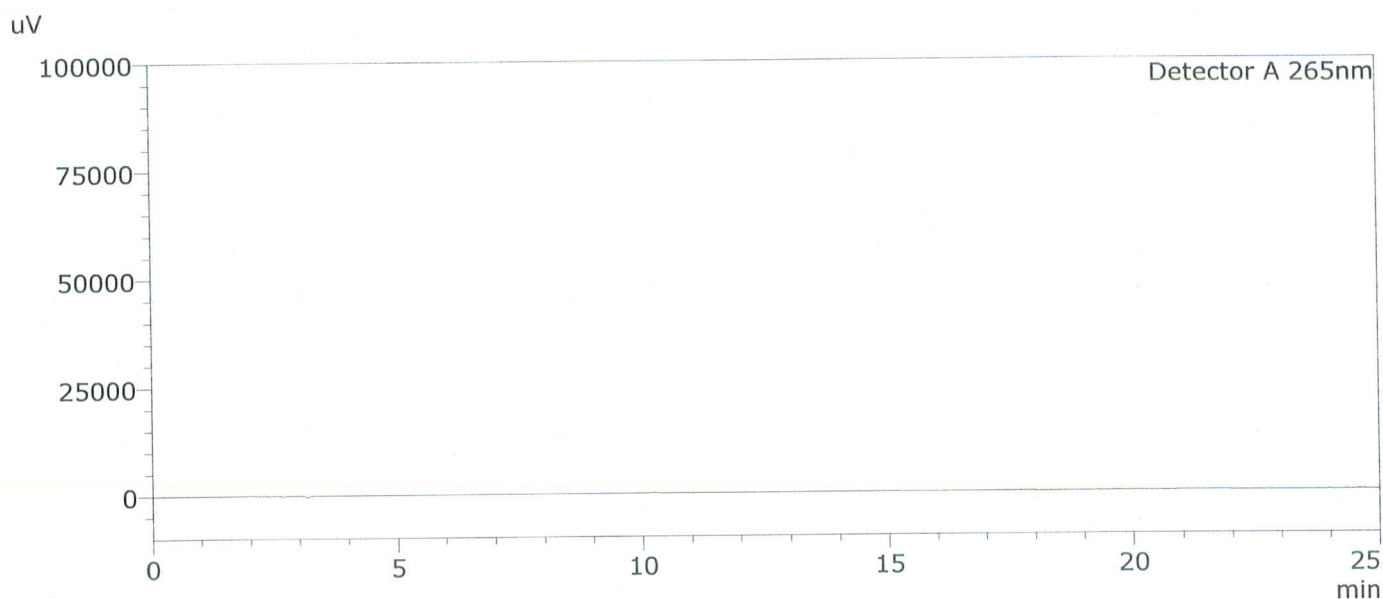
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-14.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 19:20:07
 Date Processed : 09-09-2023 10:29:38

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



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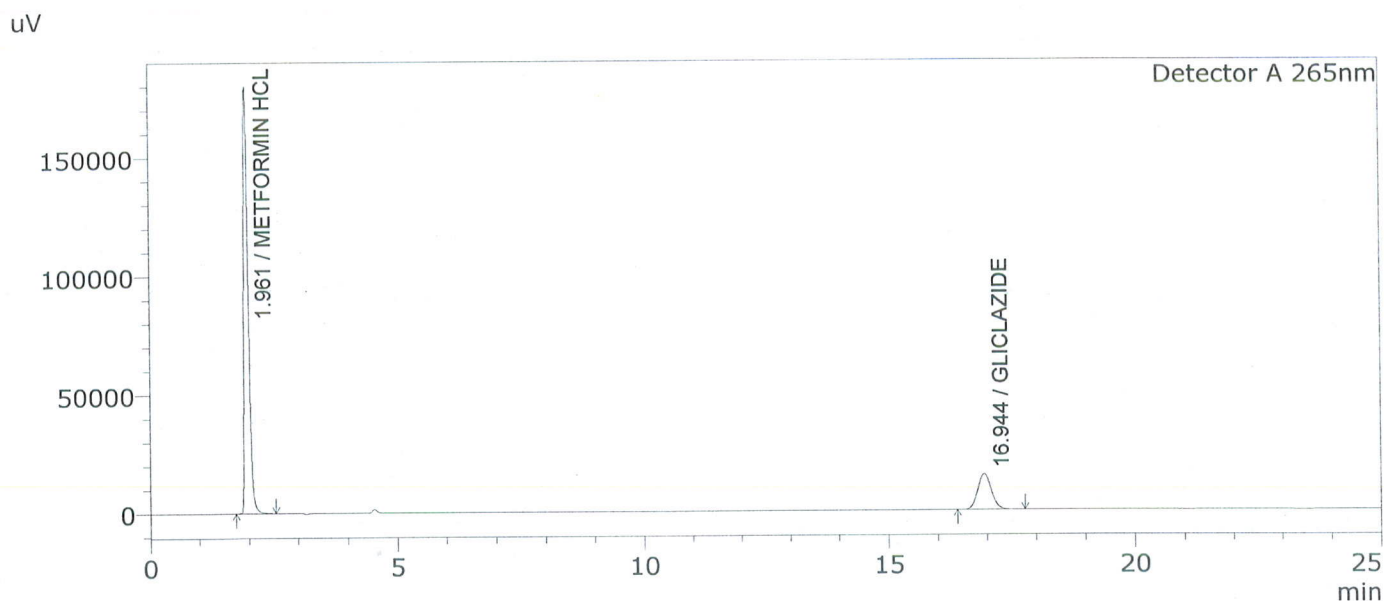
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-6H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-15.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 19:45:40
 Date Processed : 09-09-2023 10:29:39

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

<Chromatogram>



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1124093	79.62	2077	1.426	--	--
2	GLICLAZIDE	16.94	287769	20.38	18046	1.107	44.291	--
Total			1411863	100.00				

Analysed By

Checked By



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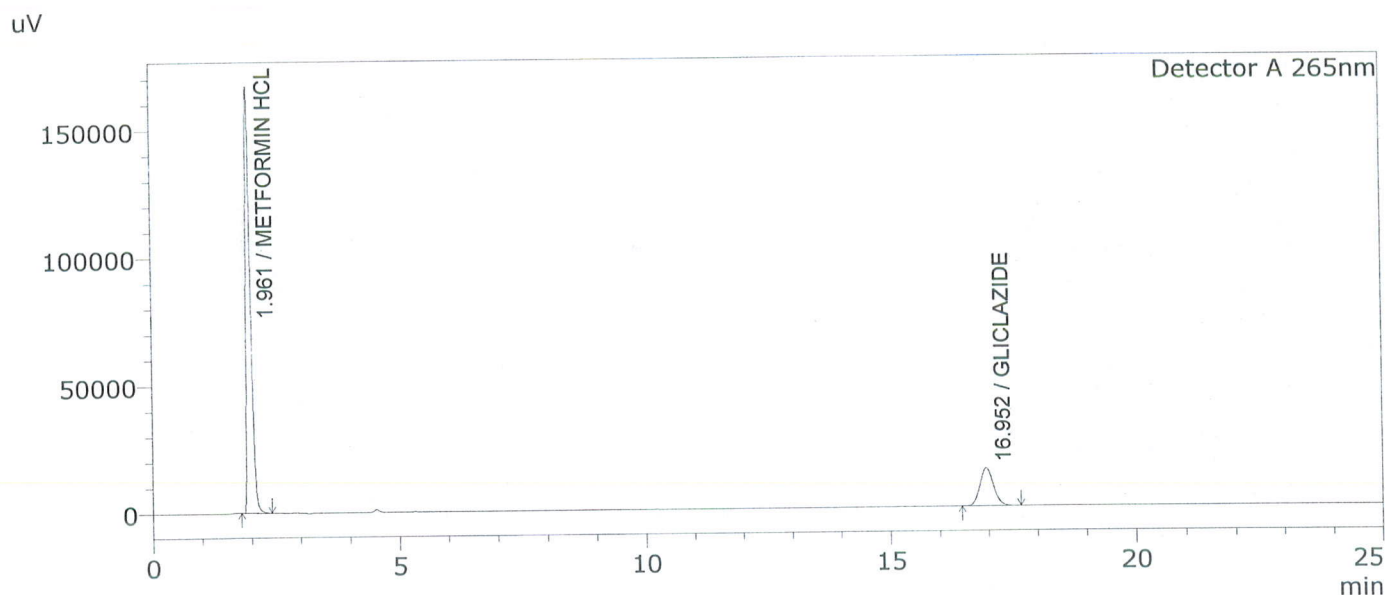
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-6H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-16.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 20:11:12
 Date Processed : 09-09-2023 10:29:39

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

<Chromatogram>



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1093160	79.30	1870	1.458	--	--
2	GLICLAZIDE	16.95	285270	20.70	17851	1.112	43.526	--
Total			1378430	100.00				

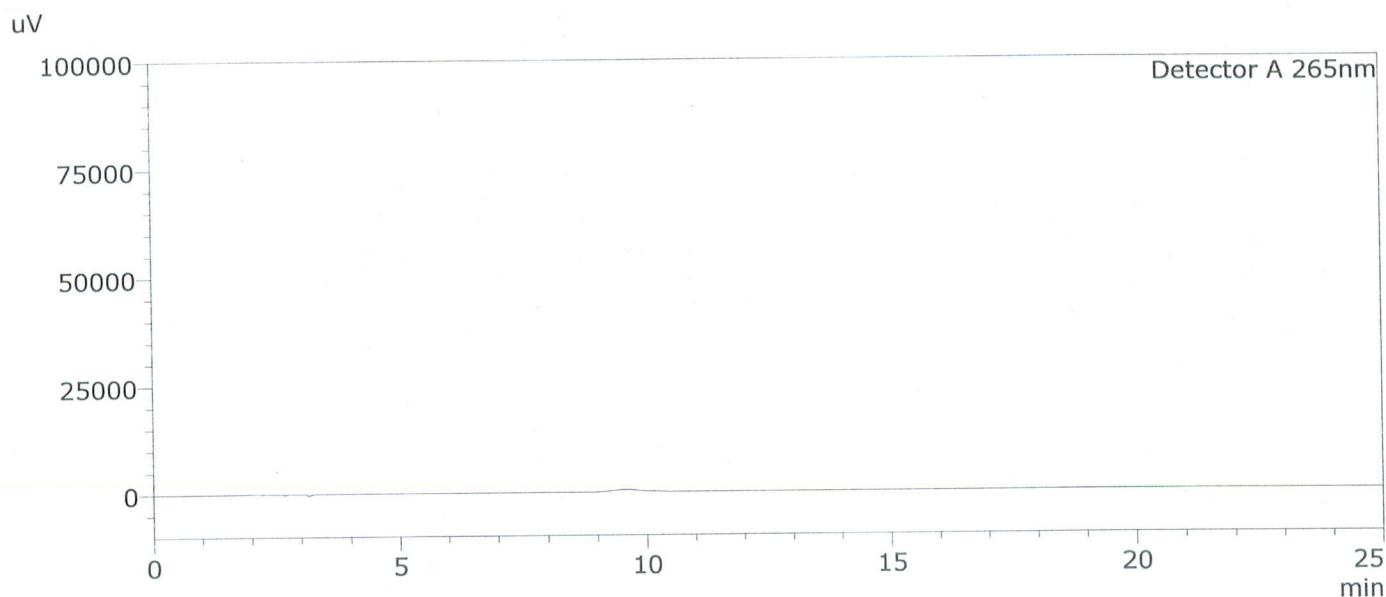
Analysed By

Checked By


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

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-17.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 20:36:44
 Date Processed : 09-09-2023 10:29:39

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

<Chromatogram>

<Peak Table>

Detector A 265nm

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

Analysed By

09/09/23

Checked By

09/09/23



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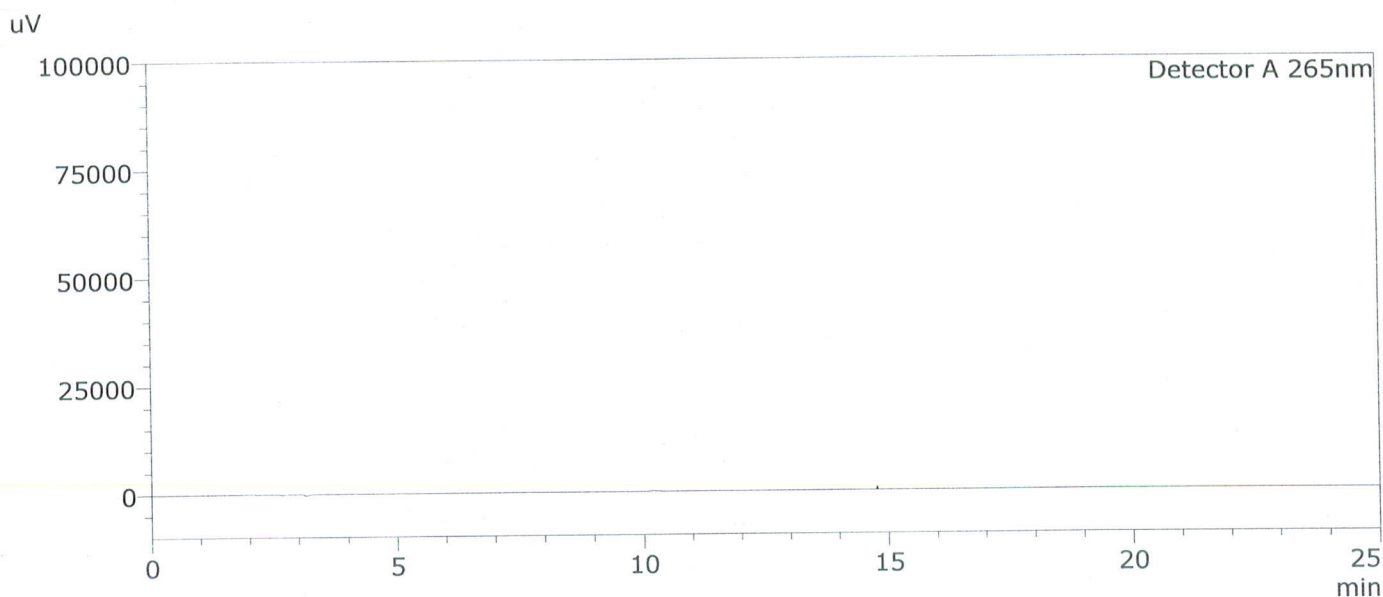
Analysis Report

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Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-18.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 21:02:16
 Date Processed : 09-09-2023 10:29:40

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



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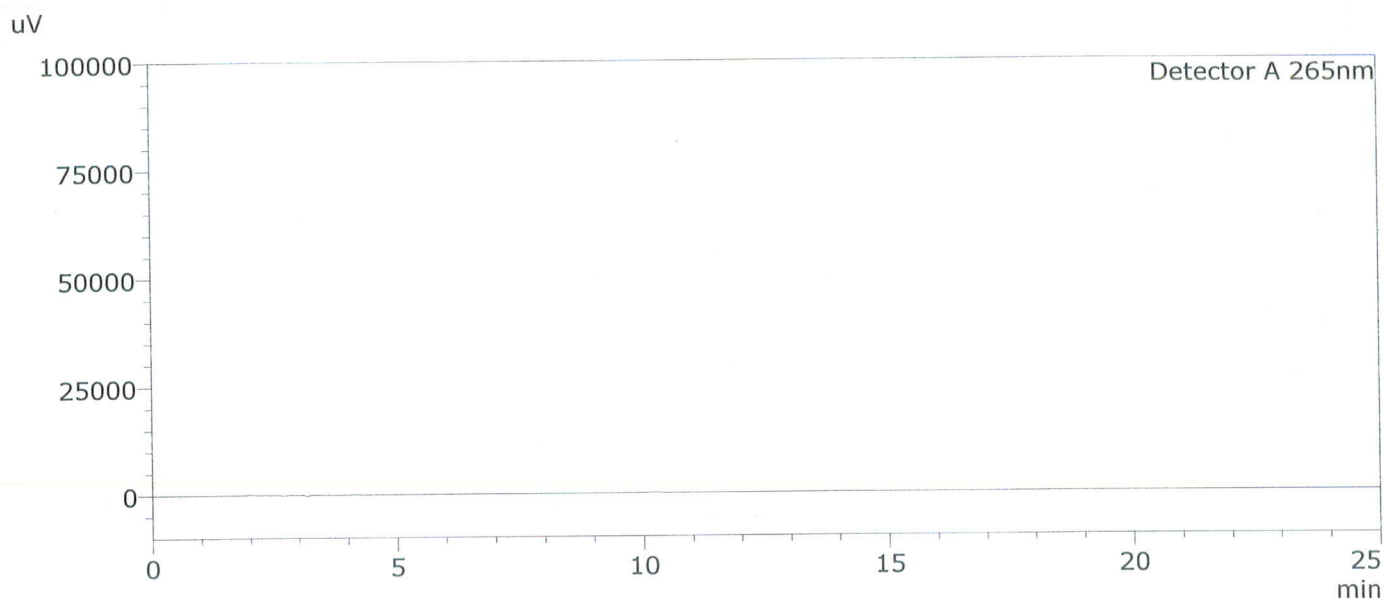
Analysis Report

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Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-19.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 21:27:48
 Date Processed : 09-09-2023 10:29:40

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



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Analysis Report

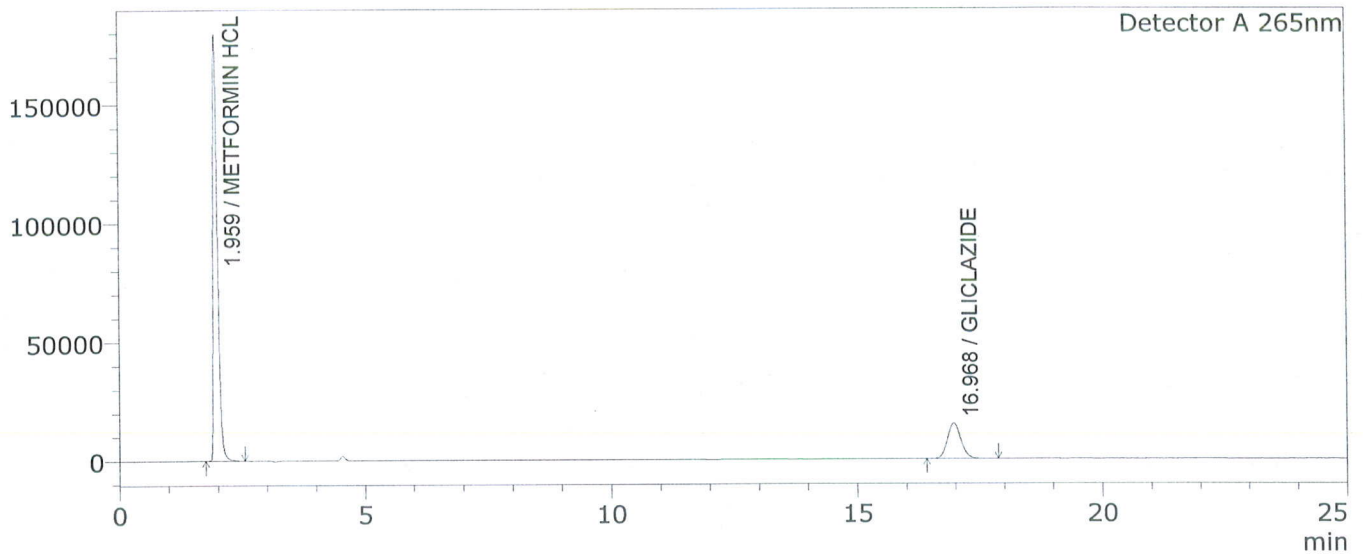
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Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-8H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-20.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 21:53:21
 Date Processed : 09-09-2023 16:26:33

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

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1125768	79.78	2093	1.432	--	--
2	GLICLAZIDE	16.97	285302	20.22	18053	1.104	44.374	--
Total			1411070	100.00				

Analysed By

Checked By


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Analysis Report

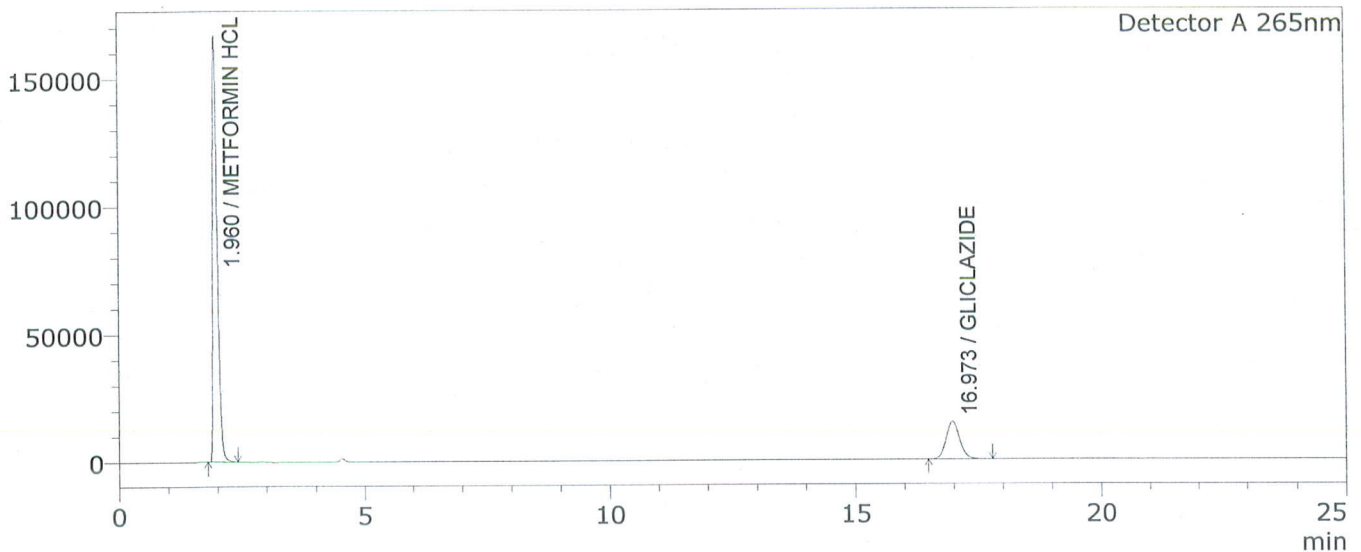
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Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-8H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-21.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 22:18:53
 Date Processed : 09-09-2023 10:29:41

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

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1095978	79.46	1856	1.466	--	--
2	GLICLAZIDE	16.97	283283	20.54	17812	1.114	43.473	--
Total			1379261	100.00				

Analysed By
Checked By



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Analysis Report

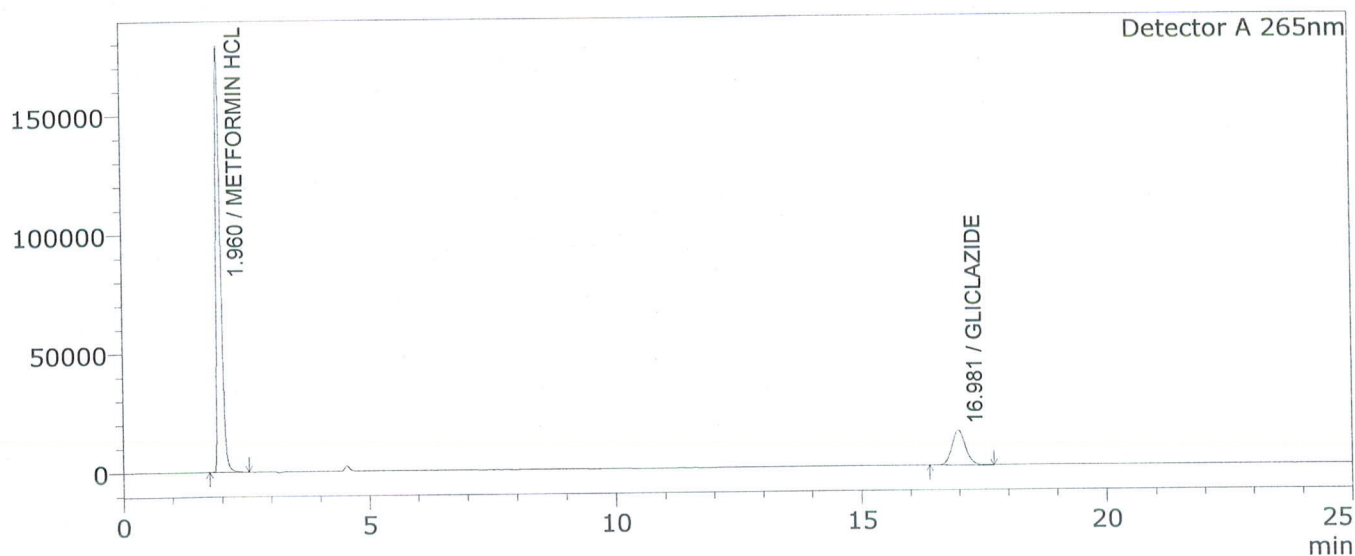
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Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-10H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-26.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 00:26:35
 Date Processed : 09-09-2023 10:29:29

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

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1128266	79.70	2044	1.438	--	--
2	GLICLAZIDE	16.98	287356	20.30	17813	1.126	44.032	--
Total			1415622	100.00				

Analysed By

Checked By



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Analysis Report

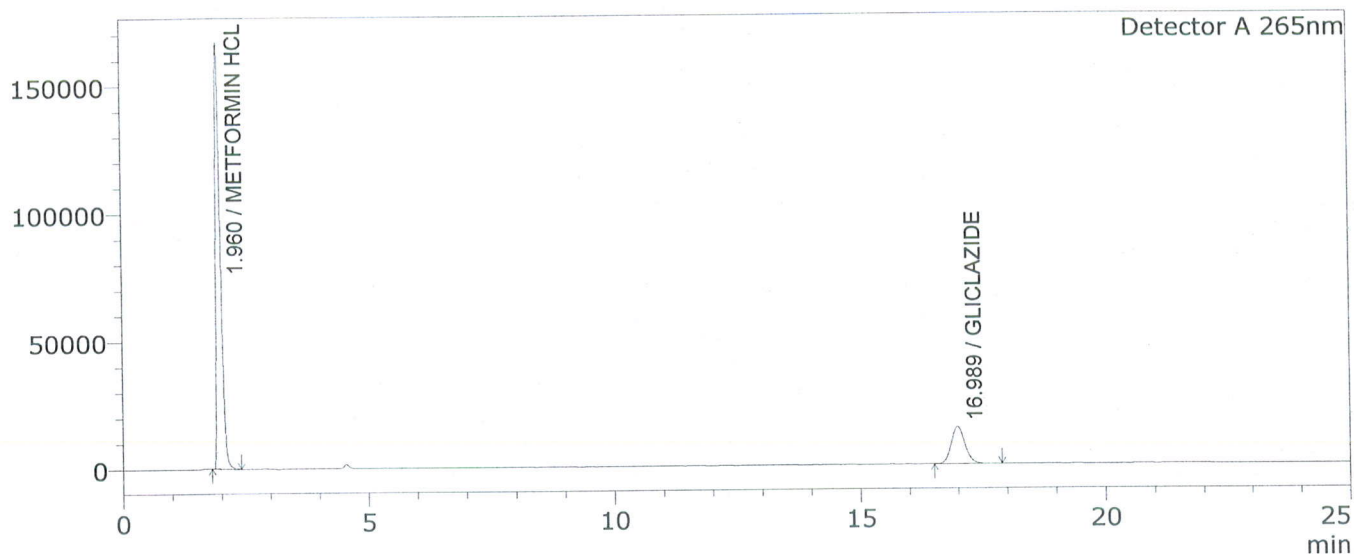
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Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-10H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-27.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 00:52:08
 Date Processed : 09-09-2023 10:29:44

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

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1098486	79.46	1855	1.472	--	--
2	GLICLAZIDE	16.99	284014	20.54	17646	1.114	43.334	--
Total			1382500	100.00				

Analysed By

Checked By



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Analysis Report

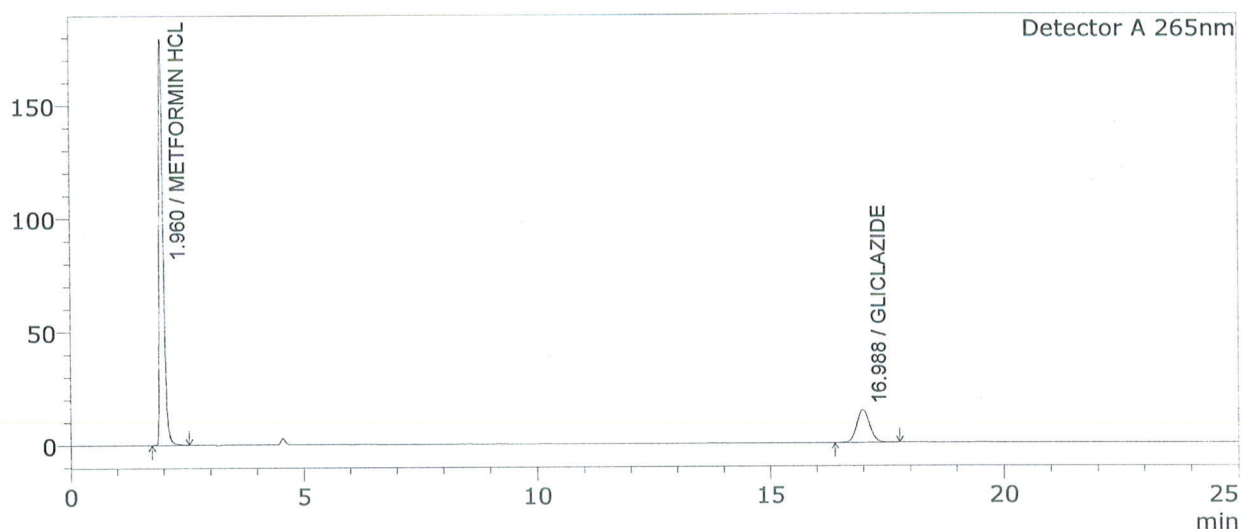
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Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-12H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-32.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 02:59:51
 Date Processed : 09-09-2023 10:29:59

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

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1129120	80.37	2048	1.439	--	--
2	GLICLAZIDE	16.99	285718	19.63	17987	1.107	44.209	--
Total			1414838	100.00				

Analysed By

Checked By



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Analysis Report

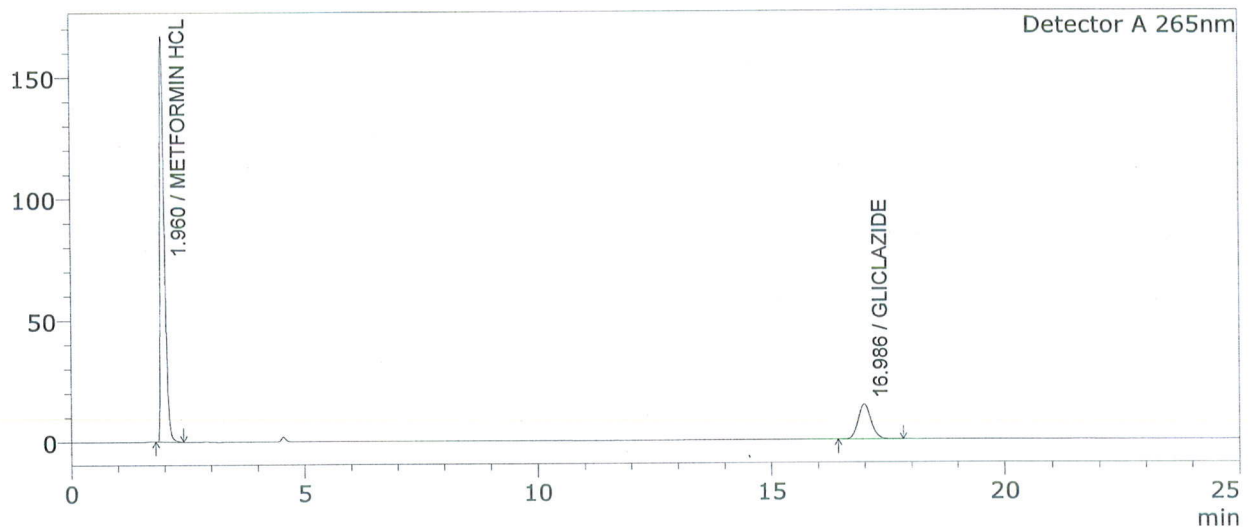
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Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-12H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-33.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 03:25:23
 Date Processed : 09-09-2023 10:30:14

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

<Chromatogram>

mV

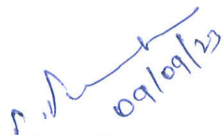


<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1099988	79.87	1849	1.473	--	--
2	GLICLAZIDE	16.99	283284	20.13	17766	1.120	43.422	--
Total			1383272	100.00				


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Analysis Report

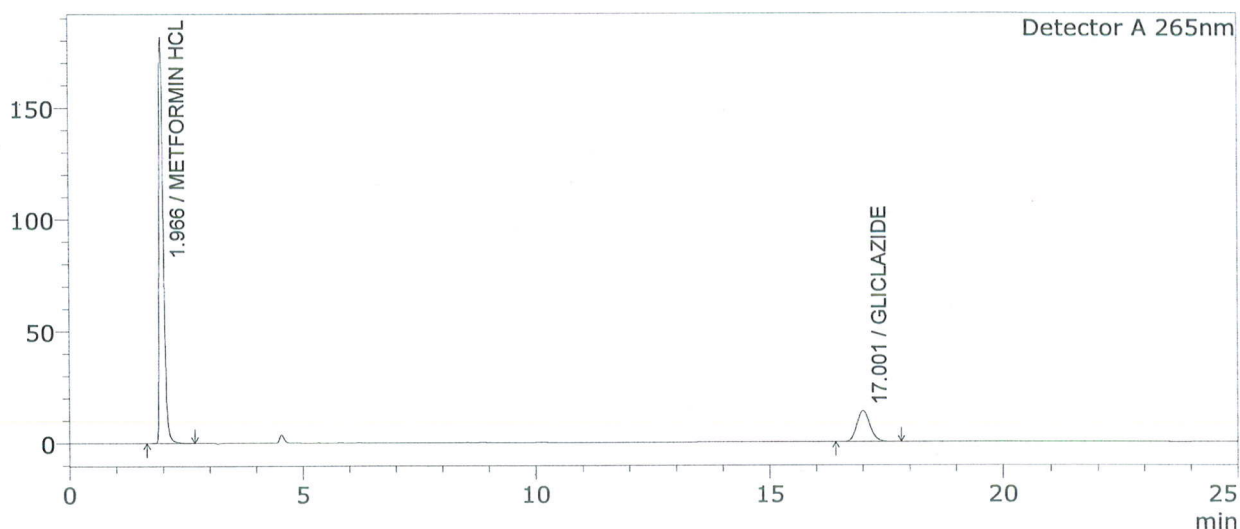
<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-18H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-46.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 08:57:30
 Date Processed : 09-09-2023 10:30:29

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

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.97	1141670	81.08	2109	1.441	--	--
2	GLICLAZIDE	17.00	286425	18.92	17699	1.124	44.067	--
Total			1428095	100.00				

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09/09/23
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Analysis Report

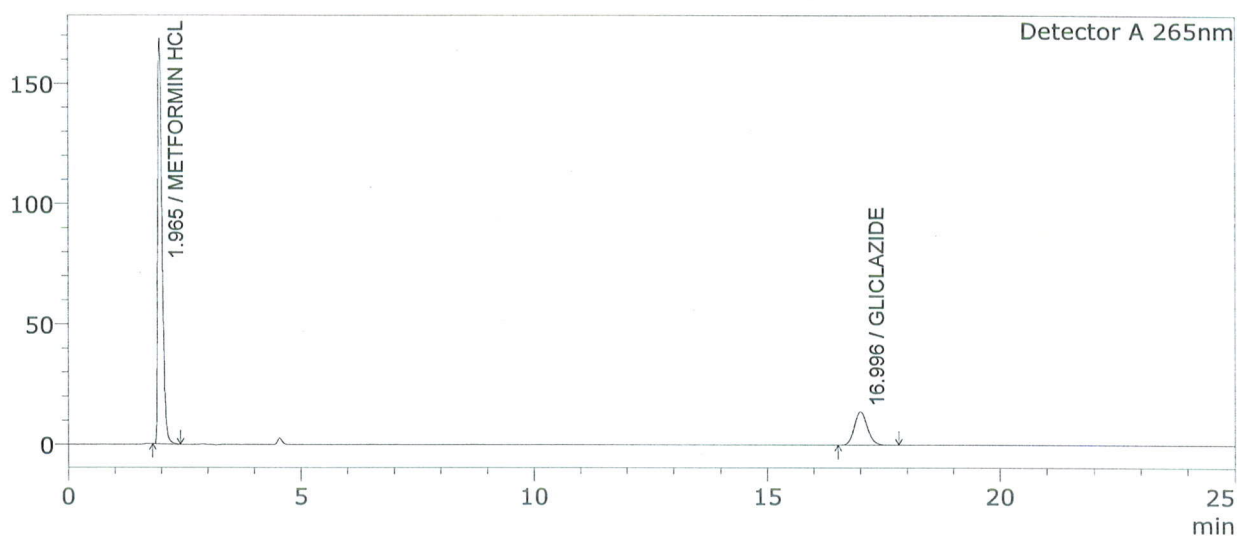
<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-18H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-47.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 09:23:33
 Date Processed : 09-09-2023 10:30:44

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

<Chromatogram>

mV

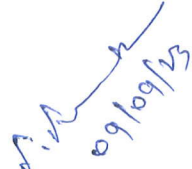


<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1110065	80.43	1894	1.481	--	--
2	GLICLAZIDE	17.00	284168	19.57	17432	1.129	43.225	--
Total			1394233	100.00				


 09/09/23
 Analysed By


 09/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

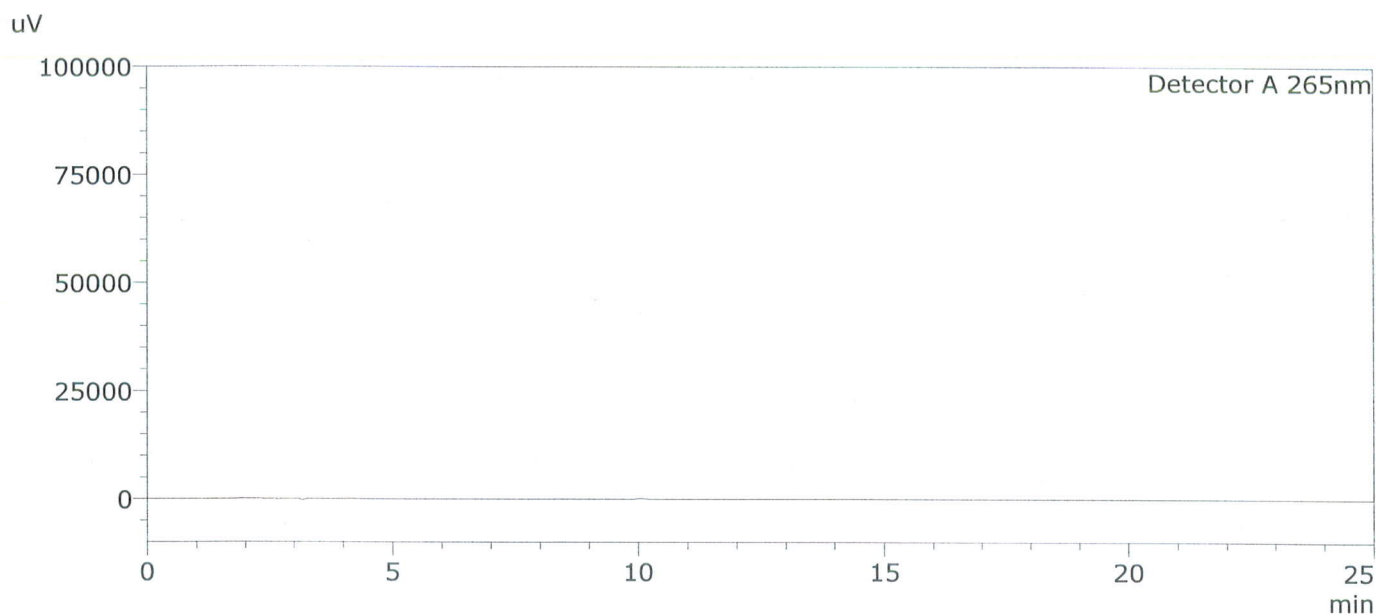
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-58.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 14:04:28
 Date Processed : 09-09-2023 10:29:51

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

09/09/23

Checked By

09/09/23



GENERIC HEALTHCARE PVT. LTD.

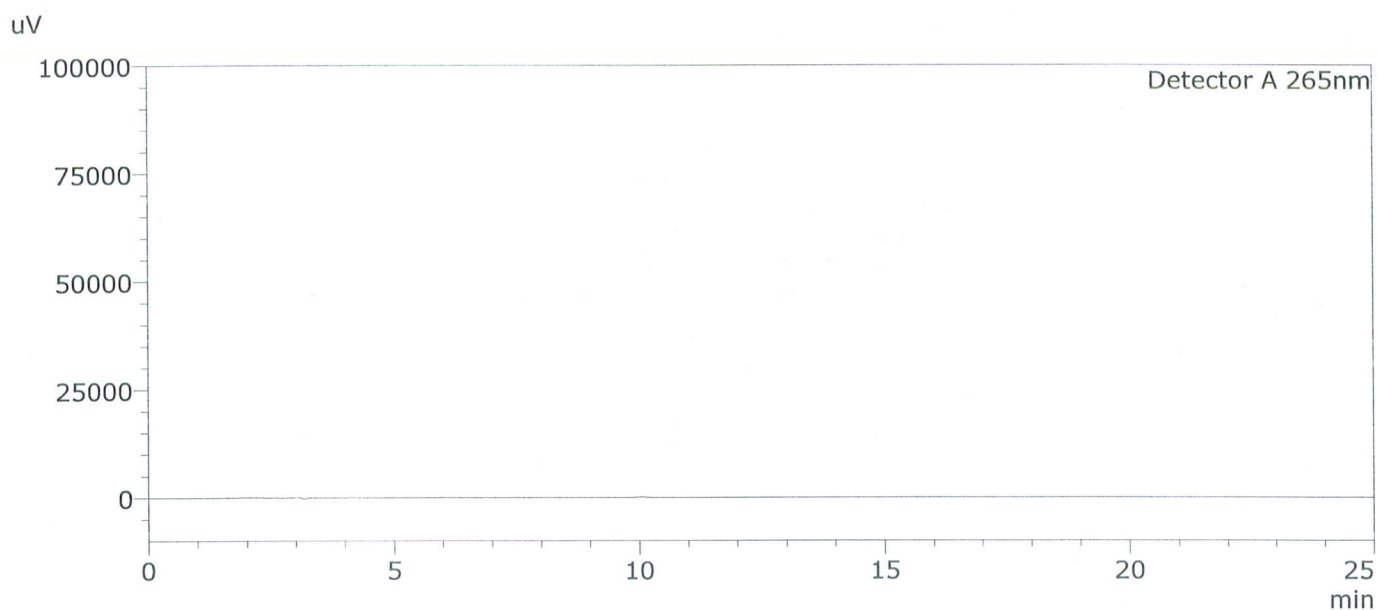
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-59.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 14:29:59
 Date Processed : 09-09-2023 10:29:51

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

09/09/23

Analysed By

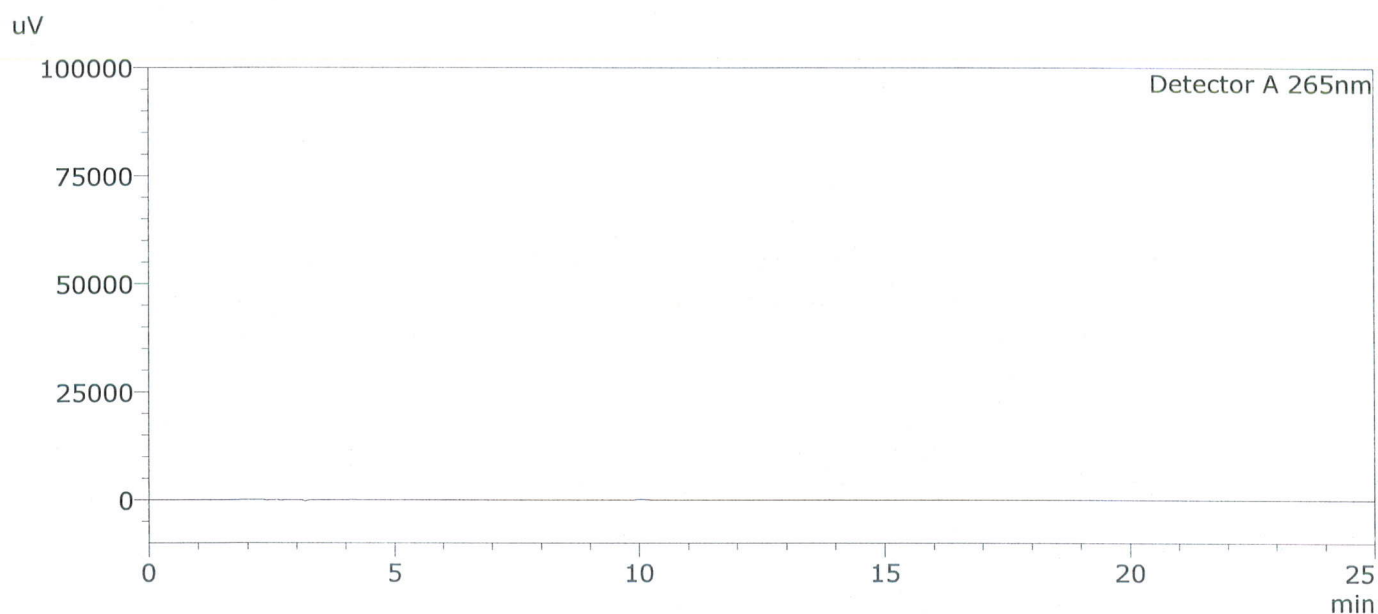
09/09/23

Checked By


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

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-60.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 14:55:32
 Date Processed : 09-09-2023 10:29:52

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

<Chromatogram>

<Peak Table>

Detector A 265nm

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

09/09/23

Analysed By

09/09/23

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Analysis Report

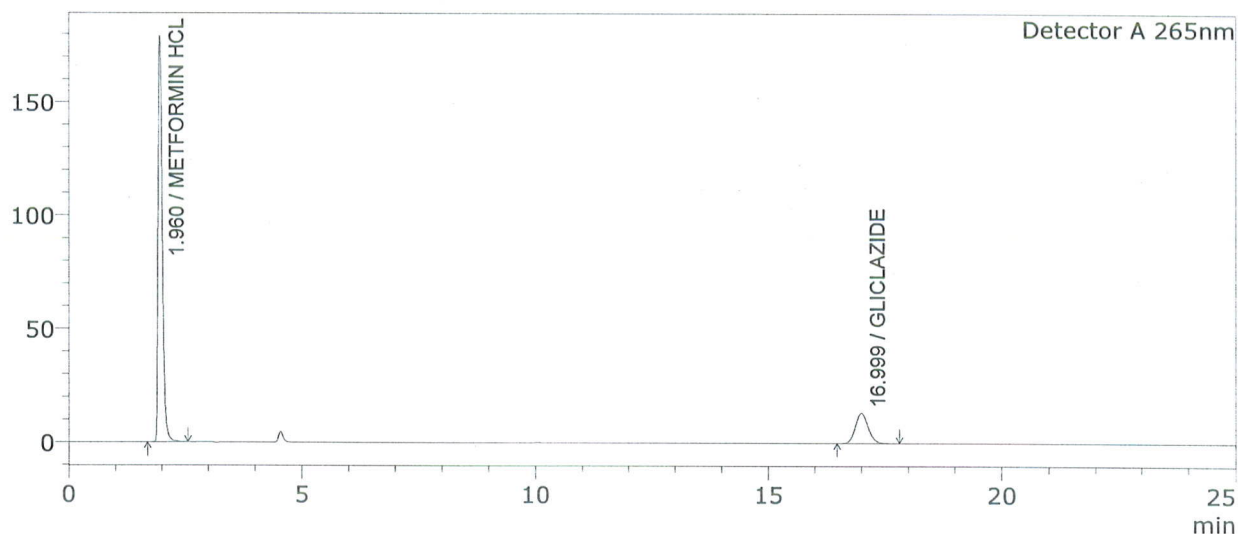
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Sample Name : SOLUTION STABILITY
 Sample ID : GLICLA+METFORMIN-24H-AS-STD
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-61.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 15:21:03
 Date Processed : 09-09-2023 10:30:59

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

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1130787	81.54	2049	1.451	--	--
2	GLICLAZIDE	17.00	285934	18.46	17871	1.111	44.112	--
Total			1416721	100.00				

Analysed By

Checked By



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Analysis Report

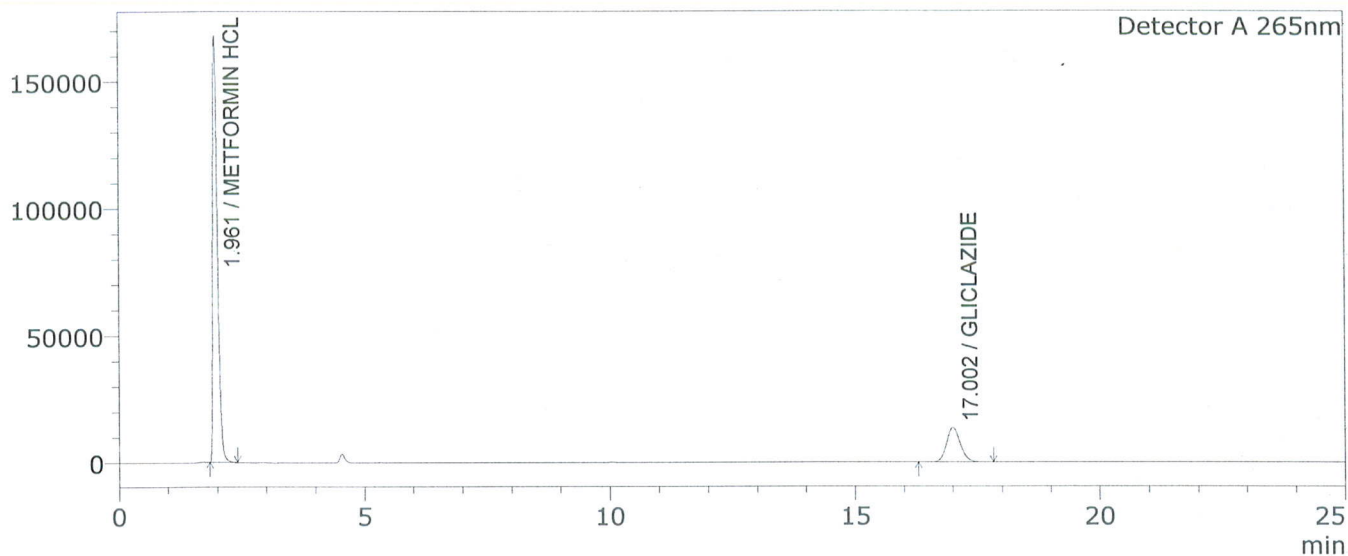
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Sample Name : SOLUTION STABILITY
 Sample ID : GLIDER-M-60-850-0801-24H-AS-SPL
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-62.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-3
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 15:46:36
 Date Processed : 09-09-2023 10:31:15

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

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1107503	80.77	1851	1.479	--	--
2	GLICLAZIDE	17.00	263651	19.23	17596	1.122	43.282	--
Total			1371154	100.00				

09/09/23

Analysed By

09/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcd

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-01.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLAZIDE+METFORMIN-AS-STD-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-02.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLAZIDE+METFORMIN-AS-STD-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-03.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLAZIDE+METFORMIN-AS-STD-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-04.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLAZIDE+METFORMIN-AS-STD-4	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-05.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLAZIDE+METFORMIN-AS-STD-5	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-06.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDERM-60-850-801-INI-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-07.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDERM-60-850-801-INI-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-08.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLAZIDE+METFORMIN-AS-STD-BKT	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-09.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-10.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-4H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-11.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-4H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-12.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-13.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-14.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-6H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-15.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-6H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-16.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-17.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-19.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-8H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-20.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-8H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-21.lcd	20.0	QC/CL/23/041
4	2	LINEARITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-22.lcd	20.0	QC/CL/23/041
5	2	LINEARITY	GLICLAZIDE+METFOR-10%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-23.lcd	20.0	QC/CL/23/041
5	2	LINEARITY	GLICLAZIDE+METFOR-10%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-24.lcd	20.0	QC/CL/23/041
5	2	LINEARITY	GLICLAZIDE+METFOR-10%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-25.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-10H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-26.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-10H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-27.lcd	20.0	QC/CL/23/041
4	2	LINEARITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-28.lcd	20.0	QC/CL/23/041
6	2	LINEARITY	GLICLAZIDE+METFOR-50%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-29.lcd	20.0	QC/CL/23/041
6	2	LINEARITY	GLICLAZIDE+METFOR-50%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-30.lcd	20.0	QC/CL/23/041
6	2	LINEARITY	GLICLAZIDE+METFOR-50%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-31.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-12H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-32.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-12H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-33.lcd	20.0	QC/CL/23/041
4	2	LINEARITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-34.lcd	20.0	QC/CL/23/041
7	2	LINEARITY	GLICLAZIDE+METFOR-75%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-35.lcd	20.0	QC/CL/23/041
7	2	LINEARITY	GLICLAZIDE+METFOR-75%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-36.lcd	20.0	QC/CL/23/041
7	2	LINEARITY	GLICLAZIDE+METFOR-75%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-37.lcd	20.0	QC/CL/23/041
4	2	LINEARITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-38.lcd	20.0	QC/CL/23/041
8	2	LINEARITY	GLICLAZIDE+METFOR-100%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-39.lcd	20.0	QC/CL/23/041
8	2	LINEARITY	GLICLAZIDE+METFOR-100%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-40.lcd	20.0	QC/CL/23/041
8	2	LINEARITY	GLICLAZIDE+METFOR-100%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-41.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
4	2	LINEARITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-42.lcd	20.0	QC/CL/23/041
9	2	LINEARITY	GLICLAZIDE+METFOR-125%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-43.lcd	20.0	QC/CL/23/041
9	2	LINEARITY	GLICLAZIDE+METFOR-125%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-44.lcd	20.0	QC/CL/23/041
9	2	LINEARITY	GLICLAZIDE+METFOR-125%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-45.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-18H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-46.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-18H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-47.lcd	20.0	QC/CL/23/041
4	2	LINEARITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-48.lcd	20.0	QC/CL/23/041
10	2	LINEARITY	GLICLAZIDE+METFOR-150%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-49.lcd	20.0	QC/CL/23/041
10	2	LINEARITY	GLICLAZIDE+METFOR-150%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-50.lcd	20.0	QC/CL/23/041
10	2	LINEARITY	GLICLAZIDE+METFOR-150%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-51.lcd	20.0	QC/CL/23/041
11	2	RECOVERY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-52.lcd	20.0	QC/CL/23/041
12	2	RECOVERY	GLICLAZIDE+METFORMIN-AS-STD-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-53.lcd	20.0	QC/CL/23/041
12	2	RECOVERY	GLICLAZIDE+METFORMIN-AS-STD-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-54.lcd	20.0	QC/CL/23/041
12	2	RECOVERY	GLICLAZIDE+METFORMIN-AS-STD-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-55.lcd	20.0	QC/CL/23/041
12	2	RECOVERY	GLICLAZIDE+METFORMIN-AS-STD-4	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-56.lcd	20.0	QC/CL/23/041
12	2	RECOVERY	GLICLAZIDE+METFORMIN-AS-STD-5	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-57.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-58.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-59.lcd	20.0	QC/CL/23/041
1	2	SOLUTION STABILITY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-60.lcd	20.0	QC/CL/23/041
2	2	SOLUTION STABILITY	GLICLA+METFORMIN-24H-AS-STD	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-61.lcd	20.0	QC/CL/23/041
3	2	SOLUTION STABILITY	GLIDER-M-60-850-0801-24H-AS-SPL	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-62.lcd	20.0	QC/CL/23/041
13	2	RECOVERY	GLICLAZIDE+METFOR-50%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-63.lcd	20.0	QC/CL/23/041
13	2	RECOVERY	GLICLAZIDE+METFOR-50%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-64.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
13	2	RECOVERY	GLICLAZIDE+METFOR-50%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-65.lcd	20.0	QC/CL/23/041
11	2	RECOVERY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-66.lcd	20.0	QC/CL/23/041
14	2	RECOVERY	GLICLAZIDE+METFOR-100%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-67.lcd	20.0	QC/CL/23/041
14	2	RECOVERY	GLICLAZIDE+METFOR-100%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-68.lcd	20.0	QC/CL/23/041
14	2	RECOVERY	GLICLAZIDE+METFOR-100%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-69.lcd	20.0	QC/CL/23/041
11	2	RECOVERY	AS-BLANK	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-70.lcd	20.0	QC/CL/23/041
15	2	RECOVERY	GLICLAZIDE+METFOR-150%-AS-SPL-1	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-71.lcd	20.0	QC/CL/23/041
15	2	RECOVERY	GLICLAZIDE+METFOR-150%-AS-SPL-2	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-72.lcd	20.0	QC/CL/23/041
15	2	RECOVERY	GLICLAZIDE+METFOR-150%-AS-SPL-3	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-73.lcd	20.0	QC/CL/23/041
12	2	RECOVERY	GLICLAZIDE+METFORMIN-AS-STD-BKT	50-500-850-TAB-AS.lcm	3ILITY-AS-SPL-74.lcd	20.0	QC/CL/23/041
-1	2	SHUTDOWN	SHUTDOWN	ETHOD\SHUTDOWN.lcm	3ILITY-AS-SPL-75.lcd	20.0	QC/CL/23/041

② 2023/09/23

Analysed By

② 2023/09/23

Checked By



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

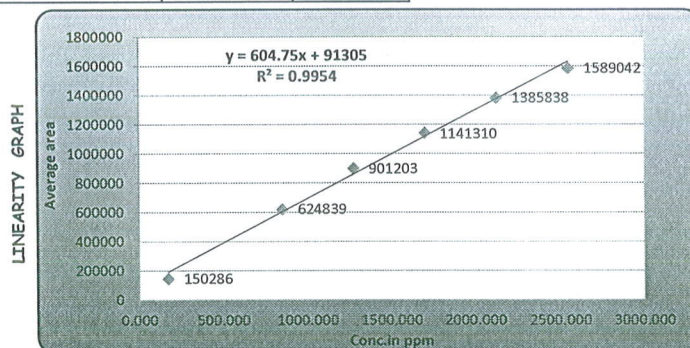
Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
Linearity Level-I :	850.24	mg to --->	100	ml to --->	5	ml to --->	250
Std.conc (in ppm)-170.048	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-II :	850.24	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-850.24	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-III :	850.24	mg to --->	100	ml to --->	7.5	ml to --->	50
Std.conc (in ppm)-1275.36	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-IV :	850.24	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.48	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-V :	850.24	mg to --->	100	ml to --->	5	ml to --->	20
Std.conc (in ppm)-2125.6	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-VI :	850.24	mg to --->	100	ml to --->	15	ml to --->	50
Std.conc (in ppm)-2550.72	1	ml to --->	1	ml to --->	1	ml to --->	1

Level"s	I	II	III	IV	V	VI
No. of injections.	10%	50%	75%	100%	125%	150%
1	150259	624472	900851	1142391	1384708	1588639
2	150420	624951	901399	1138936	1386194	1588618
3	150178	625095	901358	1142602	1386613	1589870
Average	150286	624839	901203	1141310	1385838	1589042
RSD%	0.114	0.052	0.034	0.180	0.072	0.045

LEVEL"s	Conc.in ppm (X-axis)	Average area (Y-axis)
I	170.048	150286
II	850.240	624839
III	1275.360	901203
IV	1700.480	1141310
V	2125.600	1385838
VI	2550.720	1589042



Results :

- 1) Squared correlation coefficient of Metformin HCl **0.9954**
- 2) In Range , %RSD of areas at 10%,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%,50%, 75%, 100%, 125 & 150% levels should be Not more than 2.0.

Analysed by :

E.MEENA

Date :

09-09-2023

Checked by :

Date :

09/09/23

09/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

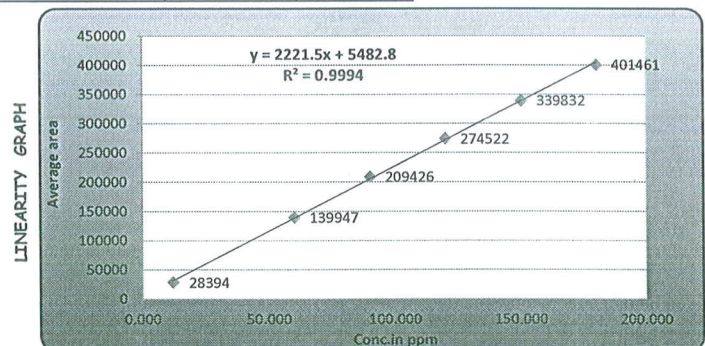
Gliclazide BP ----- 60 mg

ASSAY OF GLICLAZIDE

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
Linearity Level-I :	60.05	mg to --->	100	ml to --->	5	ml to --->	250
Std.conc (in ppm)-12.01	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-II :	60.05	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-60.05	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-III :	60.05	mg to --->	100	ml to --->	7.5	ml to --->	50
Std.conc (in ppm)-90.075	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-IV :	60.05	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.1	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-V :	60.05	mg to --->	100	ml to --->	5	ml to --->	20
Std.conc (in ppm)-150.125	1	ml to --->	1	ml to --->	1	ml to --->	1
Linearity Level-VI :	60.05	mg to --->	100	ml to --->	15	ml to --->	50
Std.conc (in ppm)-180.15	1	ml to --->	1	ml to --->	1	ml to --->	1

Level's	I	II	III	IV	V	VI
No. of injections.	10%	50%	75%	100%	125%	150%
1	28820	140270	208592	274938	340537	403013
2	27984	139776	211575	274680	340040	400731
3	28377	139795	208111	273948	338918	400638
Average	28394	139947	209426	274522	339832	401461
RSD%	0.979	0.200	0.896	0.187	0.244	0.335

LEVEL's	Conc.in ppm (X-axis)	Average area (Y-axis)
I	12.010	28394
II	60.050	139947
III	90.075	209426
IV	120.100	274522
V	150.125	339832
VI	180.150	401461

**Results :**

- 1) Squared correlation coefficient of Gliclazide **0.9994**
- 2) In Range , %RSD of areas at 10%,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%,50%, 75%, 100%, 125 & 150% levels should be Not more than 2.0.

Analysed by :

E.MEENA

Date :

09-09-2023

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

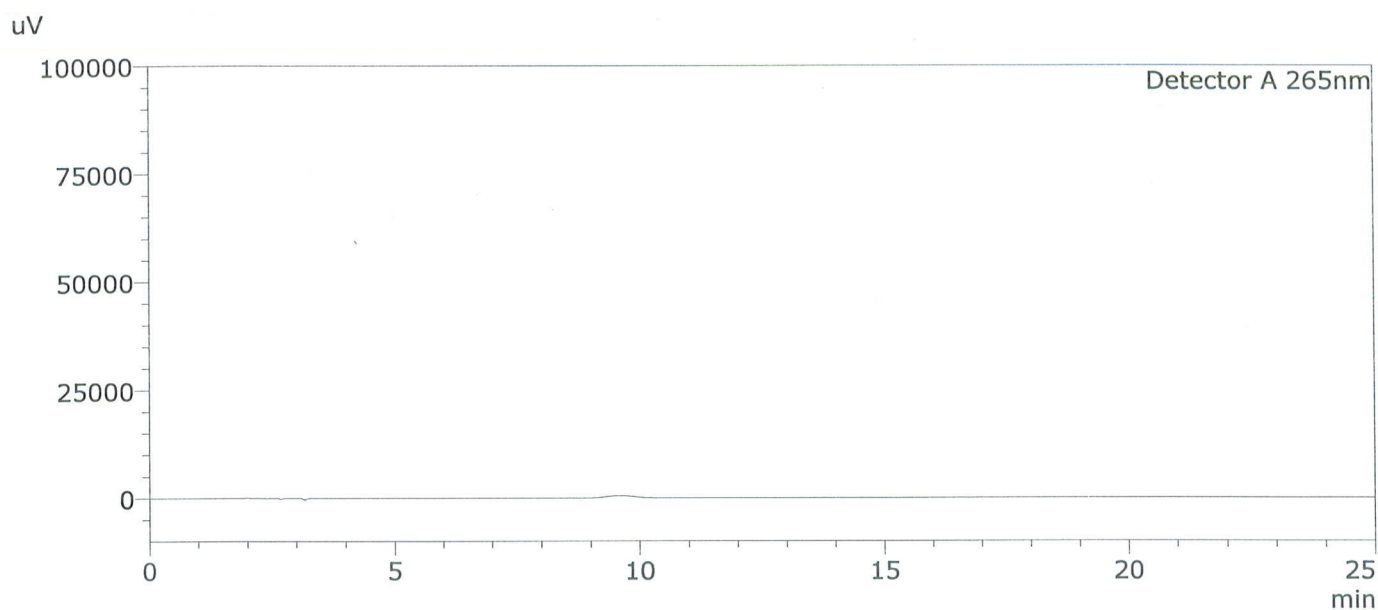
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-22.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 22:44:26
 Date Processed : 09-09-2023 10:29:41

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

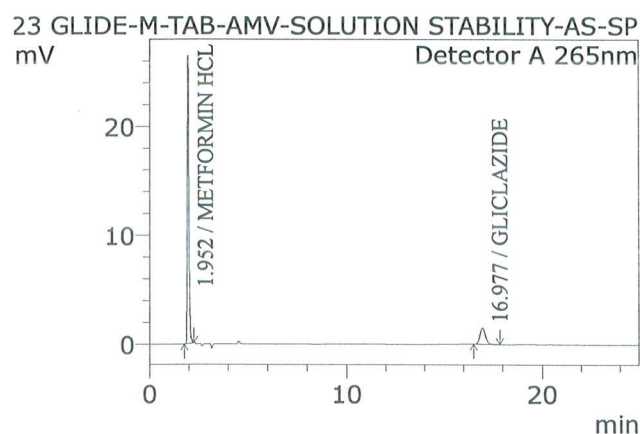
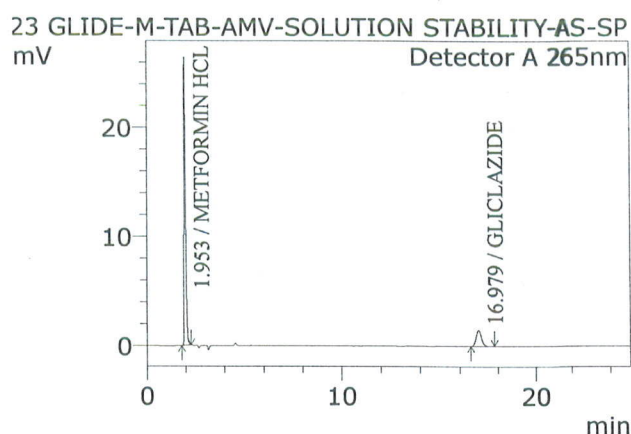
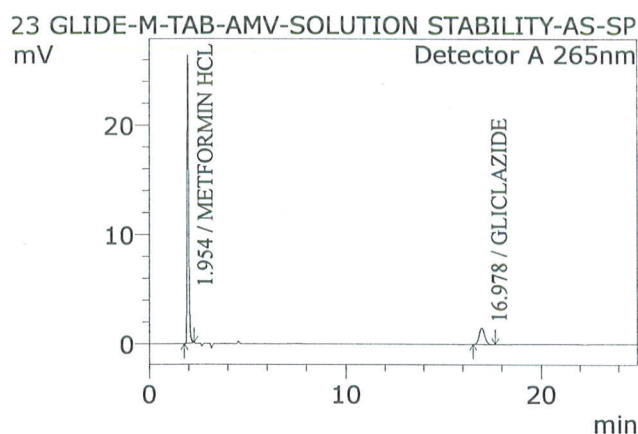
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : GLICLAZIDE+METFOR-10%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-23.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-5
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 23:09:58
 Date Processed : 09-09-2023 12:46:11

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	AS-SPL-23.lcd	GLICLAZIDE+METFOR-10%-AS-SPL-1	1.95	150259	2363	1.55
5	AS-SPL-24.lcd	GLICLAZIDE+METFOR-10%-AS-SPL-2	1.95	150420	2347	1.54
5	AS-SPL-25.lcd	GLICLAZIDE+METFOR-10%-AS-SPL-3	1.95	150178	2329	1.54
	Average		1.95	150286	2346	1.54
	%RSD		0.041	0.082	0.733	0.212

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	AS-SPL-23.lcd	GLICLAZIDE+METFOR-10%-AS-SPL-1	16.98	28820	17984	1.12
5	AS-SPL-24.lcd	GLICLAZIDE+METFOR-10%-AS-SPL-2	16.98	27984	18345	1.13
5	AS-SPL-25.lcd	GLICLAZIDE+METFOR-10%-AS-SPL-3	16.98	28377	17988	1.14
	Average		16.98	28394	18106	1.13
	%RSD		0.009	1.473	1.144	0.564

Analysed By


09/09/23

Checked By


09/09/23



GENERIC HEALTHCARE PVT. LTD.

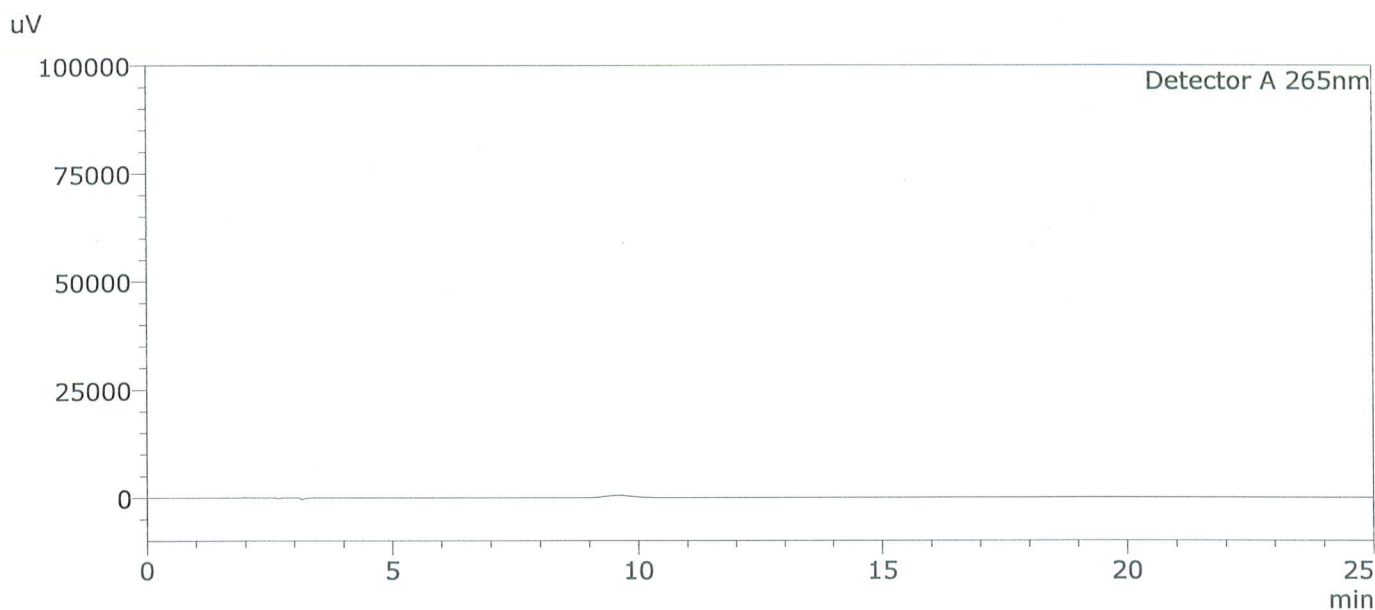
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-28.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 01:17:41
 Date Processed : 09-09-2023 10:29:43

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



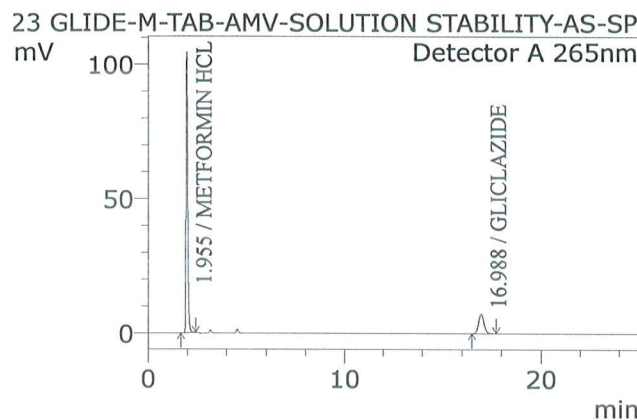
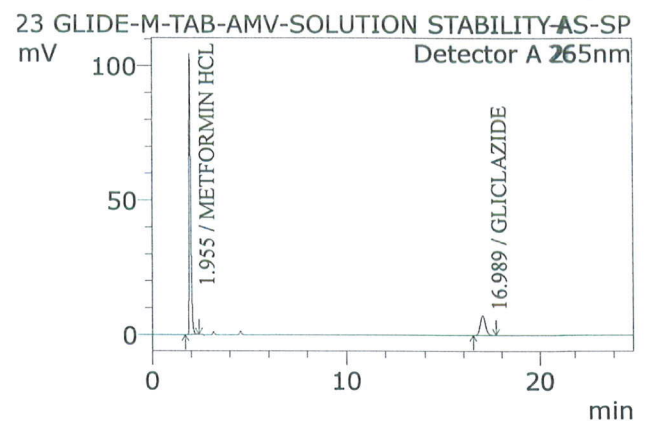
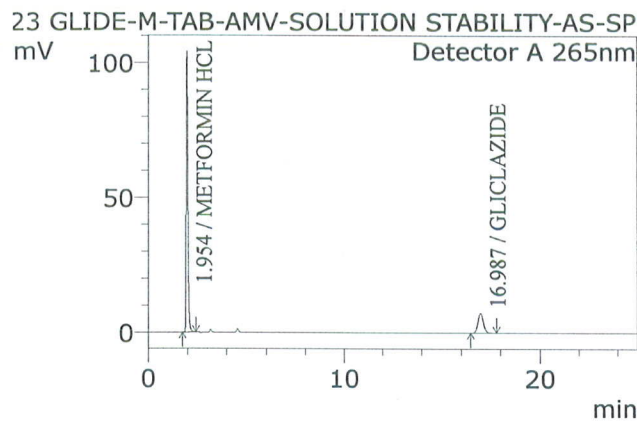
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : GLICLAZIDE+METFOR-50%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-29.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-6
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 01:43:14
 Date Processed : 09-09-2023 10:29:43
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	AS-SPL-29.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-1	1.95	624472	2251	1.51
6	AS-SPL-30.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-2	1.95	624951	2210	1.51
6	AS-SPL-31.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-3	1.95	625095	2210	1.51
	Average		1.95	624839	2224	1.51
	%RSD		0.018	0.052	1.061	0.121

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	AS-SPL-29.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-1	16.99	140270	18066	1.11
6	AS-SPL-30.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-2	16.99	139776	18059	1.11
6	AS-SPL-31.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-3	16.99	139795	18024	1.11
	Average		16.99	139947	18050	1.11
	%RSD		0.006	0.200	0.124	0.109

Analysed By


09/09/23

Checked By


09/09/23



GENERIC HEALTHCARE PVT. LTD.

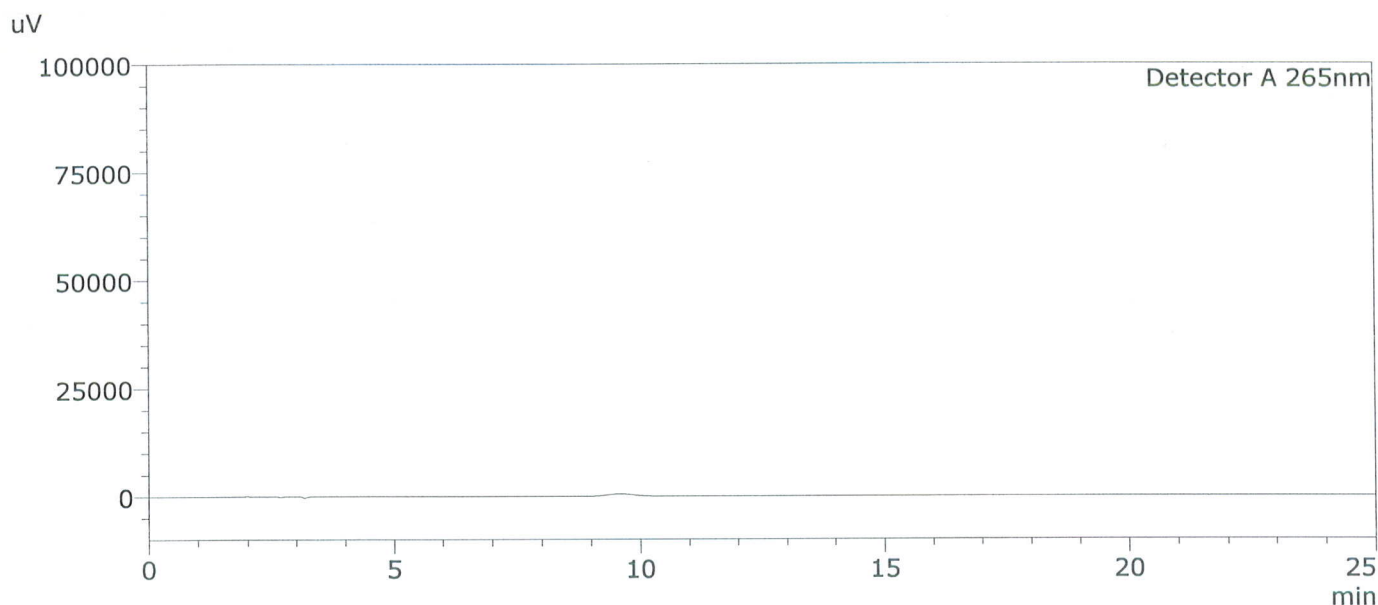
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : AS-BLANK
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 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 03:50:56
 Date Processed : 09-09-2023 10:29:44

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



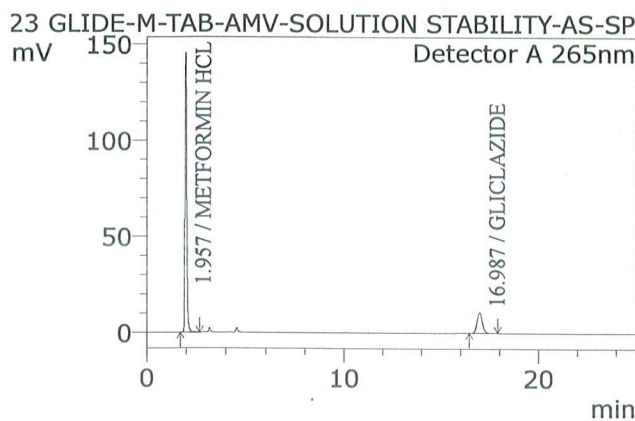
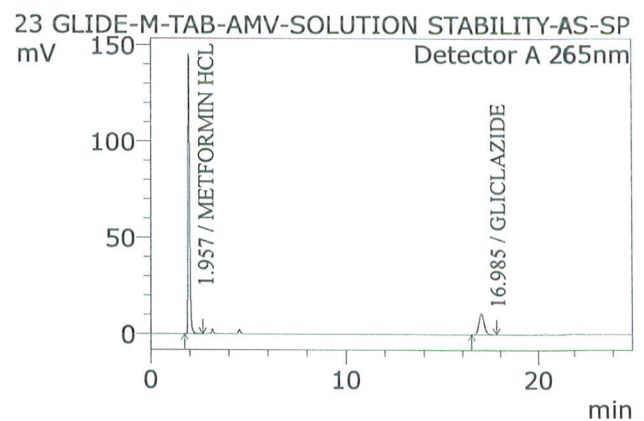
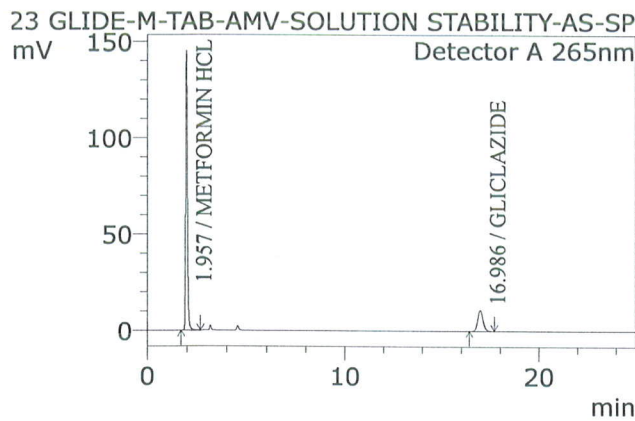
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : GLICLAZIDE+METFOR-75%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-35.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-7
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 04:16:29
 Date Processed : 09-09-2023 10:29:44
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
7	AS-SPL-35.lcd	GLICLAZIDE+METFOR-75%-AS-SPL-1	1.96	900851	2102	1.48
7	AS-SPL-36.lcd	GLICLAZIDE+METFOR-75%-AS-SPL-2	1.96	901399	2108	1.48
7	AS-SPL-37.lcd	GLICLAZIDE+METFOR-75%-AS-SPL-3	1.96	901358	2111	1.48
	Average		1.96	901203	2107	1.48
	%RSD		0.013	0.034	0.216	0.179

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
7	AS-SPL-35.lcd	GLICLAZIDE+METFOR-75%-AS-SPL-1	16.99	208592	17974	1.11
7	AS-SPL-36.lcd	GLICLAZIDE+METFOR-75%-AS-SPL-2	16.99	211575	17874	1.12
7	AS-SPL-37.lcd	GLICLAZIDE+METFOR-75%-AS-SPL-3	16.99	208111	17920	1.11
	Average		16.99	209426	17923	1.11
	%RSD		0.004	0.896	0.277	0.771

Analysed By


09/09/23

Checked By


09/09/23



GENERIC HEALTHCARE PVT. LTD.

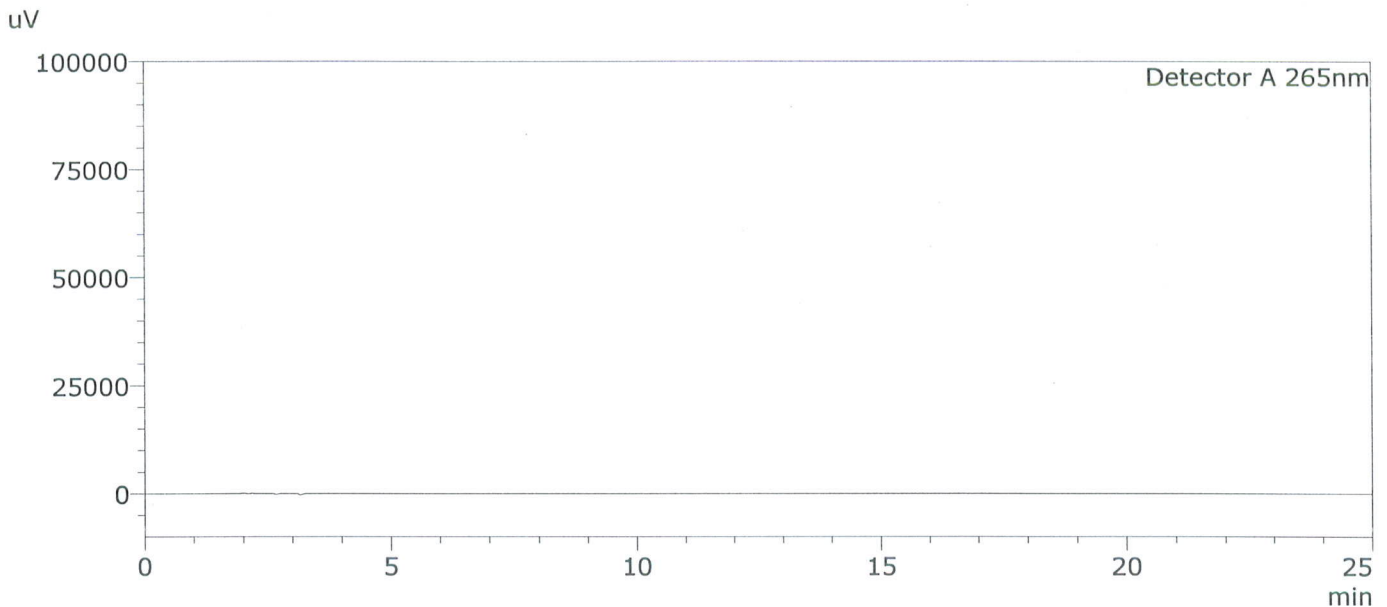
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-38.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 05:33:07
 Date Processed : 09-09-2023 10:29:45

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

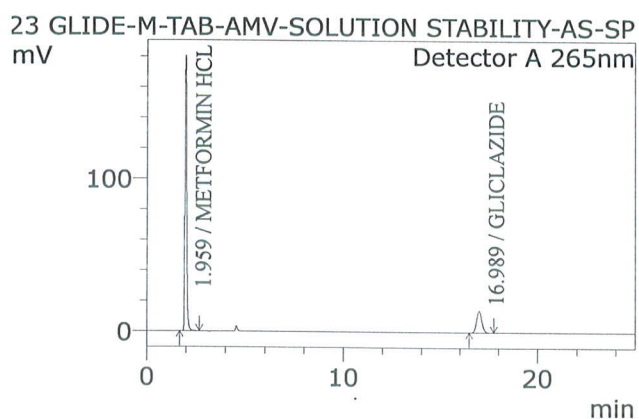
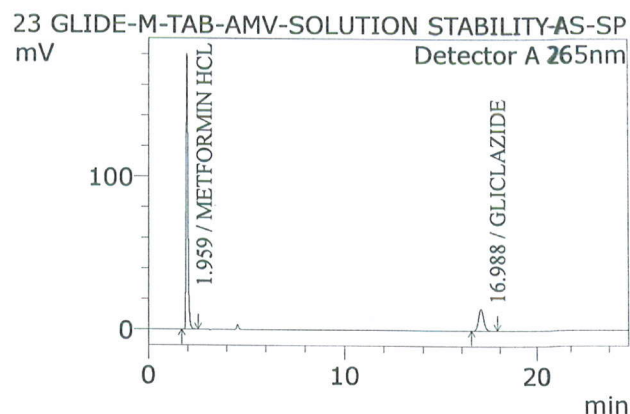
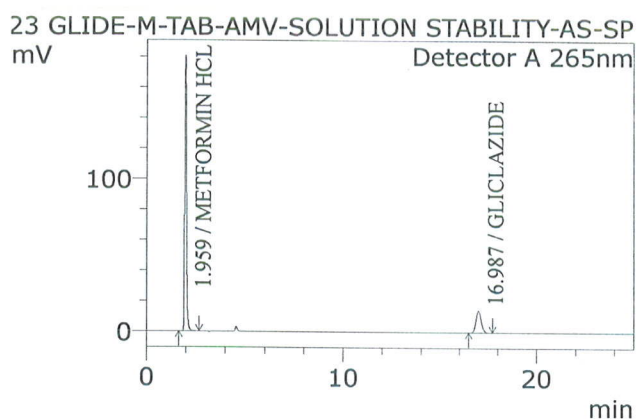
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : GLICLAZIDE+METFOR-100%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-39.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-8
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 05:58:39
 Date Processed : 09-09-2023 10:29:46

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
8	AS-SPL-39.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-1	1.96	1142391	2073	1.44
8	AS-SPL-40.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-2	1.96	1138936	2068	1.44
8	AS-SPL-41.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-3	1.96	1142602	2069	1.44
	Average		1.96	1141309	2070	1.44
	%RSD		0.007	0.180	0.115	0.051

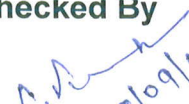
ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
8	AS-SPL-39.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-1	16.99	274938	17918	1.11
8	AS-SPL-40.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-2	16.99	274680	17891	1.11
8	AS-SPL-41.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-3	16.99	273948	17910	1.11
	Average		16.99	274522	17907	1.11
	%RSD		0.006	0.187	0.077	0.129

Analysed By


09/09/23

Checked By


09/09/23



GENERIC HEALTHCARE PVT. LTD.

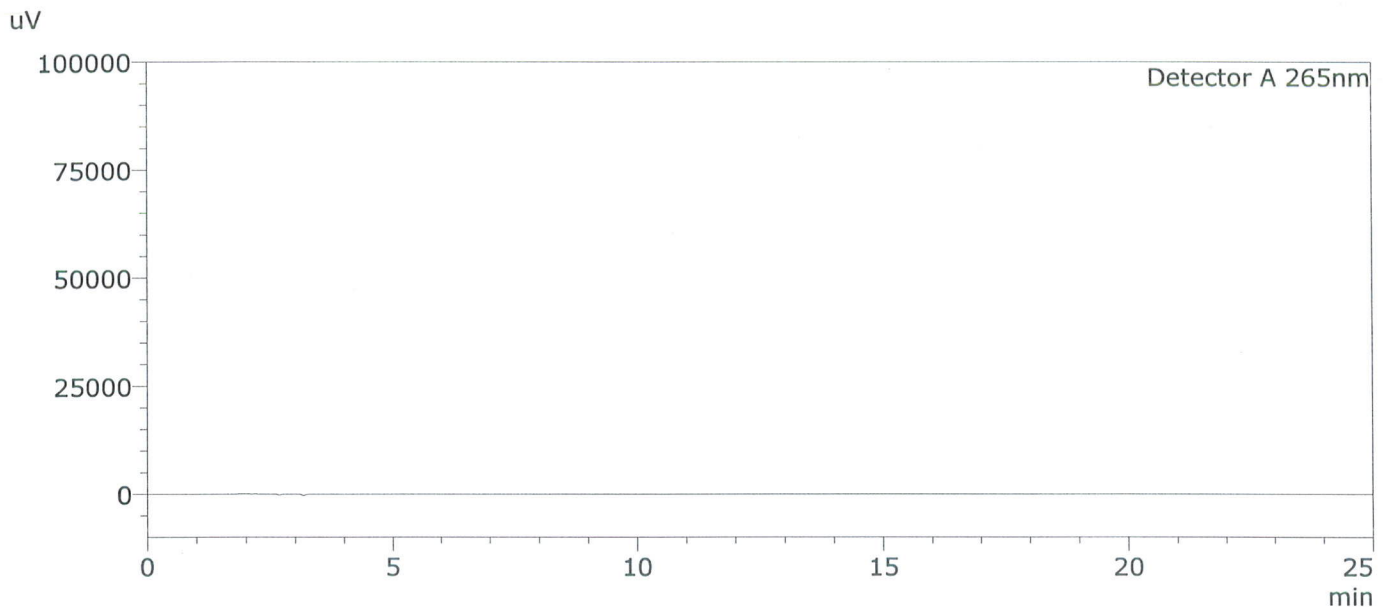
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-42.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 07:15:17
 Date Processed : 09-09-2023 10:29:46

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



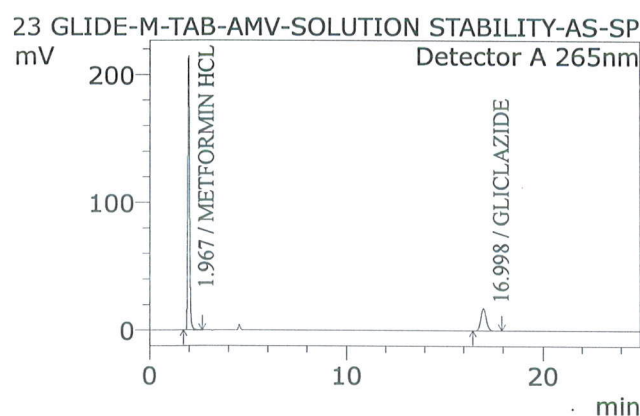
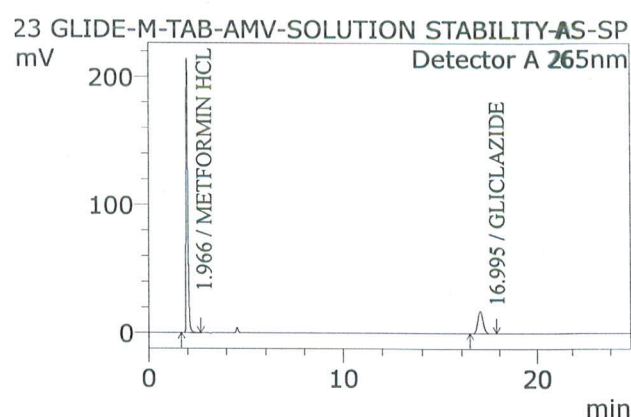
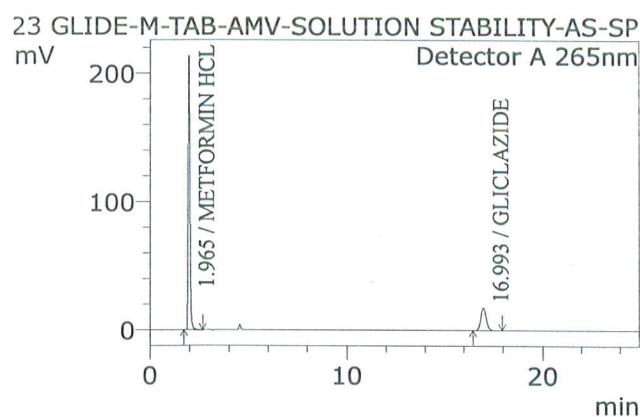
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : GLICLAZIDE+METFOR-125%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-43.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-9
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 07:40:51
 Date Processed : 09-09-2023 10:29:47
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	AS-SPL-43.lcd	GLICLAZIDE+METFOR-125%-AS-SPL-1	1.97	1384708	2002	1.41
9	AS-SPL-44.lcd	GLICLAZIDE+METFOR-125%-AS-SPL-2	1.97	1386194	2015	1.41
9	AS-SPL-45.lcd	GLICLAZIDE+METFOR-125%-AS-SPL-3	1.97	1386613	2024	1.41
	Average		1.97	1385838	2013	1.41
	%RSD		0.059	0.072	0.538	0.124

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	AS-SPL-43.lcd	GLICLAZIDE+METFOR-125%-AS-SPL-1	16.99	340537	17820	1.12
9	AS-SPL-44.lcd	GLICLAZIDE+METFOR-125%-AS-SPL-2	16.99	340040	17743	1.12
9	AS-SPL-45.lcd	GLICLAZIDE+METFOR-125%-AS-SPL-3	17.00	338918	17692	1.12
	Average		17.00	339831	17751	1.12
	%RSD		0.013	0.244	0.362	0.234

Analysed By


09/09/23

Checked By


09/09/23



GENERIC HEALTHCARE PVT. LTD.

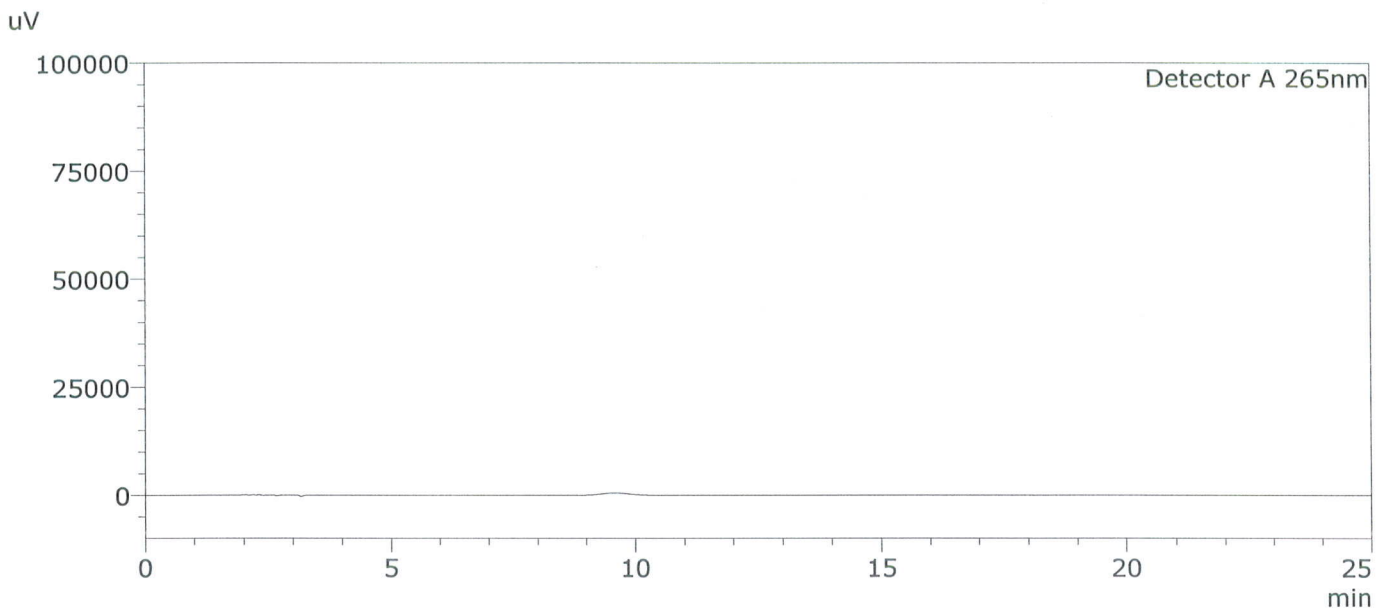
Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-48.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-4
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 09:49:06
 Date Processed : 09-09-2023 10:29:48

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

09/09/23

Analysed By

09/09/23

Checked By



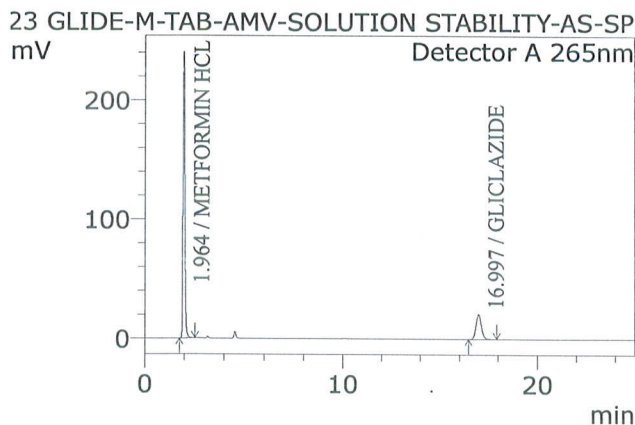
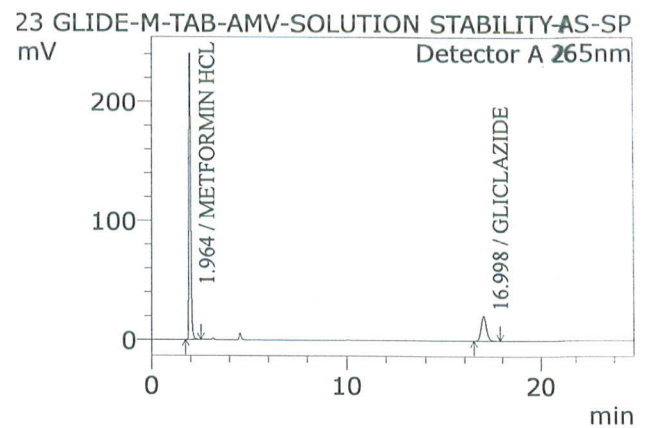
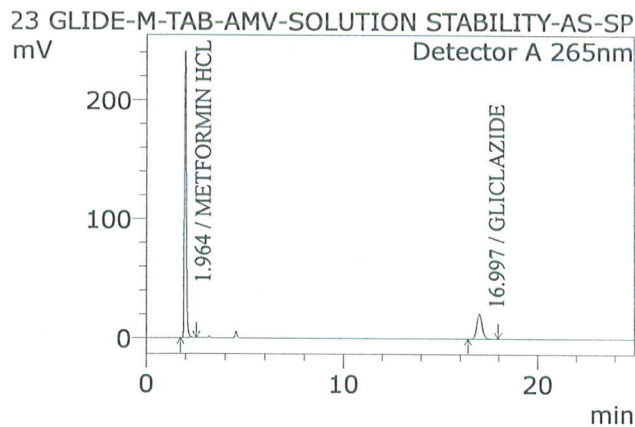
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : LINEARITY
 Sample ID : GLICLAZIDE+METFOR-150%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-49.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-10
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 10:14:38
 Date Processed : 09-09-2023 10:29:48
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
10	AS-SPL-49.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-1	1.96	1588639	1935	1.37
10	AS-SPL-50.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-2	1.96	1588618	1935	1.38
10	AS-SPL-51.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-3	1.96	1589870	1926	1.38
	Average		1.96	1589042	1932	1.37
	%RSD		0.017	0.045	0.264	0.112

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
10	AS-SPL-49.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-1	17.00	403013	17797	1.11
10	AS-SPL-50.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-2	17.00	400731	17860	1.11
10	AS-SPL-51.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-3	17.00	400638	17862	1.11
	Average		17.00	401461	17839	1.11
	%RSD		0.004	0.335	0.207	0.138

Analysed By

①
09/09/23

Checked By

S.A.
09/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	850.24	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.48	1	ml to --->	1	ml to --->	1	ml to --->	1

No.of injections	Retention time	Area	Theoretical plate	Tailing factor
1	1.925	1123345	2122	1.424
2	1.923	1121012	2125	1.429
3	1.922	1123667	2115	1.43
4	1.925	1124404	2078	1.423
5	1.928	1122907	2100	1.431
Average	1.925	1123067	2108	1.427
RSD %	0.120	0.113	Not applicable	Not applicable

ASSAY OF GLICLAZIDE

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

Standard dilution :	60.05	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.1	1	ml to --->	1	ml to --->	1	ml to --->	1

No.of injections	Retention time	Area	Theoretical plate	Tailing factor
1	15.257	290502	17651	1.086
2	15.197	291534	17585	1.099
3	15.207	290256	17553	1.111
4	15.349	290386	17495	1.112
5	15.391	289976	17537	1.112
Average	15.280	290531	17564	1.104
RSD %	0.565	0.204	Not applicable	Not applicable

Results :

System suitability Parameters	Metformin HCl	Gliclazide
1) % RSD	0.113	0.204
2) Theoretical plate	2108	17564
3) Tailing factor	1.427	1.104

Acceptance criteria:

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

Analysed by :

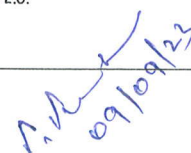
E.MEENA

Date :

09-09-2023

Checked by :

Date :





GENERIC HEALTHCARE PVT. LTD.

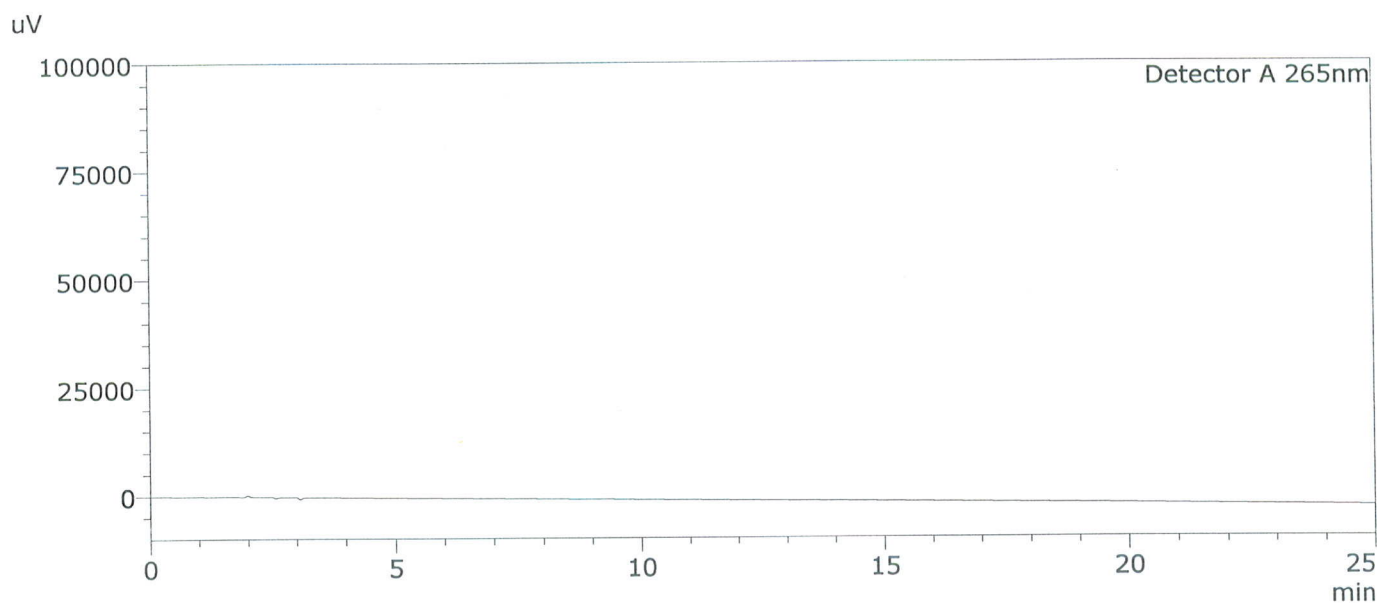
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-1
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 13:48:10
 Date Processed : 09-09-2023 10:29:35

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



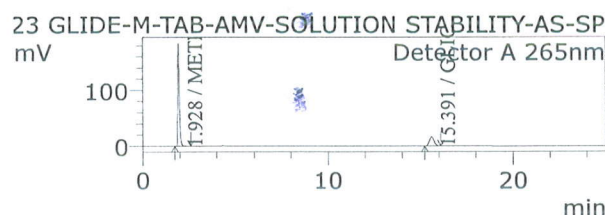
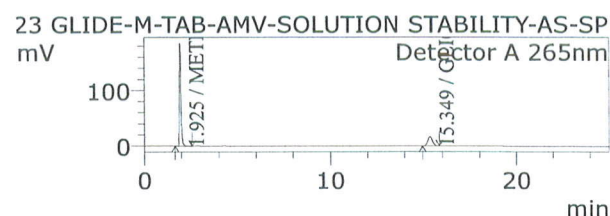
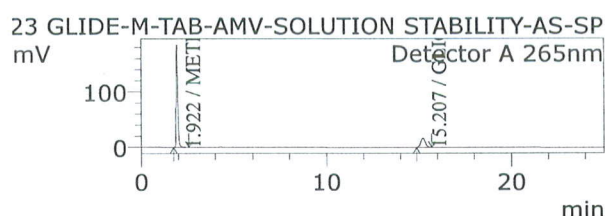
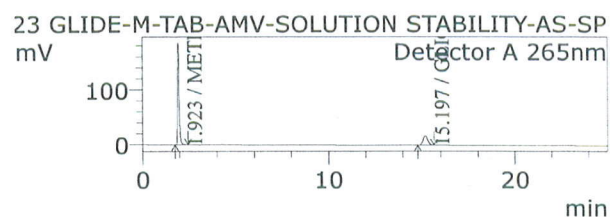
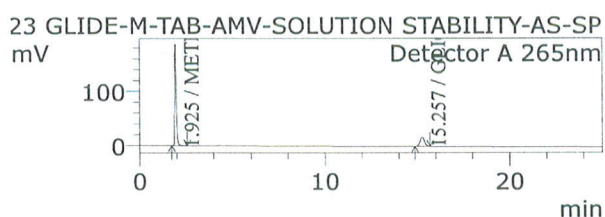
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-2
 Injection Volume : 20 uL
 Date Acquired : 07-09-2023 14:13:42
 Date Processed : 09-09-2023 16:19:32
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.93	1123345	2122	1.42
2	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.92	1121012	2125	1.43
2	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.92	1123667	2115	1.43
2	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.93	1124404	2078	1.42
2	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.93	1122907	2100	1.43
	Average		1.92	1123067	2108	1.43
	%RSD		0.108	0.113	0.918	0.265

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	15.26	290502	17651	1.09
2	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	15.20	291534	17585	1.10
2	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	15.21	290256	17553	1.11
2	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	15.35	290386	17495	1.11
2	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	15.39	289976	17537	1.11
	Average		15.28	290531	17564	1.10
	%RSD		0.565	0.204	0.333	1.043

Analysed By


09/09/23

Checked By


09/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name :	GLIDE-M 60/500 & GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G1722093 /G17230801	Mfg.Date :	Not applicable
Parameter :	SPECIFICITY	Exp.Date :	Not applicable

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL AND GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
				WS No.:	ST/WS/22/040	% Purity (aib)	100.0
Metformin Hcl Std.Dil:	850.26	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.52	1	ml to --->	1	ml to --->	1	ml to --->	1
Gliclazide Std.Dil:	60.08	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.16	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution (60/850) :	1360.32	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1700.4	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution (60/500) :	970.31	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1000.3195	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	Metformin HCl	1.911	0.998
		Gliclazide	16.99	1.000
3	Metformin WS	Metformin HCl	1.922	0.998
4	Gliclazide WS	Gliclazide	16.947	1.000
5	Blank	Blank peaks	Refer chromatogram	Not applicable
6	Plain placebo for Glide-M 60/500	Placebo peaks	Refer chromatogram	Not applicable
7	Plain placebo for Glide-M 60/850	Placebo peaks	Refer chromatogram	Not applicable
8	Plain placebo with Gliclazide WS	Gliclazide	16.948	1.000
9	Plain placebo with Metformin HCl WS	Metformin HCl	1.928	0.997
10	Plain placebo with Metformin HCl WS and Gliclazide WS	Metformin HCl	1.921	0.998
		Gliclazide	16.947	1.000
11	Blank	Blank peaks	Refer chromatogram	Not applicable
12	Test preparation for Glide-M 60/500 B.No: G1722093	Metformin HCl	1.913	0.997
		Gliclazide	16.950	1.000
13	Blank	Blank peaks	Refer chromatogram	Not applicable
14	Test preparation for Glide-M 60/850 B.No: G17230801	Metformin HCl	1.917	0.997
		Gliclazide	16.937	1.000

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 and impurity peaks.
- 2) Peak purity should not be less than 0.995 according to Lab solution software.

Analysed by :

E.MEENA

Date :

13-09-2023

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

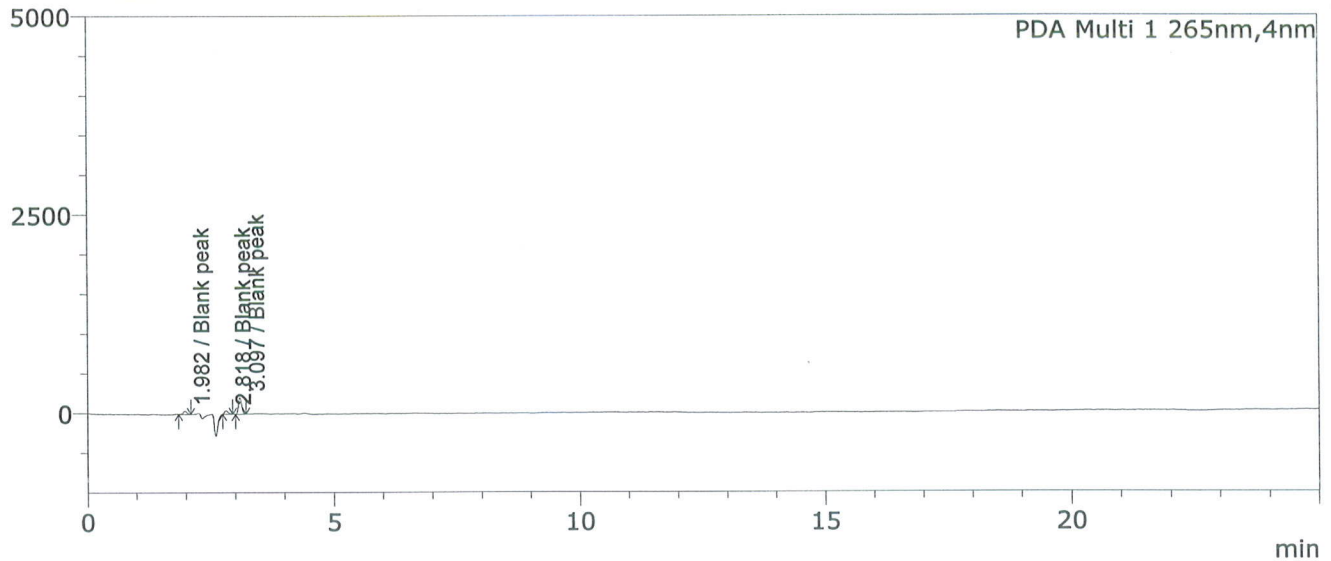
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Sample Name : SPECIFICITY
 Sample ID : AS-BLANK
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-37.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-29
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 06:55:46
 Date Processed : 13-09-2023 10:05:07

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peak	1.98	218	15.63	2460	0.963	--	--
2	Blank peak	2.82	228	16.38	5403	1.435	5.341	--
3	Blank peak	3.10	.947	67.99	8031	1.161	1.914	--
Total			1393	100.00				

13/09/23

Analysed By

13/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

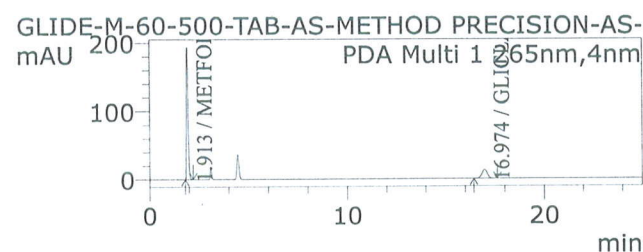
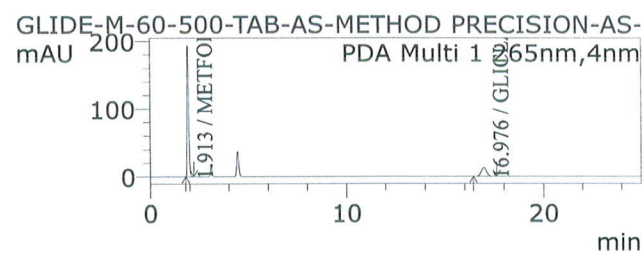
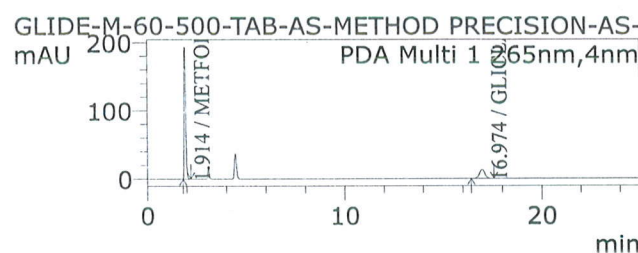
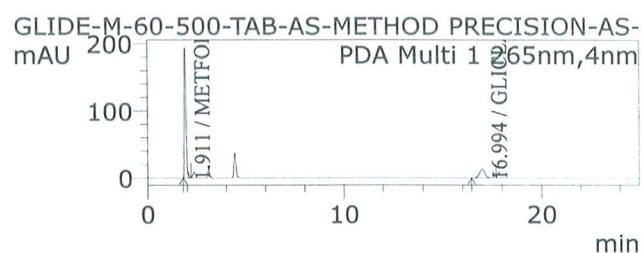
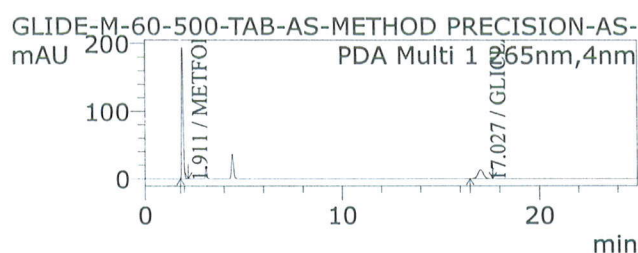
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-38.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-30
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 07:21:20
 Date Processed : 13-09-2023 10:44:43

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
30	AS-SPL-38.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.91	1127237	1979	1.27
30	AS-SPL-39.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.91	1127763	1983	1.26
30	AS-SPL-40.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.91	1127257	2024	1.26
30	AS-SPL-41.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.91	1126751	2018	1.26
30	AS-SPL-42.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.91	1127769	2010	1.26
	Average		1.91	1127356	2003	1.26
	%RSD		0.078	0.038	1.027	0.231

ID#2 Compound Name: GLICLAZIDE

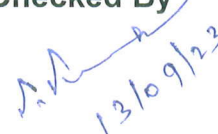
Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
30	AS-SPL-38.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	17.03	242821	18671	1.01
30	AS-SPL-39.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	16.99	242418	18690	1.01
30	AS-SPL-40.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	16.97	241678	18688	1.01
30	AS-SPL-41.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	16.98	241647	18637	1.01
30	AS-SPL-42.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	16.97	240938	18669	1.01
	Average		16.99	241900	18671	1.01
	%RSD		0.133	0.303	0.115	0.072

Analysed By



13/09/23

Checked By



13/09/23


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

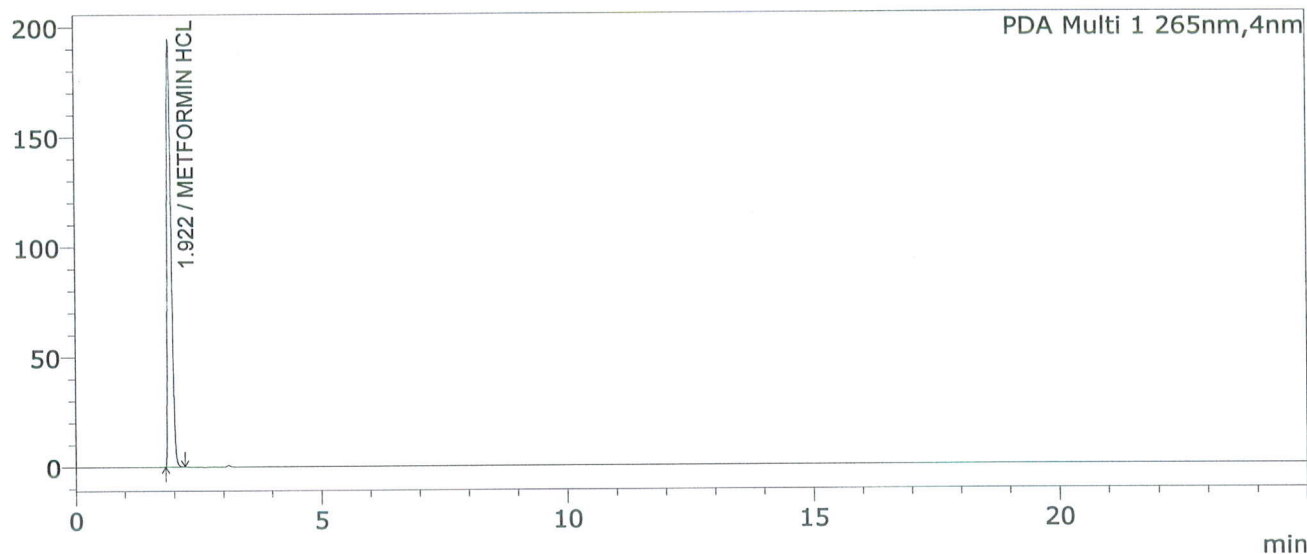
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Sample Name : SPECIFICITY
 Sample ID : AS-METFORMIN API STD
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-43.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-31
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 09:29:18
 Date Processed : 13-09-2023 10:14:09

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.92	1129744	100.00	2015	1.261	--	--
Total			1129744	100.00				

13/09/23

Analysed By

13/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

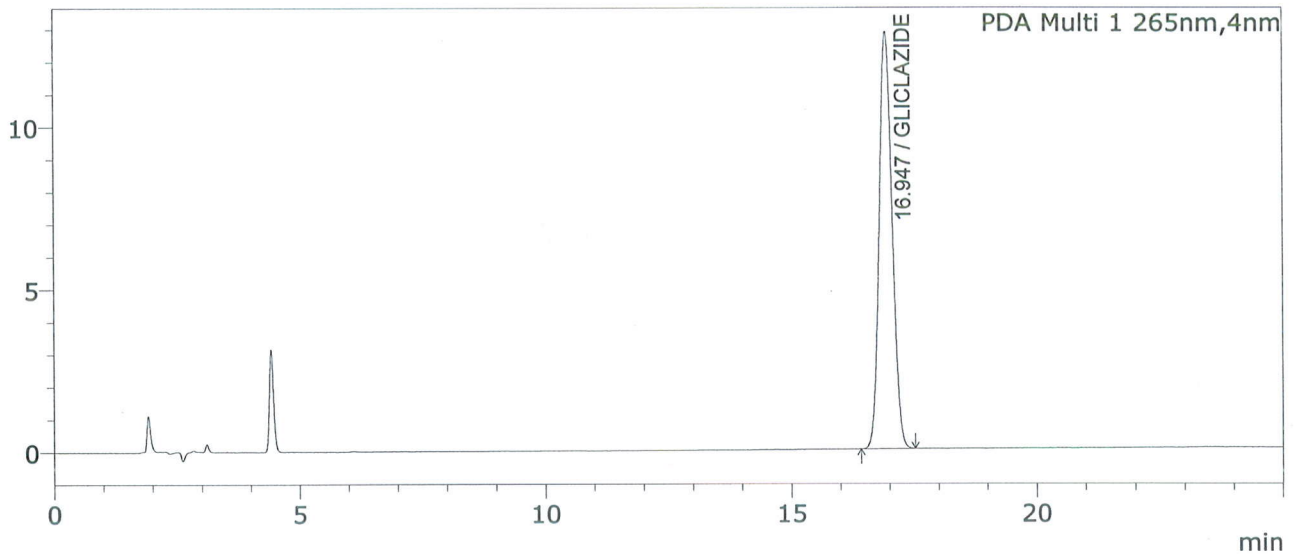
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Sample Name : SPECIFICITY
 Sample ID : AS-GLICLAZIDE API STD
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-44.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-32
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 09:54:50
 Date Processed : 13-09-2023 10:16:26

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	16.95	236471	100.00	18717	1.008	--	--
Total			236471	100.00				

13/09/23

Analysed By

13/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

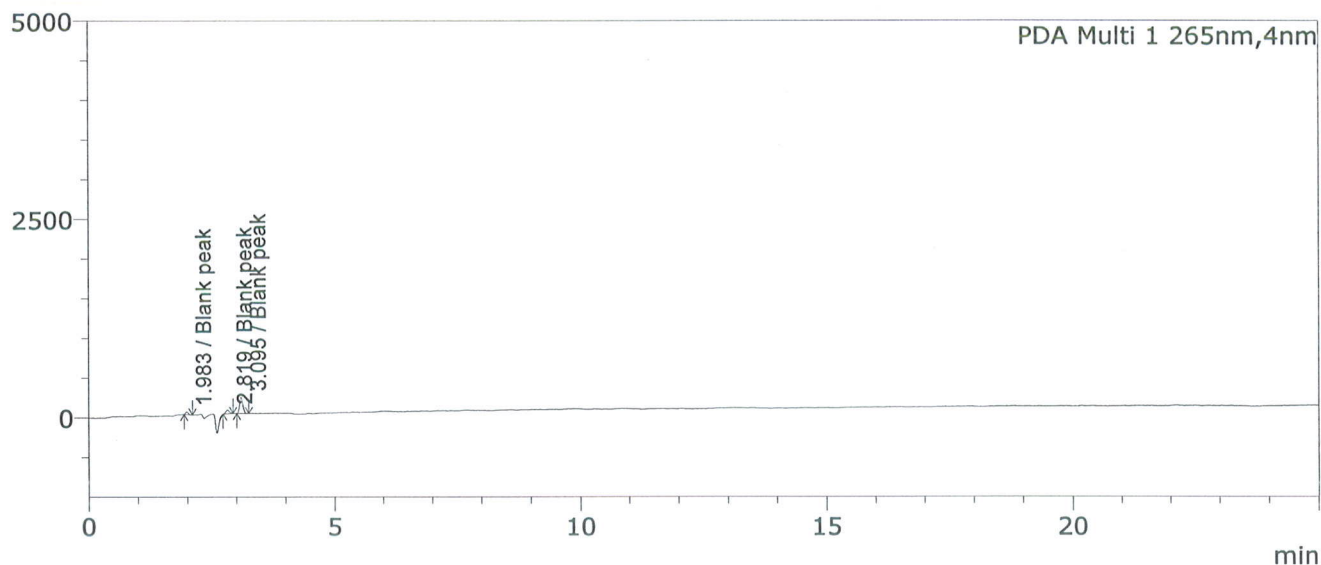
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Sample Name : SPECIFICITY
 Sample ID : AS-BLANK
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-45.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-29
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 10:20:25
 Date Processed : 13-09-2023 10:24:00

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peak	1.98	134	10.11	4327	1.376	--	--
2	Blank peak	2.82	244	18.35	5036	1.158	5.984	--
3	Blank peak	3.09	951	71.54	7854	1.229	1.849	--
Total			1330	100.00				

④
13/09/23

Analysed By

S. A
13/09/23

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

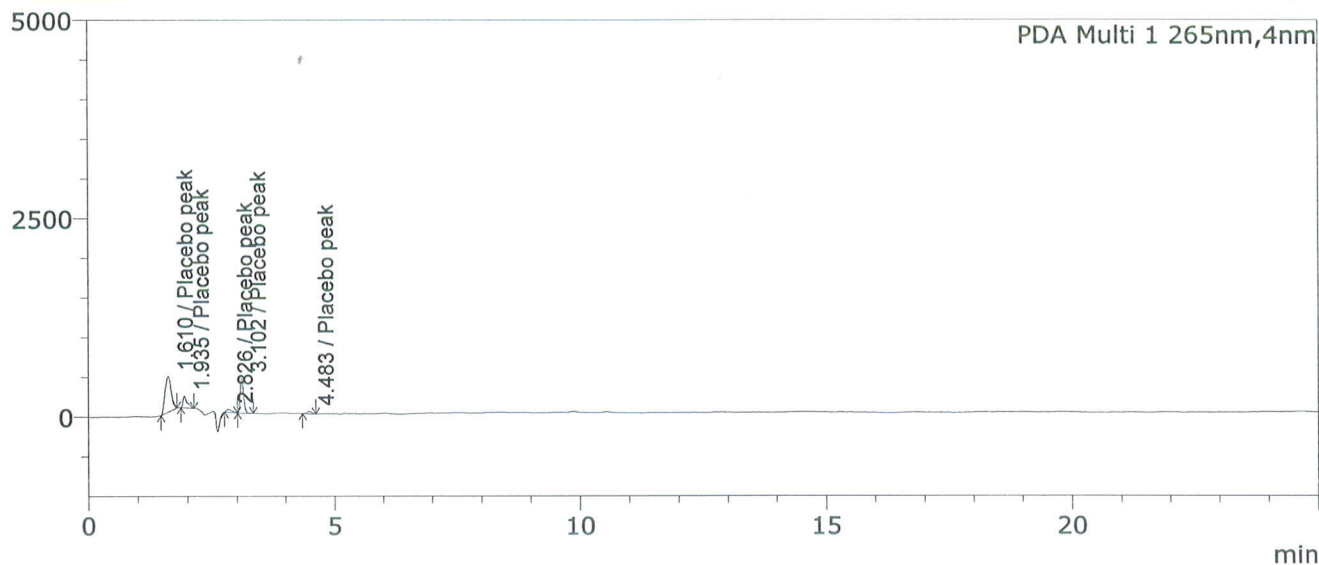
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : AS-PLAIN PLACEBO-60-500 MG
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-46.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-33
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 10:46:04
 Date Processed : 13-09-2023 10:32:24

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Placebo peak	1.61	3897	52.69	700	1.066	--	--
2	Placebo peak	1.94	902	12.19	2180	1.914	1.591	--
3	Placebo peak	2.83	268	3.62	2516	1.809	4.557	--
4	Placebo peak	3.10	2117	28.63	7438	1.276	1.490	--
5	Placebo peak	4.48	212	2.87	7356	1.016	7.829	--
Total			7396	100.00				

Analysed By

Checked By


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Analysis Report

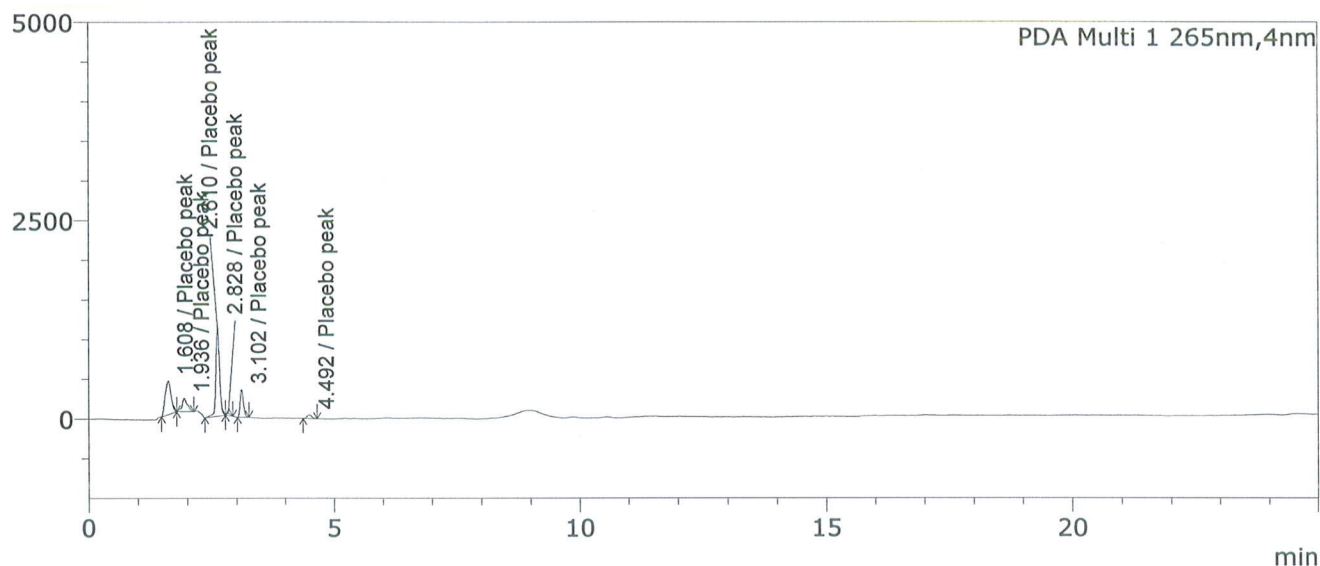
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Sample Name : SPECIFICITY
 Sample ID : AS-PLAIN PLACEBO-60-850 MG
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-47.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-34
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 11:11:38
 Date Processed : 13-09-2023 10:36:02

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Placebo peak	1.61	3487	27.50	734	1.063	--	--
2	Placebo peak	1.94	1277	10.08	1424	1.070	1.484	--
3	Placebo peak	2.61	5857	46.20	4527	1.225	3.737	--
4	Placebo peak	2.83	129	1.01	6508	1.333	1.474	--
5	Placebo peak	3.10	1610	12.70	7432	1.242	1.932	--
6	Placebo peak	4.49	318	2.51	8142	1.086	8.102	--
Total			12678	100.00				

Analysed By

Checked By



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Analysis Report

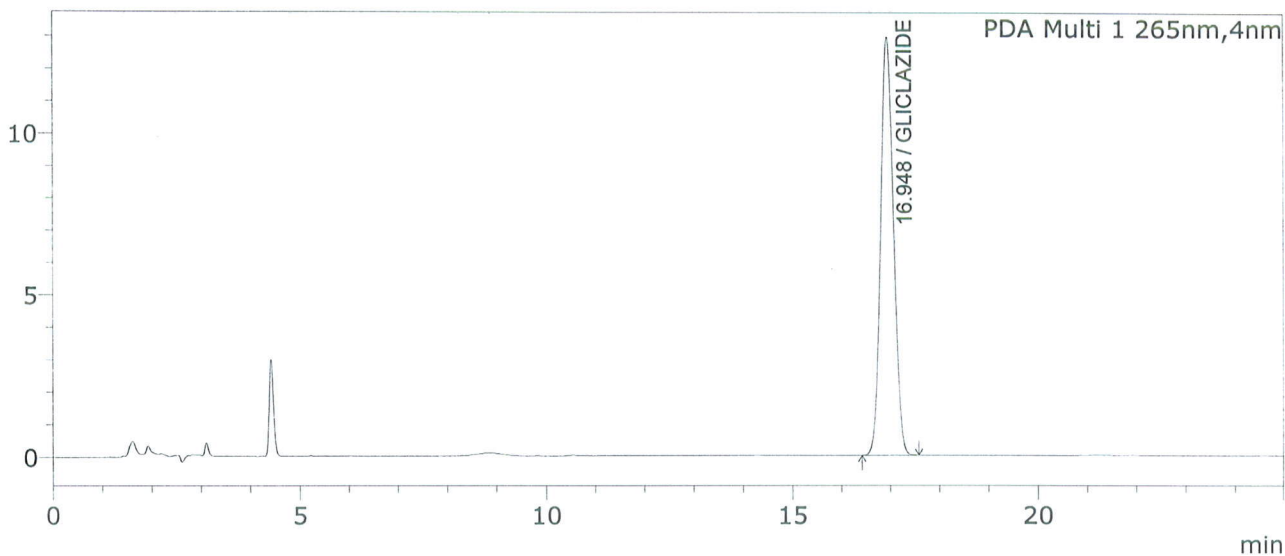
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Sample Name : SPECIFICITY
 Sample ID : AS-PLACEBO+GLICLAZIDE
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-48.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-35
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 11:37:19
 Date Processed : 13-09-2023 10:42:46

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	GLICLAZIDE	16.95	238583	100.00	18715	1.008	--	--
Total			238583	100.00				

Analysed By

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Analysis Report

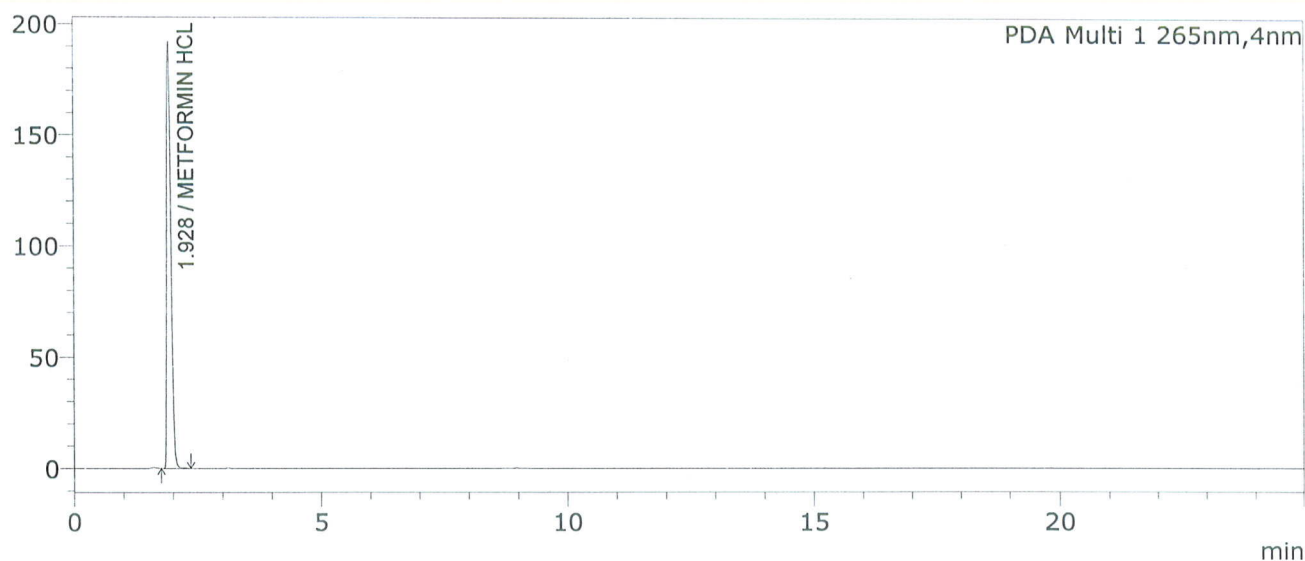
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Sample Name : SPECIFICITY
 Sample ID : AS-PLACEBO-METFORMIN
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-49.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-36
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 12:02:54
 Date Processed : 13-09-2023 10:47:04

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.93	1153949	100.00	1930	1.240	--	--
Total			1153949	100.00				

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Analysis Report

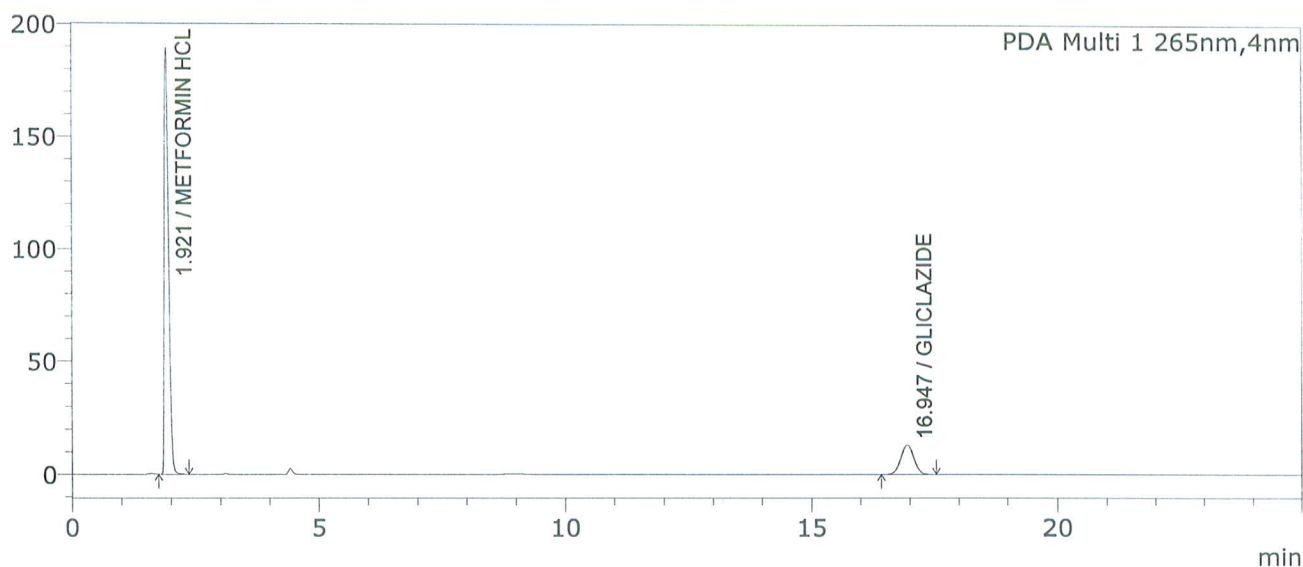
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Sample Name : SPECIFICITY
 Sample ID : AS-PLACEBO+GLICLAZIDE+METFORMIN
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-50.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-37
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 12:28:28
 Date Processed : 13-09-2023 10:48:20

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.92	1133012	82.35	1990	1.252	--	--
2	GLICLAZIDE	16.95	242835	17.65	18716	1.008	45.006	--
Total			1375847	100.00				

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Analysis Report

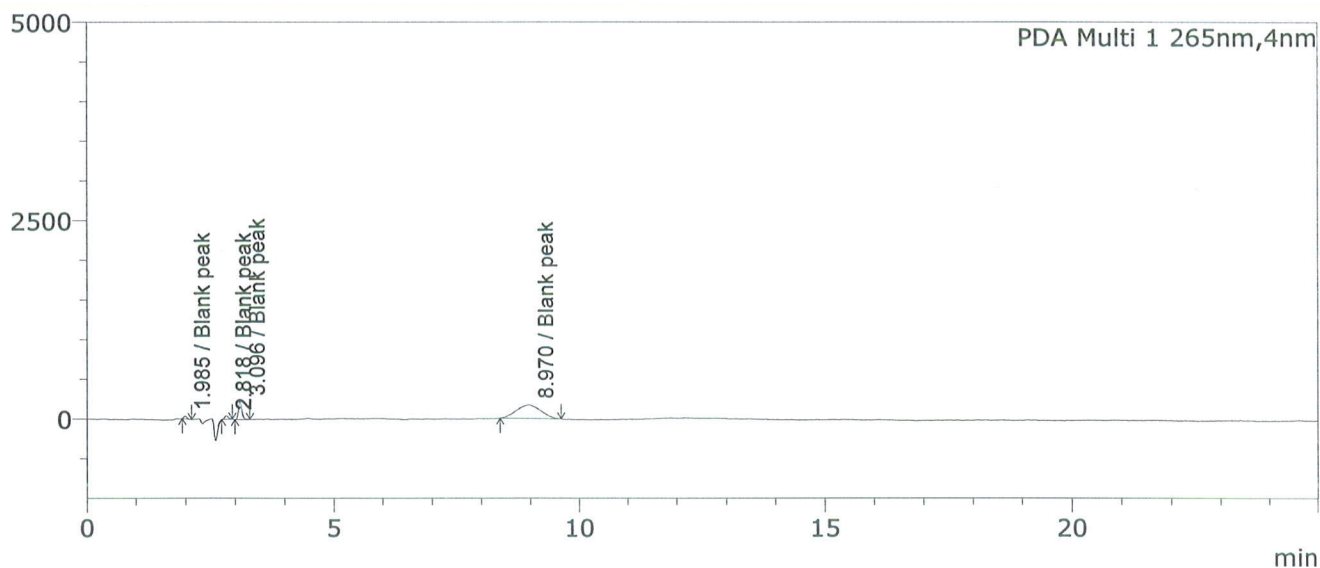
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Sample Name : SPECIFICITY
 Sample ID : AS-BLANK
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-51.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-29
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 12:54:02
 Date Processed : 13-09-2023 11:46:36

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peak	1.99	155	2.11	3470	1.470	--	--
2	Blank peak	2.82	234	3.18	4918	1.183	5.636	--
3	Blank peak	3.10	1052	14.32	7768	1.238	1.844	--
4	Blank peak	8.97	5904	80.39	1429	1.024	10.782	--
Total			7344	100.00				

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Analysis Report

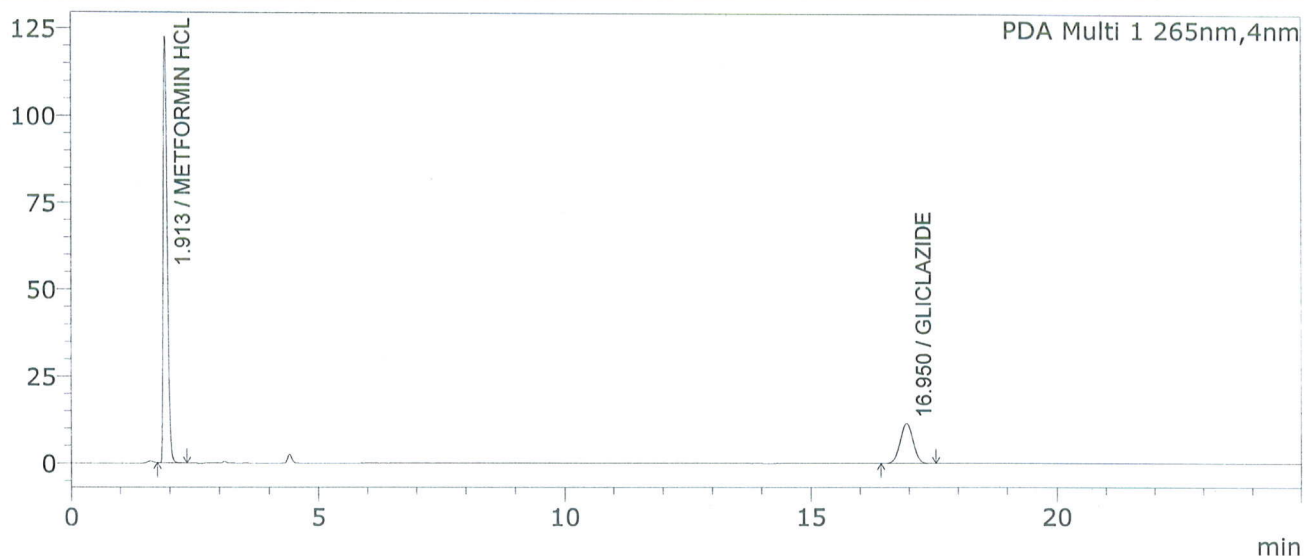
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Sample Name : SPECIFICITY
 Sample ID : GLIDE-M-60-500-TAB-093-AS-SPL
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-52.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-38
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 13:19:42
 Date Processed : 13-09-2023 10:49:15

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	697285	76.59	2106	1.334	--	--
2	GLICLAZIDE	16.95	213121	23.41	18776	1.011	45.461	--
Total			910407	100.00				

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Analysis Report

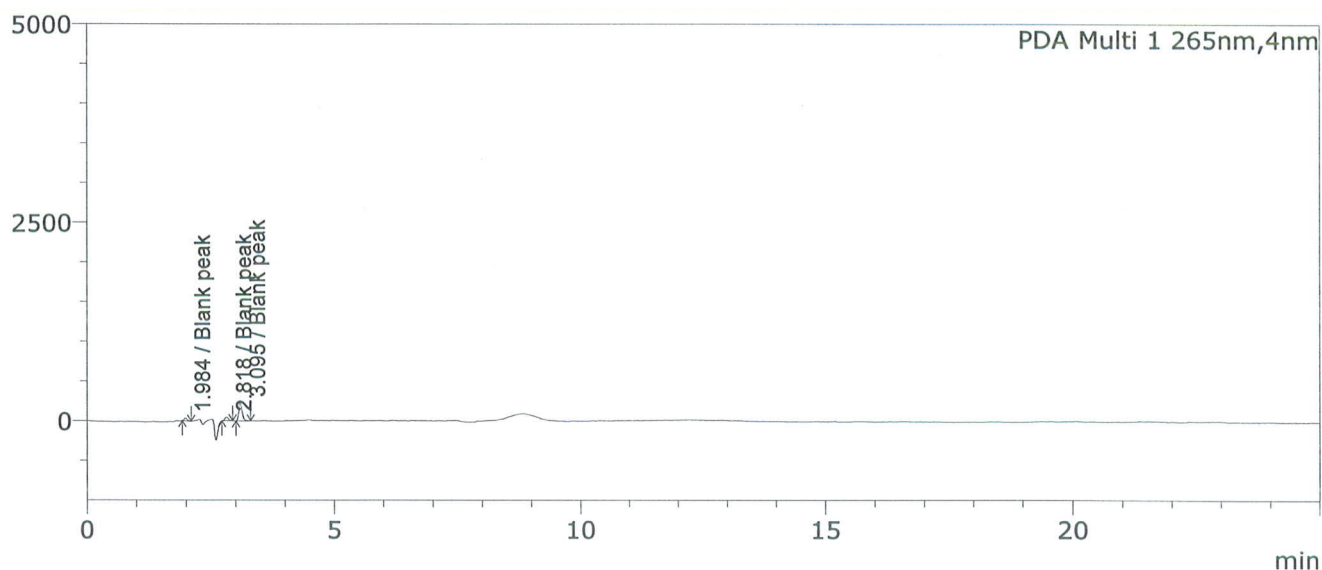
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : AS-BLANK
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-53.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-29
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 13:45:24
 Date Processed : 13-09-2023 11:55:25

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	Blank peak	1.98	150	10.37	3407	1.416	--	--
2	Blank peak	2.82	227	15.67	5204	1.232	5.709	--
3	Blank peak	3.10	1070	73.96	7641	1.255	1.863	--
Total			1446	100.00				

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Analysis Report

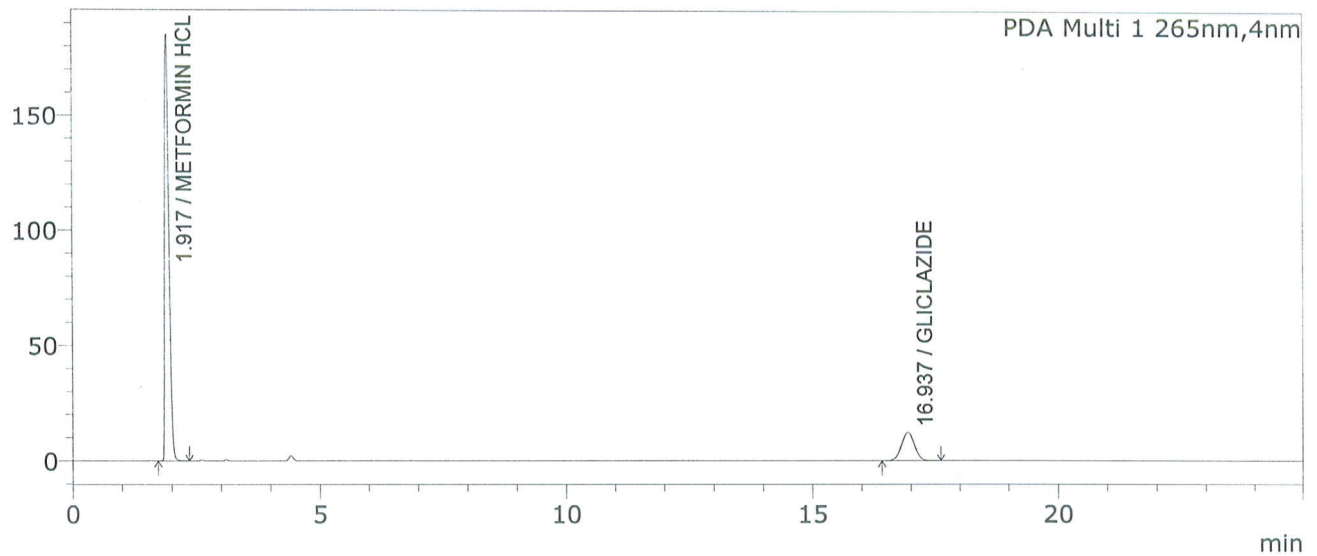
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Sample Name : SPECIFICITY
 Sample ID : GLIDE-M-60-850-TAB-0801-AS-SPL
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-54.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-39
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 14:10:58
 Date Processed : 13-09-2023 10:50:05

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.92	1101324	82.92	1952	1.258	--	--
2	GLICLAZIDE	16.94	226822	17.08	18753	1.011	44.955	--
Total			1328147	100.00				

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Analysis Report

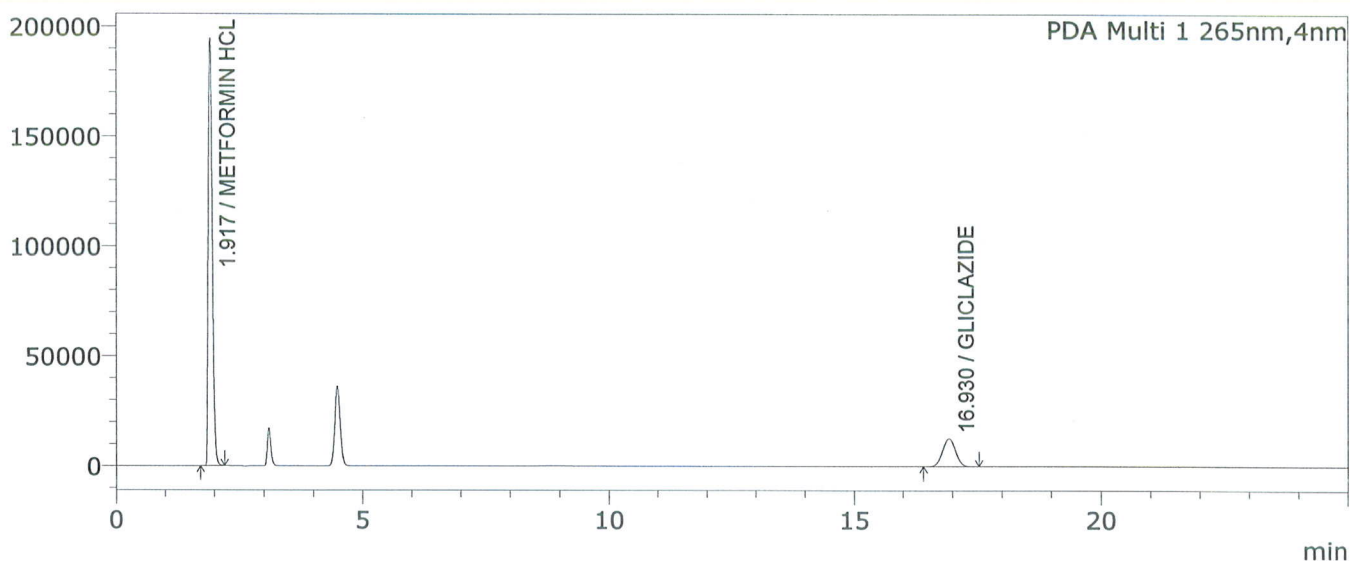
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Sample Name : SPECIFICITY
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-55.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-30
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 14:36:32
 Date Processed : 13-09-2023 09:52:34

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.92	1129379	82.87	2047	1.267	--	--
2	GLICLAZIDE	16.93	233493	17.13	18790	1.010	45.253	--
Total			1362872	100.00				

Analysed By

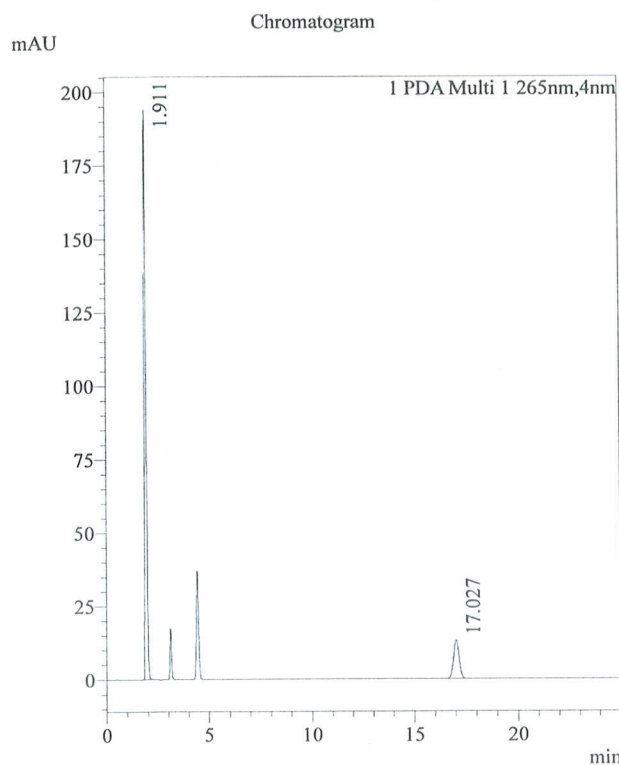
13/09/23

Checked By

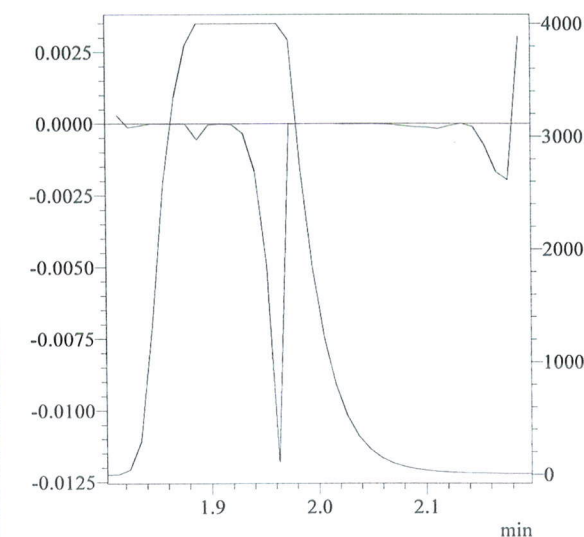
13/09/23

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

Sample Name : SPECIFICITY
Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-38.lcd
Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STL
Vial # : 3-30
Injection Volume : 20 µL
Date Acquired : 12-09-2023 07:21:20
Date Processed : 13-09-2023 10:44:43
Acquired by : E.MEENA
Processed by : C.K.SARAVANAN

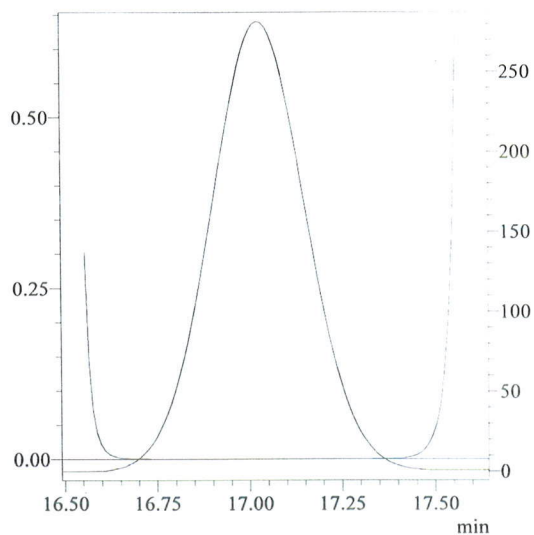
<Peak Purity>

ID# : 1
Retention Time : 1.911 min
Compound Name : METFORMIN HCL



Impurity : Detected at 1.96 min
Peak purity index : 0.998186
Single point threshold : 1.000000
Minimum peak purity index : -11813

ID# : 2
 Retention Time : 17.027 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 265nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	1.911	0.998186	1.000000	METFORMIN HCL
2	17.027	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

(Signature)
 13/09/23

Checked By

(Signature)
 13/09/23


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Analysis Report

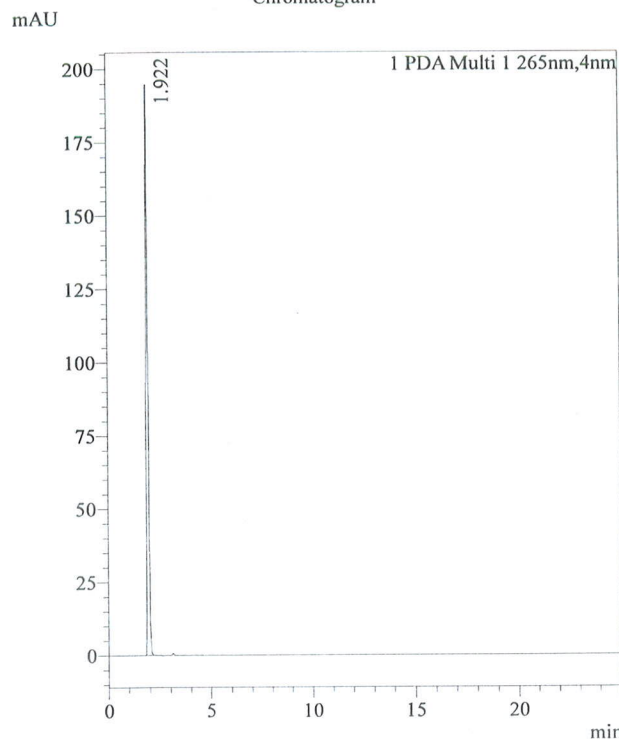
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Sample Name : SPECIFICITY
 Sample ID : AS-METFORMIN API STD
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-43.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STL
 Vial # : 3-31
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 09:29:18
 Date Processed : 13-09-2023 10:14:09

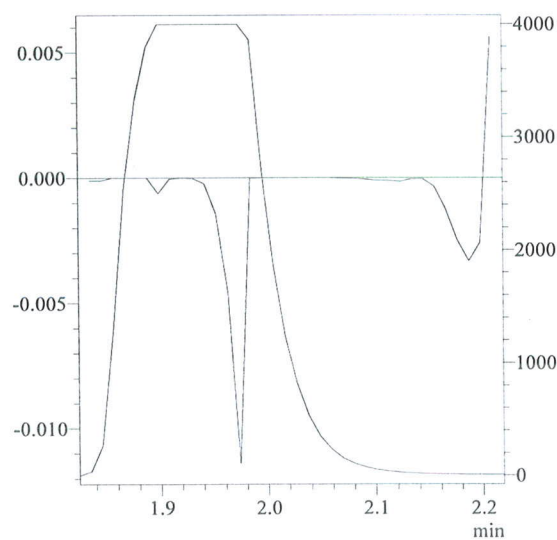
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 1.922 min
 Compound Name : METFORMIN HCL



Impurity : Detected at 1.97 min
 Peak purity index : 0.998619
 Single point threshold : 1.000000
 Minimum peak purity index : -11381

PDA Ch1 265nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	1.922	0.998619	1.000000	METFORMIN HCL
Total				

Analysed By

Checked By



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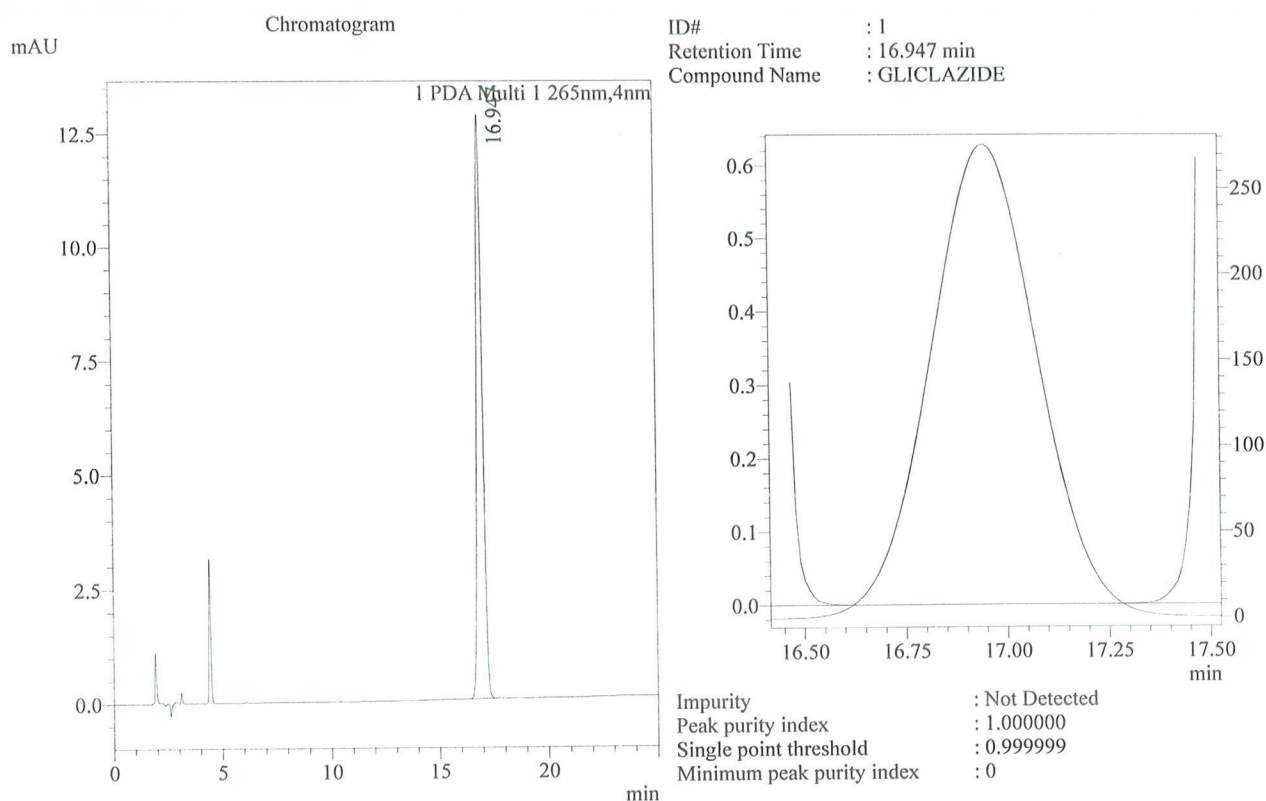
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : AS-GLICLAZIDE API STD
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-44.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STI
 Vial # : 3-32
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 09:54:50
 Date Processed : 13-09-2023 10:16:26

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

<Peak Purity>



PDA Ch1 265nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	16.947	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

Checked By



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Analysis Report

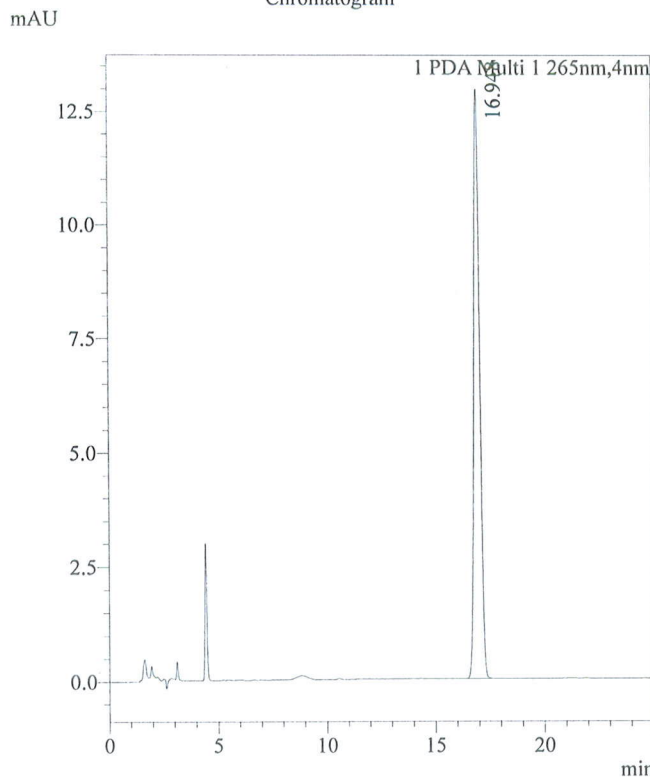
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : AS-PLACEBO+GLICLAZIDE
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-48.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STI
 Vial # : 3-35
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 11:37:19
 Date Processed : 13-09-2023 10:42:46

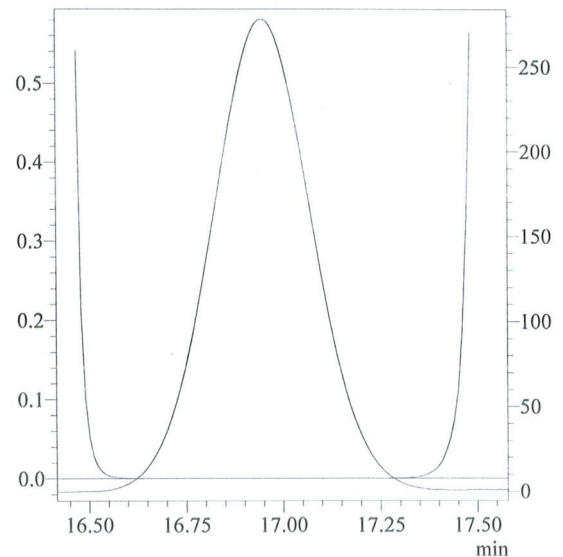
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 16.948 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 265nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	16.948	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

Checked By



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Analysis Report

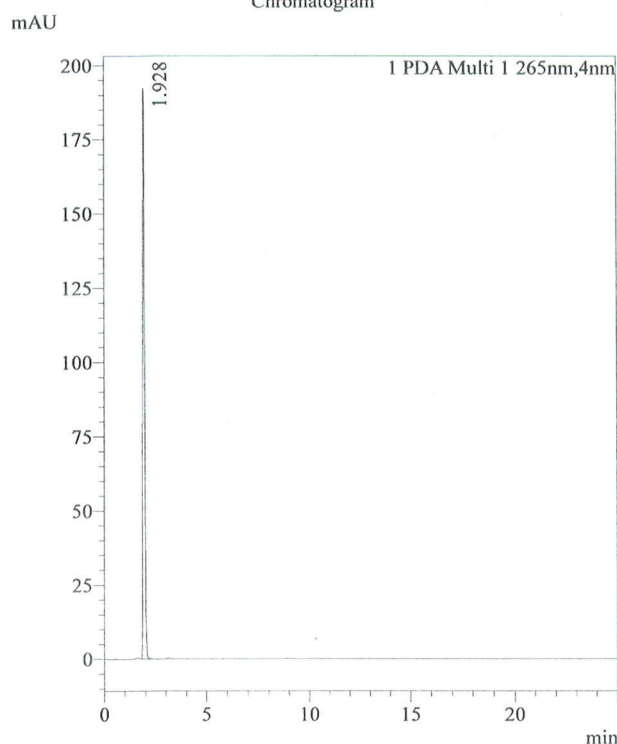
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : AS-PLACEBO-METFORMIN
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-49.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STL
 Vial # : 3-36
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 12:02:54
 Date Processed : 13-09-2023 10:47:04

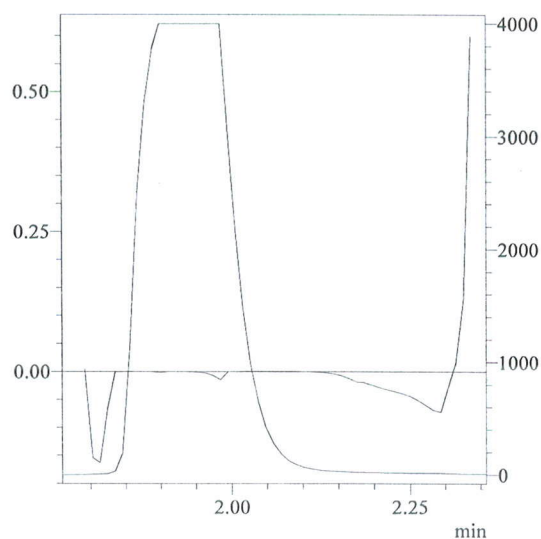
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 1.928 min
 Compound Name : METFORMIN HCL



Impurity : Detected at 1.81 min
 Peak purity index : 0.997040
 Single point threshold : 0.955910
 Minimum peak purity index : -162870

Peak Table

PDA Ch1 265nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	1.928	0.997040	0.955910	METFORMIN HCL
Total				

Analysed By

Checked By



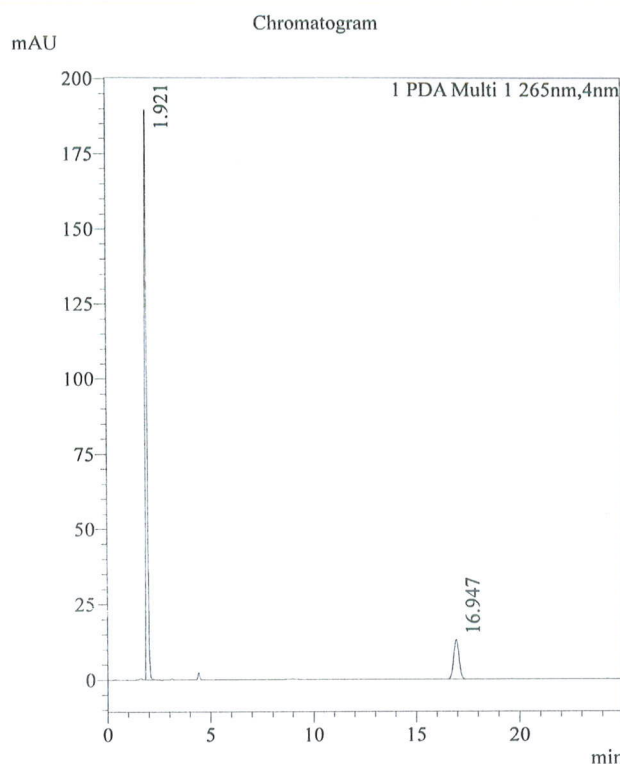
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

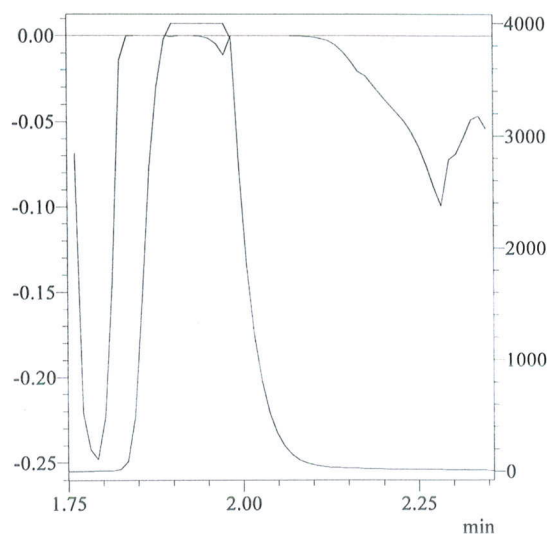
<Sample Information>

Sample Name : SPECIFICITY
 Sample ID : AS-PLACEBO+GLICLAZIDE+METFORMIN
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-50.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STL
 Vial # : 3-37
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 12:28:28
 Date Processed : 13-09-2023 10:48:20
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

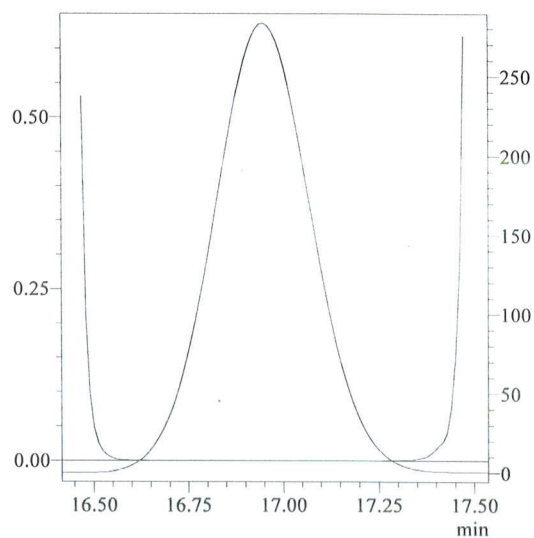


ID# : 1
 Retention Time : 1.921 min
 Compound Name : METFORMIN HCL



Impurity : Detected at 1.79 min
 Peak purity index : 0.998978
 Single point threshold : 0.996903
 Minimum peak purity index : -247924

ID# : 2
 Retention Time : 16.947 min
 Compound Name : GLICLAZIDE



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

PDA Ch1 265nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	1.921	0.998978	0.996903	METFORMIN HCL
2	16.947	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

[Signature]
 13/09/23

Checked By

[Signature]
 13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

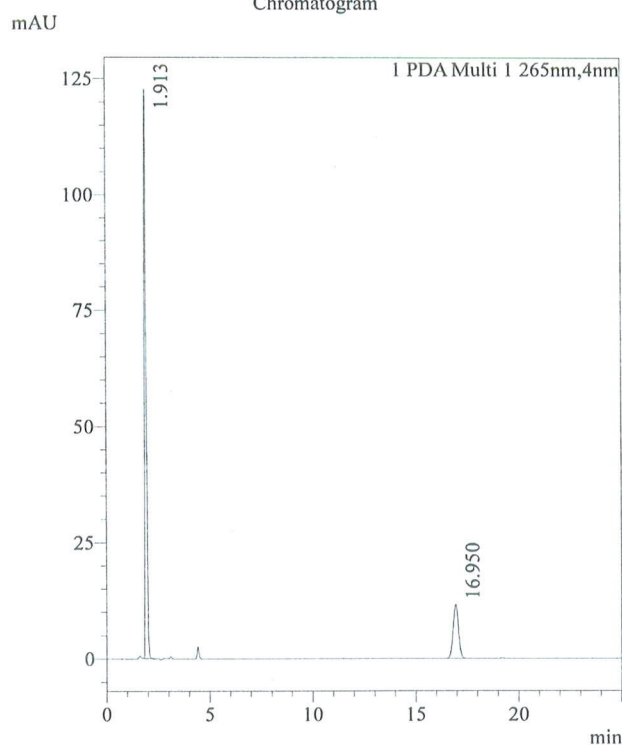
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Sample Name : SPECIFICITY
 Sample ID : GLIDE-M-60-500-TAB-093-AS-SPL
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-52.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STL
 Vial # : 3-38
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 13:19:42
 Date Processed : 13-09-2023 10:49:15

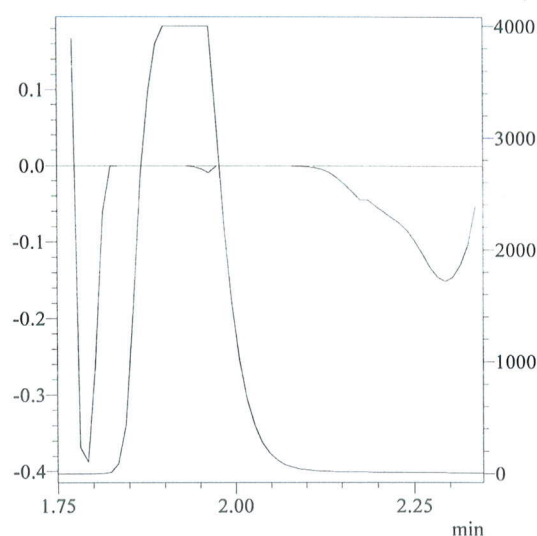
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Peak Purity>

Chromatogram

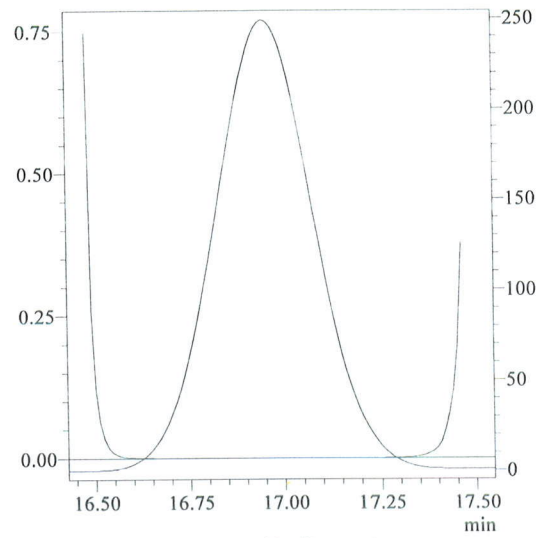


ID# : 1
 Retention Time : 1.913 min
 Compound Name : METFORMIN HCL



Impurity : Detected at 1.79 min
 Peak purity index : 0.997750
 Single point threshold : 0.937761
 Minimum peak purity index : -387010

ID# : 2
 Retention Time : 16.950 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 265nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	1.913	0.997750	0.937761	METFORMIN HCL
2	16.950	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

[Signature]
 13/09/23

Checked By

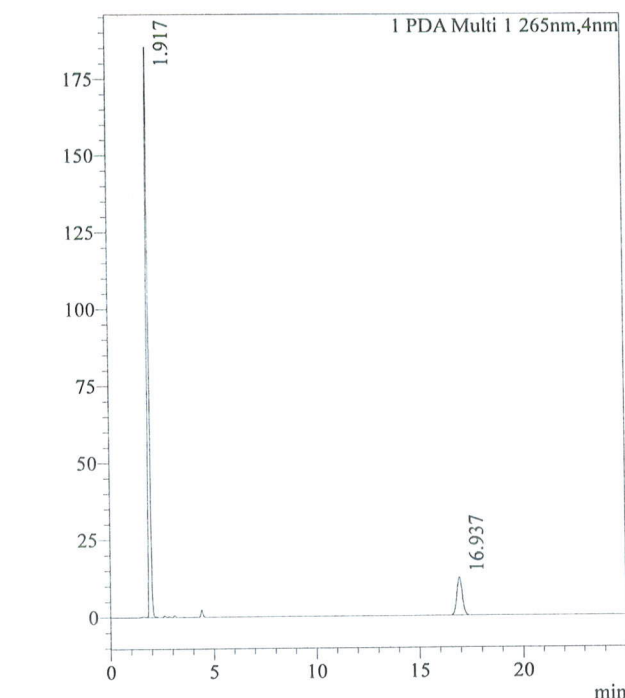
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 13/09/23

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

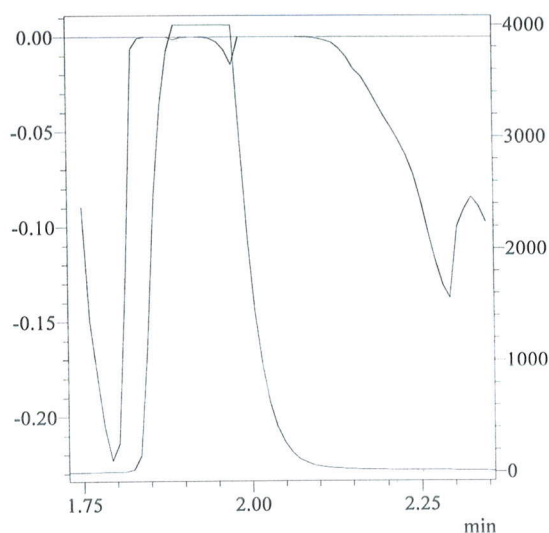
Sample Name : SPECIFICITY
Sample ID : GLIDE-M-60-850-TAB-0801-AS-SPL
Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-54.lcd
Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STL
Vial # : 3-39
Injection Volume : 20 uL
Date Acquired : 12-09-2023 14:10:58
Date Processed : 13-09-2023 10:50:05
Acquired by : E.MEENA
Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram

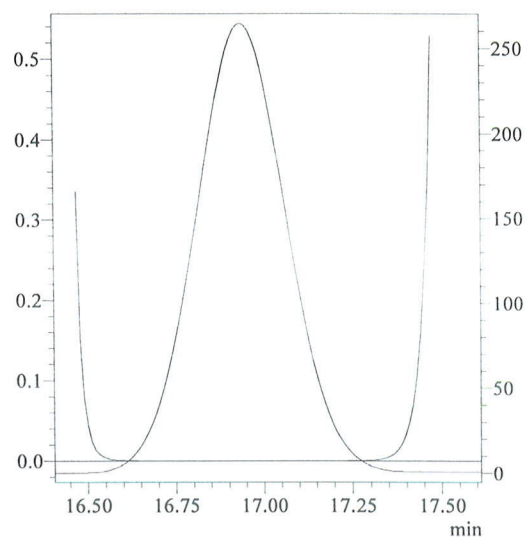


ID# : 1
Retention Time : 1.917 min
Compound Name : METFORMIN HCL



Impurity : Detected at 1.79 min
Peak purity index : 0.997318
Single point threshold : 0.998231
Minimum peak purity index : -222913

ID# : 2
 Retention Time : 16.937 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 265nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	1.917	0.997318	0.998231	METFORMIN HCL
2	16.937	1.000000	0.999999	GLICLAZIDE
Total				

Analysed By

(Signature)
 12/09/23

Checked By

(Signature)
 12/09/23



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcd

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
15	3	METHOD PRECISION	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-01.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-02.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-03.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-04.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-SPL-05.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-06.lcd	20.0	QC/CL/20/017
17	3	METHOD PRECISION	GLIDEM-60-500-093-SET1-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-07.lcd	20.0	QC/CL/20/017
17	3	METHOD PRECISION	GLIDEM-60-500-093-SET1-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-08.lcd	20.0	QC/CL/20/017
18	3	METHOD PRECISION	GLIDEM-60-500-093-SET2-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-09.lcd	20.0	QC/CL/20/017
18	3	METHOD PRECISION	GLIDEM-60-500-093-SET2-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-10.lcd	20.0	QC/CL/20/017
19	3	METHOD PRECISION	GLIDEM-60-500-093-SET3-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-11.lcd	20.0	QC/CL/20/017
19	3	METHOD PRECISION	GLIDEM-60-500-093-SET3-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-12.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLA+METFORMIN-AS-STD-BKT-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-13.lcd	20.0	QC/CL/20/017
20	3	METHOD PRECISION	GLIDEM-60-500-093-SET4-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-14.lcd	20.0	QC/CL/20/017
20	3	METHOD PRECISION	GLIDEM-60-500-093-SET4-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-15.lcd	20.0	QC/CL/20/017
21	3	METHOD PRECISION	GLIDEM-60-500-093-SET5-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-16.lcd	20.0	QC/CL/20/017
21	3	METHOD PRECISION	GLIDEM-60-500-093-SET5-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-17.lcd	20.0	QC/CL/20/017
22	3	METHOD PRECISION	GLIDEM-60-850-093-SET6-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-18.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
22	3	METHOD PRECISION	GLIDEM-60-850-093-SET6-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-19.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLA+METFORMIN-AS-STD-BKT-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-20.lcd	20.0	QC/CL/20/017
23	3	FILTER PAPER STUDY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-21.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-22.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-23.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-24.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-SPL-25.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-26.lcd	20.0	QC/CL/20/017
25	3	FILTER PAPER STUDY	GLIDEM60-500-093-CENTR-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-27.lcd	20.0	QC/CL/20/017
25	3	FILTER PAPER STUDY	GLIDEM60-500-093-CENTR-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-28.lcd	20.0	QC/CL/20/017
26	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-1-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-29.lcd	20.0	QC/CL/20/017
26	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-1-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-30.lcd	20.0	QC/CL/20/017
27	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-2-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-31.lcd	20.0	QC/CL/20/017
27	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-2-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-32.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLA+METFORMIN-AS-STD-BKT-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-33.lcd	20.0	QC/CL/20/017
28	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-3-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-34.lcd	20.0	QC/CL/20/017
28	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-3-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-35.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLA+METFORMIN-AS-STD-BKT-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-36.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-37.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-38.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-39.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-40.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-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	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-42.lcd	20.0	QC/CL/20/017
31	3	SPECIFICITY	AS-METFORMIN API STD	60-500-850-TAB-AS.lcm	ISION-AS-SPL-43.lcd	20.0	QC/CL/20/017
32	3	SPECIFICITY	AS-GLICLAZIDE API STD	60-500-850-TAB-AS.lcm	ISION-AS-SPL-44.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-45.lcd	20.0	QC/CL/20/017
33	3	SPECIFICITY	AS-PLAIN PLACEBO-60-500 MG	60-500-850-TAB-AS.lcm	ISION-AS-SPL-46.lcd	20.0	QC/CL/20/017
34	3	SPECIFICITY	AS-PLAIN PLACEBO-60-850 MG	60-500-850-TAB-AS.lcm	ISION-AS-SPL-47.lcd	20.0	QC/CL/20/017
35	3	SPECIFICITY	AS-PLACEBO+GLICLAZIDE	60-500-850-TAB-AS.lcm	ISION-AS-SPL-48.lcd	20.0	QC/CL/20/017
36	3	SPECIFICITY	AS-PLACEBO-METFORMIN	60-500-850-TAB-AS.lcm	ISION-AS-SPL-49.lcd	20.0	QC/CL/20/017
37	3	SPECIFICITY	AS-PLACEBO+GLICLAZIDE+METFORMIN	60-500-850-TAB-AS.lcm	ISION-AS-SPL-50.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-51.lcd	20.0	QC/CL/20/017
38	3	SPECIFICITY	GLIDE-M-60-500-TAB-093-AS-SPL	60-500-850-TAB-AS.lcm	ISION-AS-SPL-52.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-53.lcd	20.0	QC/CL/20/017
39	3	SPECIFICITY	GLIDE-M-60-850-TAB-0801-AS-SPL	60-500-850-TAB-AS.lcm	ISION-AS-SPL-54.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLA+METFORMIN-AS-STD-BKT	60-500-850-TAB-AS.lcm	ISION-AS-SPL-55.lcd	20.0	QC/CL/20/017
-1	3	SPECIFICITY	SHUTDOWN	HUTDOWN METHOD.lcm	ISION-AS-SPL-56.lcd	20.0	QC/CL/20/017

Analysed By

Checked By

10/10/2017

10/10/2017

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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 ----- 60mg

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
				WS No.:	ST/WS/22/040	% Purity (aib)	100.0

Metformin Hcl Std dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1
Gliclazide Std dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1
Metformin Hcl test dilution.:	1353.86	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1
Gliclazide test dilution.:	1353.86	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-119.45823529	1	ml to --->	1	ml to --->	1	ml to --->	1

Variation's of Chromatographic Condition	Tailing Factor	Theoretical plate	RSD %	Metformin Hcl assay in %	Mean assay value of method	% Difference
Low wavelength (262nm)	1.51	1974	0.200	97.6	97.9	0.30
High wavelength (268nm)	1.57	2071	0.147	96.4		1.48
Low flow rate (0.9ml/minute)	1.53	2192	0.052	97.2		0.66
High flow rate (1.1ml/minute)	1.53	1958	0.057	97.4		0.48
Low Temperature (20°C)	1.56	1954	0.082	99.4		-1.48
High Temperature (30°C)	1.49	2171	0.226	97.8		0.15

Variation's of Chromatographic Condition	Tailing Factor	Theoretical plate	RSD %	Gliclazide assay in %	Mean assay value of method	% Difference
Low wavelength (262nm)	1.11	18016	0.657	98.5	100.2	1.72
High wavelength (268nm)	1.12	17861	0.804	99.3		0.90
Low flow rate (0.9ml/minute)	1.11	18782	0.609	99.6		0.61
High flow rate (1.1ml/minute)	1.11	17410	0.922	101.9		-1.66
Low Temperature (20°C)	1.13	16967	0.848	101.6		-1.44
High Temperature (30°C)	1.11	18724	0.859	101.8		-1.62

Results:

- 1) Each chromatographic variation System suitability parameters are within limits.
- 2) % Difference of assay within limits at each variation.

Acceptance criteria:

- 1) Theoretical plates for Paracetamol and Phenylephrine Hcl peaks should be NLT 1500
- 2) Tailing Factor for Paracetamol and Phenylephrine Hcl peaks should be NMT 2.0.
- 3) % RSD of area of analyte in replicate standard injections should be NMT 2.0.
- 4) % Assay of analyte should not differ by ± 2.0 to that of method precision.

Analysed by :

C.K.SARAVANAN

Date :

11-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name	GLIDE-M 60/850	Batch size	Not applicable
Batch Number	G17230801	Mfg.Date	Aug-23
Stage	WAVELENGTH CHANGE (LOW WAVELENGTH AT 262NM)	Exp.Date	Jul-26

Each uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution.:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	850	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin Hcl	2355519	2357546	2366885	2364044	2363034	2361406	4722	0.200
With Bracketing std.	2365888					2362153	4602.8	0.195

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	2287461	829.64	97.6

Assay limit : 90.0 to 110%

ASSAY OF GLICLAZIDE

						WS No.:	ST/WS/22/040	% Purity (aib)	100.0
--	--	--	--	--	--	---------	--------------	----------------	-------

Standard dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution.:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.4582	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	60	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	298727	297712	296824	294684	294179	296425	1949	0.657
With Bracketing std.	290607					295456	2946.2	0.997

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	286970	59.09	98.5

Assay limit : 90.0 to 110%

Calculation formula :

Assay in mg/tablet	Sample area x Std.dilution X Avg.wt x Purity % (aib) x conversion factor
	Standard area x sample dilution X 100

Assay in %	Assay in mg/tablet x 100
	Labeled claim

Analysed by : C.K.SARAVANAN
Date : 11-09-2023

11/09/23

Checked by :
Date:

11/09/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name	GLIDE-M 60/850	Batch size	Not applicable
Batch Number	G17230801	Mfg.Date	Aug-23
Stage	WAVELENGTH CHANGE (HIGH WAVELENGTH AT 268NM)	Exp.Date	Jul-26

Each uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labeled content :	850
Average weight :	1360

mg

mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin Hcl	465948	467747	467367	466899	467311	467054	688	0.147
With Bracketing std.	464673					466658	1150.4	0.247

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	446931	819.56	96.4

Assay limit : 90.0 to 110%

ASSAY OF GLICLAZIDE

					WS No.:	ST/WS/22/040	% Purity (aib)	100.0
--	--	--	--	--	---------	--------------	----------------	-------

Standard dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.4582	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labeled content :	60
Average weight :	1360

mg

mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	257089	255813	254219	252879	252126	254425	2046	0.804
With Bracketing std.	247724					253308	3291.3	1.299

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	248364	59.58	99.3

Assay limit : 90.0 to 110%

Calculation fomula :

Assay in mg/tablet	Sample area x Std.dilution X Avg.wt x Purity % (aib) x conversion factor
	Standard area x sample dilution X 100

Assay in %

Assay in mg/tablet x 100
Labeled claim

Analysed by :

C.K.SARAVANAN

Date :

11-09-2023

Checked by:

Date:

11/09/23

11/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name	GLIDE-M 60/850	Batch size	Not applicable
Batch Number	G17230801	Mfg.Date	Aug-23
Stage	FLOW RATE CHANGE (LOW FLOW RATE 0.9ML/MINUTE)	Exp.Date	Jul-26

Each uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Standard dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	850	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin Hcl	1232372	1232372	1231577	1232680	1233360	1232472	643	0.052
With Bracketing std.	1234170					1232755	900.5	0.073

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	1189376	826.51	97.2

Assay limit : 90.0 to 110%

ASSAY OF GLICLAZIDE

WS No.:	ST/WS/22/040	% Purity (aib)	100.0
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Standard dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.4582	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	60	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	299948	299130	296957	295965	296108	297622	1814	0.610
With Bracketing std.	291035					296524	3140.6	1.059

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	291361	59.75	99.6

Assay limit : 90.0 to 110%

Calculation formula :

Assay in mg/tablet	Sample area x Std.dilution X Avg.wt x Purity % (aib) x conversion factor
	Standard area x sample dilution X 100

Assay in %	Assay in mg/tablet x 100
	Labeled claim

Analysed by : C.K.SARAVANAN
Date : 11-09-2023

Checked by :
Date :

11/09/23

11/09/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name	GLIDE-M 60/850	Batch size	Not applicable
Batch Number	G17230801	Mfg.Date	Aug-23
Stage	FLOW RATE CHANGE (HIGH FLOW RATE 1.1ML/MINUTE)	Exp.Date	Jul-26

Each uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Standard dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labeled content :	850 mg
Average weight :	1360 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin Hcl	1010010	1011043	1010907	1011350	1011469	1010956	575	0.057
With Bracketing std.	1012103					1011147	695.7	0.069

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	977477	828.10	97.4

Assay limit : 90.0 to 110%

ASSAY OF GLICLAZIDE

					WS No.:	ST/WS/22/040	% Purity (aib)	100.0
--	--	--	--	--	---------	--------------	----------------	-------

Standard dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.4582	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labeled content :	60 mg
Average weight :	1360 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	236021	234609	232446	232359	230505	233188	2150	0.922
With Bracketing std.	227871					232302	2899.7	1.248

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	233485	61.11	101.9

Assay limit : 90.0 to 110%

Calculation formula :

Assay in mg/tablet	Sample area x Std.dilution X Avg.wt x Purity % (aib) x conversion factor
	Standard area x sample dilution X 100

Assay in %	Assay in mg/tablet x 100
	Labeled claim

Analysed by :

C.K.SARAVANAN

Date :

11-09-2023

Checked by:

Date:

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name	GLIDE-M 60/850	Batch size	Not applicable
Batch Number	G17230801	Mfg.Date	Aug-23
Stage	COLUMN TEMPERATURE CHANGE (AT OVEN TEMPERATURE 20°C)	Exp.Date	Jul-26

Each uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Standard dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	850	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin Hcl	1113455	1115025	1114674	1115587	1115741	1114896	913	0.082
With Bracketing std.	1119810					1115715	2165.8	0.194

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	1099672	844.76	99.4

Assay limit : 90.0 to 110%

ASSAY OF GLICLAZIDE

WS No.:	ST/WS/22/040	% Purity (aib)	100.0
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Standard dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.4582	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	60	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	249227	246855	245553	245530	243561	246145	2086	0.848
With Bracketing std.	240181					245151	3067.6	1.251

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	245941	60.98	101.6

Assay limit : 90.0 to 110%

Calculation formula :

Assay in mg/tablet	Sample area x Std.dilution X Avg.wt x Purity % (aib) x conversion factor
	Standard area x sample dilution X 100

Assay in %	Assay in mg/tablet x 100
	Labeled claim

Analysed by : C.K.SARAVANAN
Date : 11-09-2023

Checked by :
Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name	GLIDE-M 60/850	Batch size	Not applicable
Batch Number	G17230801	Mfg.Date	Aug-23
Stage	COLUMN TEMPERATURE CHANGE (AT OVEN TEMPERATURE 30°C)	Exp.Date	Jul-26

Each uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID:	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	-------------	-------------	--------------	---------	--------------	----------------	-------

Standard dilution.:	850.89	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1701.78	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1692.325	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	850	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin Hcl	1125846	1126299	1126099	1120440	1123150	1124367	2541	0.226
With Bracketing std.	1124363					1124366	2272.5	0.202

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	1090781	830.88	97.8

Assay limit : 90.0 to 110%

ASSAY OF GLICLAZIDE

					WS No.:	ST/WS/22/040	% Purity (aib)	100.0
--	--	--	--	--	---------	--------------	----------------	-------

Standard dilution.:	60.76	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-121.52	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet/Pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.4582	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	60	mg
Average weight :	1360	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	238281	237478	235364	234311	233558	235798	2025	0.859
With Bracketing std.	229209					234700	3243.1	1.382

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %
1	1353.86	236012	61.09	101.8

Assay limit : 90.0 to 110%

Calculation fomula :

Assay in mg/tablet	Sample area x Std.dilution X Avg.wt x Purity % (aib) x conversion factor
	Standard area x sample dilution X 100

Assay in %	Assay in mg/tablet x 100
	Labeled claim

Analysed by : C.K.SARAVANAN
Date : 11-09-2023

11/09/23

Checked by:
Date:

11/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

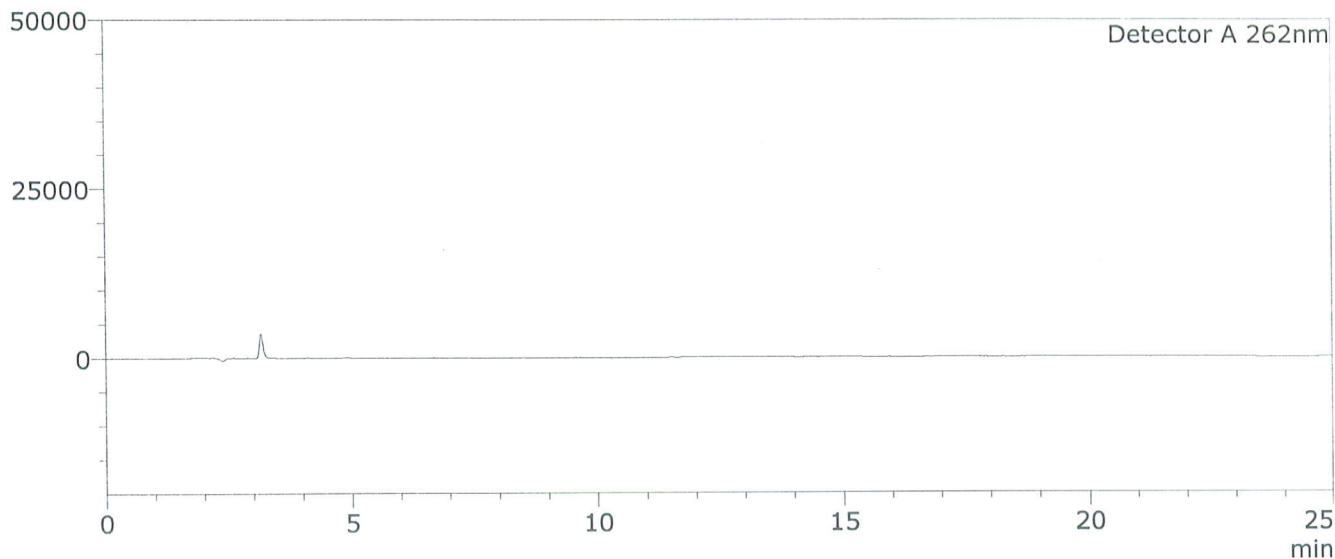
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Sample Name : ROBUSTNESS
 Sample ID : AS-LWL-BLANK
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-19
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 16:00:23
 Date Processed : 11-09-2023 16:31:38

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

uV



<Peak Table>

Detector A 262nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

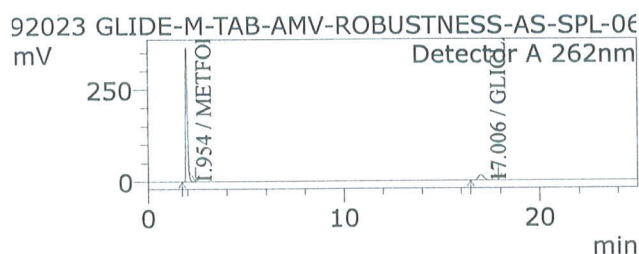
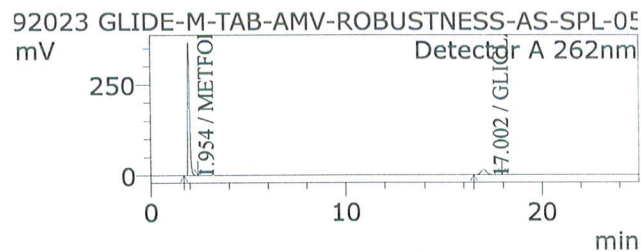
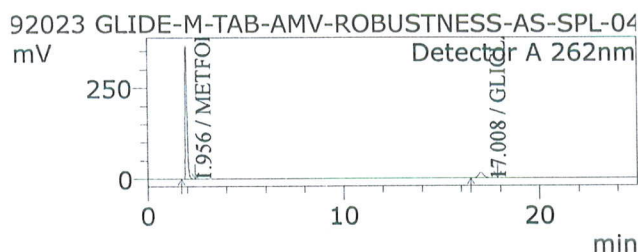
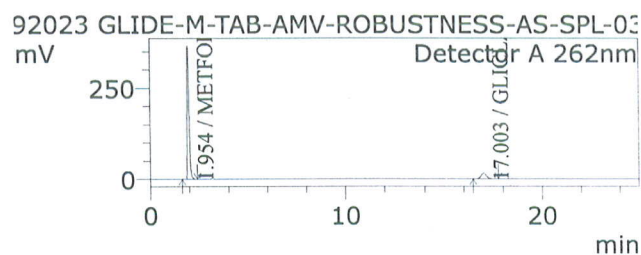
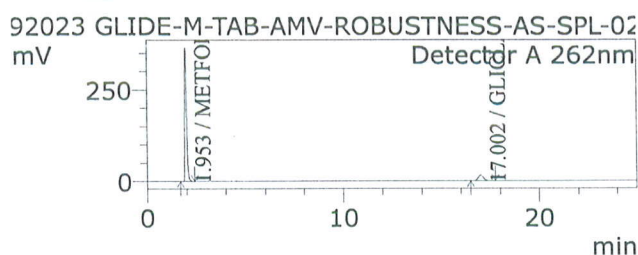
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFORMIN-AS-LWL-STD-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-20
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 16:25:56
 Date Processed : 11-09-2023 16:31:53

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

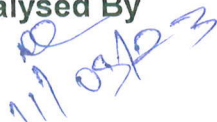
ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
20	AS-SPL-02.lcd	GLICLA+METFORMIN-AS-LWL-STD-1	1.95	2355519	1970	1.51
20	AS-SPL-03.lcd	GLICLA+METFORMIN-AS-LWL-STD-2	1.95	2357546	1971	1.51
20	AS-SPL-04.lcd	GLICLA+METFORMIN-AS-LWL-STD-3	1.96	2366885	1985	1.50
20	AS-SPL-05.lcd	GLICLA+METFORMIN-AS-LWL-STD-4	1.95	2364044	1977	1.51
20	AS-SPL-06.lcd	GLICLA+METFORMIN-AS-LWL-STD-5	1.95	2363034	1970	1.51
	Average		1.95	2361406	1974	1.51
	%RSD		0.045	0.200	0.329	0.220

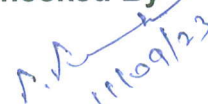
ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
20	AS-SPL-02.lcd	GLICLA+METFORMIN-AS-LWL-STD-1	17.00	298727	18031	1.11
20	AS-SPL-03.lcd	GLICLA+METFORMIN-AS-LWL-STD-2	17.00	297712	18051	1.11
20	AS-SPL-04.lcd	GLICLA+METFORMIN-AS-LWL-STD-3	17.01	296824	17993	1.12
20	AS-SPL-05.lcd	GLICLA+METFORMIN-AS-LWL-STD-4	17.00	294684	18021	1.11
20	AS-SPL-06.lcd	GLICLA+METFORMIN-AS-LWL-STD-5	17.01	294179	17987	1.11
	Average		17.00	296425	18016	1.11
	%RSD		0.015	0.657	0.148	0.163

Analysed By



Checked By





GENERIC HEALTHCARE PVT. LTD.

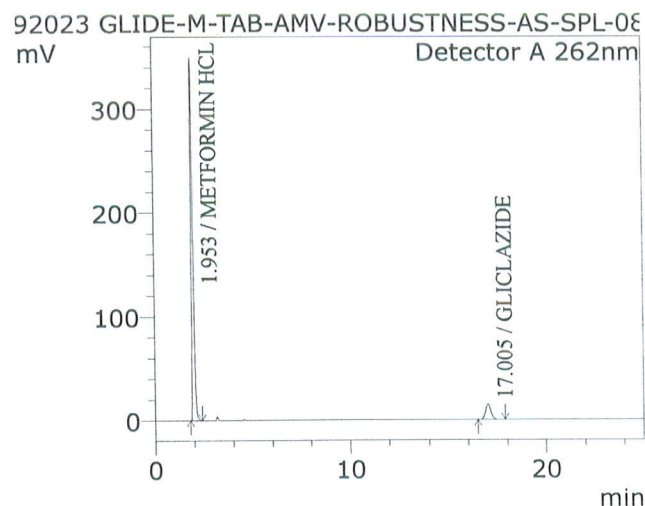
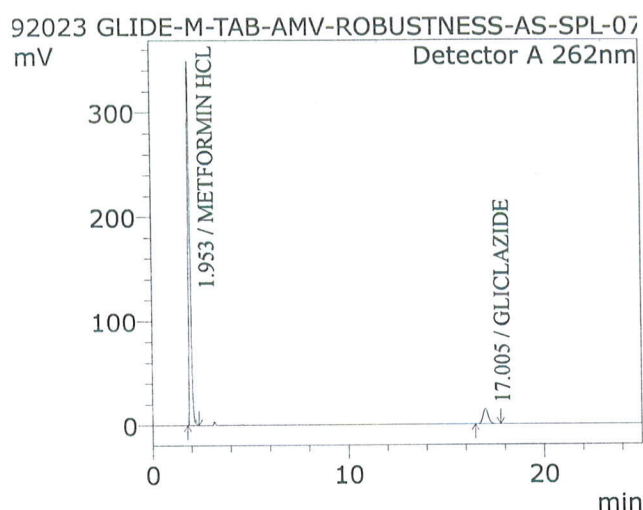
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDE-M-60-850-801-LWL-AS-SPL-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-07.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-21
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 18:33:41
 Date Processed : 11-09-2023 16:33:09

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
21	AS-SPL-07.lcd	GLIDE-M-60-850-801-LWL-AS-SPL-1	1.95	2287175	1898	1.55
21	AS-SPL-08.lcd	GLIDE-M-60-850-801-LWL-AS-SPL-2	1.95	2287748	1894	1.55
	Average		1.95	2287461	1896	1.55
	%RSD		0.006	0.018	0.143	0.075

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
21	AS-SPL-07.lcd	GLIDE-M-60-850-801-LWL-AS-SPL-1	17.01	287392	17660	1.12
21	AS-SPL-08.lcd	GLIDE-M-60-850-801-LWL-AS-SPL-2	17.00	286548	17658	1.12
	Average		17.00	286970	17659	1.12
	%RSD		0.003	0.208	0.010	0.150

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

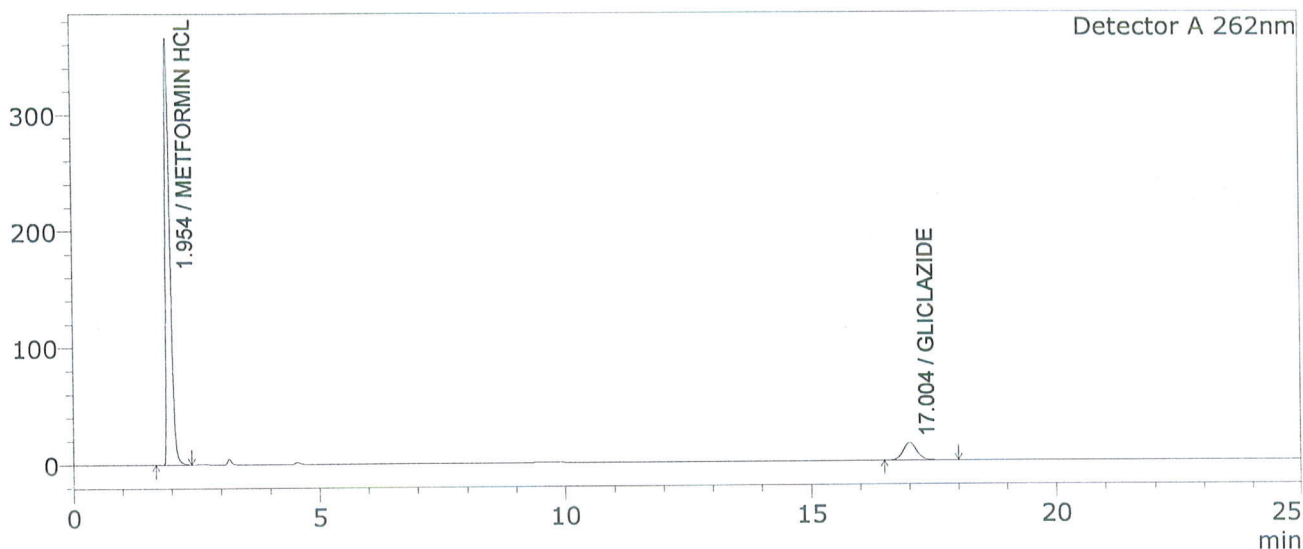
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Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFORMIN-AS-LWL-STD-BKT
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-09.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-20
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 19:24:48
 Date Processed : 11-09-2023 16:33:39

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

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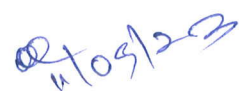
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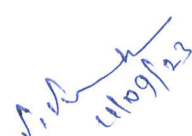


<Peak Table>

Detector A 262nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.95	2365888	89.06	1966	1.511	--	--
2	GLICLAZIDE	17.00	290607	10.94	18025	1.114	44.080	--
Total			2656496	100.00				


 Analysed By


 Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

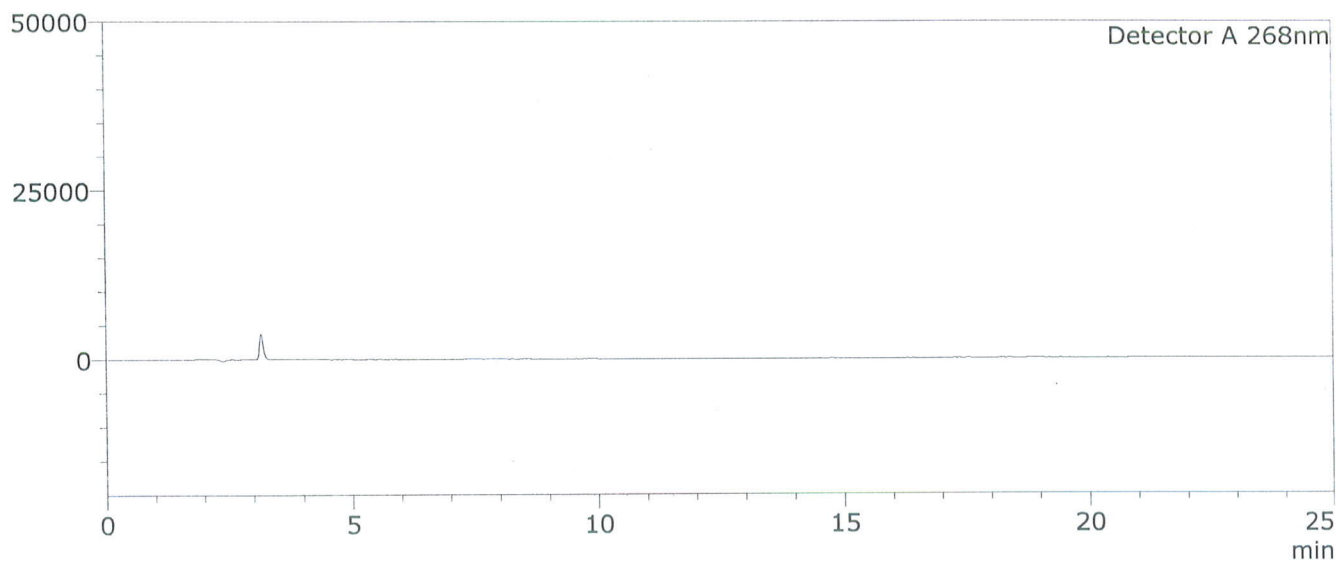
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : AS-HWL-BLANK
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-10.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-22
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 19:50:26
 Date Processed : 11-09-2023 16:37:33

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

uV



<Peak Table>

Detector A 268nm

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

11/09/23
Analysed By

11/09/23
Checked By



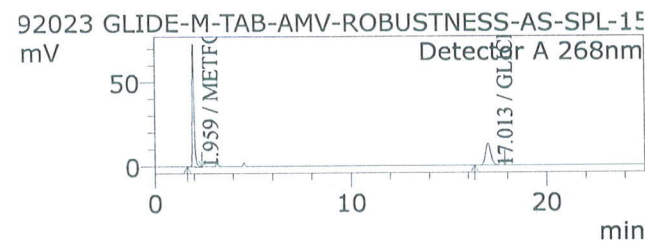
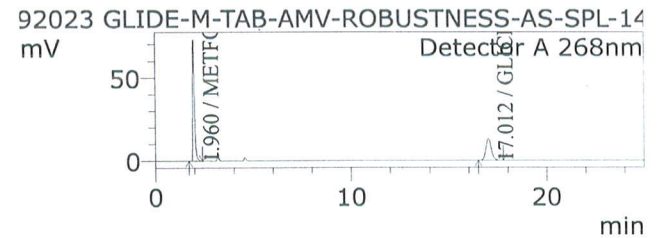
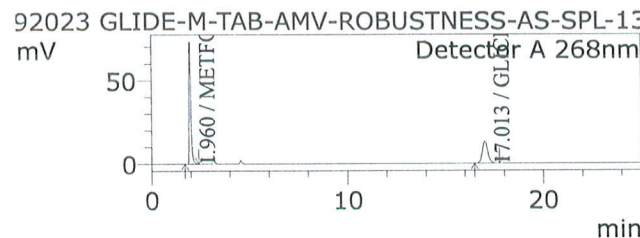
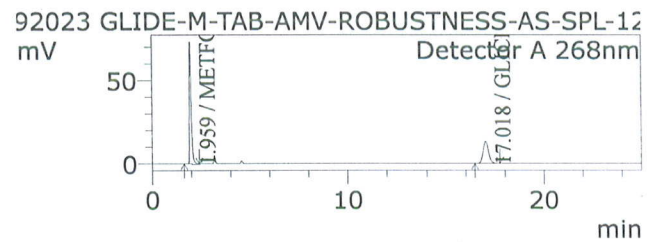
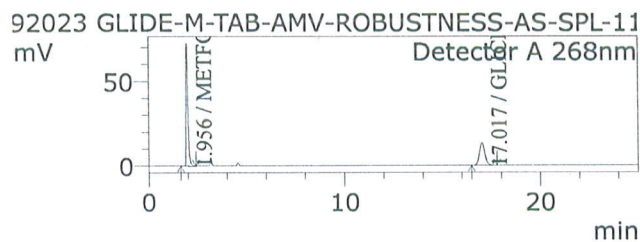
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFORMIN-AS-HWL-STD-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-11.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-23
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 20:15:59
 Date Processed : 11-09-2023 16:37:48
 Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
23	AS-SPL-11.lcd	GLICLA+METFORMIN-AS-HWL-STD-1	1.96	465948	2062	1.58
23	AS-SPL-12.lcd	GLICLA+METFORMIN-AS-HWL-STD-2	1.96	467747	2059	1.57
23	AS-SPL-13.lcd	GLICLA+METFORMIN-AS-HWL-STD-3	1.96	467367	2079	1.57
23	AS-SPL-14.lcd	GLICLA+METFORMIN-AS-HWL-STD-4	1.96	466899	2080	1.57
23	AS-SPL-15.lcd	GLICLA+METFORMIN-AS-HWL-STD-5	1.96	467311	2075	1.57
	Average		1.96	467054	2071	1.57
	%RSD		0.092	0.147	0.463	0.195

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
23	AS-SPL-11.lcd	GLICLA+METFORMIN-AS-HWL-STD-1	17.02	257089	17962	1.12
23	AS-SPL-12.lcd	GLICLA+METFORMIN-AS-HWL-STD-2	17.02	255813	17898	1.12
23	AS-SPL-13.lcd	GLICLA+METFORMIN-AS-HWL-STD-3	17.01	254219	17823	1.12
23	AS-SPL-14.lcd	GLICLA+METFORMIN-AS-HWL-STD-4	17.01	252879	17835	1.13
23	AS-SPL-15.lcd	GLICLA+METFORMIN-AS-HWL-STD-5	17.01	252126	17789	1.13
	Average		17.01	254425	17861	1.12
	%RSD		0.016	0.804	0.385	0.279

Analysed By

11/09/23

Checked By

11/09/23



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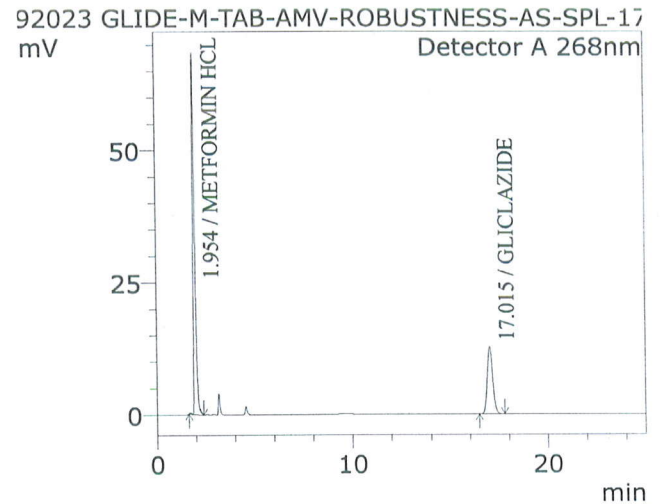
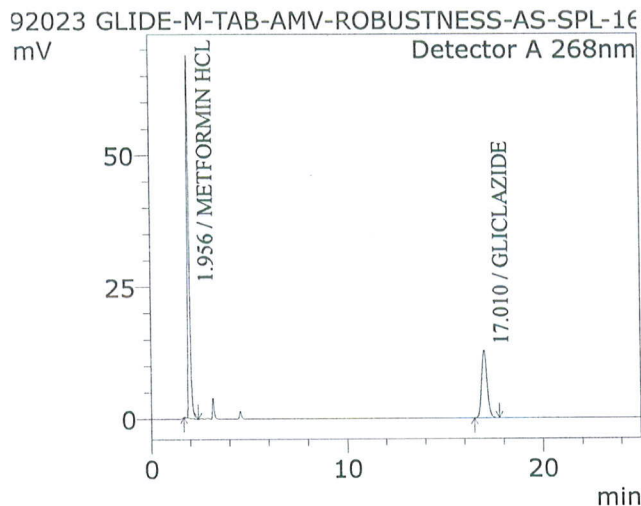
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDE-M-60-850-801-HWL-AS-SPL-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-16.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-24
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 22:23:46
 Date Processed : 11-09-2023 16:39:04

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
24	AS-SPL-16.lcd	GLIDE-M-60-850-801-HWL-AS-SPL-1	1.96	446217	2018	1.61
24	AS-SPL-17.lcd	GLIDE-M-60-850-801-HWL-AS-SPL-2	1.95	447644	2004	1.62
	Average		1.96	446931	2011	1.61
	%RSD		0.086	0.226	0.482	0.628

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
24	AS-SPL-16.lcd	GLIDE-M-60-850-801-HWL-AS-SPL-1	17.01	248741	17479	1.13
24	AS-SPL-17.lcd	GLIDE-M-60-850-801-HWL-AS-SPL-2	17.02	247987	17569	1.12
	Average		17.01	248364	17524	1.13
	%RSD		0.022	0.215	0.366	0.048

Analysed By

Checked By



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Analysis Report

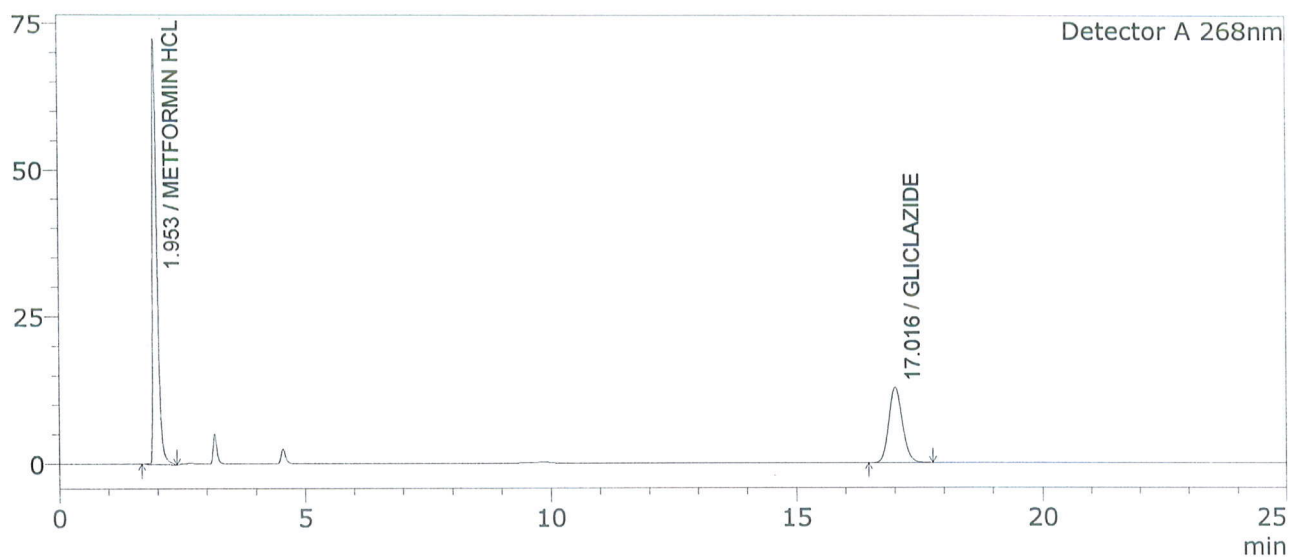
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Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFORMIN-AS-HWL-STD-BKT
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-18.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH WAVE LENGTH_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-23
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 23:14:53
 Date Processed : 11-09-2023 16:39:34

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 268nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.95	464673	65.23	2056	1.589	--	--
2	GLICLAZIDE	17.02	247724	34.77	18005	1.115	44.331	--
Total			712398	100.00				

Analysed By

Checked By



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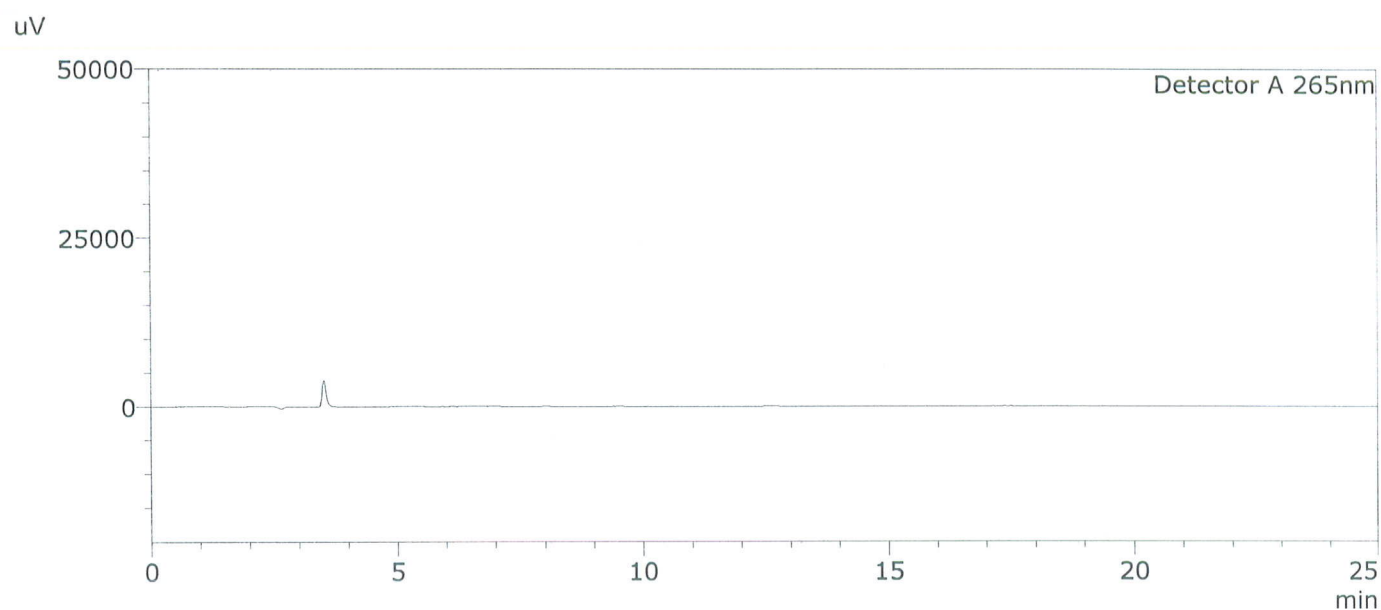
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : AS-LOW FLOW-BLANK
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-19.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-25
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 23:40:32
 Date Processed : 11-09-2023 16:41:46

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



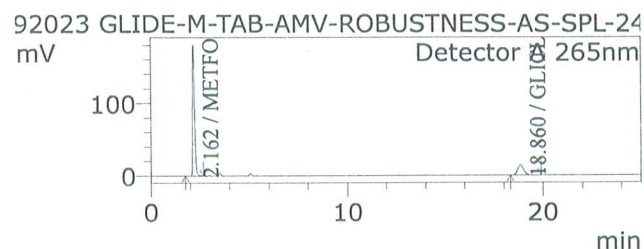
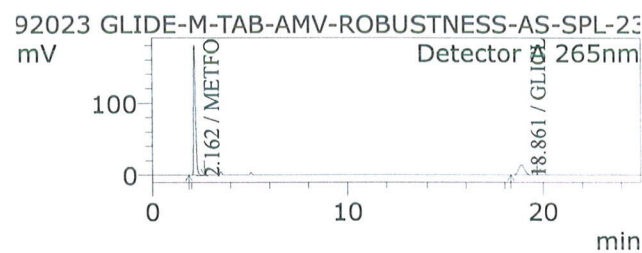
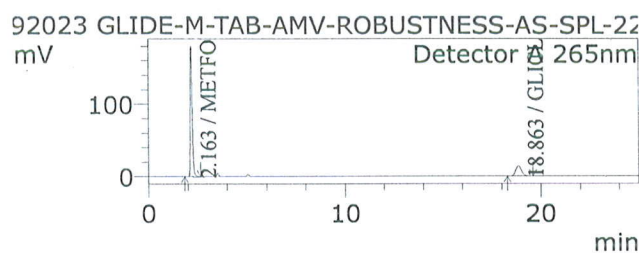
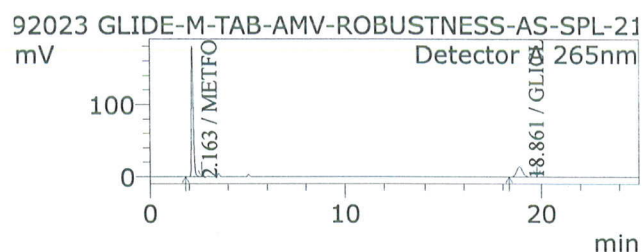
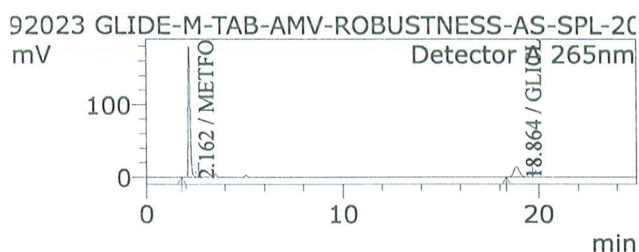
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-LOW FLOW-STD-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-20.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-26
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 00:06:06
 Date Processed : 11-09-2023 16:42:02
 Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
26	AS-SPL-20.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-1	2.16	1232372	2186	1.53
26	AS-SPL-21.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-2	2.16	1232372	2193	1.53
26	AS-SPL-22.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-3	2.16	1231577	2192	1.54
26	AS-SPL-23.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-4	2.16	1232680	2193	1.54
26	AS-SPL-24.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-5	2.16	1233360	2193	1.54
	Average		2.16	1232472	2192	1.53
	%RSD		0.019	0.052	0.133	0.138

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
26	AS-SPL-20.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-1	18.86	299948	18778	1.11
26	AS-SPL-21.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-2	18.86	299130	18757	1.11
26	AS-SPL-22.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-3	18.86	296957	18804	1.11
26	AS-SPL-23.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-4	18.86	295965	18809	1.11
26	AS-SPL-24.lcd	GLICLA+METFOR-AS-LOW FLOW-STD-5	18.86	296108	18762	1.11
	Average		18.86	297622	18782	1.11
	%RSD		0.008	0.609	0.126	0.119

Analysed By


11/09/23

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11/09/23



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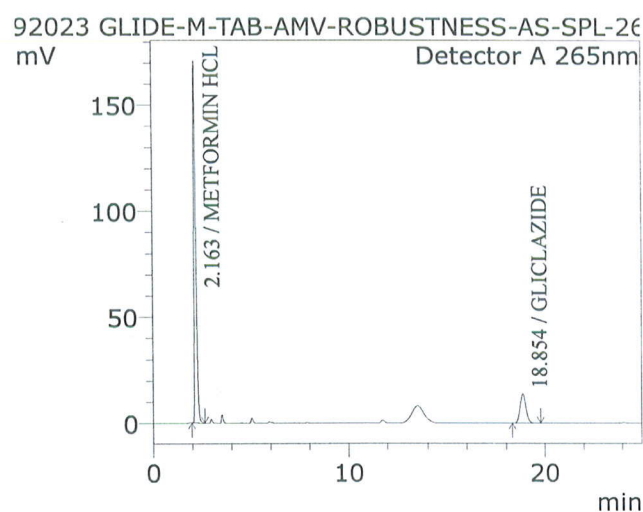
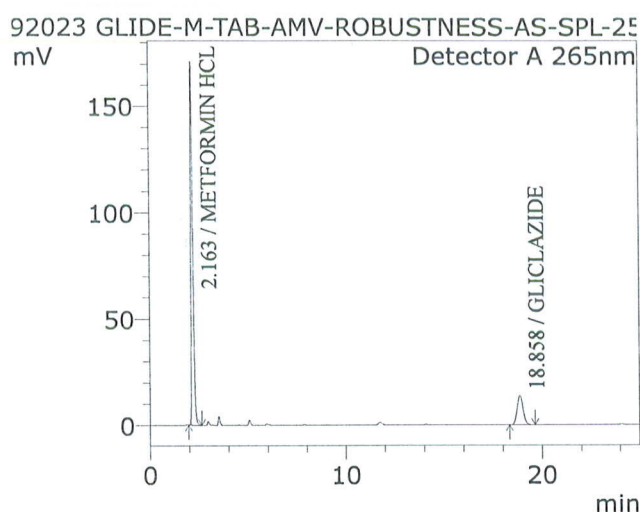
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDE-M-60-850-801-LFL-AS-SPL-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-25.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-27
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 02:13:53
 Date Processed : 11-09-2023 16:43:17

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
27	AS-SPL-25.lcd	GLIDE-M-60-850-801-LFL-AS-SPL-1	2.16	1189587	2120	1.56
27	AS-SPL-26.lcd	GLIDE-M-60-850-801-LFL-AS-SPL-2	2.16	1189166	2116	1.56
	Average		2.16	1189376	2118	1.56
	%RSD		0.004	0.025	0.146	0.012

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
27	AS-SPL-25.lcd	GLIDE-M-60-850-801-LFL-AS-SPL-1	18.86	291307	18420	1.12
27	AS-SPL-26.lcd	GLIDE-M-60-850-801-LFL-AS-SPL-2	18.85	291414	18370	1.12
	Average		18.86	291361	18395	1.12
	%RSD		0.014	0.026	0.190	0.163

Analysed By

Checked By



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Analysis Report

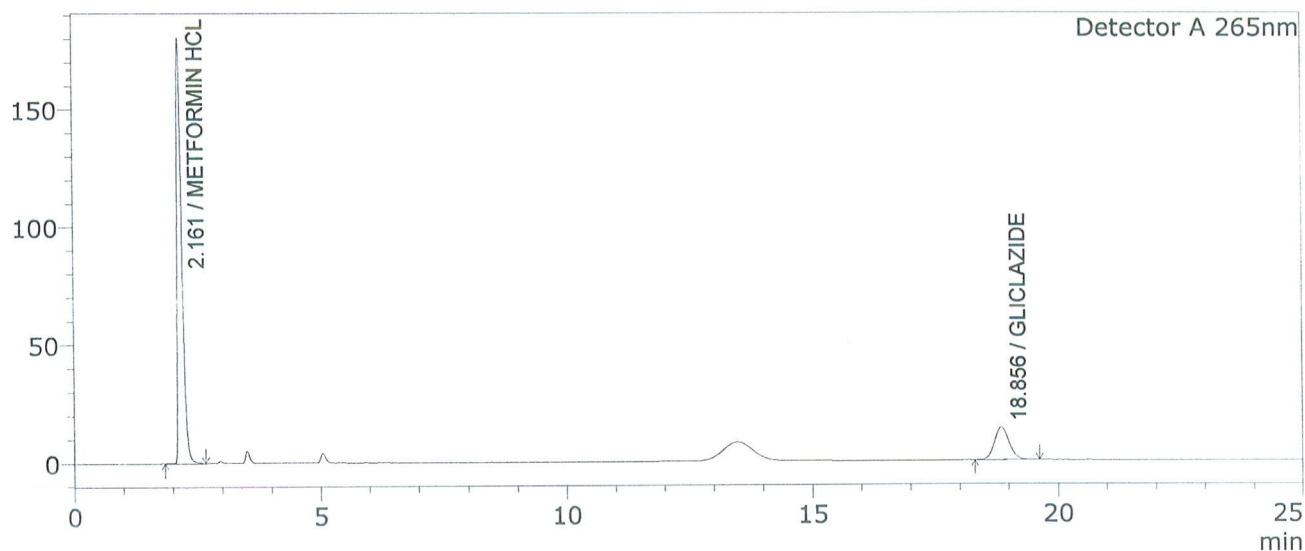
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Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-LFL-STD-BKT
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-27.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-26
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 03:05:00
 Date Processed : 11-09-2023 16:43:48

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	2.16	1234170	80.92	2179	1.536	--	--
2	GLICLAZIDE	18.86	291035	19.08	18789	1.108	45.404	--
Total			1525205	100.00				

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11/09/23
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Analysis Report

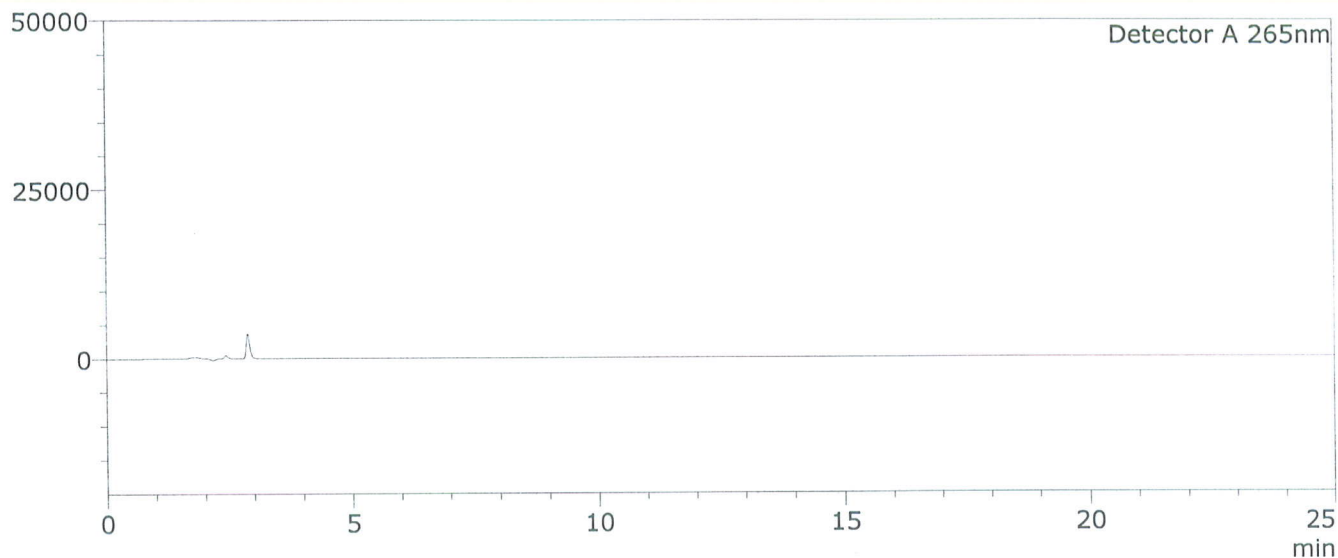
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Sample Name : ROBUSTNESS
 Sample ID : AS-HIGH FLOW-BLANK
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-28.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-28
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 03:30:38
 Date Processed : 11-09-2023 16:46:18

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



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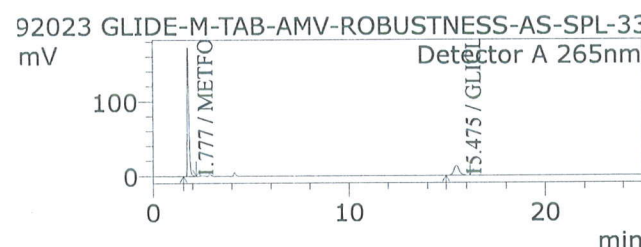
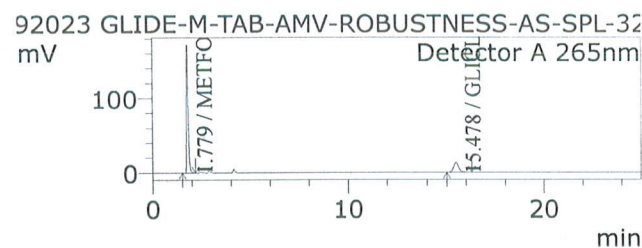
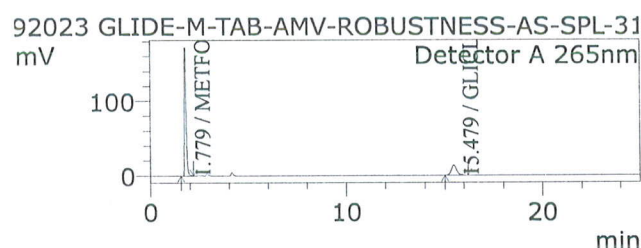
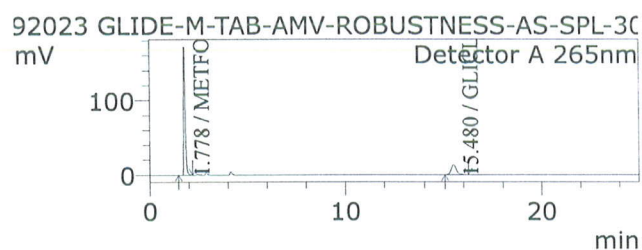
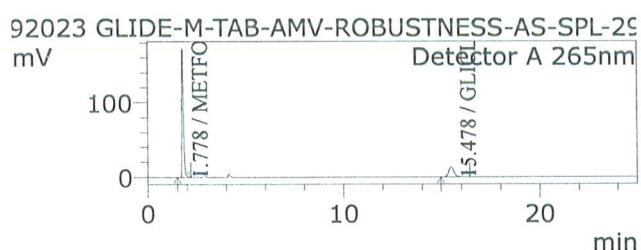
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-HIGHFLOW-STD-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-29.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-29
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 03:56:11
 Date Processed : 11-09-2023 16:46:33

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
29	AS-SPL-29.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-1	1.78	1010010	1958	1.53
29	AS-SPL-30.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-2	1.78	1011043	1961	1.53
29	AS-SPL-31.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-3	1.78	1010907	1962	1.53
29	AS-SPL-32.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-4	1.78	1011350	1959	1.53
29	AS-SPL-33.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-5	1.78	1011469	1951	1.53
	Average		1.78	1010956	1958	1.53
	%RSD		0.044	0.057	0.210	0.216

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
29	AS-SPL-29.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-1	15.48	236021	17405	1.12
29	AS-SPL-30.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-2	15.48	234609	17380	1.12
29	AS-SPL-31.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-3	15.48	232446	17426	1.11
29	AS-SPL-32.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-4	15.48	232359	17402	1.12
29	AS-SPL-33.lcd	GLICLA+METFOR-AS-HIGHFLOW-STD-5	15.48	230505	17437	1.11
	Average		15.48	233188	17410	1.11
	%RSD		0.011	0.922	0.127	0.264

Analysed By

11/09/23

Checked By

11/09/23



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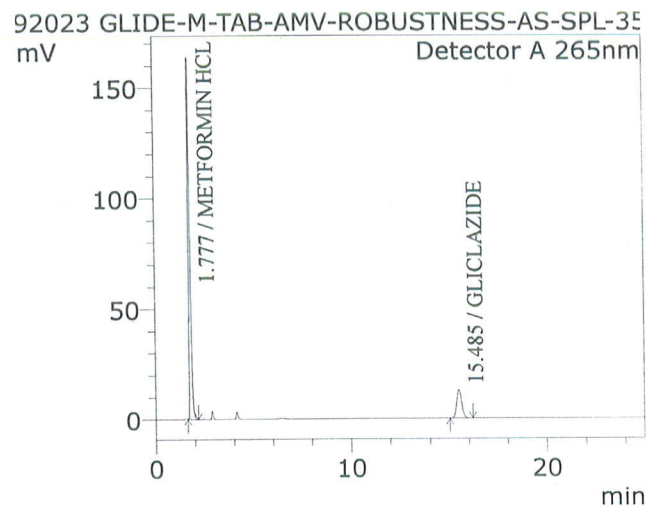
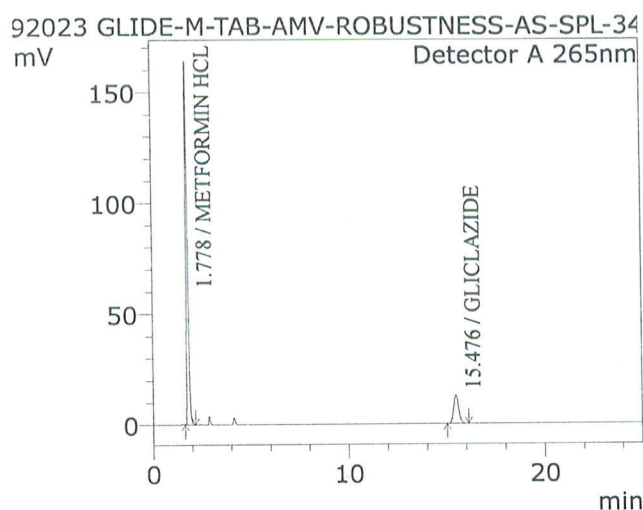
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDE-M-60-850-801-HFL-AS-SPL-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-34.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-30
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 06:03:56
 Date Processed : 11-09-2023 16:47:49

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
30	AS-SPL-34.lcd	GLIDE-M-60-850-801-HFL-AS-SPL-1	1.78	978007	1890	1.59
30	AS-SPL-35.lcd	GLIDE-M-60-850-801-HFL-AS-SPL-2	1.78	976947	1885	1.59
	Average		1.78	977477	1887	1.59
	%RSD		0.030	0.077	0.175	0.118

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
30	AS-SPL-34.lcd	GLIDE-M-60-850-801-HFL-AS-SPL-1	15.48	233433	17027	1.12
30	AS-SPL-35.lcd	GLIDE-M-60-850-801-HFL-AS-SPL-2	15.48	233538	16994	1.12
	Average		15.48	233485	17011	1.12
	%RSD		0.039	0.032	0.136	0.158

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

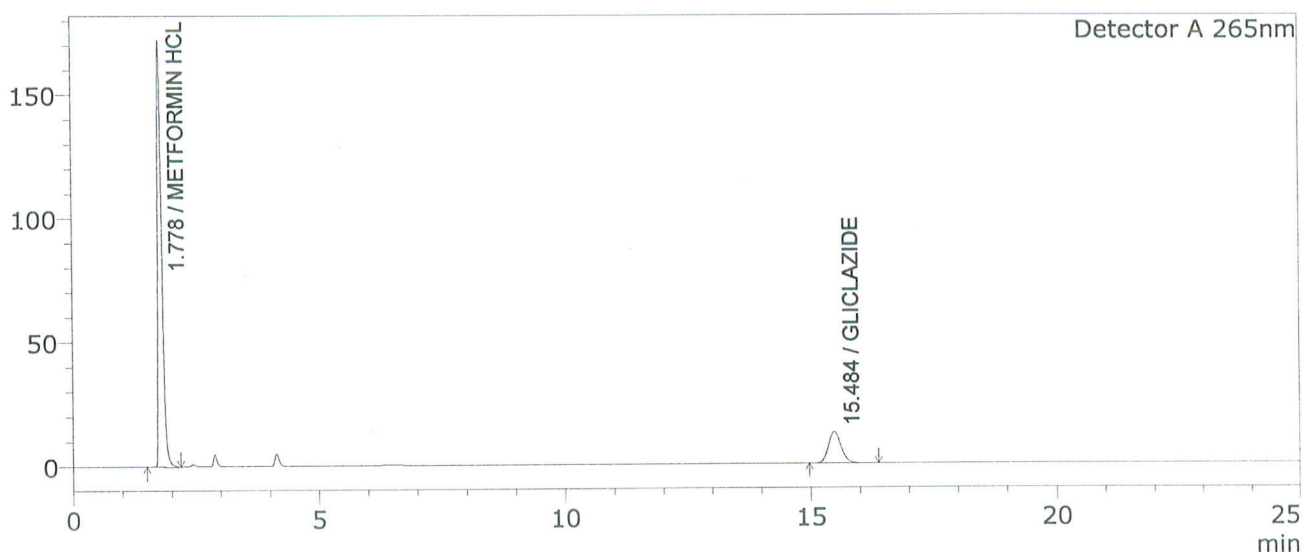
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-HFL-STD-BKT
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-36.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH FLOW_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-29
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 06:55:02
 Date Processed : 11-09-2023 16:48:20

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.78	1012103	81.62	1952	1.528	--	--
2	GLICLAZIDE	15.48	227871	18.38	17415	1.114	43.491	--
Total			1239974	100.00				

 11/09/23
Analysed By

 11/09/23
Checked By

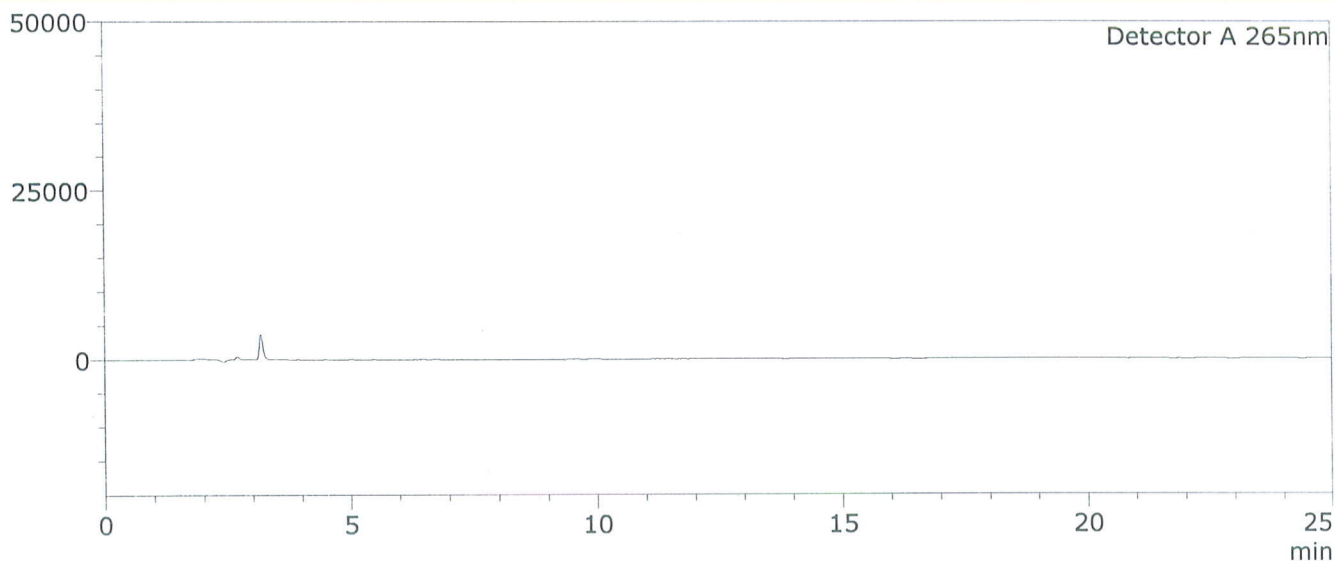

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : AS-LOW TEMP-BLANK
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-37.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-31
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 07:26:45
 Date Processed : 11-09-2023 16:50:12

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

uV


<Peak Table>

Detector A 265nm

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

Analysed By
Checked By



GENERIC HEALTHCARE PVT. LTD.

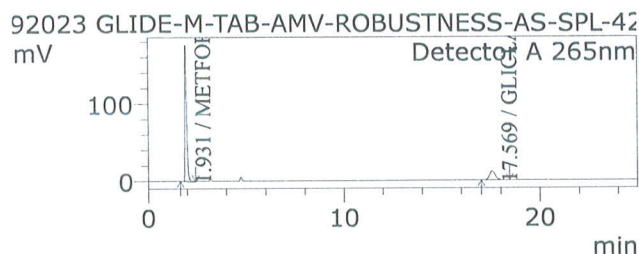
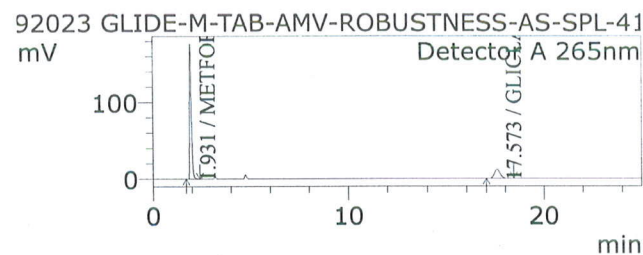
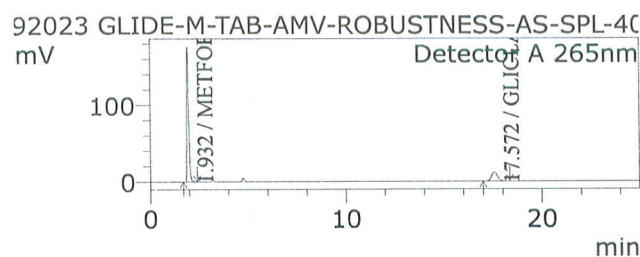
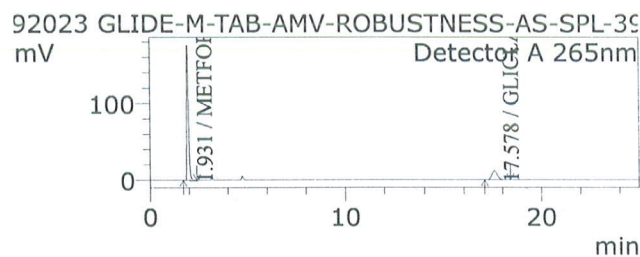
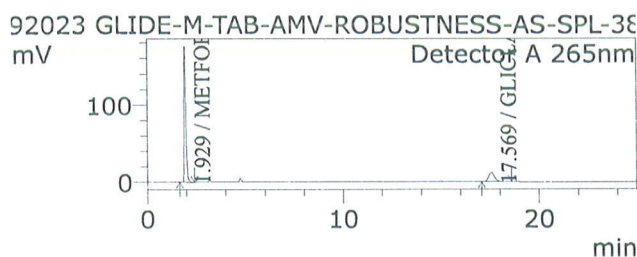
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-LOW TEMP-STD-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-38.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-32
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 07:52:17
 Date Processed : 11-09-2023 16:50:32

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

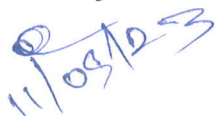
ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
32	AS-SPL-38.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-1	1.93	1113455	1971	1.57
32	AS-SPL-39.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-2	1.93	1115025	1944	1.56
32	AS-SPL-40.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-3	1.93	1114674	1957	1.56
32	AS-SPL-41.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-4	1.93	1115587	1947	1.56
32	AS-SPL-42.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-5	1.93	1115741	1949	1.56
	Average		1.93	1114896	1954	1.56
	%RSD		0.054	0.082	0.549	0.261

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
32	AS-SPL-38.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-1	17.57	249227	17015	1.13
32	AS-SPL-39.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-2	17.58	246855	16994	1.13
32	AS-SPL-40.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-3	17.57	245553	16957	1.13
32	AS-SPL-41.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-4	17.57	245530	16922	1.13
32	AS-SPL-42.lcd	GLICLA+METFOR-AS-LOW TEMP-STD-5	17.57	243561	16948	1.13
	Average		17.57	246145	16967	1.13
	%RSD		0.021	0.848	0.220	0.115

Analysed By


11/09/23

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11/09/23



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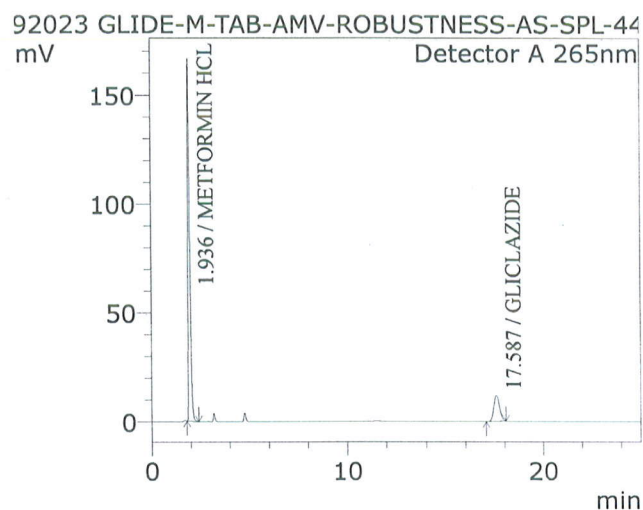
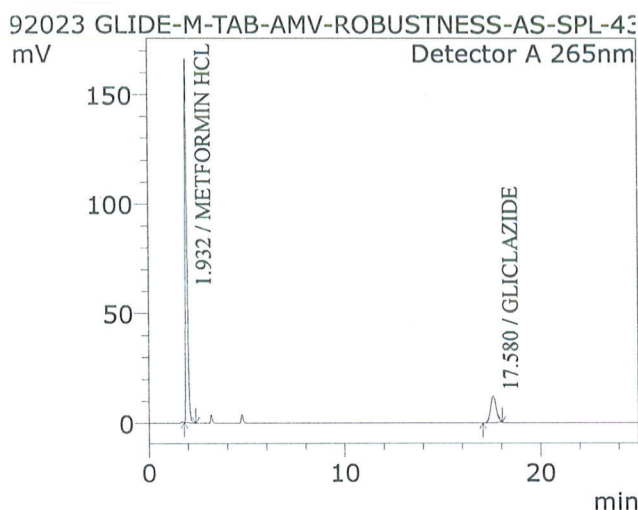
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDE-M-60-850-801-LTM-AS-SPL-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-43.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-33
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 10:00:01
 Date Processed : 11-09-2023 16:51:53

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
33	AS-SPL-43.lcd	GLIDE-M-60-850-801-LTM-AS-SPL-1	1.93	1097509	1828	1.58
33	AS-SPL-44.lcd	GLIDE-M-60-850-801-LTM-AS-SPL-2	1.94	1101836	1828	1.58
	Average		1.93	1099672	1828	1.58
	%RSD		0.159	0.278	0.008	0.009

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
33	AS-SPL-43.lcd	GLIDE-M-60-850-801-LTM-AS-SPL-1	17.58	245809	16853	1.11
33	AS-SPL-44.lcd	GLIDE-M-60-850-801-LTM-AS-SPL-2	17.59	246073	16747	1.12
	Average		17.58	245941	16800	1.11
	%RSD		0.029	0.076	0.445	0.659

Analysed By

Checked By



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Analysis Report

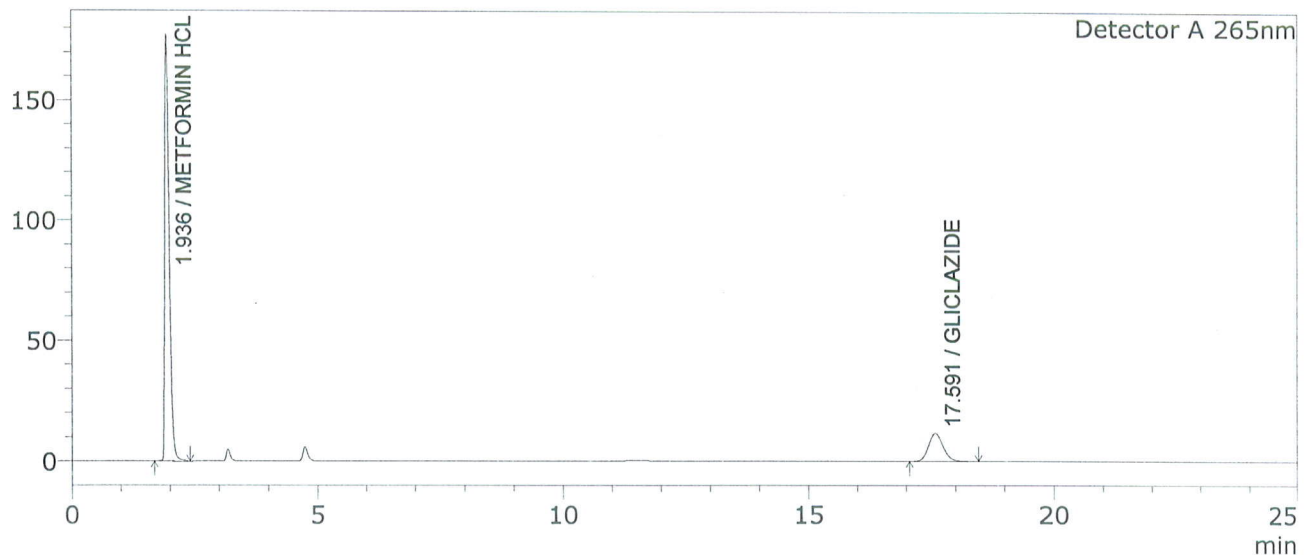
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Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-LTM-STD-BKT
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-45.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-LOW TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-32
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 10:51:06
 Date Processed : 11-09-2023 16:52:23

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.94	1119810	82.34	1988	1.560	--	--
2	GLICLAZIDE	17.59	240181	17.66	16807	1.140	43.704	--
Total			1359991	100.00				

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Analysis Report

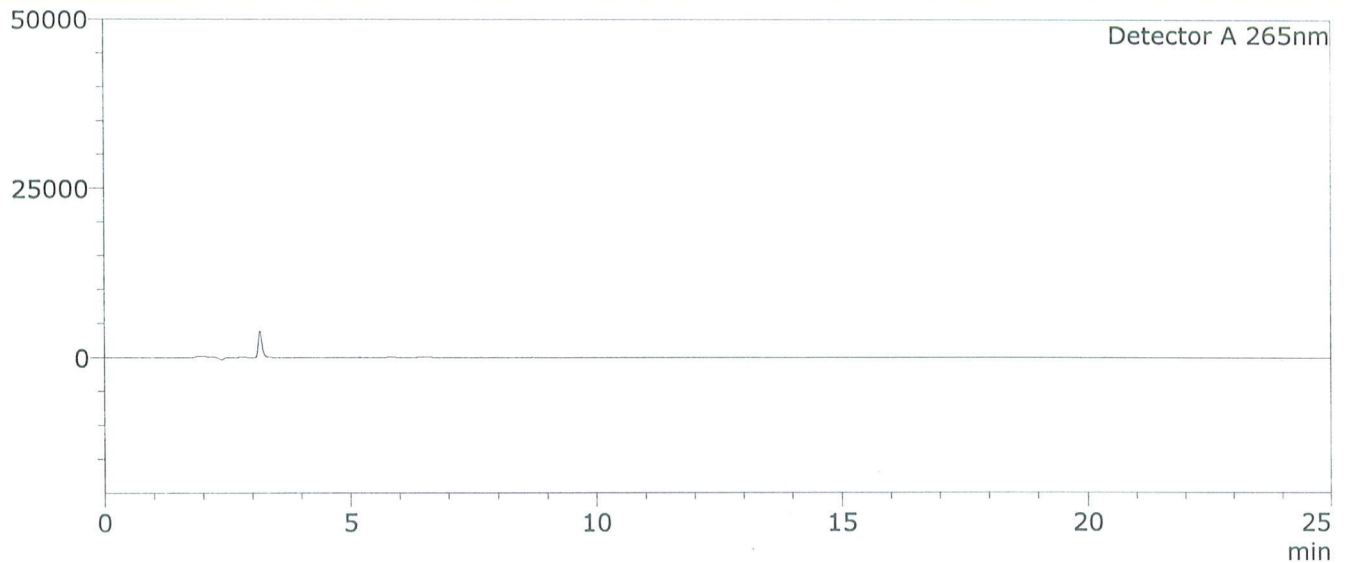
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : AS-HIGH TEMP-BLANK
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-46.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-34
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 11:22:26
 Date Processed : 11-09-2023 16:53:48

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

uV



<Peak Table>

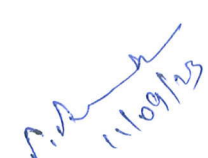
Detector A 265nm

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

 Analysed By



 Checked By





GENERIC HEALTHCARE PVT. LTD.

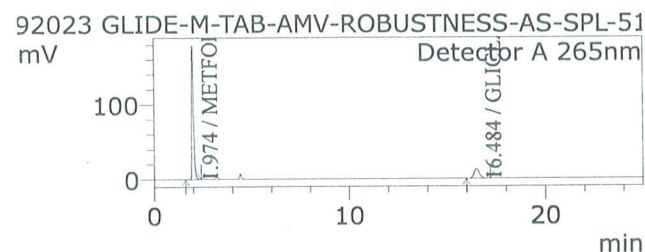
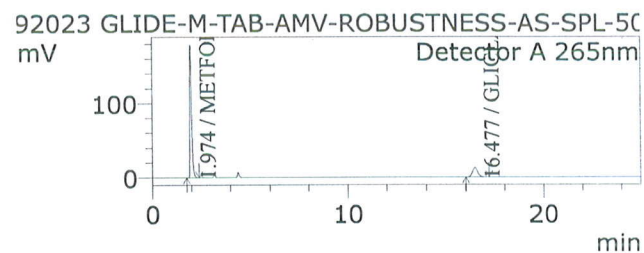
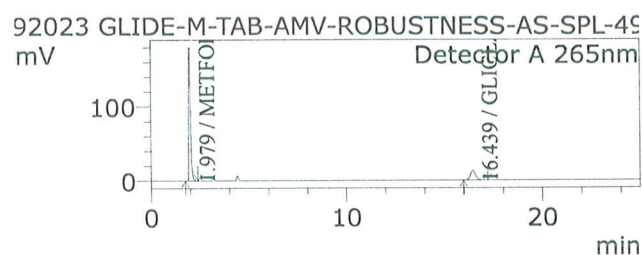
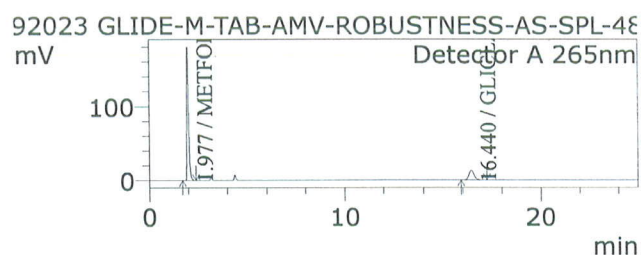
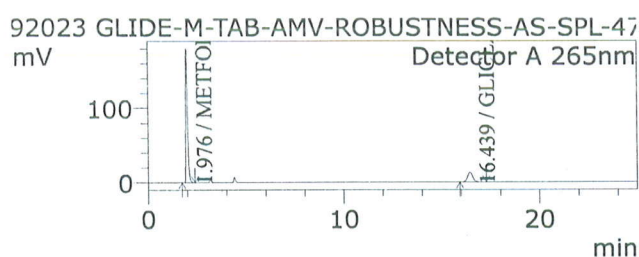
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-HIGHTEMP-STD-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-47.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-35
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 11:47:59
 Date Processed : 11-09-2023 16:54:03

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
35	AS-SPL-47.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-1	1.98	1125846	2150	1.49
35	AS-SPL-48.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-2	1.98	1126299	2164	1.49
35	AS-SPL-49.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-3	1.98	1126099	2180	1.50
35	AS-SPL-50.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-4	1.97	1120440	2182	1.49
35	AS-SPL-51.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-5	1.97	1123150	2178	1.49
	Average		1.98	1124367	2171	1.49
	%RSD		0.093	0.226	0.627	0.255

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
35	AS-SPL-47.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-1	16.44	238281	18709	1.11
35	AS-SPL-48.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-2	16.44	237478	18681	1.11
35	AS-SPL-49.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-3	16.44	235364	18686	1.11
35	AS-SPL-50.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-4	16.48	234311	18769	1.10
35	AS-SPL-51.lcd	GLICLA+METFOR-AS-HIGHTEMP-STD-5	16.48	233558	18774	1.10
	Average		16.46	235798	18724	1.11
	%RSD		0.137	0.859	0.240	0.267

Analysed By


11/09/23

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11/09/23



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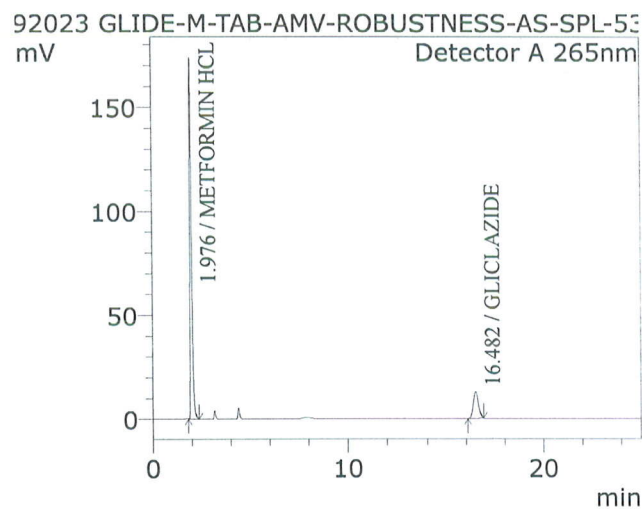
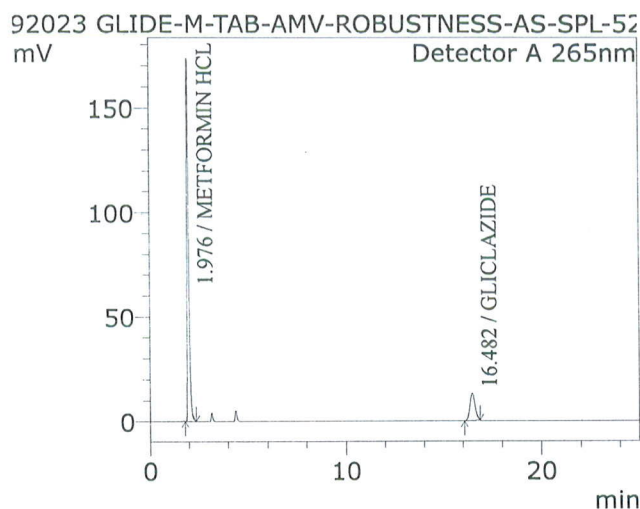
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLIDE-M-60-850-801-HTM-AS-SPL-1
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-52.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-36
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 13:55:43
 Date Processed : 11-09-2023 16:55:19

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
36	AS-SPL-52.lcd	GLIDE-M-60-850-801-HTM-AS-SPL-1	1.98	1090639	2134	1.54
36	AS-SPL-53.lcd	GLIDE-M-60-850-801-HTM-AS-SPL-2	1.98	1090923	2142	1.53
	Average		1.98	1090781	2138	1.53
	%RSD		0.009	0.018	0.266	0.289

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
36	AS-SPL-52.lcd	GLIDE-M-60-850-801-HTM-AS-SPL-1	16.48	235661	18626	1.08
36	AS-SPL-53.lcd	GLIDE-M-60-850-801-HTM-AS-SPL-2	16.48	236362	18481	1.09
	Average		16.48	236012	18553	1.08
	%RSD		0.003	0.210	0.551	0.632

Analysed By

Checked By

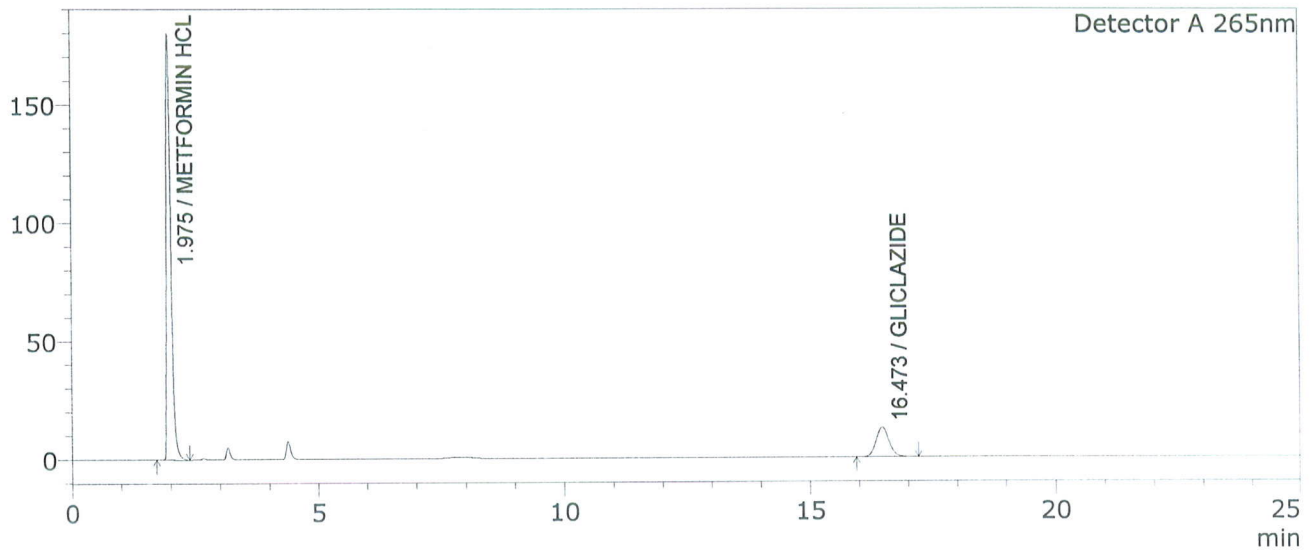

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS
 Sample ID : GLICLA+METFOR-AS-HTM-STD-BKT
 Data Filename : 09092023 GLIDE-M-TAB-AMV-ROBUSTNESS-AS-SPL-54.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS-HIGH TEMP_P.lcm
 Batch Filename : 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb
 Vial # : 2-35
 Injection Volume : 20 uL
 Date Acquired : 10-09-2023 14:46:48
 Date Processed : 11-09-2023 16:55:49

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV


<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.98	1124363	83.07	2150	1.489	--	--
2	GLICLAZIDE	16.47	229209	16.93	18753	1.108	44.500	--
Total			1353572	100.00				

Analysed By

Checked By



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Batch Table

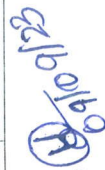
Batch Table 09092023 GLIDE-M-AMV-AS-ROBUSTNESS.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
19	2	ROBUSTNESS	AS-LWL-BLANK	LOW WAVE LENGTH.lcm	NESS-AS-SPL-01.lcd	20.0	QC/CL/23/041
20	2	ROBUSTNESS	GLICLA+METFORMIN-AS-LWL-STD-1	LOW WAVE LENGTH.lcm	NESS-AS-SPL-02.lcd	20.0	QC/CL/23/041
20	2	ROBUSTNESS	GLICLA+METFORMIN-AS-LWL-STD-2	LOW WAVE LENGTH.lcm	NESS-AS-SPL-03.lcd	20.0	QC/CL/23/041
20	2	ROBUSTNESS	GLICLA+METFORMIN-AS-LWL-STD-3	LOW WAVE LENGTH.lcm	NESS-AS-SPL-04.lcd	20.0	QC/CL/23/041
20	2	ROBUSTNESS	GLICLA+METFORMIN-AS-LWL-STD-4	LOW WAVE LENGTH.lcm	NESS-AS-SPL-05.lcd	20.0	QC/CL/23/041
20	2	ROBUSTNESS	GLICLA+METFORMIN-AS-LWL-STD-5	LOW WAVE LENGTH.lcm	NESS-AS-SPL-06.lcd	20.0	QC/CL/23/041
21	2	ROBUSTNESS	GLIDE-M-60-850-801-LWL-AS-SPL-1	LOW WAVE LENGTH.lcm	NESS-AS-SPL-07.lcd	20.0	QC/CL/23/041
21	2	ROBUSTNESS	GLIDE-M-60-850-801-LWL-AS-SPL-2	LOW WAVE LENGTH.lcm	NESS-AS-SPL-08.lcd	20.0	QC/CL/23/041
20	2	ROBUSTNESS	GLICLA+METFORMIN-AS-LWL-STD-BKT	LOW WAVE LENGTH.lcm	NESS-AS-SPL-09.lcd	20.0	QC/CL/23/041
22	2	ROBUSTNESS	AS-HWL-BLANK	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-10.lcd	20.0	QC/CL/23/041
23	2	ROBUSTNESS	GLICLA+METFORMIN-AS-HWL-STD-1	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-11.lcd	20.0	QC/CL/23/041
23	2	ROBUSTNESS	GLICLA+METFORMIN-AS-HWL-STD-2	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-12.lcd	20.0	QC/CL/23/041
23	2	ROBUSTNESS	GLICLA+METFORMIN-AS-HWL-STD-3	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-13.lcd	20.0	QC/CL/23/041
23	2	ROBUSTNESS	GLICLA+METFORMIN-AS-HWL-STD-4	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-14.lcd	20.0	QC/CL/23/041
23	2	ROBUSTNESS	GLICLA+METFORMIN-AS-HWL-STD-5	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-15.lcd	20.0	QC/CL/23/041
24	2	ROBUSTNESS	GLIDE-M-60-850-801-HWL-AS-SPL-1	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-16.lcd	20.0	QC/CL/23/041
24	2	ROBUSTNESS	GLIDE-M-60-850-801-HWL-AS-SPL-2	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-17.lcd	20.0	QC/CL/23/041
23	2	ROBUSTNESS	GLICLA+METFORMIN-AS-HWL-STD-BKT	HIGH WAVE LENGTH.lcm	NESS-AS-SPL-18.lcd	20.0	QC/CL/23/041

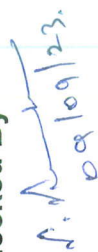
Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
25	2	ROBUSTNESS	AS-LOW FLOW-BLANK	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-19.lcd	20.0	QC/CL/23/041
26	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW FLOW-STD-1	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-20.lcd	20.0	QC/CL/23/041
26	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW FLOW-STD-2	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-21.lcd	20.0	QC/CL/23/041
26	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW FLOW-STD-3	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-22.lcd	20.0	QC/CL/23/041
26	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW FLOW-STD-4	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-23.lcd	20.0	QC/CL/23/041
26	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW FLOW-STD-5	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-24.lcd	20.0	QC/CL/23/041
27	2	ROBUSTNESS	GLIDE-M-60-850-801-LFL-AS-SPL-1	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-25.lcd	20.0	QC/CL/23/041
27	2	ROBUSTNESS	GLIDE-M-60-850-801-LFL-AS-SPL-2	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-26.lcd	20.0	QC/CL/23/041
26	2	ROBUSTNESS	GLICLA+METFOR-AS-LFL-STD-BKT	-TAB-AS-LOW FLOW.lcm	NESS-AS-SPL-27.lcd	20.0	QC/CL/23/041
28	2	ROBUSTNESS	AS-HIGH FLOW-BLANK	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-28.lcd	20.0	QC/CL/23/041
29	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHFLOW-STD-1	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-29.lcd	20.0	QC/CL/23/041
29	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHFLOW-STD-2	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-30.lcd	20.0	QC/CL/23/041
29	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHFLOW-STD-3	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-31.lcd	20.0	QC/CL/23/041
29	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHFLOW-STD-4	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-32.lcd	20.0	QC/CL/23/041
29	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHFLOW-STD-5	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-33.lcd	20.0	QC/CL/23/041
30	2	ROBUSTNESS	GLIDE-M-60-850-801-HFL-AS-SPL-1	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-34.lcd	20.0	QC/CL/23/041
30	2	ROBUSTNESS	GLIDE-M-60-850-801-HFL-AS-SPL-2	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-35.lcd	20.0	QC/CL/23/041
29	2	ROBUSTNESS	GLICLA+METFOR-AS-HFL-STD-BKT	TAB-AS-HIGH FLOW.lcm	NESS-AS-SPL-36.lcd	20.0	QC/CL/23/041
31	2	ROBUSTNESS	AS-LOW TEMP-BLANK	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-37.lcd	20.0	QC/CL/23/041
32	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW TEMP-STD-1	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-38.lcd	20.0	QC/CL/23/041
32	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW TEMP-STD-2	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-39.lcd	20.0	QC/CL/23/041
32	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW TEMP-STD-3	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-40.lcd	20.0	QC/CL/23/041
32	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW TEMP-STD-4	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-41.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
32	2	ROBUSTNESS	GLICLA+METFOR-AS-LOW TEMP-STD-5	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-42.lcd	20.0	QC/CL/23/041
33	2	ROBUSTNESS	GLIDE-M-60-850-801-LTM-AS-SPL-1	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-43.lcd	20.0	QC/CL/23/041
33	2	ROBUSTNESS	GLIDE-M-60-850-801-LTM-AS-SPL-2	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-44.lcd	20.0	QC/CL/23/041
32	2	ROBUSTNESS	GLICLA+METFOR-AS-LTM-STD-BKT	-TAB-AS-LOW TEMP.lcm	NESS-AS-SPL-45.lcd	20.0	QC/CL/23/041
34	2	ROBUSTNESS	AS-HIGH TEMP-BLANK	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-46.lcd	20.0	QC/CL/23/041
35	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHTEMP-STD-1	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-47.lcd	20.0	QC/CL/23/041
35	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHTEMP-STD-2	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-48.lcd	20.0	QC/CL/23/041
35	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHTEMP-STD-3	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-49.lcd	20.0	QC/CL/23/041
35	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHTEMP-STD-4	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-50.lcd	20.0	QC/CL/23/041
35	2	ROBUSTNESS	GLICLA+METFOR-AS-HIGHTEMP-STD-5	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-51.lcd	20.0	QC/CL/23/041
36	2	ROBUSTNESS	GLIDE-M-60-850-801-HTM-AS-SPL-1	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-52.lcd	20.0	QC/CL/23/041
36	2	ROBUSTNESS	GLIDE-M-60-850-801-HTM-AS-SPL-2	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-53.lcd	20.0	QC/CL/23/041
35	2	ROBUSTNESS	GLICLA+METFOR-AS-HTM-STD-BKT	-TAB-AS-HIGH TEMP.lcm	NESS-AS-SPL-54.lcd	20.0	QC/CL/23/041
-1	2	SHUTDOWN	SHUTDOWN	ETHOD\SHUTDOWN.lcm	NESS-AS-SPL-55.lcd	20.0	QC/CL/23/041

Analysed By



Checked By



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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

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

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60 mg

ASSAY 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 :	60.19	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.38	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120.015	1	ml to --->	1	ml to --->	1	ml to --->	1

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

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	241054	240479	240159	239448	239534	240135	670	0.279
Bracketing Std.	235398	231146				238174	3608	1.515

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	1360.17	242472	60.77	101.3	100.2	1.48
Sample Preparation-2	1360.08	241602	60.55	100.9		
Sample Preparation-3	1360.01	244608	61.31	102.2		
Sample Preparation-4	1360.12	235643	59.06	98.4		
Sample Preparation-5	1360.19	236766	59.34	98.9		
Sample Preparation-6	1360.02	238220	59.71	99.5		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

E.MEENA

Date :

11-09-2023

Checked by :

Date :

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

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

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	850.21	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.42	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1700.2125	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	850
Average weight :	1360

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	1126691	1126540	1125953	1125827	1126556	1126313	393	0.035
Bracketing Std.	1126159	1124991				1126313	393	0.035

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	1360.17	1105084	835.75	98.3	97.9	1.52
Sample Preparation-2	1360.08	1118042	845.60	99.5		
Sample Preparation-3	1360.01	1119782	846.96	99.6		
Sample Preparation-4	1360.12	1080840	817.44	96.2		
Sample Preparation-5	1360.19	1090694	824.85	97.0		
Sample Preparation-6	1360.02	1085680	821.16	96.6		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by : E.MEENA
Date : 11-09-2023

11/09/23

Checked by :
Date : 11/09/23



GENERIC HEALTHCARE PVT. LTD.

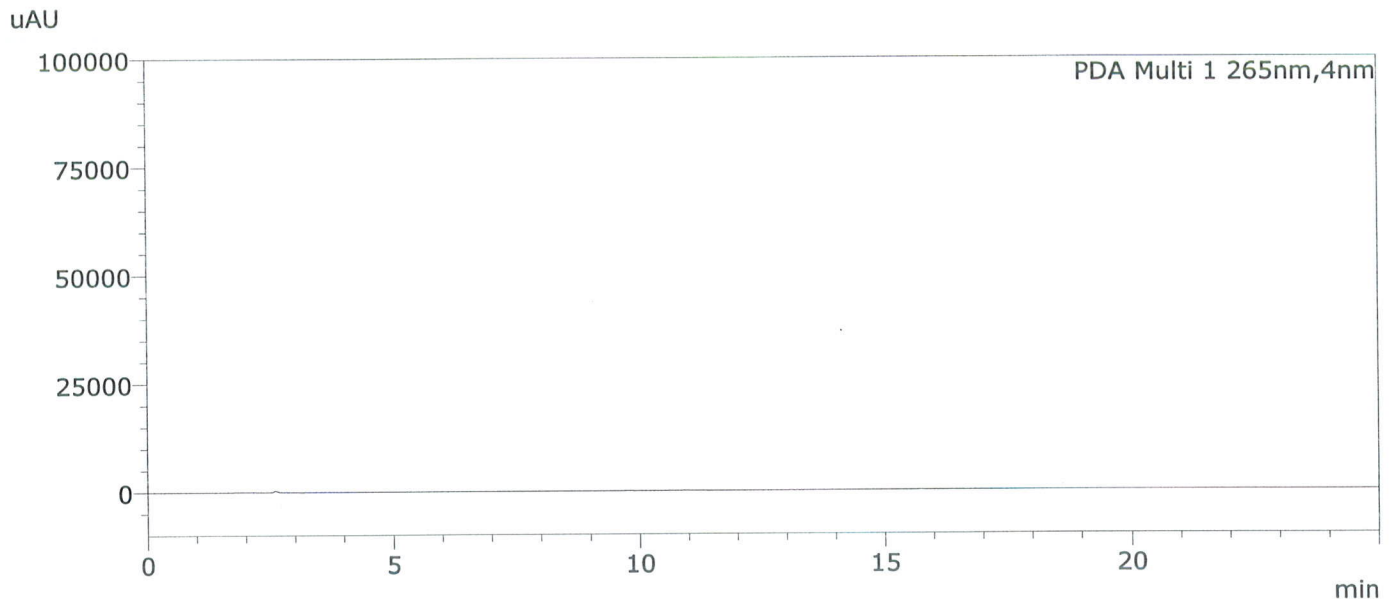
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : AS-BLANK
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-01.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY
 Vial # : 3-1
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 16:35:25
 Date Processed : 11-09-2023 09:41:39

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

<Chromatogram>



<Peak Table>

PDA Ch1 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

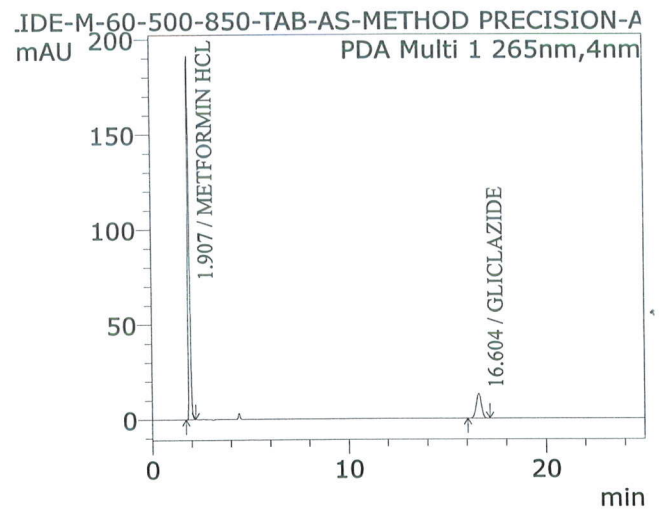
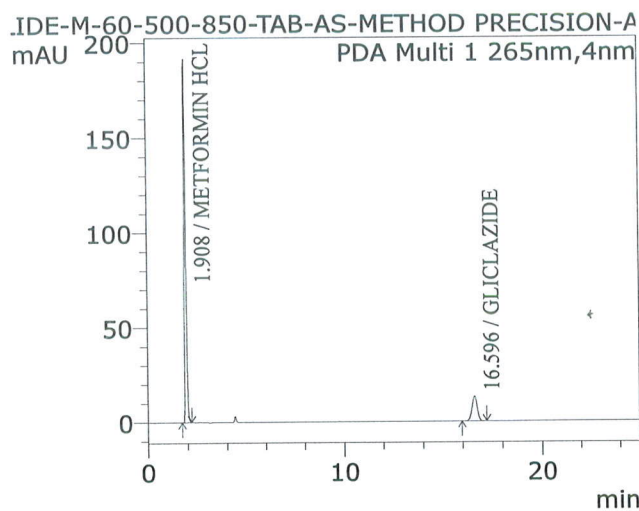
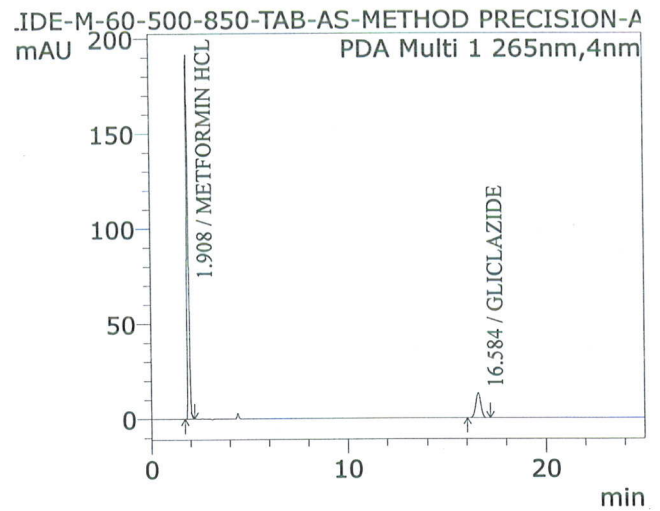
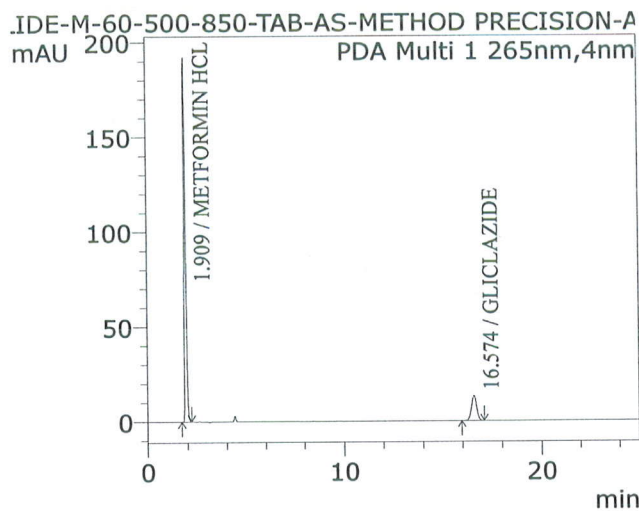
Analysis Report

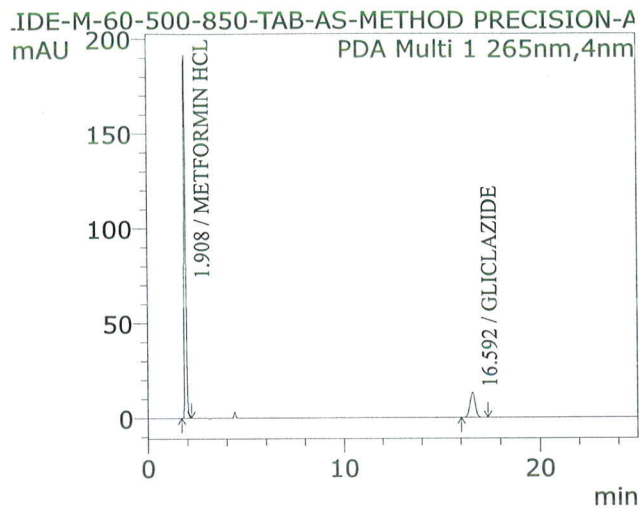
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Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-02.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER 5
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 17:00:59
 Date Processed : 11-09-2023 09:41:39

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

<Chromatogram>





<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.91	1126691	2043	1.29
2	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.91	1126540	2019	1.29
2	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.91	1125953	2026	1.29
2	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.91	1125827	1984	1.30
2	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.91	1126556	2029	1.29
	Average		1.91	1126313	2020	1.29
	%RSD		0.040	0.035	1.083	0.268

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	16.57	241054	18285	0.99
2	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	16.58	240479	18279	0.99
2	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	16.60	240159	18261	0.99
2	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	16.60	239448	18305	0.99
2	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	16.59	239534	18334	1.00
	Average		16.59	240135	18293	0.99
	%RSD		0.071	0.279	0.152	0.050

Analysed By

①
11/09/23

Checked By

11/09/23



GENERIC HEALTHCARE PVT. LTD.

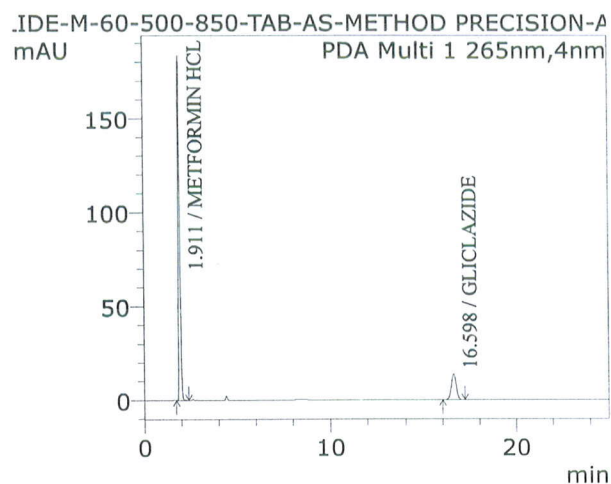
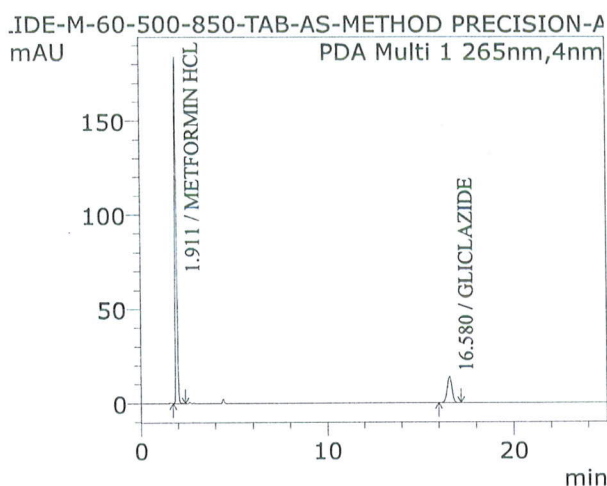
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-801-SET1-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-07.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-3
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 19:08:52
 Date Processed : 11-09-2023 10:41:23

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	AS-SPL-07.lcd	GLIDEM-60-850-801-SET1-AS-SPL-1	1.91	1104718	1871	1.27
3	AS-SPL-08.lcd	GLIDEM-60-850-801-SET1-AS-SPL-2	1.91	1105450	1860	1.28
	Average		1.91	1105084	1866	1.27
	%RSD		0.010	0.047	0.434	0.116

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	AS-SPL-07.lcd	GLIDEM-60-850-801-SET1-AS-SPL-1	16.58	241409	18353	0.99
3	AS-SPL-08.lcd	GLIDEM-60-850-801-SET1-AS-SPL-2	16.60	243535	18372	0.99
	Average		16.59	242472	18362	0.99
	%RSD		0.077	0.620	0.073	0.109

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

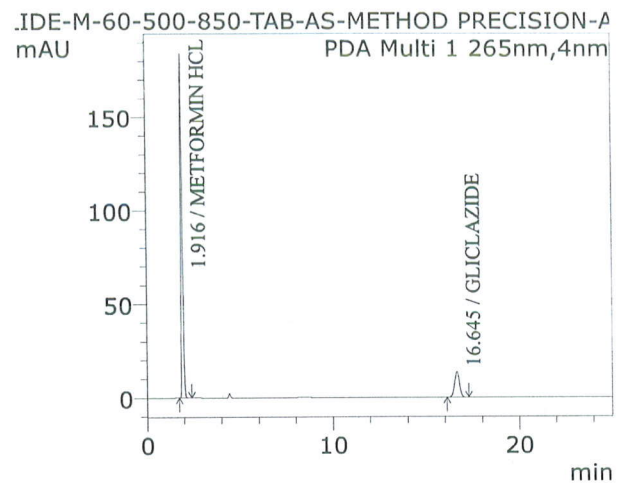
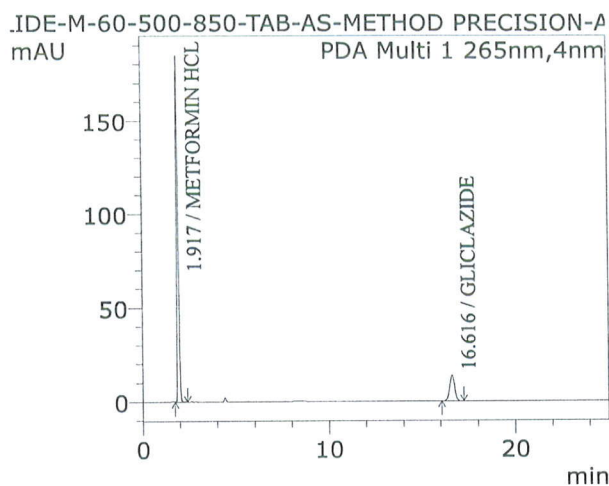
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-801-SET2-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-09.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-4
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 20:00:07
 Date Processed : 11-09-2023 10:41:53

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
4	AS-SPL-09.lcd	GLIDEM-60-850-801-SET2-AS-SPL-1	1.92	1118867	1921	1.28
4	AS-SPL-10.lcd	GLIDEM-60-850-801-SET2-AS-SPL-2	1.92	1117217	1881	1.28
	Average		1.92	1118042	1901	1.28
	%RSD		0.051	0.104	1.469	0.072

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
4	AS-SPL-09.lcd	GLIDEM-60-850-801-SET2-AS-SPL-1	16.62	242733	18465	1.00
4	AS-SPL-10.lcd	GLIDEM-60-850-801-SET2-AS-SPL-2	16.64	240471	18434	1.00
	Average		16.63	241602	18450	1.00
	%RSD		0.122	0.662	0.116	0.187

Analysed By

Checked By

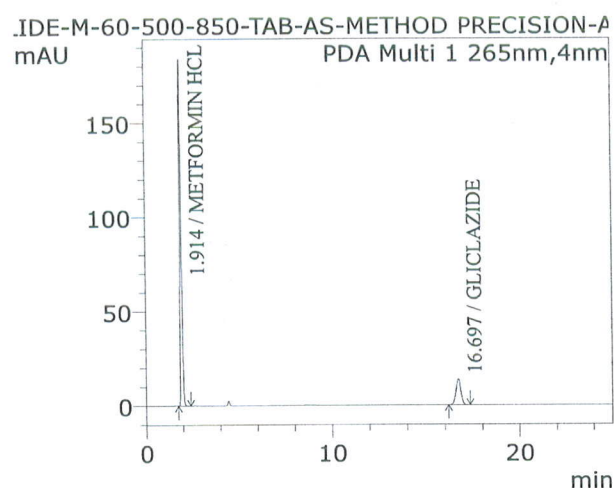
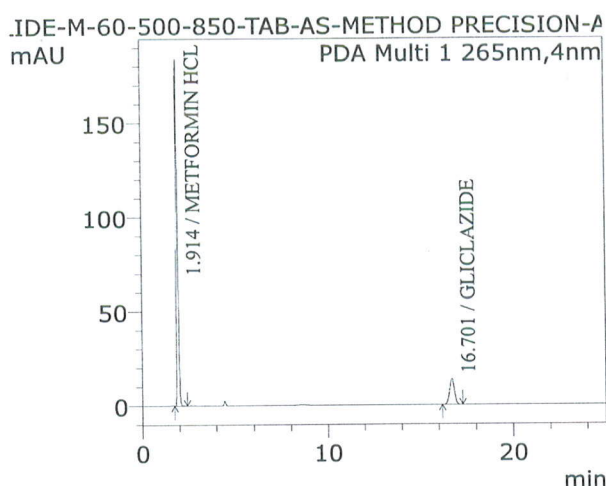

GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-801-SET3-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-11.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-5
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 20:51:27
 Date Processed : 11-09-2023 10:42:24
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	AS-SPL-11.lcd	GLIDEM-60-850-801-SET3-AS-SPL-1	1.91	1119344	1864	1.28
5	AS-SPL-12.lcd	GLIDEM-60-850-801-SET3-AS-SPL-2	1.91	1120220	1858	1.28
	Average		1.91	1119782	1861	1.28
	%RSD		0.004	0.055	0.207	0.014

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	AS-SPL-11.lcd	GLIDEM-60-850-801-SET3-AS-SPL-1	16.70	243519	18420	1.00
5	AS-SPL-12.lcd	GLIDEM-60-850-801-SET3-AS-SPL-2	16.70	245696	18468	1.00
	Average		16.70	244608	18444	1.00
	%RSD		0.016	0.629	0.184	0.057

Analysed By

11/09/23

Checked By

11/09/23


GENERIC HEALTHCARE PVT. LTD.

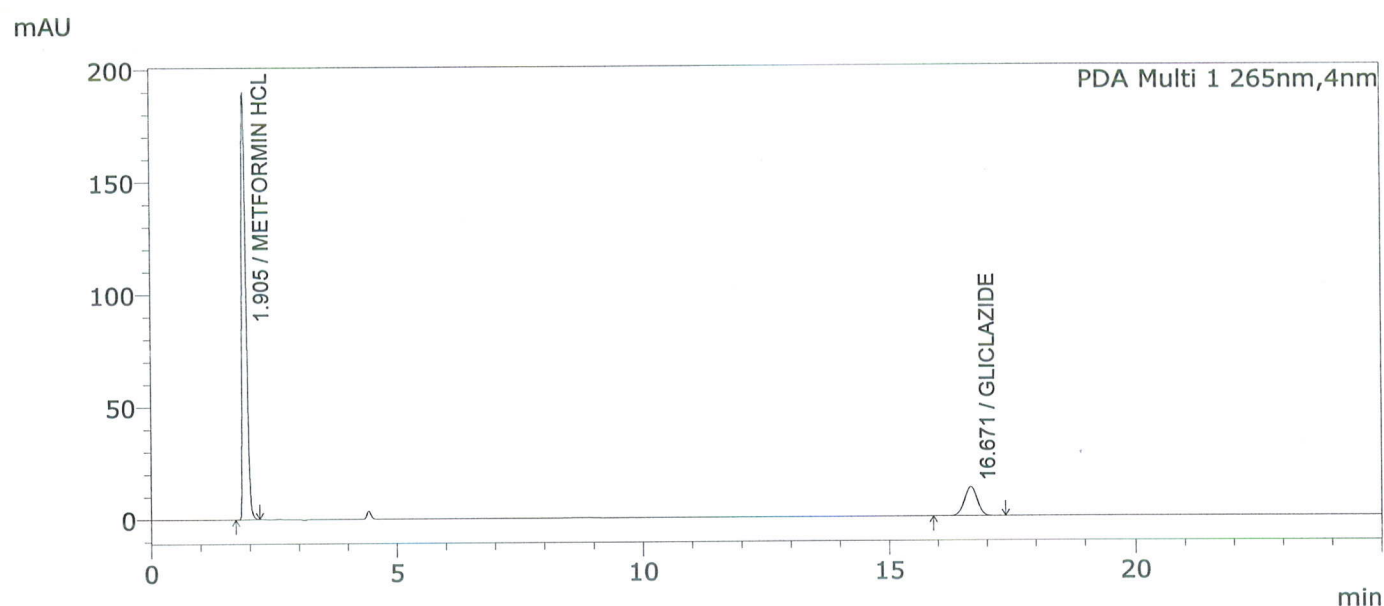
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-13.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 21:42:36
 Date Processed : 11-09-2023 09:41:42

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

<Chromatogram>



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	1126159	82.71	1965	1.306	--	--
2	GLICLAZIDE	16.67	235398	17.29	18491	1.003	44.590	--
Total			1361557	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

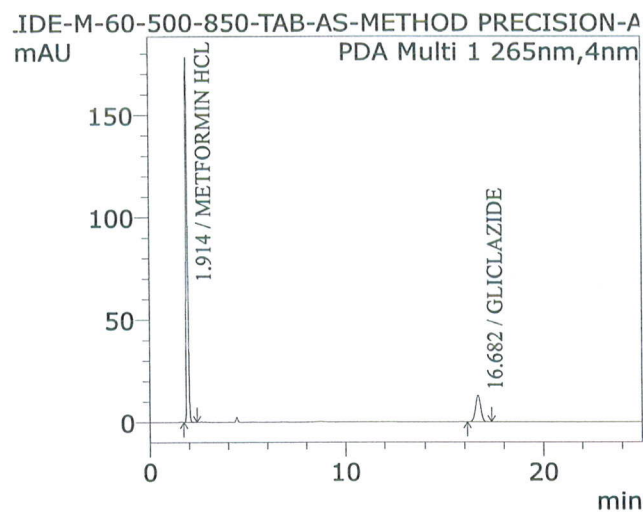
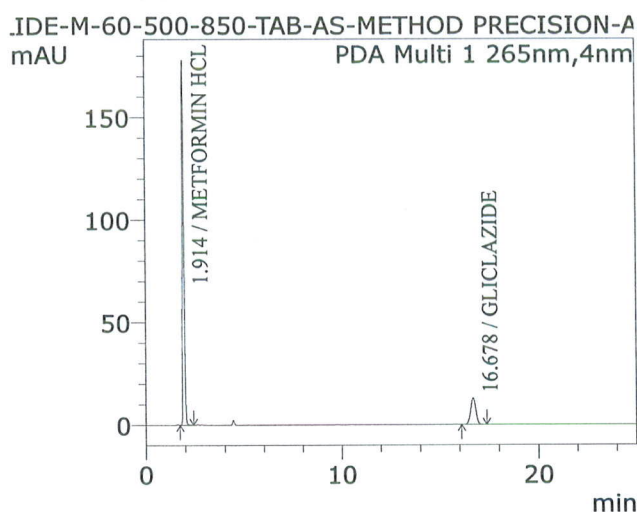
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-801-SET4-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-14.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-6
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 22:08:09
 Date Processed : 11-09-2023 09:41:43

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	AS-SPL-14.lcd	GLIDEM-60-850-801-SET4-AS-SPL-1	1.91	1080546	1880	1.28
6	AS-SPL-15.lcd	GLIDEM-60-850-801-SET4-AS-SPL-2	1.91	1081134	1873	1.28
	Average		1.91	1080840	1876	1.28
	%RSD		0.023	0.038	0.260	0.023

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	AS-SPL-14.lcd	GLIDEM-60-850-801-SET4-AS-SPL-1	16.68	235953	18497	1.00
6	AS-SPL-15.lcd	GLIDEM-60-850-801-SET4-AS-SPL-2	16.68	235334	18522	1.01
	Average		16.68	235643	18509	1.01
	%RSD		0.015	0.186	0.096	0.064

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

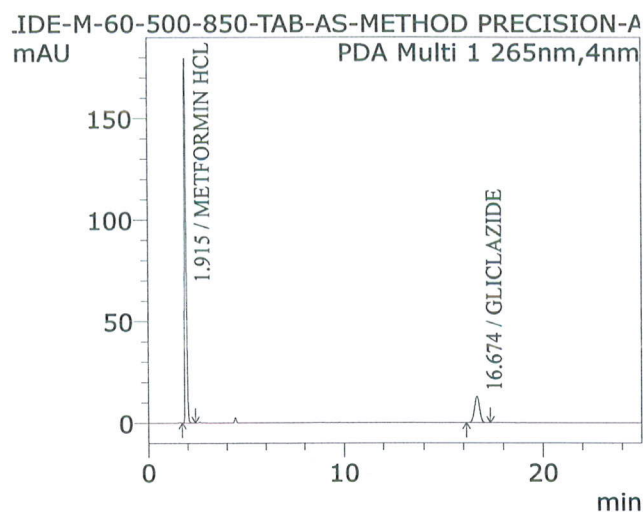
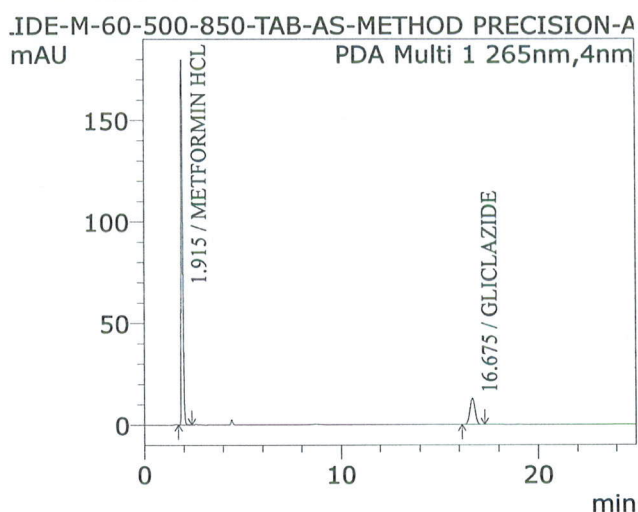
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-801-SET5-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-16.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-7
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 22:59:18
 Date Processed : 11-09-2023 09:41:43

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
7	AS-SPL-16.lcd	GLIDEM-60-850-801-SET5-AS-SPL-1	1.91	1091113	1887	1.29
7	AS-SPL-17.lcd	GLIDEM-60-850-801-SET5-AS-SPL-2	1.91	1090275	1888	1.29
	Average		1.91	1090694	1888	1.29
	%RSD		0.002	0.054	0.035	0.037

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
7	AS-SPL-16.lcd	GLIDEM-60-850-801-SET5-AS-SPL-1	16.68	237018	18503	1.01
7	AS-SPL-17.lcd	GLIDEM-60-850-801-SET5-AS-SPL-2	16.67	236515	18515	1.01
	Average		16.67	236766	18509	1.01
	%RSD		0.006	0.150	0.045	0.097

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

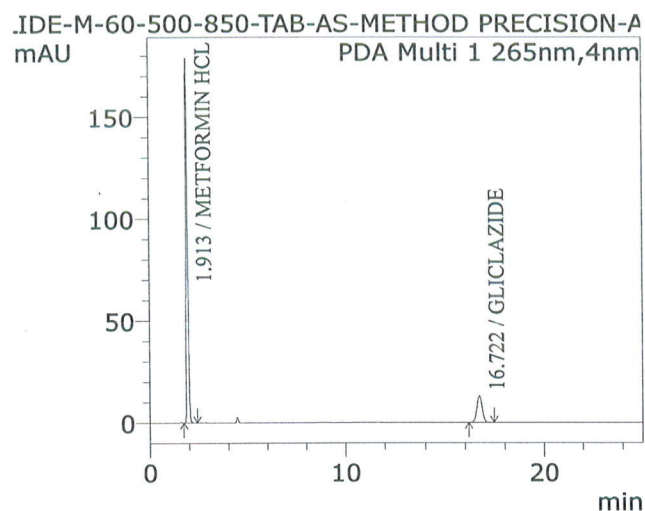
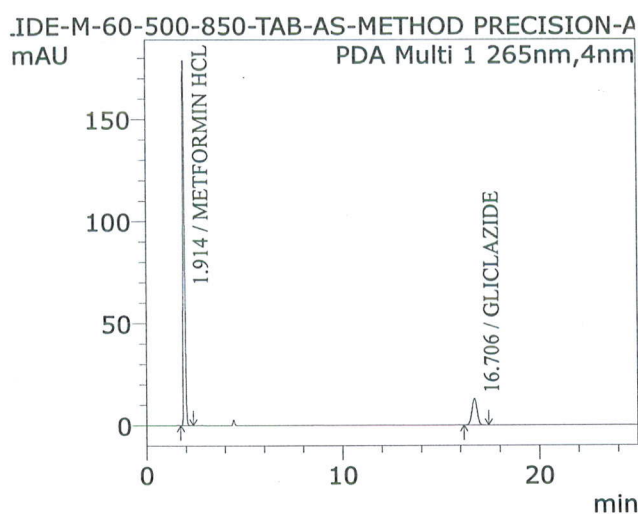
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-801-SET6-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-18.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-8
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 23:50:27
 Date Processed : 11-09-2023 09:41:44

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
8	AS-SPL-18.lcd	GLIDEM-60-850-801-SET6-AS-SPL-1	1.91	1084998	1882	1.29
8	AS-SPL-19.lcd	GLIDEM-60-850-801-SET6-AS-SPL-2	1.91	1086362	1858	1.29
	Average		1.91	1085680	1870	1.29
	%RSD		0.054	0.089	0.919	0.026

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
8	AS-SPL-18.lcd	GLIDEM-60-850-801-SET6-AS-SPL-1	16.71	238483	18475	1.01
8	AS-SPL-19.lcd	GLIDEM-60-850-801-SET6-AS-SPL-2	16.72	237957	18492	1.01
	Average		16.71	238220	18483	1.01
	%RSD		0.069	0.156	0.062	0.075

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

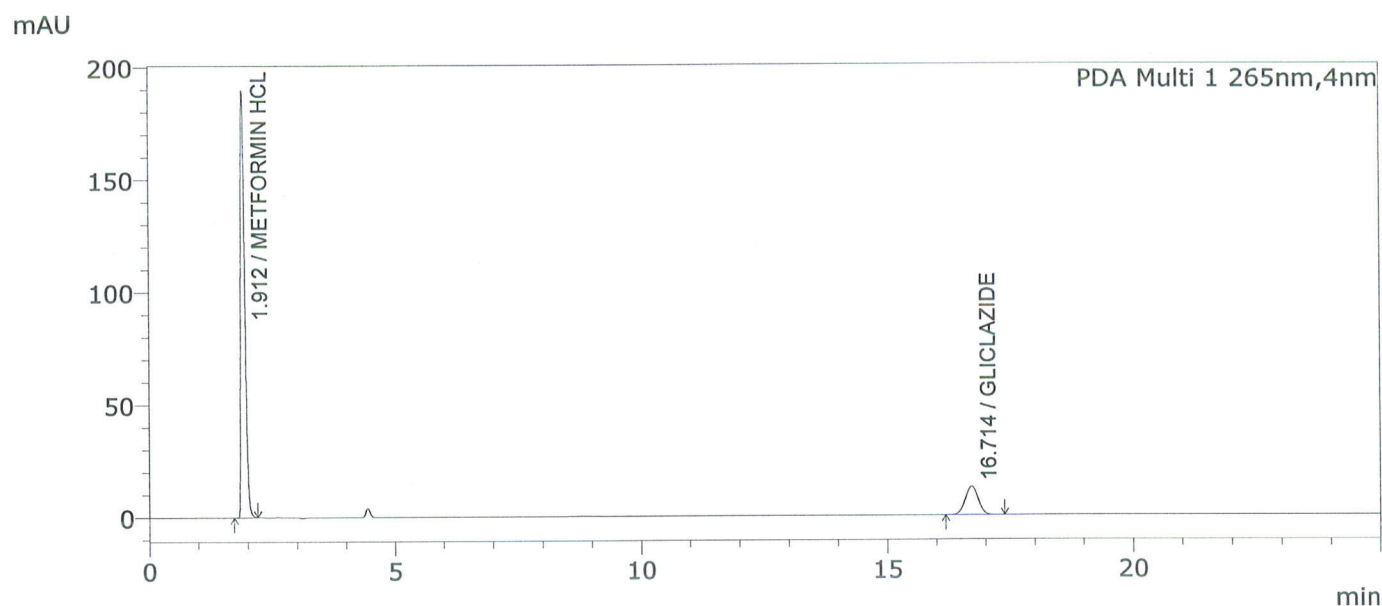
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-2
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-20.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY
 Vial # : 3-2
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 00:41:36
 Date Processed : 11-09-2023 09:41:44

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

<Chromatogram>



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	1124991	82.96	1952	1.294	--	--
2	GLICLAZIDE	16.71	231146	17.04	18538	1.008	44.572	--
Total			1356137	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 08092023_GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	3	METHOD PRECISION	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-01.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-02.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-03.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-04.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-SPL-05.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-06.lcd	20.0	QC/CL/20/017
3	3	METHOD PRECISION	GLIDEM-60-850-801-SET1-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-07.lcd	20.0	QC/CL/20/017
3	3	METHOD PRECISION	GLIDEM-60-850-801-SET1-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-08.lcd	20.0	QC/CL/20/017
4	3	METHOD PRECISION	GLIDEM-60-850-801-SET2-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-09.lcd	20.0	QC/CL/20/017
4	3	METHOD PRECISION	GLIDEM-60-850-801-SET2-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-10.lcd	20.0	QC/CL/20/017
5	3	METHOD PRECISION	GLIDEM-60-850-801-SET3-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-11.lcd	20.0	QC/CL/20/017
5	3	METHOD PRECISION	GLIDEM-60-850-801-SET3-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-12.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLA+METFORMIN-AS-STD-BKT-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-13.lcd	20.0	QC/CL/20/017
6	3	METHOD PRECISION	GLIDEM-60-850-801-SET4-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-14.lcd	20.0	QC/CL/20/017
6	3	METHOD PRECISION	GLIDEM-60-850-801-SET4-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-15.lcd	20.0	QC/CL/20/017
7	3	METHOD PRECISION	GLIDEM-60-850-801-SET5-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-16.lcd	20.0	QC/CL/20/017
7	3	METHOD PRECISION	GLIDEM-60-850-801-SET5-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-17.lcd	20.0	QC/CL/20/017
8	3	METHOD PRECISION	GLIDEM-60-850-801-SET6-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-18.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
8	3	METHOD PRECISION	GLIDEM60-850-801-SET6-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-19.lcd	20.0	QC/CL/20/017
2	3	METHOD PRECISION	GLICLA+METFORMIN-AS-STD-BKT-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-20.lcd	20.0	QC/CL/20/017
9	3	FILTER PAPER STUDY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-21.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-22.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-23.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-24.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-SPL-25.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-26.lcd	20.0	QC/CL/20/017
11	3	FILTER PAPER STUDY	GLIDEM60-850-801-CENTR-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-27.lcd	20.0	QC/CL/20/017
11	3	FILTER PAPER STUDY	GLIDEM60-850-801-CENTR-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-28.lcd	20.0	QC/CL/20/017
12	3	FILTER PAPER STUDY	GLIDEM60-850-801-FIL-1-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-29.lcd	20.0	QC/CL/20/017
12	3	FILTER PAPER STUDY	GLIDEM60-850-801-FIL-1-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-30.lcd	20.0	QC/CL/20/017
13	3	FILTER PAPER STUDY	GLIDEM60-850-801-FIL-2-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-31.lcd	20.0	QC/CL/20/017
13	3	FILTER PAPER STUDY	GLIDEM60-850-801-FIL-2-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-32.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLA+METFORMIN-AS-STD-BKT-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-33.lcd	20.0	QC/CL/20/017
14	3	FILTER PAPER STUDY	GLIDEM60-850-801-FIL-3-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-34.lcd	20.0	QC/CL/20/017
14	3	FILTER PAPER STUDY	GLIDEM60-850-801-FIL-3-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-35.lcd	20.0	QC/CL/20/017
10	3	FILTER PAPER STUDY	GLICLA+METFORMIN-AS-STD-BKT-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-36.lcd	20.0	QC/CL/20/017
-1	3	SHUTDOWN	SHUTDOWN	HUTDOWN METHOD.lcm	ISION-AS-SPL-37.lcd	20.0	QC/CL/20/017

08/09/23

Analysed By

Checked By

08/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF METFORMIN HCL AND GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
				WS No.:	ST/WS/22/040	% Purity (aib)	100.0

Metformin Std.Dil:	850.21	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.42	1	ml to --->	1	ml to --->	1	ml to --->	1

Gliclazide Std.Dil:	60.19	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.38	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	1360.28	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1700.35	1	ml to --->	1	ml to --->	1	ml to --->	1

Average weight : 1360 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	1126349	1127042	1127368	1127941	1126860	1127112	592	0.053
With Bracketing std	1130777	1131923				1128323	2149	0.190
Gliclazide	230021	229485	229533	227884	227973	228979	982	0.429
With Bracketing std	224256	222786				227420	2814	1.237

Sample Name	METFORMIN HCL			GLICLAZIDE		
	Sample Area	Assay in %	% Difference from unfiltered	Sample Area	Assay in %	% Difference from unfiltered
Unfiltered sample (Centrifuged)	1108223	98.5	Not applicable	234759	102.8	Not applicable
Filter Set-1 (0.45µ Nylon membrane)	1095068	97.4	1.17	235286	103.1	-0.23
Filter Set-2 (0.45µ Nylon membrane)	1092342	97.1	1.41	232844	102.0	0.84
Filter Set-3 (0.45µ Nylon membrane)	1090956	97.0	1.54	231066	101.2	1.62

Results : The % difference on filtered Sample (0.45 µm nylon 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 : 11-09-2023

11/09/23

Checked by :
Date : 11/09/23



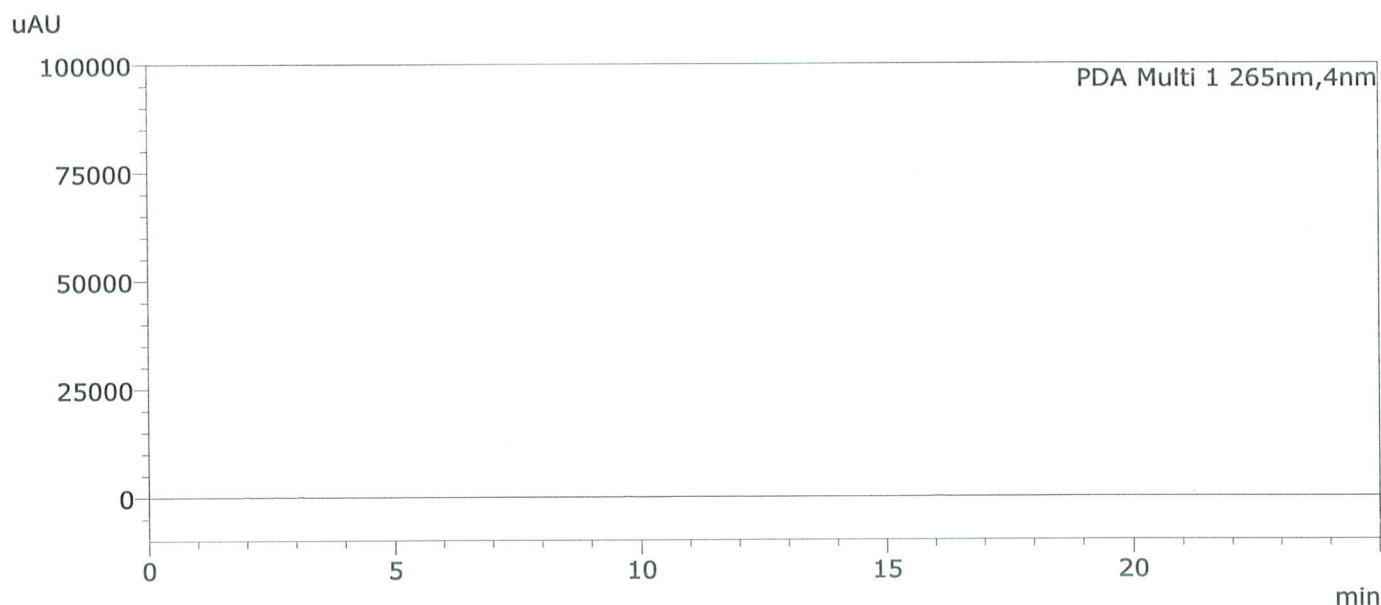
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : AS-BLANK
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-21.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY
 Vial # : 3-9
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 01:07:10
 Date Processed : 11-09-2023 09:41:45
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

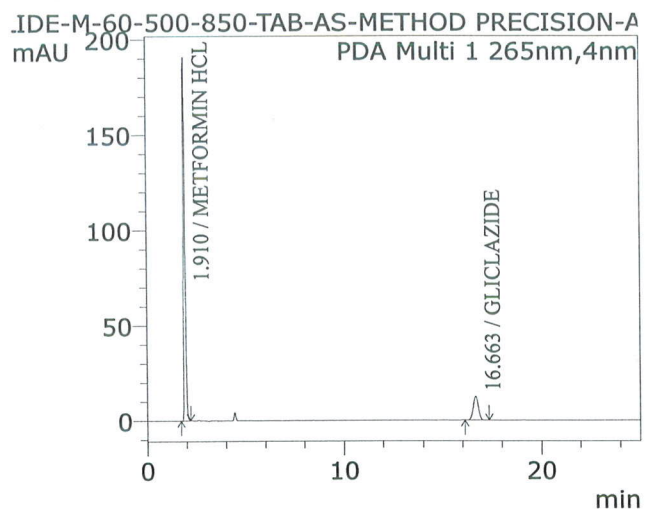
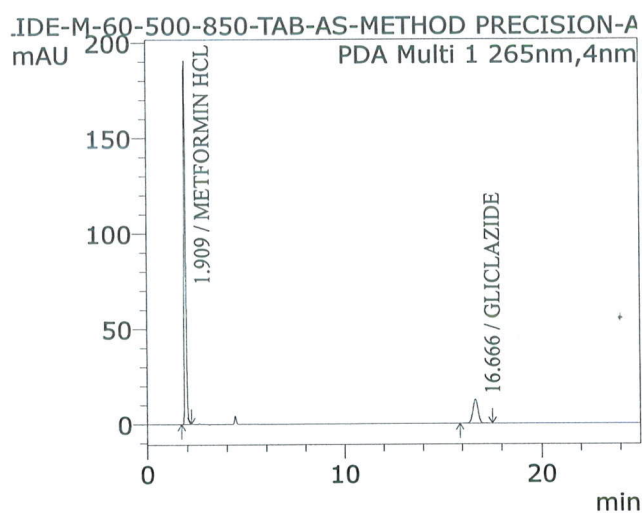
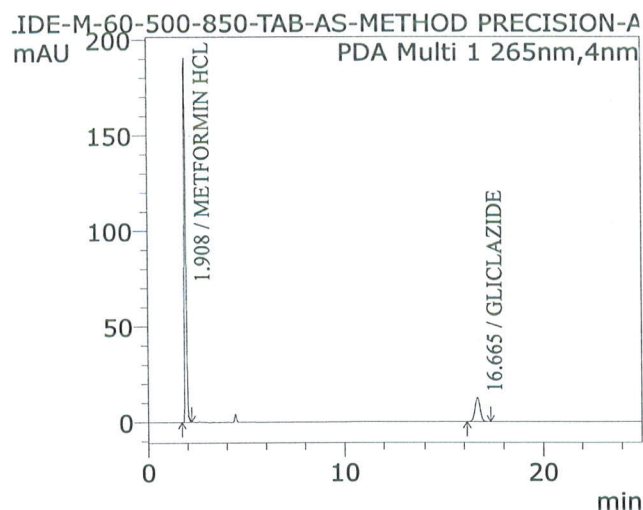
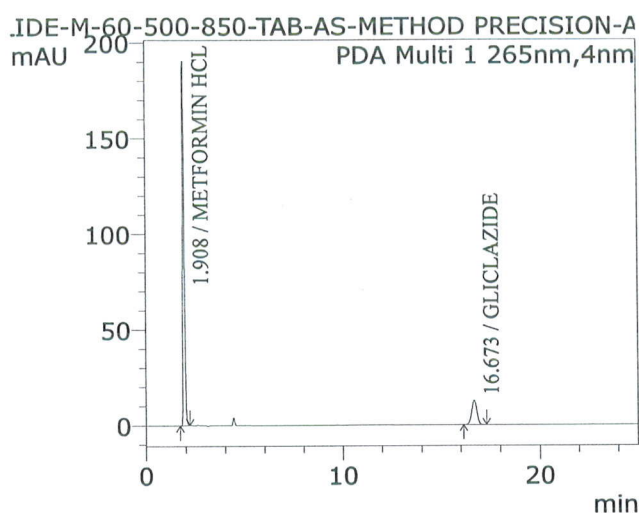
Analysis Report

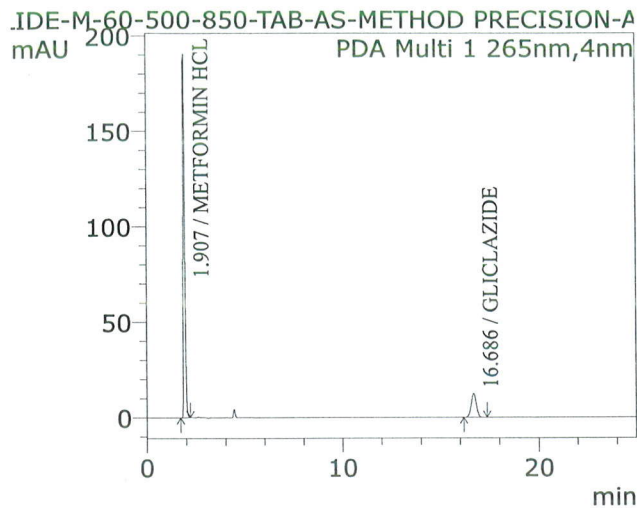
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Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-22.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-10
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 01:32:45
 Date Processed : 11-09-2023 09:41:45

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

<Chromatogram>





<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
10	AS-SPL-22.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.91	1126349	2008	1.30
10	AS-SPL-23.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.91	1127042	2009	1.30
10	AS-SPL-24.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.91	1127368	2018	1.30
10	AS-SPL-25.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.91	1127941	1921	1.30
10	AS-SPL-26.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.91	1126860	2003	1.31
	Average		1.91	1127112	1992	1.30
	%RSD		0.047	0.053	2.010	0.260

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
10	AS-SPL-22.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	16.67	230021	18554	1.01
10	AS-SPL-23.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	16.67	229485	18583	1.01
10	AS-SPL-24.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	16.67	229533	18583	1.01
10	AS-SPL-25.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	16.66	227884	18584	1.01
10	AS-SPL-26.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	16.69	227973	18481	1.01
	Average		16.67	228979	18557	1.01
	%RSD		0.057	0.429	0.239	0.055

Analysed By

11/09/23

Checked By

11/09/23



GENERIC HEALTHCARE PVT. LTD.

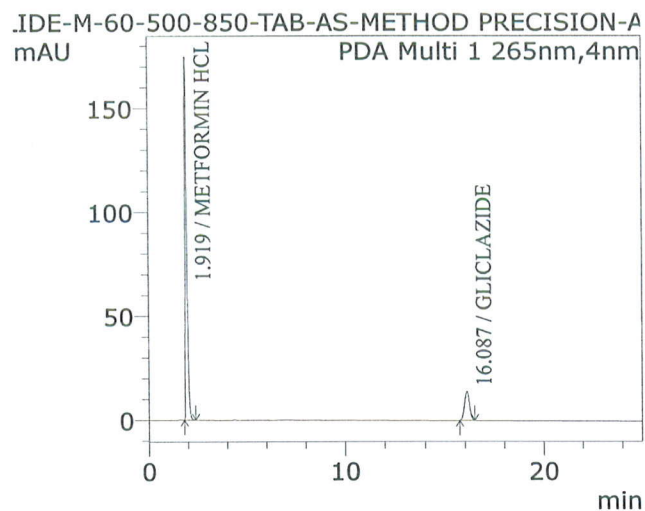
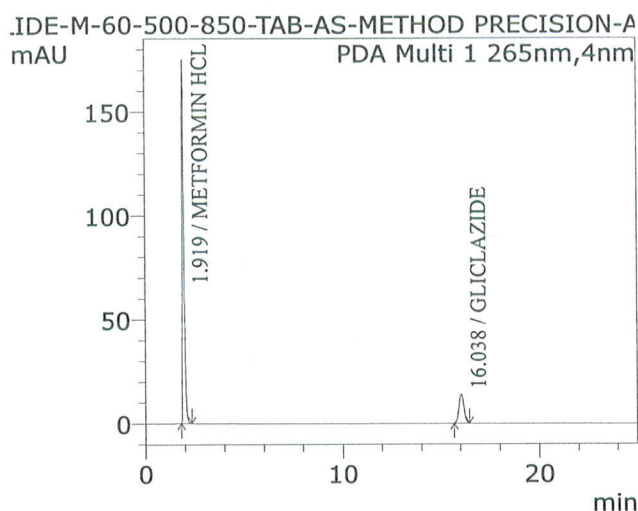
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-850-801-CENTR-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-27.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-11
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 03:40:38
 Date Processed : 11-09-2023 09:44:26

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
11	AS-SPL-27.lcd	GLIDEM60-850-801-CENTR-AS-SPL-1	1.92	1166461	1684	1.58
11	AS-SPL-28.lcd	GLIDEM60-850-801-CENTR-AS-SPL-2	1.92	1169984	1667	1.58
	Average		1.92	1168223	1676	1.58
	%RSD		0.012	0.213	0.702	0.181

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
11	AS-SPL-27.lcd	GLIDEM60-850-801-CENTR-AS-SPL-1	16.04	245647	18188	1.03
11	AS-SPL-28.lcd	GLIDEM60-850-801-CENTR-AS-SPL-2	16.09	245871	18175	1.03
	Average		16.06	245759	18181	1.03
	%RSD		0.216	0.064	0.052	0.140

Analysed By

11/09/23

Checked By

11/09/23



GENERIC HEALTHCARE PVT. LTD.

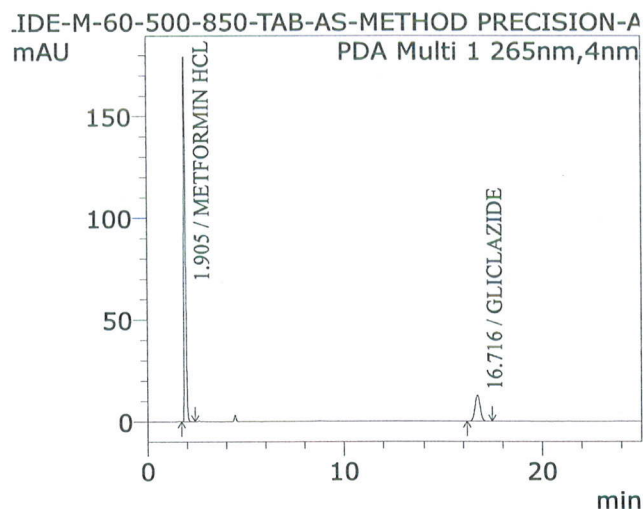
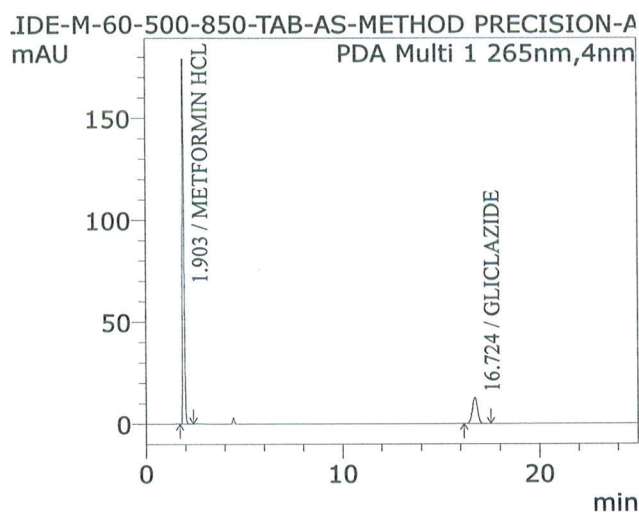
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-850-801-FIL-1-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-29.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-12
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 04:31:58
 Date Processed : 11-09-2023 09:41:47

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	AS-SPL-29.lcd	GLIDEM60-850-801-FIL-1-AS-SPL-1	1.90	1095308	1829	1.29
12	AS-SPL-30.lcd	GLIDEM60-850-801-FIL-1-AS-SPL-2	1.90	1094827	1842	1.29
	Average		1.90	1095068	1835	1.29
	%RSD		0.043	0.031	0.484	0.098

* ID#2 Compound Name: GLICLAZIDE *

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	AS-SPL-29.lcd	GLIDEM60-850-801-FIL-1-AS-SPL-1	16.72	235346	18356	1.01
12	AS-SPL-30.lcd	GLIDEM60-850-801-FIL-1-AS-SPL-2	16.72	235226	18422	1.01
	Average		16.72	235286	18389	1.01
	%RSD		0.034	0.036	0.256	0.067

Analysed By

[Signature]
11/09/23

Checked By

[Signature]
11/09/23



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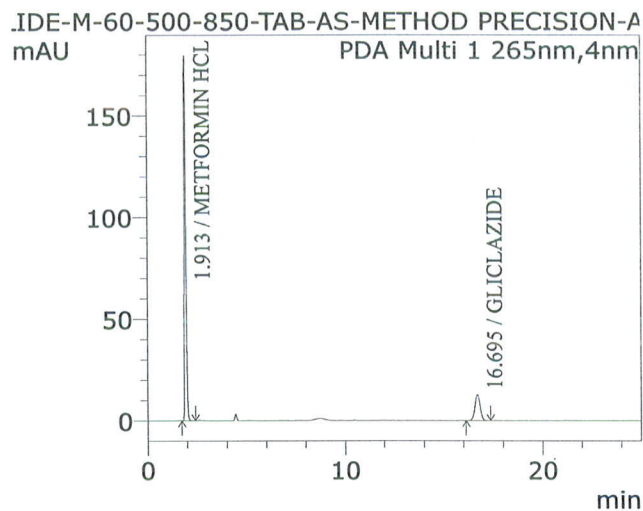
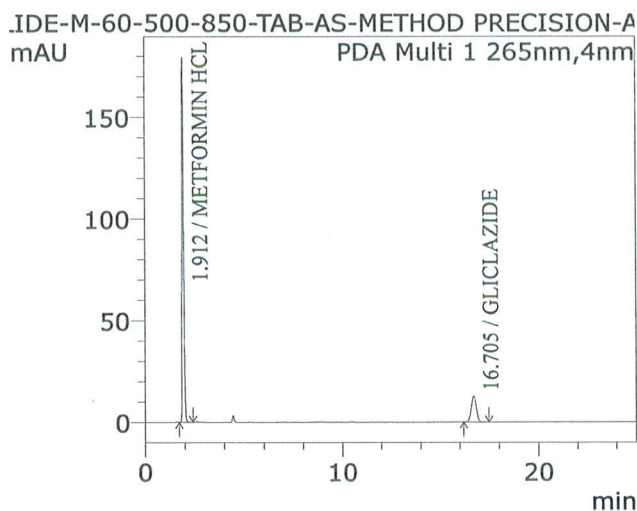
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-850-801-FIL-2-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-31.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-13
 Injection Volume : 20 µL
 Date Acquired : 09-09-2023 05:23:12
 Date Processed : 11-09-2023 09:41:48

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	AS-SPL-31.lcd	GLIDEM60-850-801-FIL-2-AS-SPL-1	1.91	1091864	1846	1.29
13	AS-SPL-32.lcd	GLIDEM60-850-801-FIL-2-AS-SPL-2	1.91	1092821	1851	1.28
	Average		1.91	1092342	1849	1.28
	%RSD		0.025	0.062	0.208	0.062

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	AS-SPL-31.lcd	GLIDEM60-850-801-FIL-2-AS-SPL-1	16.71	233077	18474	1.01
13	AS-SPL-32.lcd	GLIDEM60-850-801-FIL-2-AS-SPL-2	16.69	232610	18507	1.01
	Average		16.70	232844	18491	1.01
	%RSD		0.044	0.142	0.128	0.014

Analysed By

11/09/23

Checked By

11/09/23



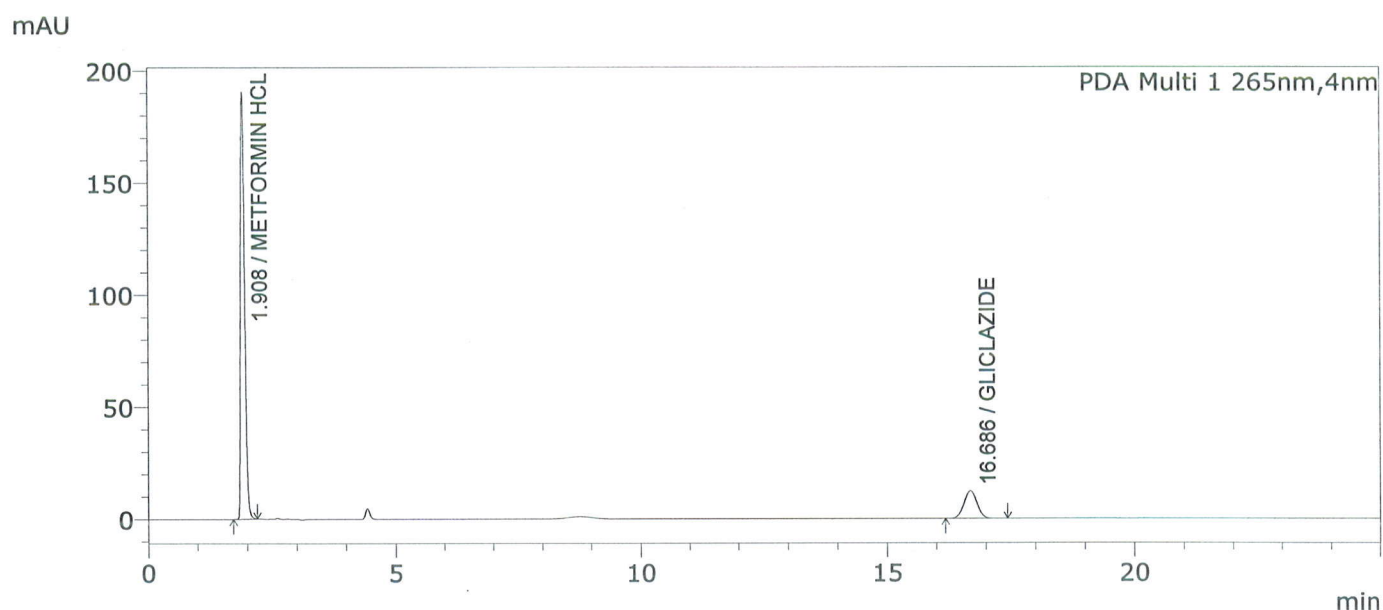
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-33.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY
 Vial # : 3-10
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 06:14:25
 Date Processed : 11-09-2023 09:41:48
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	1130777	83.45	2001	1.305	--	--
2	GLICLAZIDE	16.69	224256	16.55	18528	1.013	44.714	--
Total			1355034	100.00				

Analysed By

Checked By



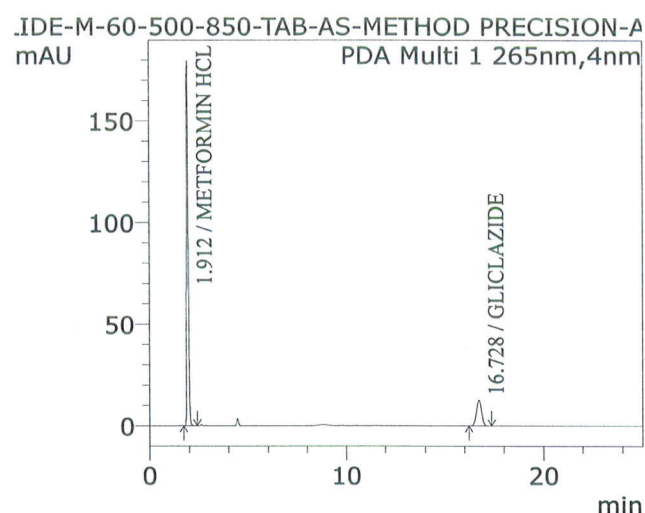
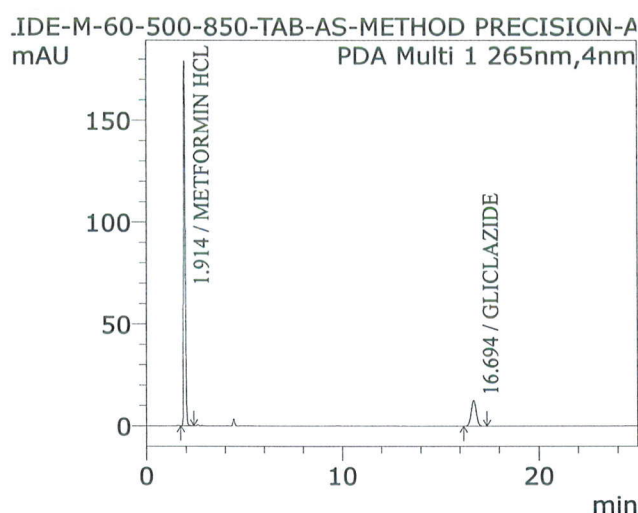
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-850-801-FIL-3-AS-SPL-1
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-34.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER S
 Vial # : 3-14
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 06:40:00
 Date Processed : 11-09-2023 09:41:49
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	AS-SPL-34.lcd	GLIDEM60-850-801-FIL-3-AS-SPL-1	1.91	1091160	1859	1.29
14	AS-SPL-35.lcd	GLIDEM60-850-801-FIL-3-AS-SPL-2	1.91	1090751	1841	1.29
	Average		1.91	1090956	1850	1.29
	%RSD		0.075	0.027	0.680	0.167

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	AS-SPL-34.lcd	GLIDEM60-850-801-FIL-3-AS-SPL-1	16.69	231127	18483	1.01
14	AS-SPL-35.lcd	GLIDEM60-850-801-FIL-3-AS-SPL-2	16.73	231004	18500	1.01
	Average		16.71	231066	18492	1.01
	%RSD		0.144	0.038	0.068	0.044

Analysed By *[Signature]* 11/09/23

Checked By *[Signature]* 11/09/23



GENERIC HEALTHCARE PVT. LTD.

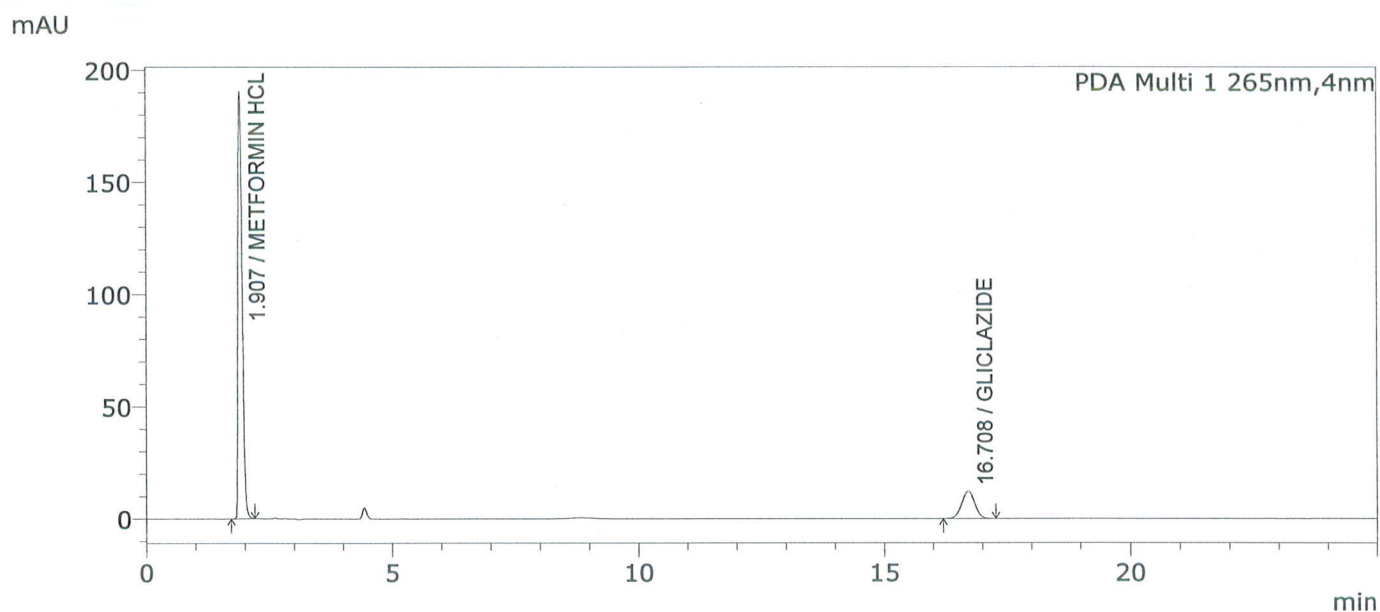
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-2
 Data Filename : 08092023 GLIDE-M-60-500-850-TAB-AS-METHOD PRECISION-AS-SPL-36.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 08092023 GLIDE-M-60-500-850-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY
 Vial # : 3-10
 Injection Volume : 20 uL
 Date Acquired : 09-09-2023 07:31:08
 Date Processed : 11-09-2023 09:41:49

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

<Chromatogram>



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	1131923	83.55	1988	1.310	--	--
2	GLICLAZIDE	16.71	222786	16.45	18500	1.013	44.684	--
Total			1354709	100.00				

Analysed By

Checked By

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Parameter :	INTERFERENCE FROM DEGRADANTS (5N)	Exp.Date :	Jul-26

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL AND GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
				WS No.:	ST/WS/22/040	% Purity (aib)	100.0

Metformin Std. Dil:	850.04	mg to --->	100	ml to --->	5	ml to --->	25
Std. conc (in ppm)-1700.08	1	ml to --->	1	ml to --->	1	ml to --->	1

Gliclazide Std. Dil:	62.16	mg to --->	100	ml to --->	5	ml to --->	25
Std. conc (in ppm)-124.32	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :Acid	1360.20	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1700.25	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :Alkali	1360.50	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1700.625	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :Peroxide	1361.60	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1702	1	ml to --->	1	ml to --->	1	ml to --->	1

Average weight : 1360 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	1116454	1116820	1117286	1116915	1116780	1116851	299	0.027
With Bracketing std	1118604					1117143	764	0.068
Gliclazide	261306	260630	260073	259562	259111	260136	866	0.333
With Bracketing std	251973					258776	3421	1.322

Sample Name	METFORMIN HCL				GLICLAZIDE			
	Sample Area	Assay in %	Degradation in %	Peak purity	Sample Area	Assay in %	Degradation in %	Peak purity
As such sample (Method Precision)	Not applicable	97.9	Not applicable	Not applicable	Not applicable	100.2	Not applicable	Not applicable
Acid degradation	1046230	93.9	4.05	0.99	155406	61.9	38.32	1.00
Alkali degradation	897465	80.5	17.41	0.99	251123	100.0	0.23	1.00
Peroxide degradation	1118059	100.2	-2.30	0.99	236218	94.0	6.24	1.00

Results :

- 1) There is No any interference due to degranants with analyte in stresses samples.
- 2) Peak purity was passes According to Lab solution.

Acceptance criteria:

- 1) There should not be any interference due to degradants with analyte in stressed samples.
- 2) The desired degradation should be 10-30% in acid, alkali and peroxide degradation, (if possible).
- 3) If about 10% and 30% degradation is not achieved by applying above harsher stressed condition, same shall be documented .
- 4) Peak purity should not be less than 0.950 according to Lab solution.

Analysed by : E.MEENA

Date : 14-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

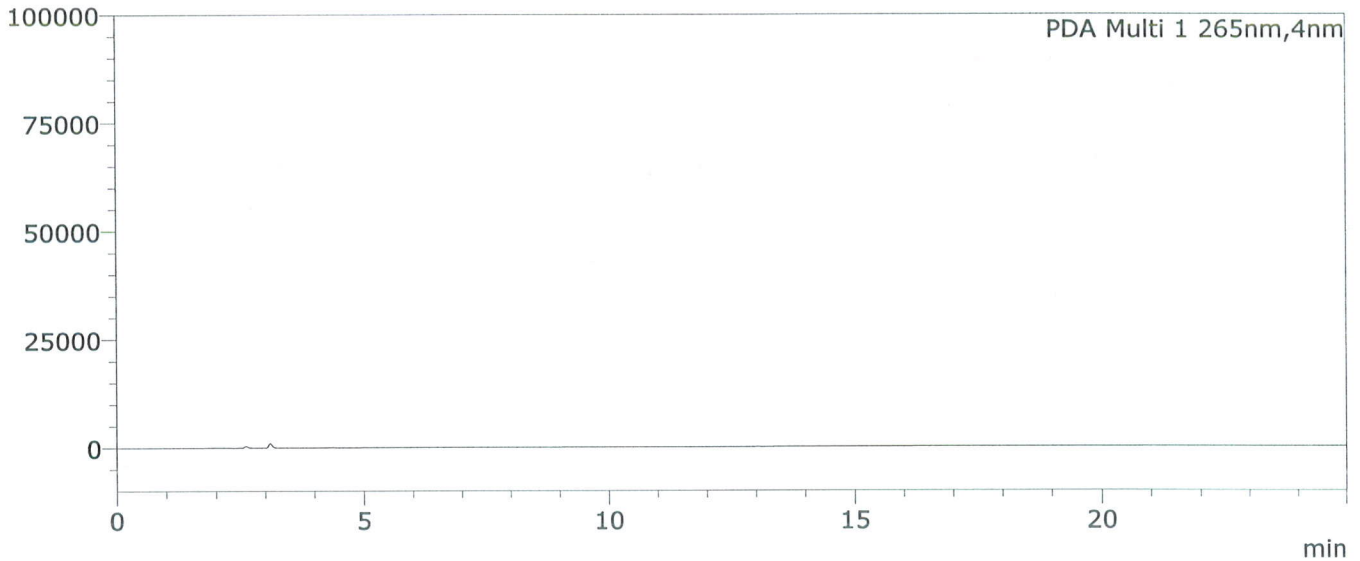
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Sample Name : FORCED DEGRADATION
 Sample ID : BLANK-AS
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-01.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-46
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 18:54:41
 Date Processed : 14-09-2023 09:50:11

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

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

Analysed By

14/09/23

Checked By

14/09/23



GENERIC HEALTHCARE PVT. LTD.

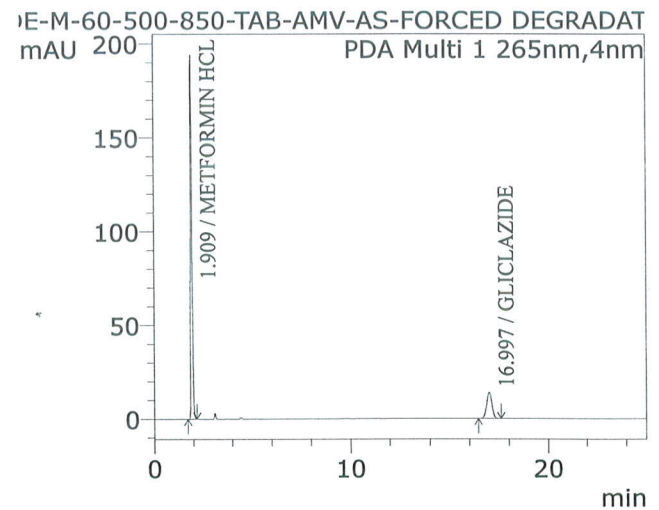
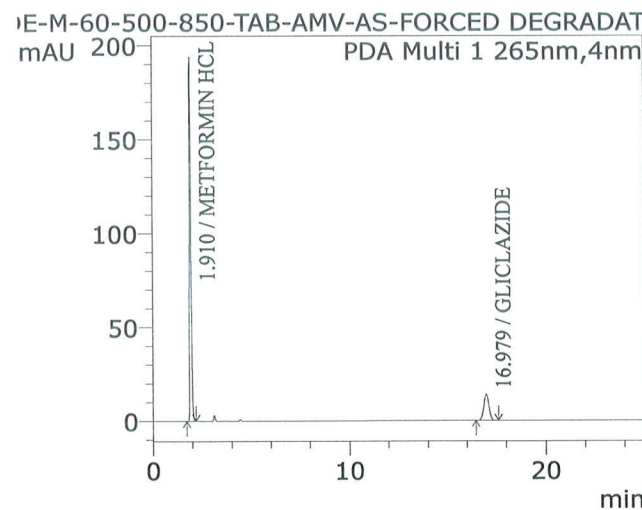
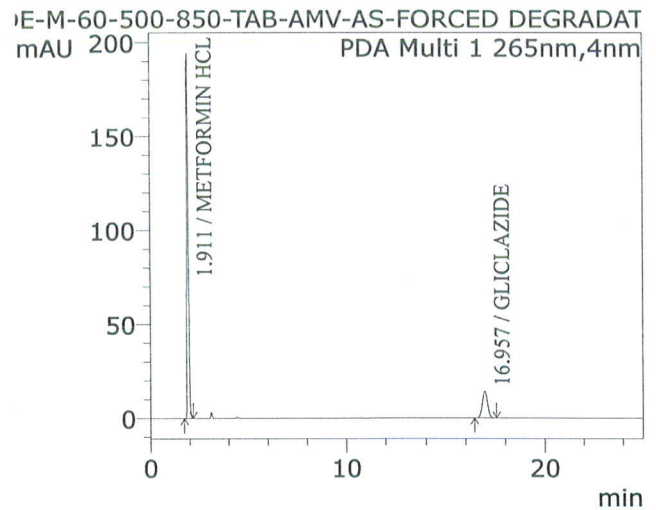
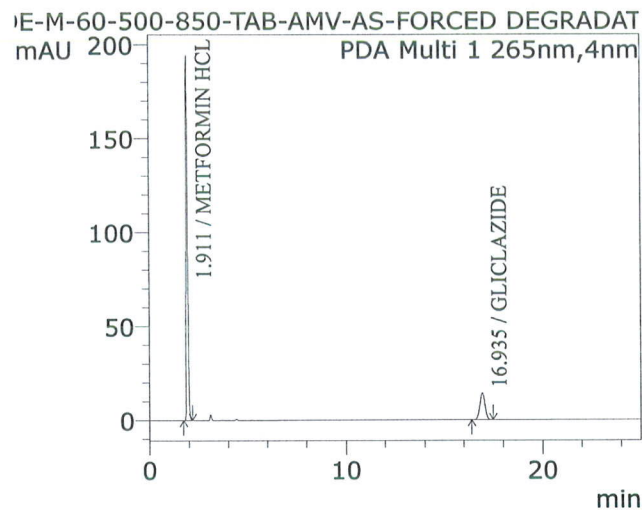
Analysis Report

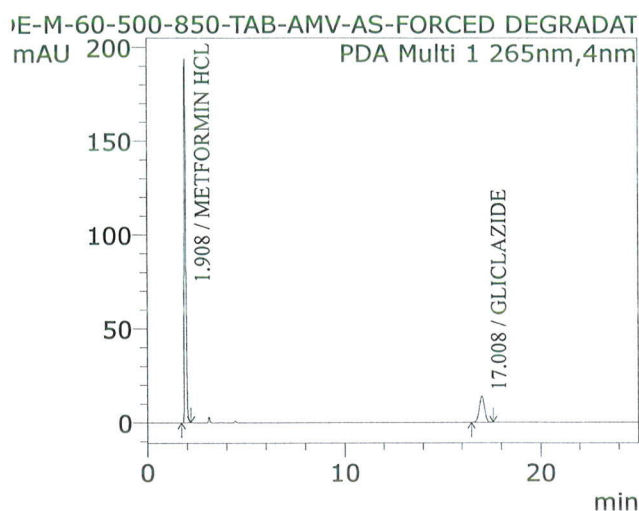
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Sample Name : FORCED DEGRADATION
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-01
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-02.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-47
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 19:20:22
 Date Processed : 14-09-2023 12:59:59

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

<Chromatogram>





<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
47	ON-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-01	1.91	1116454	2034	1.28
47	ON-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-02	1.91	1116820	2028	1.28
47	ON-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-03	1.91	1117286	2009	1.28
47	ON-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-04	1.91	1116915	2003	1.28
47	ON-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-05	1.91	1116780	2104	1.28
	Average		1.91	1116851	2036	1.28
	%RSD		0.060	0.027	1.996	0.242

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
47	ON-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-01	16.93	261306	18742	1.01
47	ON-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-02	16.96	260630	18744	1.01
47	ON-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-03	16.98	260073	18719	1.01
47	ON-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-04	17.00	259562	18711	1.01
47	ON-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-05	17.01	259111	18720	1.01
	Average		16.98	260136	18727	1.01
	%RSD		0.174	0.333	0.079	0.039

Analysed By

14/09/23

Checked By

14/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

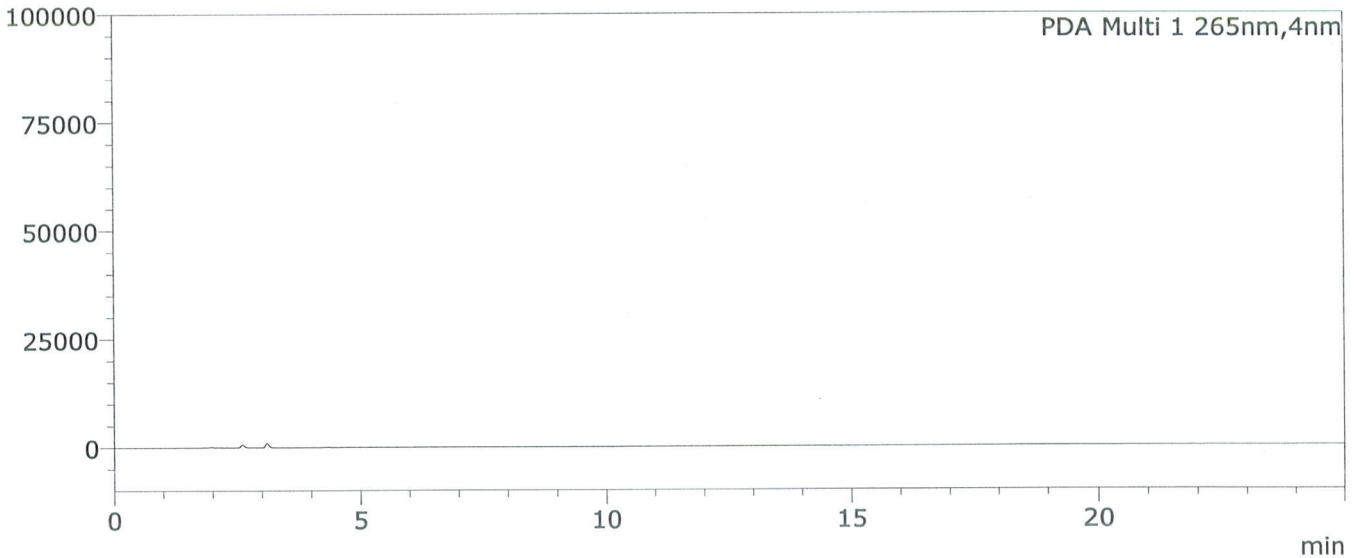
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Sample Name : FORCED DEGRADATION
 Sample ID : BLANK
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-07.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-46
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 21:28:25
 Date Processed : 14-09-2023 09:51:42

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

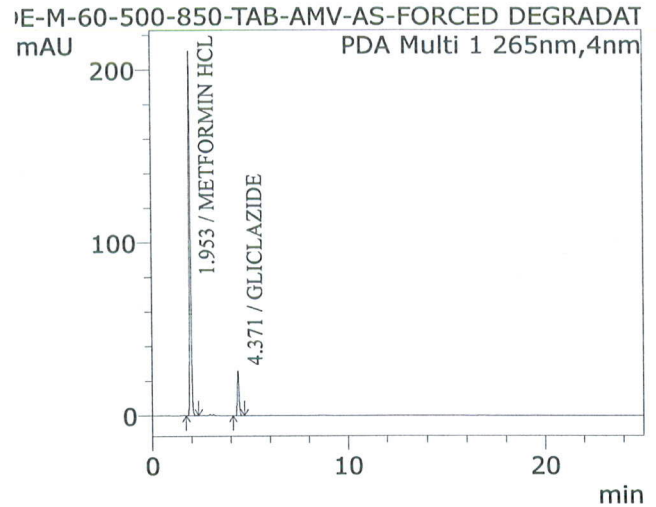
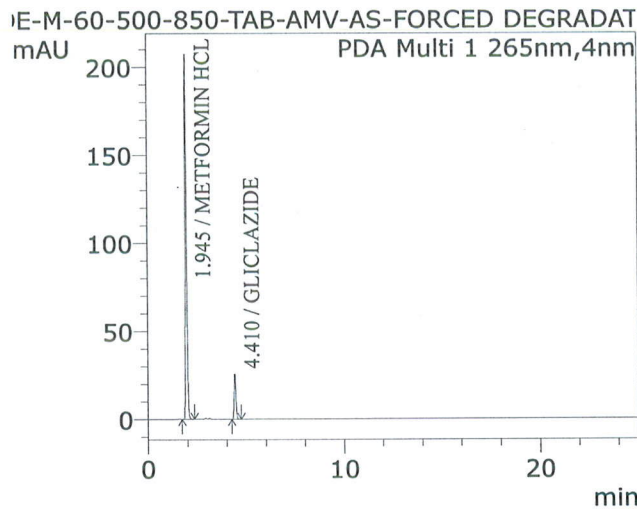
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION
 Sample ID : ACID DEGRADATION-AS-SPL-01
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-08.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS.lcm
 Batch Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-48
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 21:54:01
 Date Processed : 14-09-2023 13:04:22

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
48	ON-SPL-08.lcd	ACID DEGRADATION-AS-SPL-01	1.95	1047316	2715	1.14
48	ON-SPL-09.lcd	ACID DEGRADATION-AS-SPL-02	1.95	1045145	2806	1.15
	Average		1.95	1046230	2760	1.14
	%RSD		0.285	0.147	2.316	0.671

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
48	ON-SPL-08.lcd	ACID DEGRADATION-AS-SPL-01	4.41	155232	9916	1.17
48	ON-SPL-09.lcd	ACID DEGRADATION-AS-SPL-02	4.37	155580	9853	1.18
	Average		4.39	155406	9884	1.17
	%RSD		0.636	0.158	0.445	0.335

Analysed By

14/09/23

Checked By

14/09/23

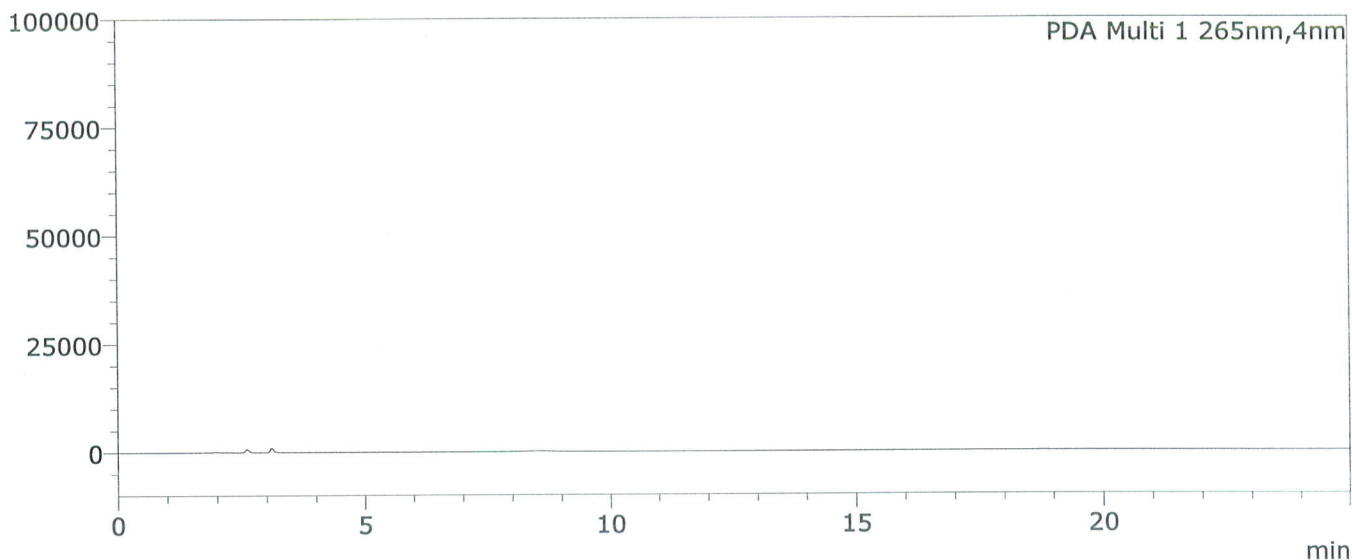

GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : FORCED DEGRADATION
 Sample ID : BLANK
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-10.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-46
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 22:45:13
 Date Processed : 14-09-2023 09:51:57

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

<Chromatogram>

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<Peak Table>

PDA Ch1 265nm

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

Analysed By

14/09/23

Checked By

14/09/23



GENERIC HEALTHCARE PVT. LTD.

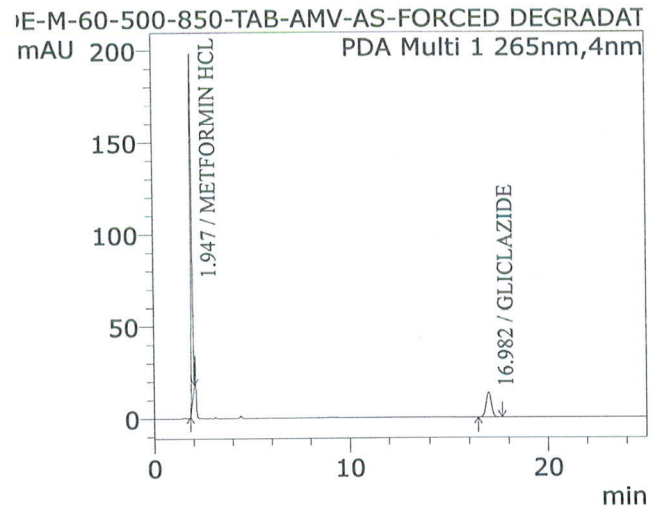
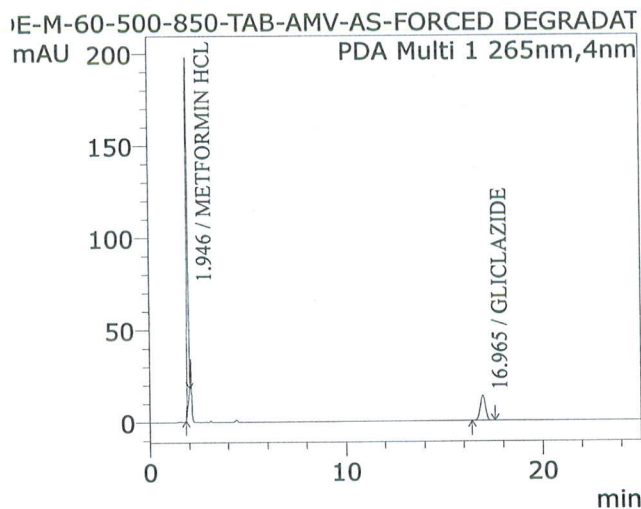
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION
 Sample ID : ALKALI DEGRADATION-AS-SPL-01
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-11.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-49
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 23:10:49
 Date Processed : 14-09-2023 13:24:31

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
49	ON-SPL-11.lcd	ALKALI DEGRADATION-AS-SPL-01	1.95	894063	3026	1.04
49	ON-SPL-12.lcd	ALKALI DEGRADATION-AS-SPL-02	1.95	900866	2813	1.04
	Average		1.95	897465	2919	1.04
	%RSD		0.049	0.536	5.163	0.157

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
49	ON-SPL-11.lcd	ALKALI DEGRADATION-AS-SPL-01	16.96	251200	18671	1.01
49	ON-SPL-12.lcd	ALKALI DEGRADATION-AS-SPL-02	16.98	251046	18721	1.01
	Average		16.97	251123	18696	1.01
	%RSD		0.073	0.043	0.188	0.098

Analysed By

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14/09/23

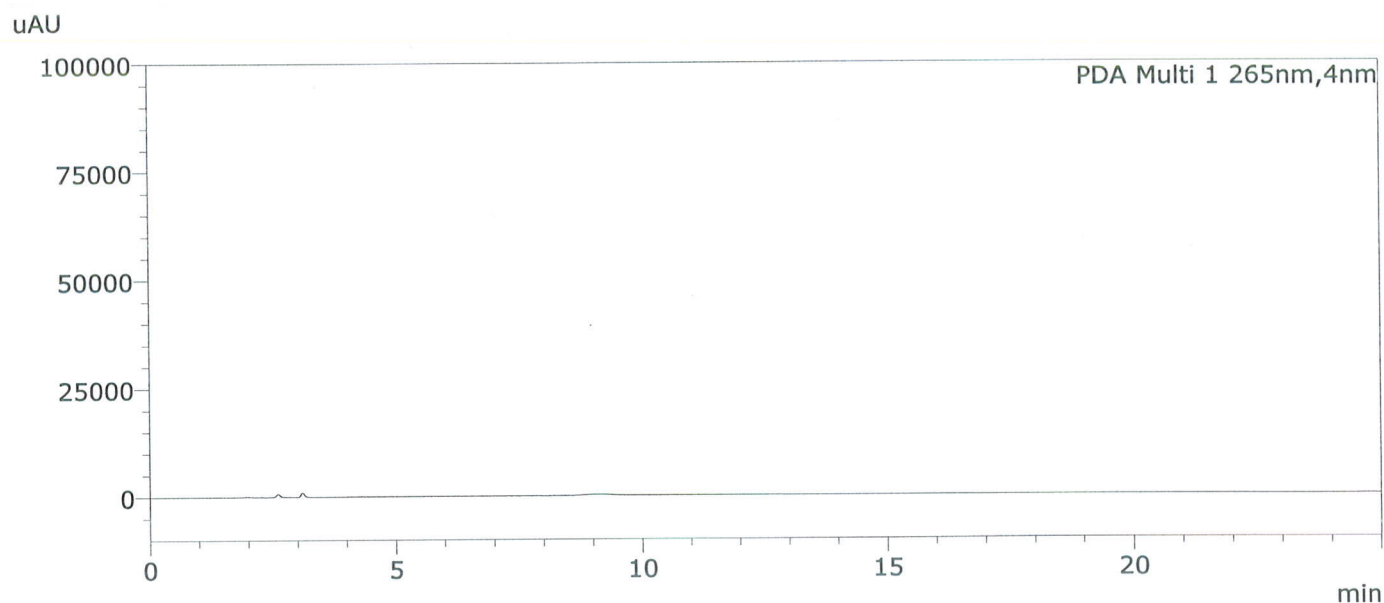
Checked By

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14/09/23


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

Sample Name : FORCED DEGRADATION
 Sample ID : BLANK
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-13.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-46
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 00:02:01
 Date Processed : 14-09-2023 09:52:43

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

<Chromatogram>

<Peak Table>

PDA Ch1 265nm

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

Analysed By

14/09/23

Checked By

14/09/23



GENERIC HEALTHCARE PVT. LTD.

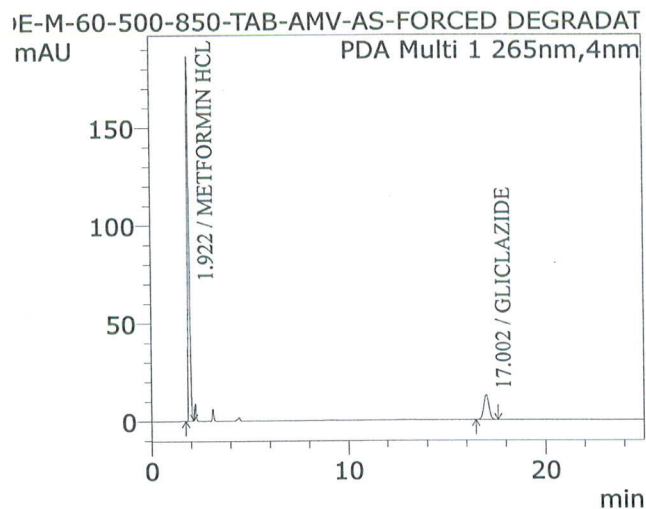
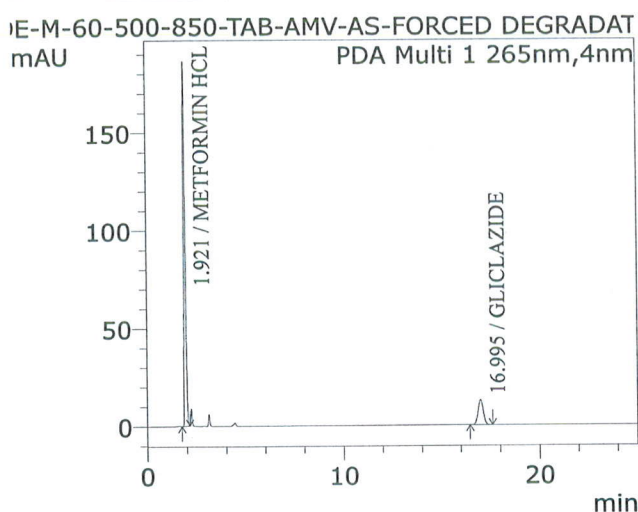
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION
 Sample ID : OXIDATIVE DEGRADATION-AS-SPL-01
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-14.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-50
 Injection Volume : 20 µL
 Date Acquired : 13-09-2023 00:27:37
 Date Processed : 14-09-2023 13:26:03

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
50	ON-SPL-14.lcd	OXIDATIVE DEGRADATION-AS-SPL-01	1.92	1118359	1977	1.25
50	ON-SPL-15.lcd	OXIDATIVE DEGRADATION-AS-SPL-02	1.92	1117759	1987	1.25
	Average		1.92	1118059	1982	1.25
	%RSD		0.025	0.038	0.364	0.082

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
50	ON-SPL-14.lcd	OXIDATIVE DEGRADATION-AS-SPL-01	17.00	236435	18736	1.01
50	ON-SPL-15.lcd	OXIDATIVE DEGRADATION-AS-SPL-02	17.00	236000	18763	1.01
	Average		17.00	236218	18750	1.01
	%RSD		0.029	0.130	0.101	0.045

Analysed By

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14/09/23

Checked By

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14/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

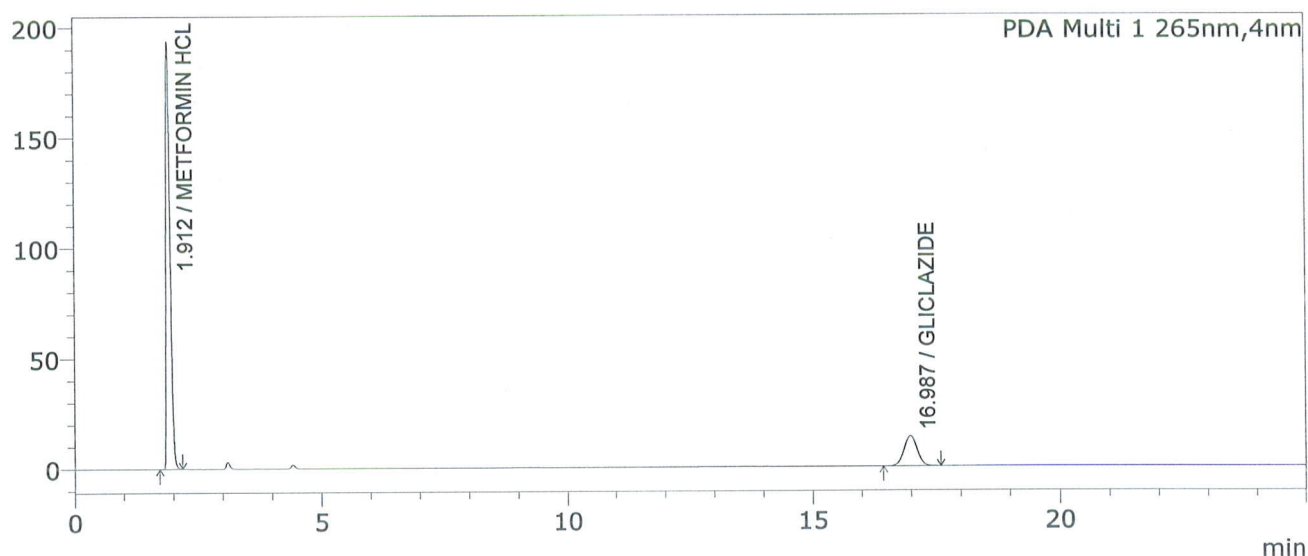
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Sample Name : FORCED DEGRADATION
 Sample ID : DAPOXETINE-AS-BKT-STD
 Data Filename : 12092023 GLIDE-M-60-500-850-TAB-AMV-AS-FORCED DEGRADATION-SPL-16.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcb
 Vial # : 2-47
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 01:18:55
 Date Processed : 14-09-2023 13:27:24

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	1118604	81.62	2044	1.279	--	--
2	GLICLAZIDE	16.99	251973	18.38	18812	1.008	45.365	--
Total			1370577	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table_12092023_GLIDE-M-60-850-TAB-AMV-AS-FORCED DEGRADATION.lcd

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
46	2	FORCED DEGRADATION	BLANK-AS	60-500-850-TAB-AS.lcm	ADATION-SPL-01.lcd	20.0	QC/CL/20/017
47	2	FORCED DEGRADATION	GLICLAZIDE+METFORMIN-AS-STD-01	60-500-850-TAB-AS.lcm	ADATION-SPL-02.lcd	20.0	QC/CL/20/017
47	2	FORCED DEGRADATION	GLICLAZIDE+METFORMIN-AS-STD-02	60-500-850-TAB-AS.lcm	ADATION-SPL-03.lcd	20.0	QC/CL/20/017
47	2	FORCED DEGRADATION	GLICLAZIDE+METFORMIN-AS-STD-03	60-500-850-TAB-AS.lcm	ADATION-SPL-04.lcd	20.0	QC/CL/20/017
47	2	FORCED DEGRADATION	GLICLAZIDE+METFORMIN-AS-STD-04	60-500-850-TAB-AS.lcm	ADATION-SPL-05.lcd	20.0	QC/CL/20/017
47	2	FORCED DEGRADATION	GLICLAZIDE+METFORMIN-AS-STD-05	60-500-850-TAB-AS.lcm	ADATION-SPL-06.lcd	20.0	QC/CL/20/017
46	2	FORCED DEGRADATION	BLANK	60-500-850-TAB-AS.lcm	ADATION-SPL-07.lcd	20.0	QC/CL/20/017
48	2	FORCED DEGRADATION	ACID DEGRADATION-AS-SPL-01	60-500-850-TAB-AS.lcm	ADATION-SPL-08.lcd	20.0	QC/CL/20/017
48	2	FORCED DEGRADATION	ACID DEGRADATION-AS-SPL-02	60-500-850-TAB-AS.lcm	ADATION-SPL-09.lcd	20.0	QC/CL/20/017
46	2	FORCED DEGRADATION	BLANK	60-500-850-TAB-AS.lcm	ADATION-SPL-10.lcd	20.0	QC/CL/20/017
49	2	FORCED DEGRADATION	ALKALI DEGRADATION-AS-SPL-01	60-500-850-TAB-AS.lcm	ADATION-SPL-11.lcd	20.0	QC/CL/20/017
49	2	FORCED DEGRADATION	ALKALI DEGRADATION-AS-SPL-02	60-500-850-TAB-AS.lcm	ADATION-SPL-12.lcd	20.0	QC/CL/20/017
46	2	FORCED DEGRADATION	BLANK	60-500-850-TAB-AS.lcm	ADATION-SPL-13.lcd	20.0	QC/CL/20/017
50	2	FORCED DEGRADATION	OXIDATIVE DEGRADATION-AS-SPL-01	60-500-850-TAB-AS.lcm	ADATION-SPL-14.lcd	20.0	QC/CL/20/017
50	2	FORCED DEGRADATION	OXIDATIVE DEGRADATION-AS-SPL-02	60-500-850-TAB-AS.lcm	ADATION-SPL-15.lcd	20.0	QC/CL/20/017
47	2	FORCED DEGRADATION	DAPOXETINE-AS-BKT-STD	60-500-850-TAB-AS.lcm	ADATION-SPL-16.lcd	20.0	QC/CL/20/017
-1	2	FORCED DEGRADATION	WASH	IOD\WASH METHOD.lcm	ADATION-SPL-17.lcd	20.0	QC/CL/20/017
-1	2	FORCED DEGRADATION	SHUT	HUTDOWN METHOD.lcm	ADATION-SPL-18.lcd	20.0	QC/CL/20/017

Analysed By


12/09/23

Checked By


12/09/23,
Page 2 / 2

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

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

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 500 mg
Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	500.13	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1000.26	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1004.247	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	500
Average weight :	970

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	730742	730529	731435	730898	730775	730876	340	0.046
Bracketing Std.	731732	731218				730876	340	0.046

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	974.12	716380	489.11	97.8	98.0	0.81
Sample Preparation-2	974.02	722876	493.60	98.7		
Sample Preparation-3	974.40	720339	491.68	98.3		
Sample Preparation-4	974.00	707859	483.36	96.7		
Sample Preparation-5	974.11	714889	488.10	97.6		
Sample Preparation-6	974.20	723136	493.69	98.7		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

E.MEENA

Date :

13-09-2023

Checked by :

Date :

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 500 mg
Gliclazide BP ----- 60 mg

ASSAY OF GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/22/040	% Purity (aib)	100.0
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Standard dilution :	61.90	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-123.8	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120.5096	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	60
Average weight :	970

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	261786	260843	260125	259784	259472	260402	926	0.356
Bracketing Std.	255110	250950				258296	3867	1.497

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	974.12	252326	59.73	99.5	98.4	1.40
Sample Preparation-2	974.02	253743	60.07	100.1		
Sample Preparation-3	974.40	250794	59.35	98.9		
Sample Preparation-4	974.00	245016	58.00	96.7		
Sample Preparation-5	974.11	246447	58.34	97.2		
Sample Preparation-6	974.20	247523	58.58	97.6		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

E.MEENA

Date :

13-09-2023

Checked by :

Date :


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

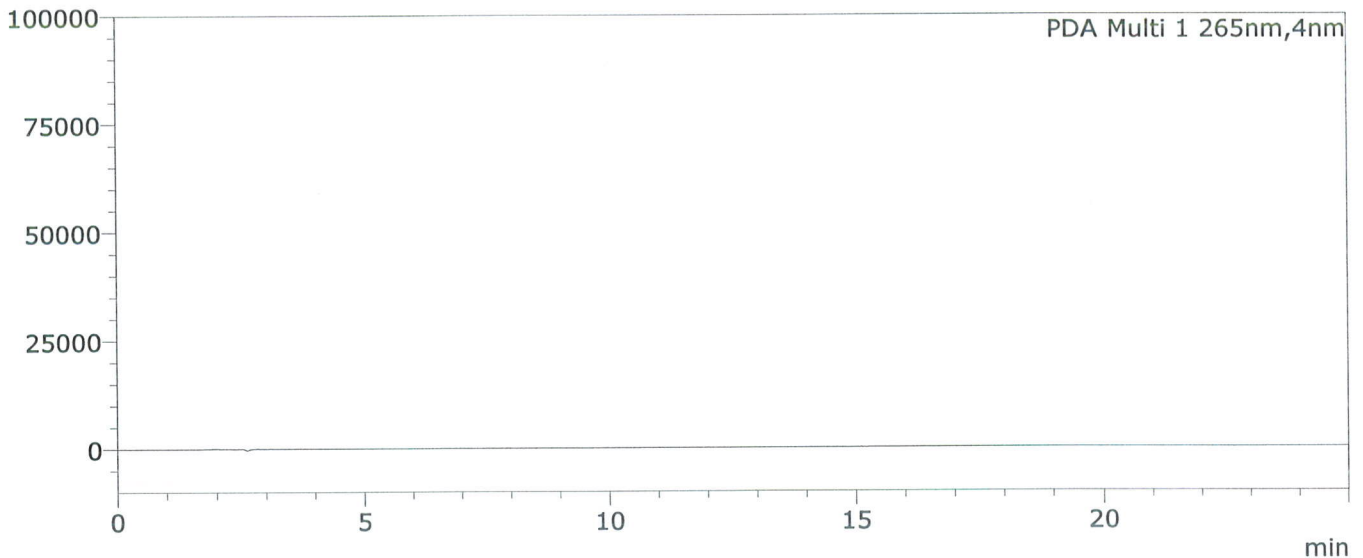
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 Sample ID : AS-BLANK
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-01.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-15
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 15:34:50
 Date Processed : 13-09-2023 09:52:23

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

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

Analysed By

13/09/23

Checked By

13/09/23



GENERIC HEALTHCARE PVT. LTD.

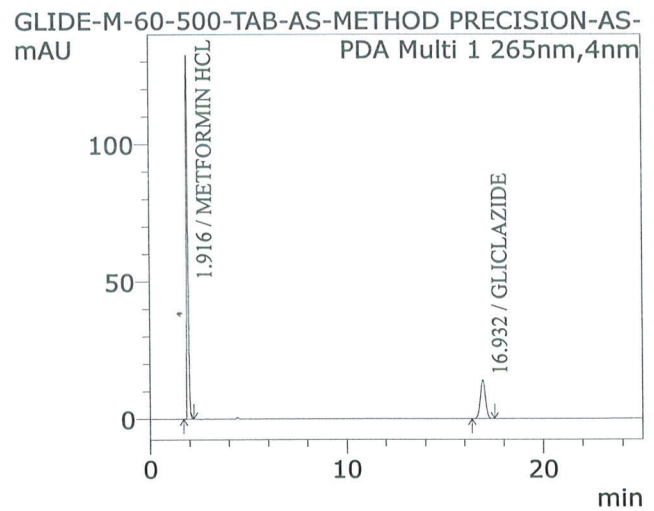
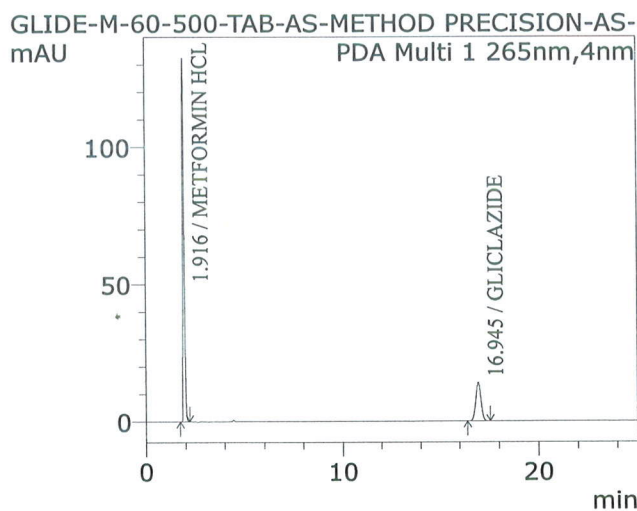
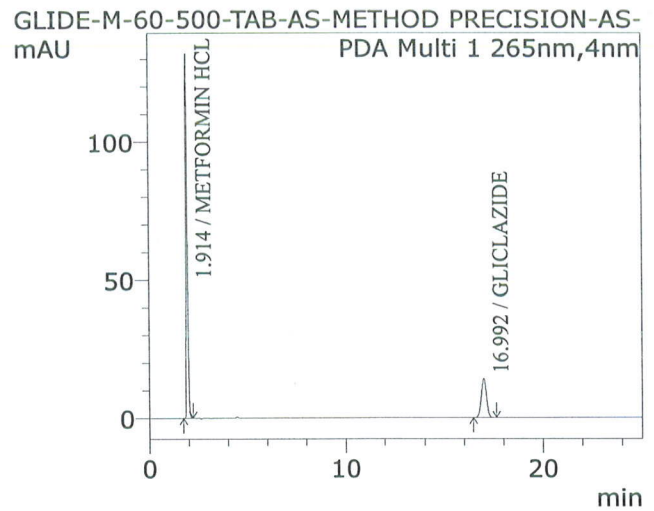
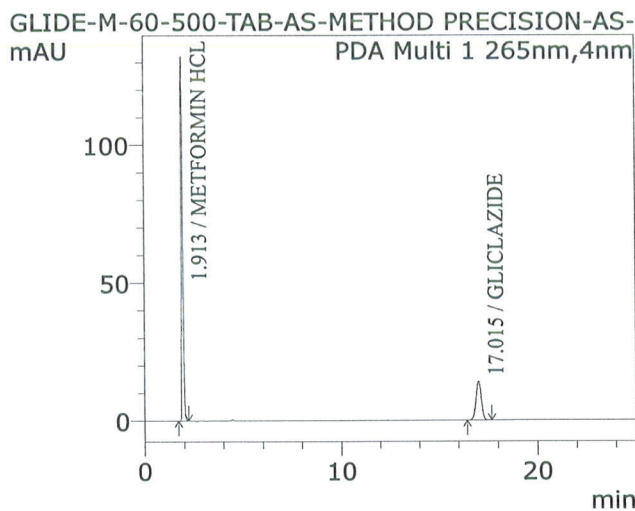
Analysis Report

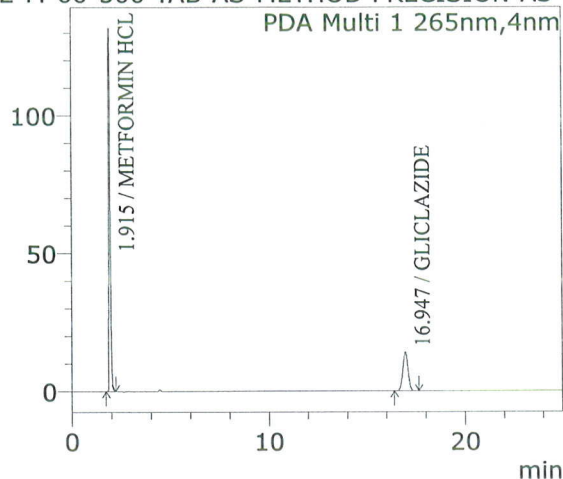
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Sample Name : METHOD PRECISION
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-02.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-16
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 16:00:25
 Date Processed : 13-09-2023 09:52:23

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

<Chromatogram>



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-
mAU

<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
16	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.91	730742	2223	1.34
16	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.91	730529	2238	1.34
16	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.92	731435	2125	1.33
16	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.92	730898	2260	1.33
16	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.91	730775	2253	1.33
	Average		1.91	730876	2220	1.34
	%RSD		0.076	0.046	2.472	0.497

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
16	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	17.01	261786	18671	1.01
16	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	16.99	260843	18718	1.01
16	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	16.95	260125	18745	1.01
16	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	16.93	259784	18693	1.01
16	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	16.95	259472	18704	1.01
	Average		16.97	260402	18706	1.01
	%RSD		0.209	0.356	0.148	0.043

Analysed By

13/09/23

Checked By

13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

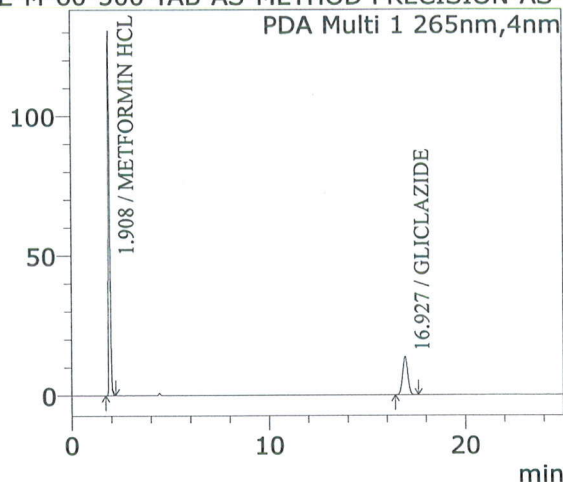
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Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-500-093-SET1-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-07.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-17
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 18:08:21
 Date Processed : 13-09-2023 09:52:24

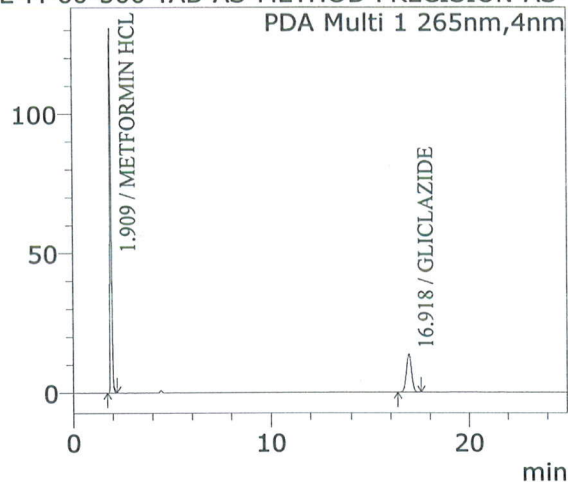
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
17	AS-SPL-07.lcd	GLIDEM-60-500-093-SET1-AS-SPL-1	1.91	716304	2143	1.34
17	AS-SPL-08.lcd	GLIDEM-60-500-093-SET1-AS-SPL-2	1.91	716455	2147	1.34
	Average		1.91	716380	2145	1.34
	%RSD		0.034	0.015	0.154	0.155

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
17	AS-SPL-07.lcd	GLIDEM-60-500-093-SET1-AS-SPL-1	16.93	252761	18709	1.01
17	AS-SPL-08.lcd	GLIDEM-60-500-093-SET1-AS-SPL-2	16.92	251892	18738	1.01
	Average		16.92	252326	18724	1.01
	%RSD		0.037	0.244	0.106	0.003

Analysed By

13/09/23

Checked By

13/09/23


GENERIC HEALTHCARE PVT. LTD.

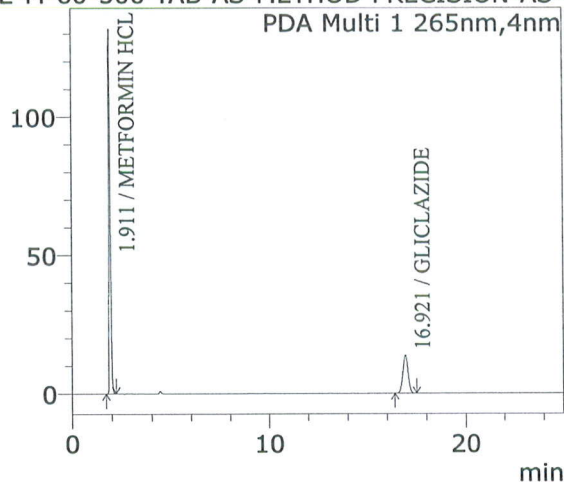
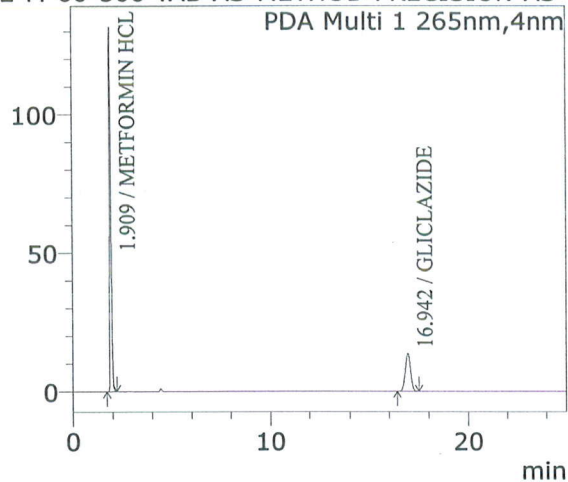
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-500-093-SET2-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-09.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-18
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 18:59:31
 Date Processed : 13-09-2023 09:52:25

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

<Chromatogram>

 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-
 mAU PDA Multi 1 265nm,4nm

 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-
 mAU PDA Multi 1 265nm,4nm


<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
18	AS-SPL-09.lcd	GLIDEM-60-500-093-SET2-AS-SPL-1	1.91	722723	2213	1.35
18	AS-SPL-10.lcd	GLIDEM-60-500-093-SET2-AS-SPL-2	1.91	723030	2138	1.33
	Average		1.91	722876	2175	1.34
	%RSD		0.082	0.030	2.452	0.759

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
18	AS-SPL-09.lcd	GLIDEM-60-500-093-SET2-AS-SPL-1	16.92	254002	18699	1.01
18	AS-SPL-10.lcd	GLIDEM-60-500-093-SET2-AS-SPL-2	16.94	253484	18641	1.01
	Average		16.93	253743	18670	1.01
	%RSD		0.088	0.145	0.219	0.031

Analysed By

13/09/23

Checked By

13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

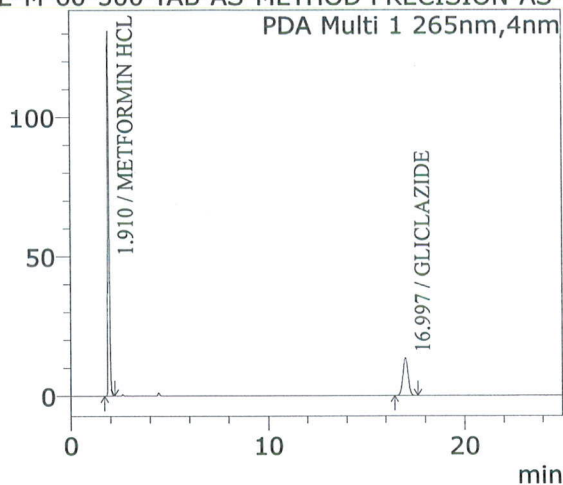
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 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-11.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-19
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 19:50:40
 Date Processed : 13-09-2023 09:52:26

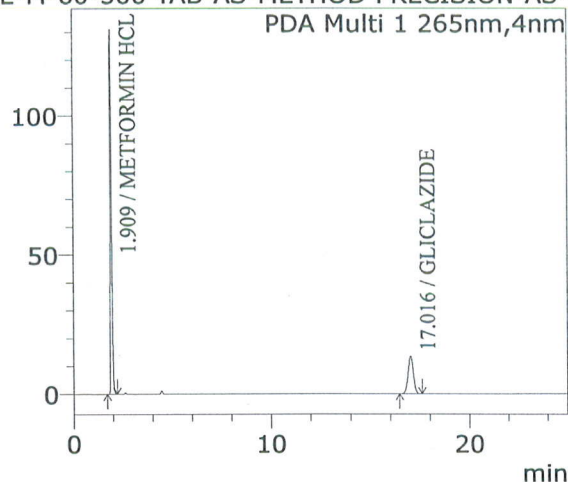
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
19	AS-SPL-11.lcd	GLIDEM-60-500-093-SET3-AS-SPL-1	1.91	720415	2191	1.35
19	AS-SPL-12.lcd	GLIDEM-60-500-093-SET3-AS-SPL-2	1.91	720264	2138	1.34
	Average		1.91	720339	2165	1.35
	%RSD		0.040	0.015	1.717	0.263

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
19	AS-SPL-11.lcd	GLIDEM-60-500-093-SET3-AS-SPL-1	17.00	251090	18597	1.01
19	AS-SPL-12.lcd	GLIDEM-60-500-093-SET3-AS-SPL-2	17.02	250498	18643	1.01
	Average		17.01	250794	18620	1.01
	%RSD		0.079	0.167	0.176	0.023

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Analysis Report

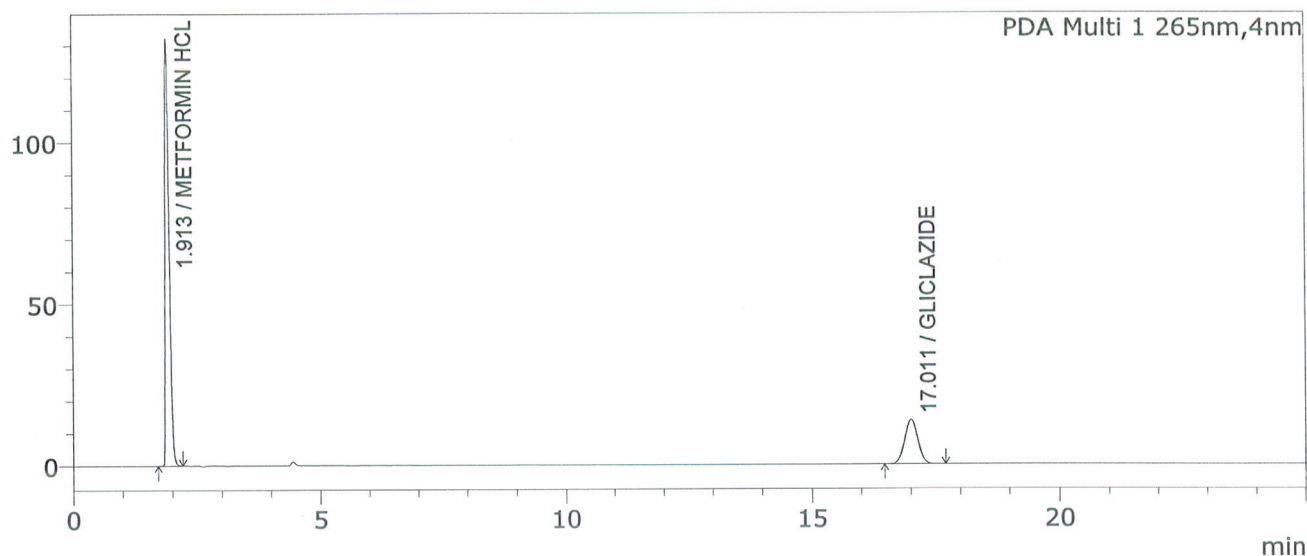
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Sample Name : METHOD PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-13.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-16
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 20:41:54
 Date Processed : 13-09-2023 09:52:26

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	731732	74.15	2233	1.341	--	--
2	GLICLAZIDE	17.01	255110	25.85	18660	1.008	45.744	--
Total			986842	100.00				

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Analysis Report

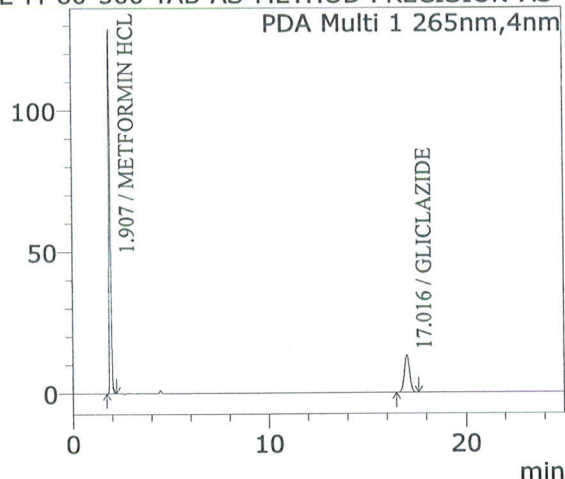
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Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-500-093-SET4-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-14.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-20
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 21:07:28
 Date Processed : 13-09-2023 09:52:26

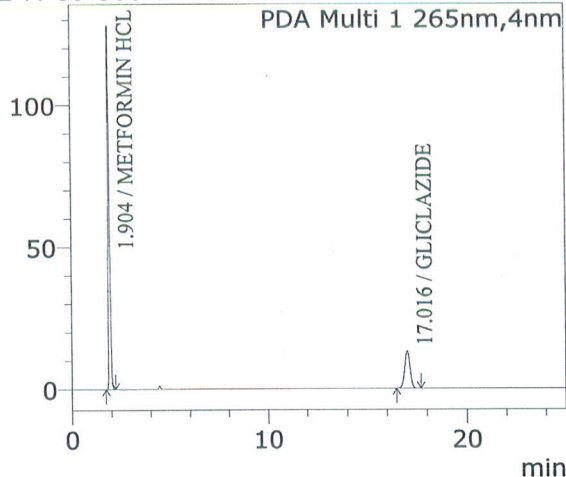
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
20	AS-SPL-14.lcd	GLIDEM-60-500-093-SET4-AS-SPL-1	1.91	707733	2126	1.34
20	AS-SPL-15.lcd	GLIDEM-60-500-093-SET4-AS-SPL-2	1.90	707985	2240	1.34
	Average		1.91	707859	2183	1.34
	%RSD		0.081	0.025	3.708	0.085

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
20	AS-SPL-14.lcd	GLIDEM-60-500-093-SET4-AS-SPL-1	17.02	245224	18611	1.01
20	AS-SPL-15.lcd	GLIDEM-60-500-093-SET4-AS-SPL-2	17.02	244807	18624	1.01
	Average		17.02	245016	18617	1.01
	%RSD		0.002	0.120	0.051	0.142

Analysed By

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13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

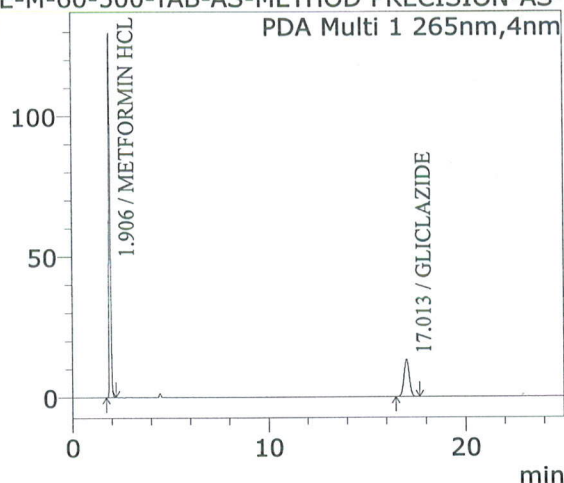
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Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-500-093-SET5-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-16.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-21
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 21:58:37
 Date Processed : 13-09-2023 09:52:27

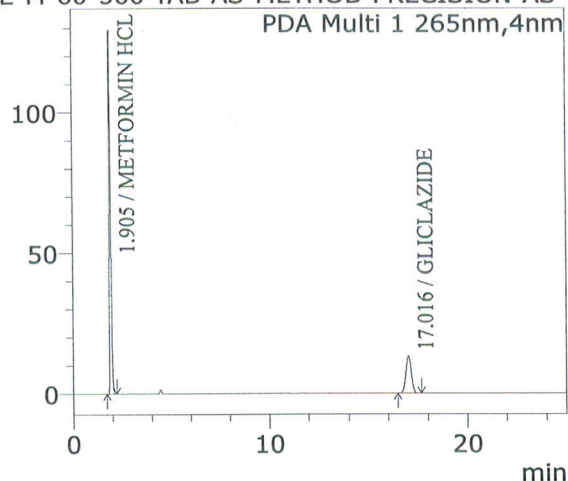
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU PDA Multi 1 265nm,4nm



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
21	AS-SPL-16.lcd	GLIDEM-60-500-093-SET5-AS-SPL-1	1.91	714892	2109	1.33
21	AS-SPL-17.lcd	GLIDEM-60-500-093-SET5-AS-SPL-2	1.91	714886	2104	1.34
	Average		1.91	714889	2107	1.34
	%RSD		0.012	0.001	0.180	0.029

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
21	AS-SPL-16.lcd	GLIDEM-60-500-093-SET5-AS-SPL-1	17.01	246748	18635	1.01
21	AS-SPL-17.lcd	GLIDEM-60-500-093-SET5-AS-SPL-2	17.02	246146	18630	1.01
	Average		17.01	246447	18632	1.01
	%RSD		0.014	0.173	0.019	0.022

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

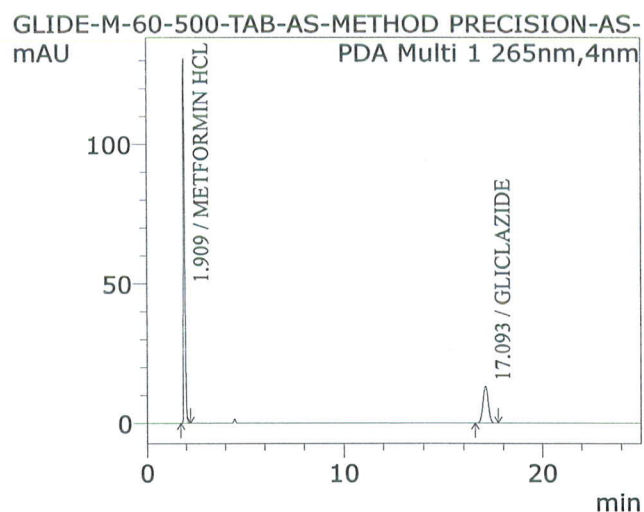
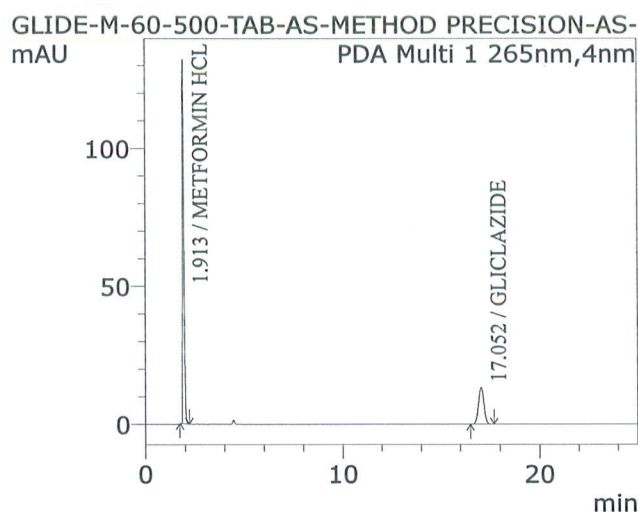
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION
 Sample ID : GLIDEM-60-850-093-SET6-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-18.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-22
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 22:49:45
 Date Processed : 13-09-2023 09:58:42

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
22	AS-SPL-18.lcd	GLIDEM-60-850-093-SET6-AS-SPL-1	1.91	725987	2237	1.34
22	AS-SPL-19.lcd	GLIDEM-60-850-093-SET6-AS-SPL-2	1.91	720285	2171	1.35
	Average		1.91	723136	2204	1.34
	%RSD		0.150	0.558	2.123	0.394

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
22	AS-SPL-18.lcd	GLIDEM-60-850-093-SET6-AS-SPL-1	17.05	247809	18558	1.01
22	AS-SPL-19.lcd	GLIDEM-60-850-093-SET6-AS-SPL-2	17.09	247278	18497	1.01
	Average		17.07	247543	18528	1.01
	%RSD		0.172	0.152	0.234	0.006

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

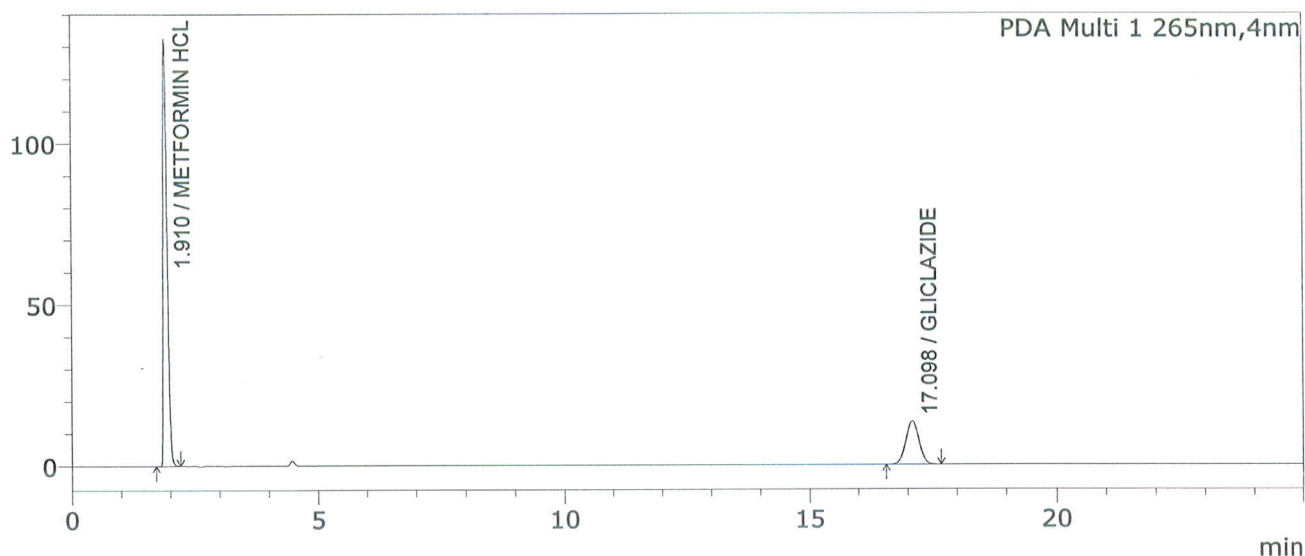
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Sample Name : METHOD PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-2
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 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-16
 Injection Volume : 20 uL
 Date Acquired : 11-09-2023 23:40:53
 Date Processed : 13-09-2023 09:52:28

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	731218	74.45	2177	1.350	--	--
2	GLICLAZIDE	17.10	250950	25.55	18591	1.009	45.653	--
Total			982168	100.00				

13/09/23

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13/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name :	GLIDE-M 60/500	Batch size :	Not applicable
Batch Number :	G1722093	Mfg.Date :	Oct-22
Parameter :	FILTER PAPER STUDY	Exp.Date :	Sep-25

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500 mg

Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL AND GLICLAZIDE

Instrument ID:	ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
				WS No.:	ST/WS/22/040	% Purity (aib)	100.0

Metformin Std.Dil:	500.13	mg to ---->	100	ml to ---->	5	ml to ---->	25
Std.conc (in ppm)-1000.26	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Gliclazide Std.Dil:	61.90	mg to ---->	100	ml to ---->	5	ml to ---->	25
Std.conc (in ppm)-123.8	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Test dilution .:	974.10	mg to ---->	100	ml to ---->	5	ml to ---->	25
Test.conc (in ppm)-1004.22	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Average weight : 970 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	730687	730756	730994	731077	731204	730944	217	0.030
With Bracketing std	732282	733810				731544	1131	0.155
Gliclazide	249461	249366	248269	248114	247606	248563	815	0.328
With Bracketing std	243608	242304				246961	2841	1.150

Sample Name	METFORMIN HCL			GLICLAZIDE		
	Sample Area	Assay in %	% Difference from unfiltered	Sample Area	Assay in %	% Difference from unfiltered
Unfiltered sample (Centrifuged)	714711	97.6	Not applicable	239754	99.1	Not applicable
Filter Set-1 (0.45µ Nylon membrane)	718550	98.1	-0.52	240674	99.5	-0.38
Filter Set-2 (0.45µ Nylon membrane)	710237	97.0	0.61	236121	97.6	1.50
Filter Set-3 (0.45µ Nylon membrane)	716955	97.9	-0.31	237427	98.1	0.96

Results : The % difference on filtered Sample (0.45 µm nylon 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 : 13-09-2023

13/09/23

Checked by :
Date : 13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

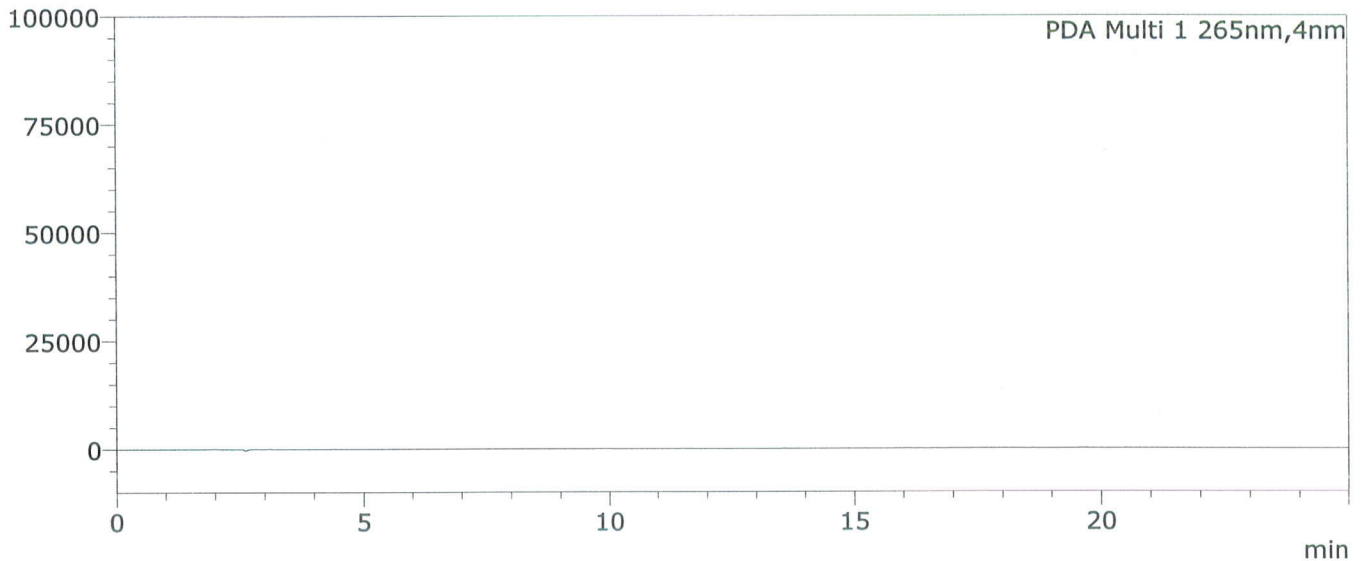
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 Sample ID : AS-BLANK
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 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-23
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 00:06:26
 Date Processed : 13-09-2023 09:52:28

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

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 265nm

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

Analysed By

[Signature]
13/09/23

Checked By

[Signature]
13/09/23



GENERIC HEALTHCARE PVT. LTD.

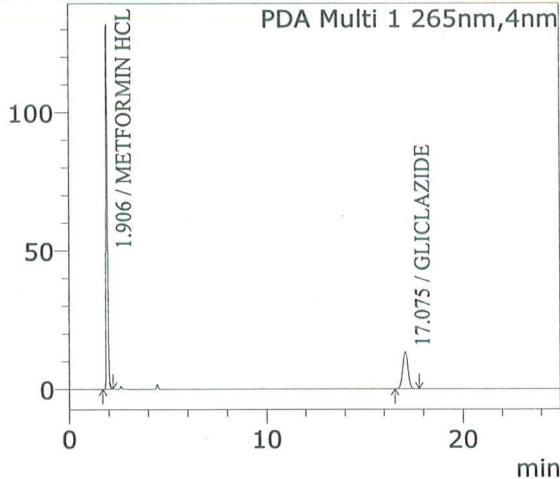
Analysis Report

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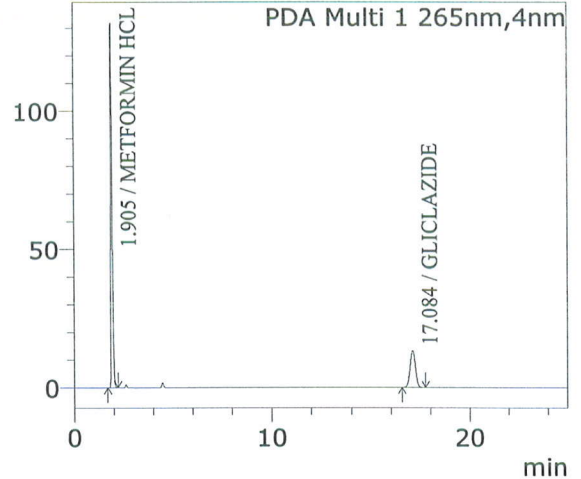
Sample Name	: FILTER PAPER STUDY	
Sample ID	: GLICLAZIDE+METFORMIN-AS-STD-1	
Data Filename	: 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-22.lcd	
Method Filename	: GLIDE-M 60-500-850-TAB-AS_P.lcm	
Batch Filename	: 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD	
Vial #	: 3-24	
Injection Volume	: 20 uL	
Date Acquired	: 12-09-2023 00:32:00	Acquired by : E.MEENA
Date Processed	: 13-09-2023 09:52:28	Processed by : C.K.SARAVANAN

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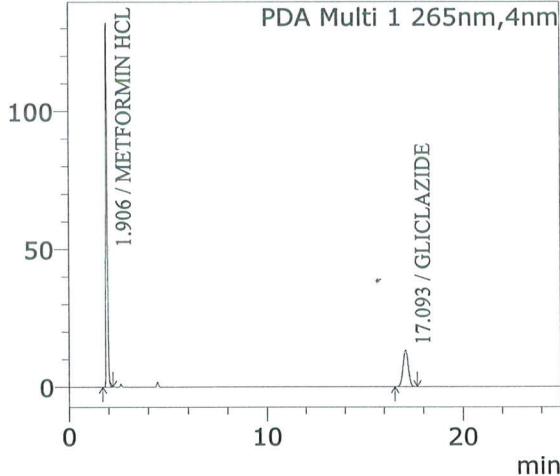
GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU
PDA Multi 1 265nm,4nm



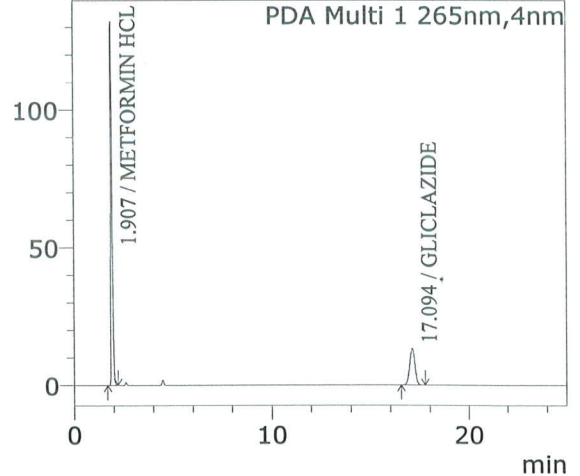
GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU
PDA Multi 1 265nm,4nm

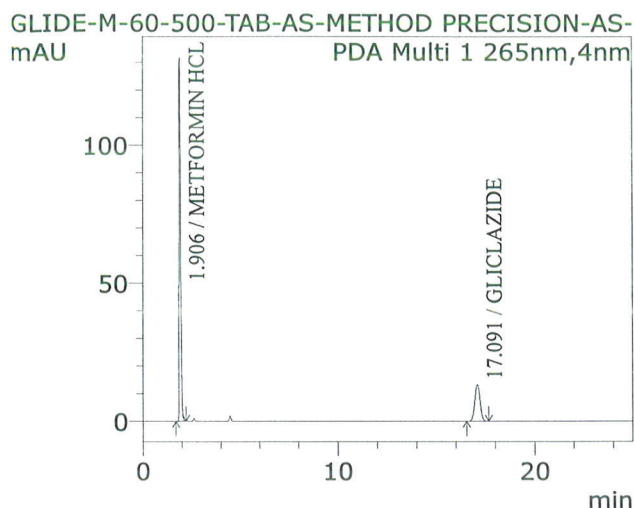


GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU
PDA Multi 1 265nm,4nm



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU
PDA Multi 1 265nm,4nm





<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
24	AS-SPL-22.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.91	730687	2091	1.33
24	AS-SPL-23.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.91	730756	2089	1.34
24	AS-SPL-24.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.91	730994	2098	1.34
24	AS-SPL-25.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.91	731077	2101	1.34
24	AS-SPL-26.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.91	731204	2090	1.34
	Average		1.91	730943	2094	1.34
	%RSD		0.029	0.030	0.264	0.030

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
24	AS-SPL-22.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	17.08	249461	18570	1.01
24	AS-SPL-23.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	17.08	249366	18545	1.01
24	AS-SPL-24.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	17.09	248269	18500	1.01
24	AS-SPL-25.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	17.09	248114	18521	1.01
24	AS-SPL-26.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	17.09	247606	18542	1.01
	Average		17.09	248563	18535	1.01
	%RSD		0.046	0.328	0.141	0.035

Analysed By

13/09/23

Checked By

13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

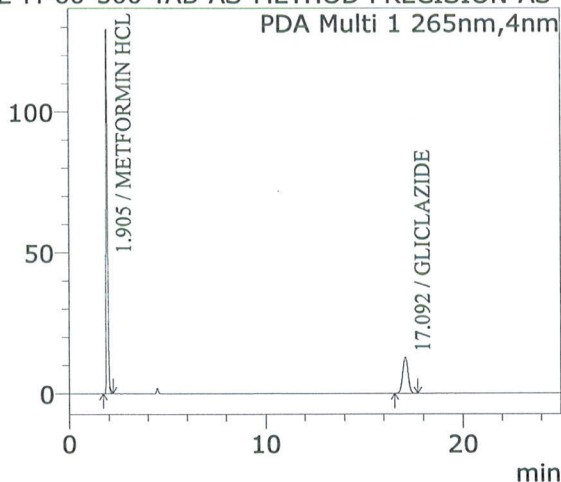
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Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-500-093-CENTR-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-27.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-25
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 02:40:01
 Date Processed : 13-09-2023 09:52:30

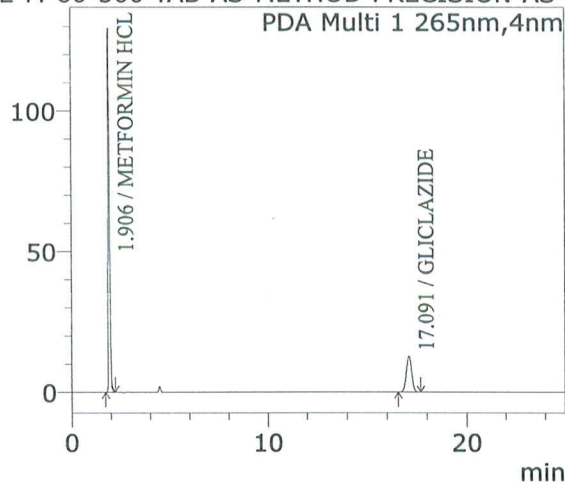
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-
mAU PDA Multi 1 265nm,4nm



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-
mAU PDA Multi 1 265nm,4nm



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
25	AS-SPL-27.lcd	GLIDEM60-500-093-CENTR-AS-SPL-1	1.90	715386	2234	1.34
25	AS-SPL-28.lcd	GLIDEM60-500-093-CENTR-AS-SPL-2	1.91	714036	2112	1.34
	Average		1.91	714711	2173	1.34
	%RSD		0.052	0.134	3.974	0.089

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
25	AS-SPL-27.lcd	GLIDEM60-500-093-CENTR-AS-SPL-1	17.09	240130	18563	1.01
25	AS-SPL-28.lcd	GLIDEM60-500-093-CENTR-AS-SPL-2	17.09	239378	18577	1.01
	Average		17.09	239754	18570	1.01
	%RSD		0.003	0.222	0.055	0.024

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

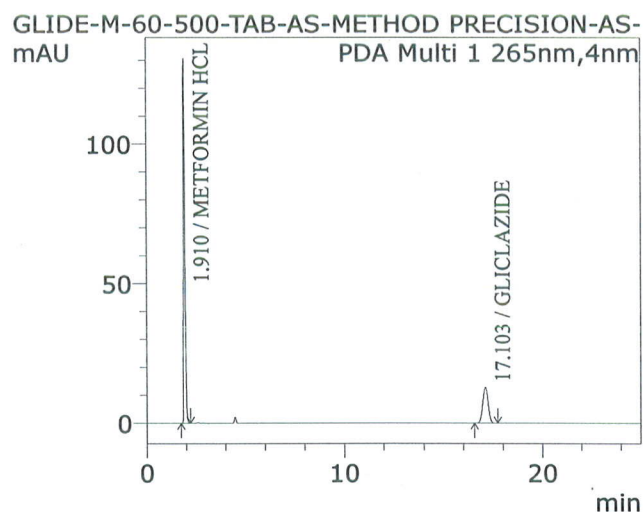
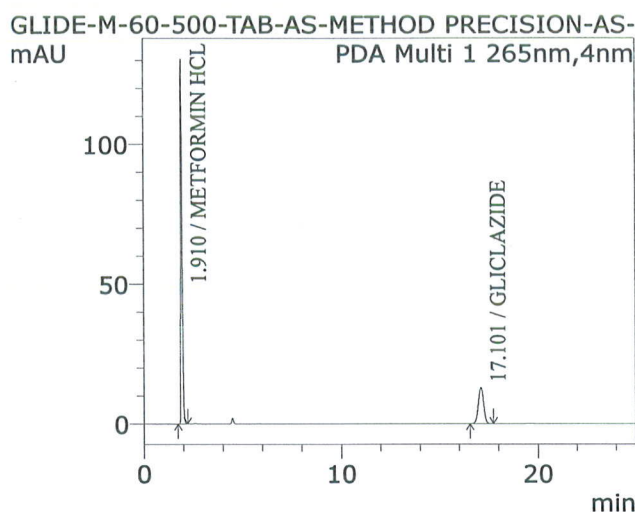
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-500-093-FIL-1-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-29.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-26
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 03:31:09
 Date Processed : 13-09-2023 09:52:30

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

<Chromatogram>



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
26	AS-SPL-29.lcd	GLIDEM60-500-093-FIL-1-AS-SPL-1	1.91	718417	2178	1.35
26	AS-SPL-30.lcd	GLIDEM60-500-093-FIL-1-AS-SPL-2	1.91	718683	2185	1.35
	Average		1.91	718550	2181	1.35
	%RSD		0.006	0.026	0.214	0.080

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
26	AS-SPL-29.lcd	GLIDEM60-500-093-FIL-1-AS-SPL-1	17.10	241082	18567	1.01
26	AS-SPL-30.lcd	GLIDEM60-500-093-FIL-1-AS-SPL-2	17.10	240265	18504	1.01
	Average		17.10	240674	18535	1.01
	%RSD		0.009	0.240	0.239	0.029

Analysed By

13/09/23

Checked By

13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

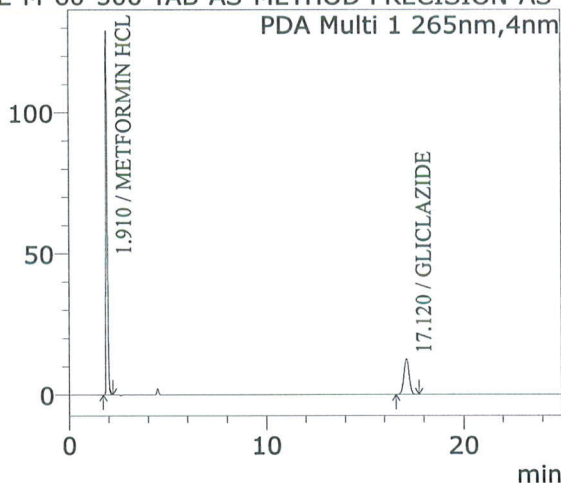
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Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-500-093-FIL-2-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-31.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-27
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 04:22:18
 Date Processed : 13-09-2023 09:52:31

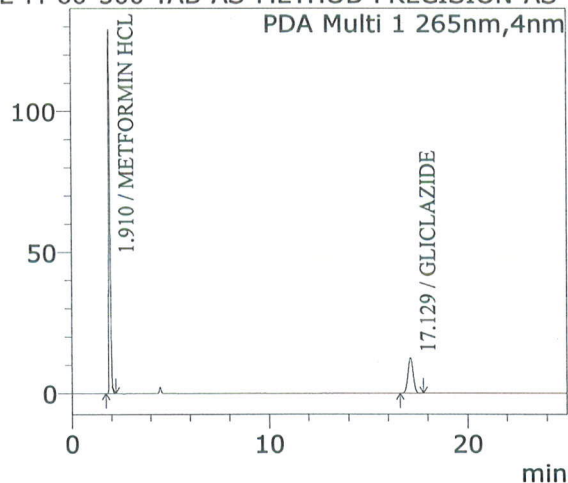
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
27	AS-SPL-31.lcd	GLIDEM60-500-093-FIL-2-AS-SPL-1	1.91	710044	2195	1.36
27	AS-SPL-32.lcd	GLIDEM60-500-093-FIL-2-AS-SPL-2	1.91	710430	2192	1.36
	Average		1.91	710237	2193	1.36
	%RSD		0.003	0.038	0.107	0.073

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
27	AS-SPL-31.lcd	GLIDEM60-500-093-FIL-2-AS-SPL-1	17.12	236362	18561	1.01
27	AS-SPL-32.lcd	GLIDEM60-500-093-FIL-2-AS-SPL-2	17.13	235880	18532	1.01
	Average		17.12	236121	18546	1.01
	%RSD		0.039	0.144	0.109	0.011

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

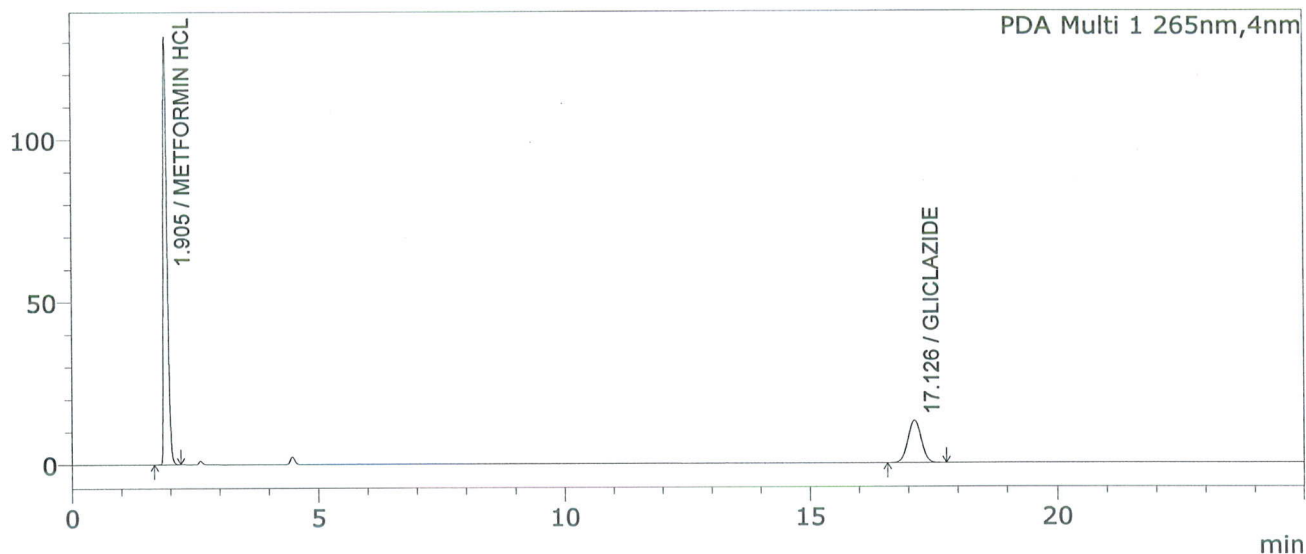
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Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-33.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-24
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 05:13:28
 Date Processed : 13-09-2023 09:52:31

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.91	732282	75.04	2211	1.338	--	--
2	GLICLAZIDE	17.13	243608	24.96	18519	1.010	45.746	--
Total			.975891	100.00				

Analysed By

13/09/23

Checked By

13/09/23



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

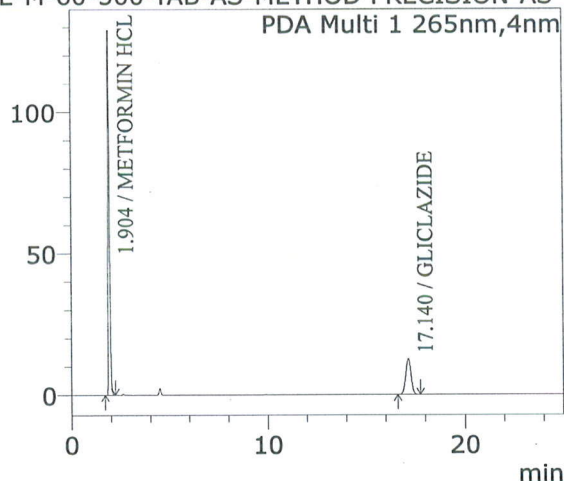
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Sample Name : FILTER PAPER STUDY
 Sample ID : GLIDEM60-500-093-FIL-3-AS-SPL-1
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-34.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUD
 Vial # : 3-28
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 05:39:03
 Date Processed : 13-09-2023 09:52:32

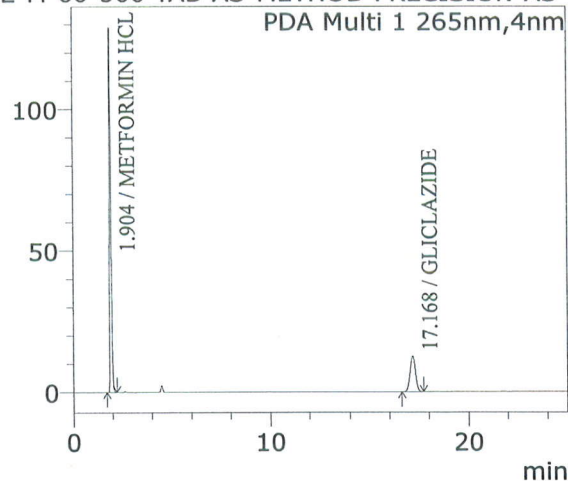
Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU



GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-mAU



<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
28	AS-SPL-34.lcd	GLIDEM60-500-093-FIL-3-AS-SPL-1	1.90	716887	2215	1.34
28	AS-SPL-35.lcd	GLIDEM60-500-093-FIL-3-AS-SPL-2	1.90	717023	2212	1.35
	Average		1.90	716955	2213	1.34
	%RSD		0.003	0.013	0.108	0.086

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
28	AS-SPL-34.lcd	GLIDEM60-500-093-FIL-3-AS-SPL-1	17.14	237653	18508	1.01
28	AS-SPL-35.lcd	GLIDEM60-500-093-FIL-3-AS-SPL-2	17.17	237200	18469	1.01
	Average		17.15	237427	18489	1.01
	%RSD		0.115	0.135	0.148	0.068

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

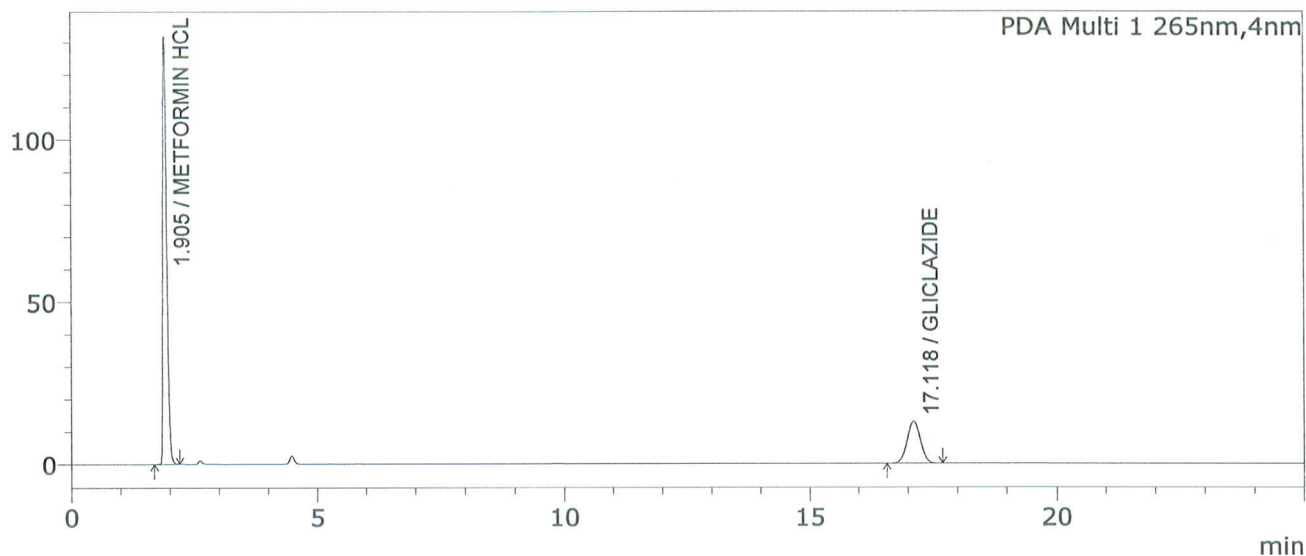
<Sample Information>

Sample Name : FILTER PAPER STUDY
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-2
 Data Filename : 11092023 GLIDE-M-60-500-TAB-AS-METHOD PRECISION-AS-SPL-36.lcd
 Method Filename : GLIDE-M 60-500-850-TAB-AS_P.lcm
 Batch Filename : 11092023 GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb
 Vial # : 3-24
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 06:30:10
 Date Processed : 13-09-2023 09:52:32

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

<Chromatogram>

mAU



<Peak Table>

PDA Ch1 265nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.90	733810	75.18	2210	1.340	--	--
2	GLICLAZIDE	17.12	242304	24.82	18662	1.008	45.872	--
. Total			976114	100.00				

13/09/23

Analysed By

13/09/23

Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch_Table_11092023_GLIDE-M-60-500-TAB-AMV-AS-METHOD PRECISION&FILTER PAPER STUDY.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
15	3	METHOD PRECISION	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-01.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-02.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-03.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-04.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-SPL-05.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-06.lcd	20.0	QC/CL/20/017
17	3	METHOD PRECISION	GLIDEM-60-500-093-SET1-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-07.lcd	20.0	QC/CL/20/017
17	3	METHOD PRECISION	GLIDEM-60-500-093-SET1-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-08.lcd	20.0	QC/CL/20/017
18	3	METHOD PRECISION	GLIDEM-60-500-093-SET2-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-09.lcd	20.0	QC/CL/20/017
18	3	METHOD PRECISION	GLIDEM-60-500-093-SET2-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-10.lcd	20.0	QC/CL/20/017
19	3	METHOD PRECISION	GLIDEM-60-500-093-SET3-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-11.lcd	20.0	QC/CL/20/017
19	3	METHOD PRECISION	GLIDEM-60-500-093-SET3-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-12.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLA+METFORMIN-AS-STD-BKT-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-13.lcd	20.0	QC/CL/20/017
20	3	METHOD PRECISION	GLIDEM-60-500-093-SET4-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-14.lcd	20.0	QC/CL/20/017
20	3	METHOD PRECISION	GLIDEM-60-500-093-SET4-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-15.lcd	20.0	QC/CL/20/017
21	3	METHOD PRECISION	GLIDEM-60-500-093-SET5-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-16.lcd	20.0	QC/CL/20/017
21	3	METHOD PRECISION	GLIDEM-60-500-093-SET5-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-17.lcd	20.0	QC/CL/20/017
22	3	METHOD PRECISION	GLIDEM-60-850-093-SET6-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-18.lcd	20.0	QC/CL/20/017

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
22	3	METHOD PRECISION	GLIDEM-60-850-093-SET6-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-19.lcd	20.0	QC/CL/20/017
16	3	METHOD PRECISION	GLICLA+METFORMIN-AS-STD-BKT-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-20.lcd	20.0	QC/CL/20/017
23	3	FILTER PAPER STUDY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-21.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-22.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-23.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-24.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-SPL-25.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-26.lcd	20.0	QC/CL/20/017
25	3	FILTER PAPER STUDY	GLIDEM60-500-093-CENTR-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-27.lcd	20.0	QC/CL/20/017
25	3	FILTER PAPER STUDY	GLIDEM60-500-093-CENTR-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-28.lcd	20.0	QC/CL/20/017
26	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-1-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-29.lcd	20.0	QC/CL/20/017
26	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-1-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-30.lcd	20.0	QC/CL/20/017
27	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-2-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-31.lcd	20.0	QC/CL/20/017
27	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-2-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-32.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLA+METFORMIN-AS-STD-BKT-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-33.lcd	20.0	QC/CL/20/017
28	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-3-AS-SPL-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-34.lcd	20.0	QC/CL/20/017
28	3	FILTER PAPER STUDY	GLIDEM60-500-093-FIL-3-AS-SPL-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-35.lcd	20.0	QC/CL/20/017
24	3	FILTER PAPER STUDY	GLICLA+METFORMIN-AS-STD-BKT-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-36.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-37.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-1	60-500-850-TAB-AS.lcm	ISION-AS-SPL-38.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-2	60-500-850-TAB-AS.lcm	ISION-AS-SPL-39.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-3	60-500-850-TAB-AS.lcm	ISION-AS-SPL-40.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-4	60-500-850-TAB-AS.lcm	ISION-AS-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	SPECIFICITY	GLICLAZIDE+METFORMIN-AS-STD-5	60-500-850-TAB-AS.lcm	ISION-AS-SPL-42.lcd	20.0	QC/CL/20/017
31	3	SPECIFICITY	AS-METFORMIN API STD	60-500-850-TAB-AS.lcm	ISION-AS-SPL-43.lcd	20.0	QC/CL/20/017
32	3	SPECIFICITY	AS-GLICLAZIDE API STD	60-500-850-TAB-AS.lcm	ISION-AS-SPL-44.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-45.lcd	20.0	QC/CL/20/017
33	3	SPECIFICITY	AS-PLAIN PLACEBO-60-500 MG	60-500-850-TAB-AS.lcm	ISION-AS-SPL-46.lcd	20.0	QC/CL/20/017
34	3	SPECIFICITY	AS-PLAIN PLACEBO-60-850 MG	60-500-850-TAB-AS.lcm	ISION-AS-SPL-47.lcd	20.0	QC/CL/20/017
35	3	SPECIFICITY	AS-PLACEBO+GLICLAZIDE	60-500-850-TAB-AS.lcm	ISION-AS-SPL-48.lcd	20.0	QC/CL/20/017
36	3	SPECIFICITY	AS-PLACEBO-METFORMIN	60-500-850-TAB-AS.lcm	ISION-AS-SPL-49.lcd	20.0	QC/CL/20/017
37	3	SPECIFICITY	AS-PLACEBO+GLICLAZIDE+METFORMIN	60-500-850-TAB-AS.lcm	ISION-AS-SPL-50.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-51.lcd	20.0	QC/CL/20/017
38	3	SPECIFICITY	GLIDE-M-60-500-TAB-093-AS-SPL	60-500-850-TAB-AS.lcm	ISION-AS-SPL-52.lcd	20.0	QC/CL/20/017
29	3	SPECIFICITY	AS-BLANK	60-500-850-TAB-AS.lcm	ISION-AS-SPL-53.lcd	20.0	QC/CL/20/017
39	3	SPECIFICITY	GLIDE-M-60-850-TAB-0801-AS-SPL	60-500-850-TAB-AS.lcm	ISION-AS-SPL-54.lcd	20.0	QC/CL/20/017
30	3	SPECIFICITY	GLICLA+METFORMIN-AS-STD-BKT	60-500-850-TAB-AS.lcm	ISION-AS-SPL-55.lcd	20.0	QC/CL/20/017
-1	3	SPECIFICITY	SHUTDOWN	HUTDOWN METHOD.lcm	ISION-AS-SPL-56.lcd	20.0	QC/CL/20/017

Analysed By

11/09/23

Checked By

11/09/23

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY 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
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Standard dilution :	about 60 mg	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION			INTERMEDIATE PRECISION			CUMMULATIVE PRECISION
No.of preparation	Drug Release in %	Minimum	No.of preparation	Drug Release in %	Minimum	Average in %
Preparation-1	101.3	98.4	Preparation-1	100.9	96.5	99.32
Preparation-2	100.9		Preparation-2	100.2		
Preparation-3	102.2	Maximum	Preparation-3	96.6	Maximum	% RSD
Preparation-4	98.4		Preparation-4	98.5		
Preparation-5	98.9	102.2	Preparation-5	96.5	100.9	1.85
Preparation-6	99.5		Preparation-6	97.9		
Average	100.2	Not applicable	Average	98.4	Not applicable	
% RSD	1.49	Not applicable	% RSD	1.85	Not applicable	

Results:

- 1) % RSD for Assay of six preparations of Method precision
- 2) % RSD for Assay of six preparations of Intermediate precision
- 3) Cumulative %RSD for Assay of twelve preparations

1.49

1.85

1.85

Acceptance criteria:

- 1) % RSD for Assay of Six preparations should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

C.K.SARAVANAN

Date :

14-09-2023

Checked by :

Date :

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/006 & ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	about 850 mg	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1700	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION			INTERMEDIATE PRECISION			CUMMULATIVE PRECISION
No.of preparation	Drug Release in %	Minimum	No.of preparation	Drug Release in %	Minimum	Average in %
Preparation-1	98.3	96.2	Preparation-1	99.5	97.9	98.78
Preparation-2	99.5		Preparation-2	99.0		
Preparation-3	99.6	Maximum	Preparation-3	97.9	Maximum	% RSD
Preparation-4	96.2		Preparation-4	100.3		
Preparation-5	97.0	99.6	Preparation-5	99.7	101.7	1.64
Preparation-6	96.6		Preparation-6	101.7		
Average	97.9	Not applicable	Average	99.7	Not applicable	
% RSD	1.52	Not applicable	% RSD	1.28	Not applicable	

Results:

- 1) % RSD for Assay of six preparations of Method precision
- 2) % RSD for Assay of six preparations of Intermediate precision
- 3) Cumulative %RSD for Assay of twelve preparations

1.52

1.28

1.64

Acceptance criteria:

- 1) % RSD for Assay of Six preparations should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

C.K.SARAVANAN

Date :

14-09-2023

Checked by :

Date :

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET****Title****ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS**

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Mar-23
Parameter :	INTERMEDIATE PRECISION	Exp.Date :	Feb-26

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60 mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	-------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	850.04	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.08	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-1700.225	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	850
Average weight :	1360

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Metformin HCl	1120159	1119623	1119552	1119941	1120498	1119955	390	0.035
Bracketing Std.	1121261	1122060				1120442	921	0.082

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	1360.18	1112143	845.69	99.5	99.7	1.27
Sample Preparation-2	1360.19	1106707	841.55	99.0		
Sample Preparation-3	1360.00	1094140	832.11	97.9		
Sample Preparation-4	1322.47	1089817	852.34	100.3		
Sample Preparation-5	1360.19	1114027	847.11	99.7		
Sample Preparation-6	1325.65	1107761	864.30	101.7		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

C.K.SARAVANAN

Date :

14-09-2023

Checked by :

Date :

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE TABLETS

Product Name :	GLIDE-M 60/850	Batch size :	Not applicable
Batch Number :	G17230801	Mfg.Date :	Mar-23
Parameter :	INTERMEDIATE PRECISION	Exp.Date :	Feb-26

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 850 mg
Gliclazide BP ----- 60 mg

ASSAY OF GLICLAZIDE

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

Standard dilution :	62.16	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-124.32	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution :	Sample weight	mg to --->	100	ml to --->	5	ml to --->	25
Test.conc (in ppm)-120.0158	1	ml to --->	1	ml to --->	1	ml to --->	1

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

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Gliclazide	290285	289283	289560	288274	287434	288967	1120	0.388
Bracketing Std.	281793	275149				285968	5545	1.939

Sample Preparation	Sample weight	Sample Area	Assay in mg/tablet	Assay in %	Average in %	RSD %
Sample Preparation-1	1360.18	281591	60.57	100.9	98.4	1.85
Sample Preparation-2	1360.19	279478	60.11	100.2		
Sample Preparation-3	1360.00	269496	57.97	96.6		
Sample Preparation-4	1322.47	267065	59.08	98.5		
Sample Preparation-5	1360.19	269314	57.92	96.5		
Sample Preparation-6	1325.65	266154	58.74	97.9		

Acceptance criteria:

- 1) % RSD for Assay of Six preparations Should not be more than 2.0.
- 2) Cumulative % RSD for Assay of twelve preparations (i.e. Method precision and Intermediate precision) should not be more than 2.0.

Analysed by :

C.K.SARAVANAN

Date :

14-09-2023

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

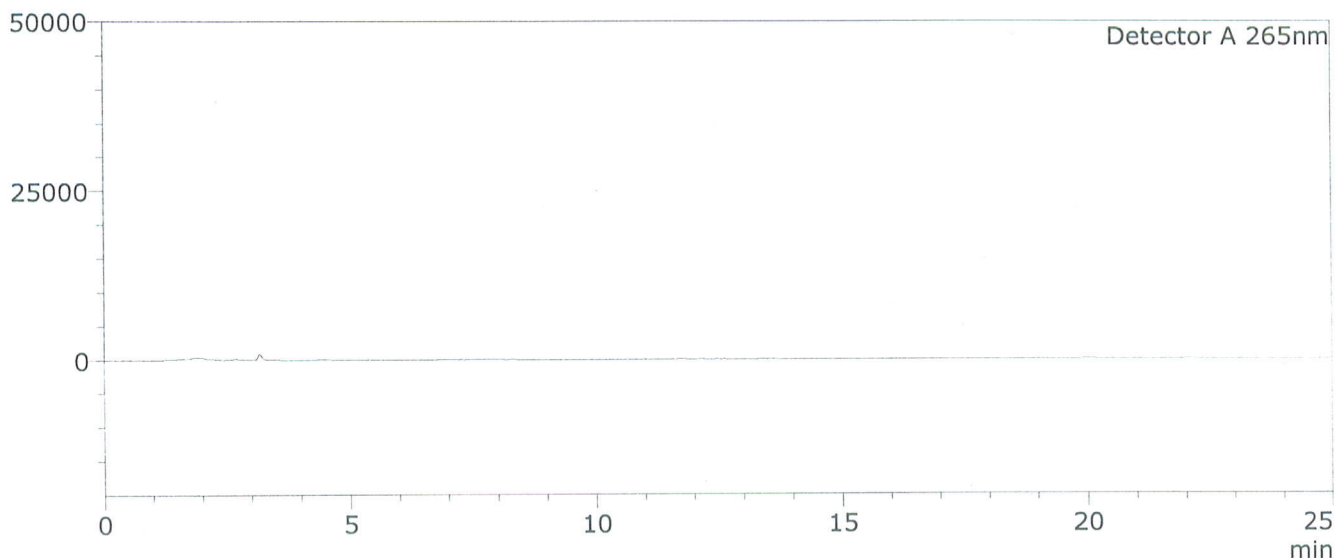
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Sample Name : INTERMEDIATE PRECISION
 Sample ID : AS-BLANK
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-01.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-10
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 19:27:13
 Date Processed : 14-09-2023 10:01:00

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

uV



<Peak Table>

Detector A 265nm

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

12/09/23
 Analysed By

14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

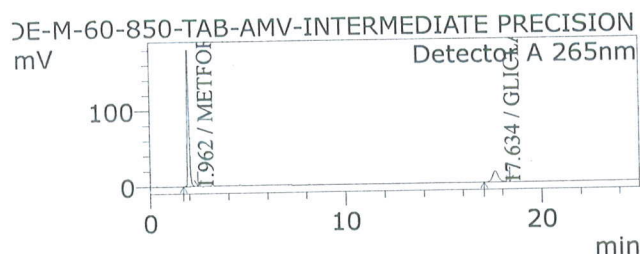
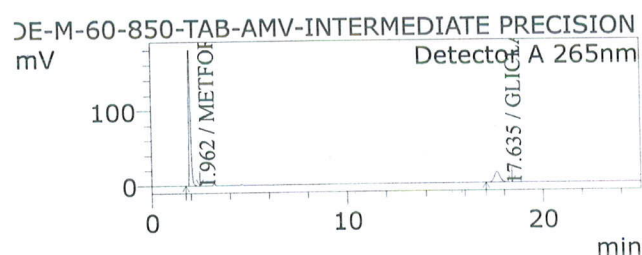
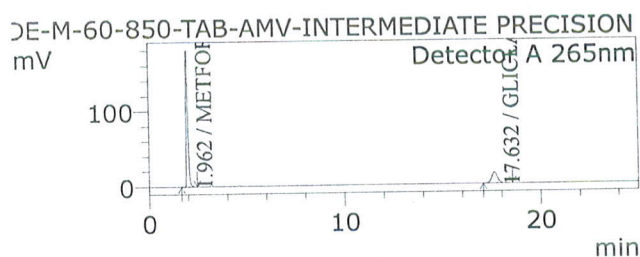
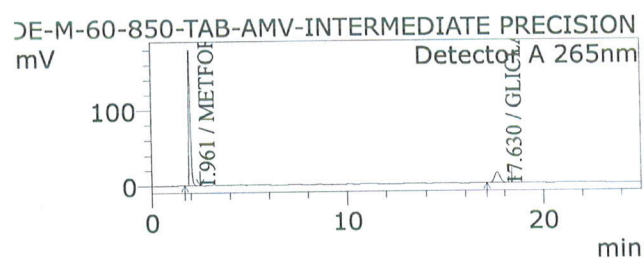
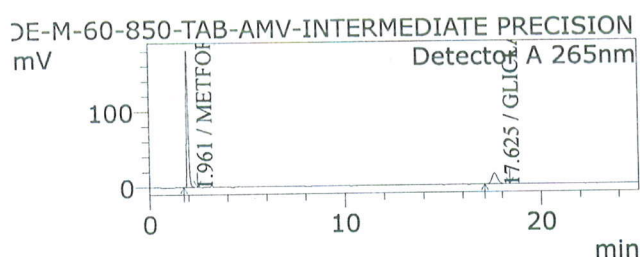
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-02.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-11
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 19:52:44
 Date Processed : 14-09-2023 10:05:48

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

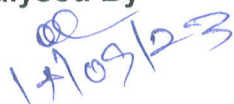
ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
11	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.96	1120159	2132	1.48
11	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.96	1119623	2133	1.48
11	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.96	1119552	2134	1.48
11	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.96	1119941	2128	1.48
11	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.96	1120498	2132	1.48
	Average		1.96	1119955	2132	1.48
	%RSD		0.021	0.035	0.115	0.062

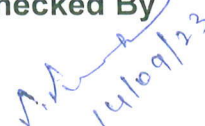
ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
11	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	17.63	290285	17812	1.12
11	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	17.63	289283	17843	1.11
11	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	17.63	289560	17795	1.12
11	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	17.63	288274	17825	1.12
11	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	17.63	287434	17796	1.12
	Average		17.63	288967	17814	1.12
	%RSD		0.022	0.388	0.114	0.170

Analysed By


12/09/23

Checked By


14/09/23



GENERIC HEALTHCARE PVT. LTD.

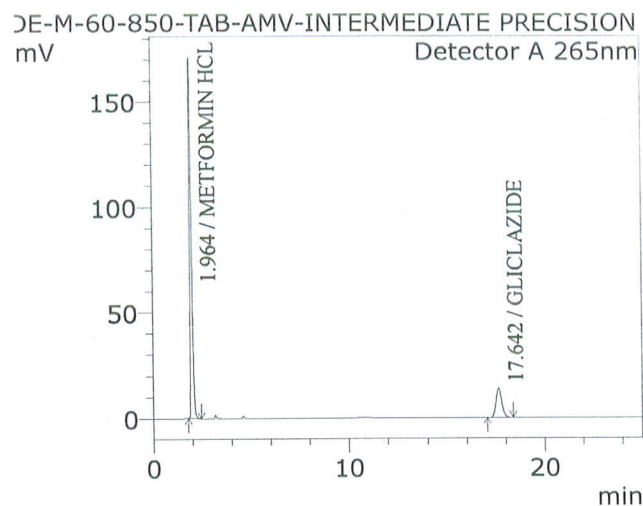
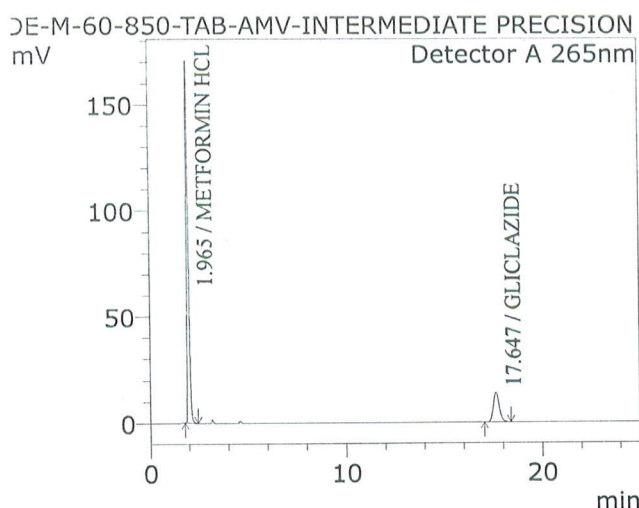
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-850-801-SET1-AS-SPL-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-07.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-12
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 22:00:25
 Date Processed : 14-09-2023 10:02:16

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	AS-SPL-07.lcd	GLIDEM-60-850-801-SET1-AS-SPL-1	1.96	1112576	1947	1.50
12	AS-SPL-08.lcd	GLIDEM-60-850-801-SET1-AS-SPL-2	1.96	1111710	1951	1.50
	Average		1.96	1112143	1949	1.50
	%RSD		0.008	0.055	0.155	0.022

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	AS-SPL-07.lcd	GLIDEM-60-850-801-SET1-AS-SPL-1	17.65	282077	17403	1.13
12	AS-SPL-08.lcd	GLIDEM-60-850-801-SET1-AS-SPL-2	17.64	281104	17412	1.13
	Average		17.64	281591	17407	1.13
	%RSD		0.022	0.244	0.036	0.007

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

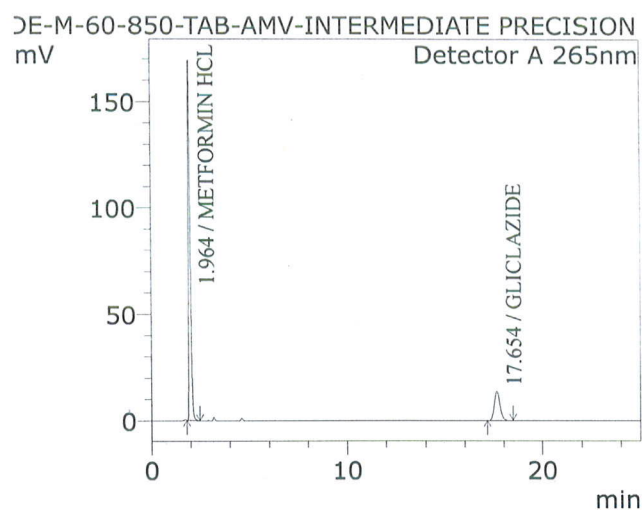
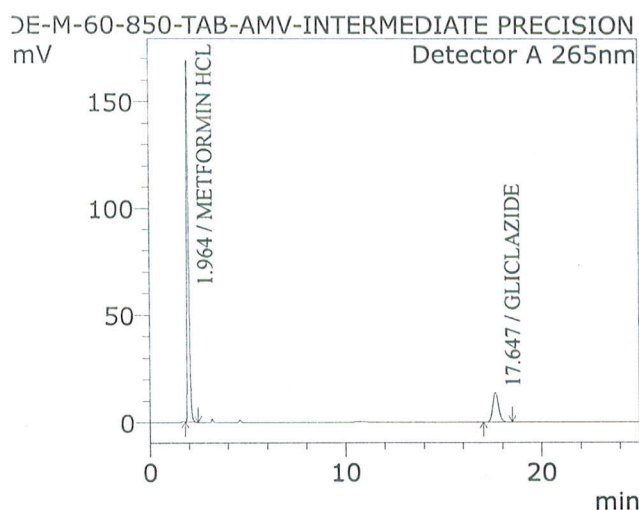
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-850-801-SET2-AS-SPL-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-09.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-13
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 22:51:30
 Date Processed : 14-09-2023 10:02:46

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	AS-SPL-09.lcd	GLIDEM-60-850-801-SET2-AS-SPL-1	1.96	1107154	1934	1.52
13	AS-SPL-10.lcd	GLIDEM-60-850-801-SET2-AS-SPL-2	1.96	1106259	1932	1.52
	Average		1.96	1106707	1933	1.52
	%RSD		0.024	0.057	0.061	0.307

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	AS-SPL-09.lcd	GLIDEM-60-850-801-SET2-AS-SPL-1	17.65	280033	17427	1.13
13	AS-SPL-10.lcd	GLIDEM-60-850-801-SET2-AS-SPL-2	17.65	278922	17443	1.13
	Average		17.65	279478	17435	1.13
	%RSD		0.028	0.281	0.064	0.142

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

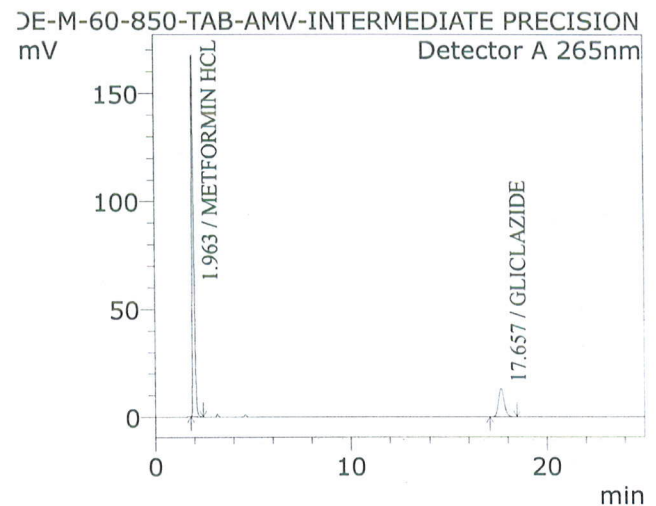
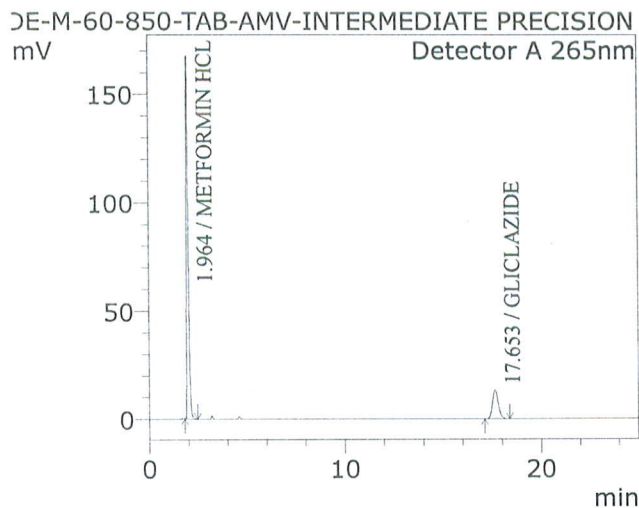
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-850-801-SET3-AS-SPL-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-11.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-14
 Injection Volume : 20 uL
 Date Acquired : 12-09-2023 23:42:36
 Date Processed : 14-09-2023 10:03:17

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	AS-SPL-11.lcd	GLIDEM-60-850-801-SET3-AS-SPL-1	1.96	1094107	1934	1.52
14	AS-SPL-12.lcd	GLIDEM-60-850-801-SET3-AS-SPL-2	1.96	1094173	1930	1.53
	Average		1.96	1094140	1932	1.52
	%RSD		0.033	0.004	0.172	0.138

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	AS-SPL-11.lcd	GLIDEM-60-850-801-SET3-AS-SPL-1	17.65	269383	17463	1.13
14	AS-SPL-12.lcd	GLIDEM-60-850-801-SET3-AS-SPL-2	17.66	269610	17436	1.13
	Average		17.65	269496	17449	1.13
	%RSD		0.015	0.059	0.107	0.063

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

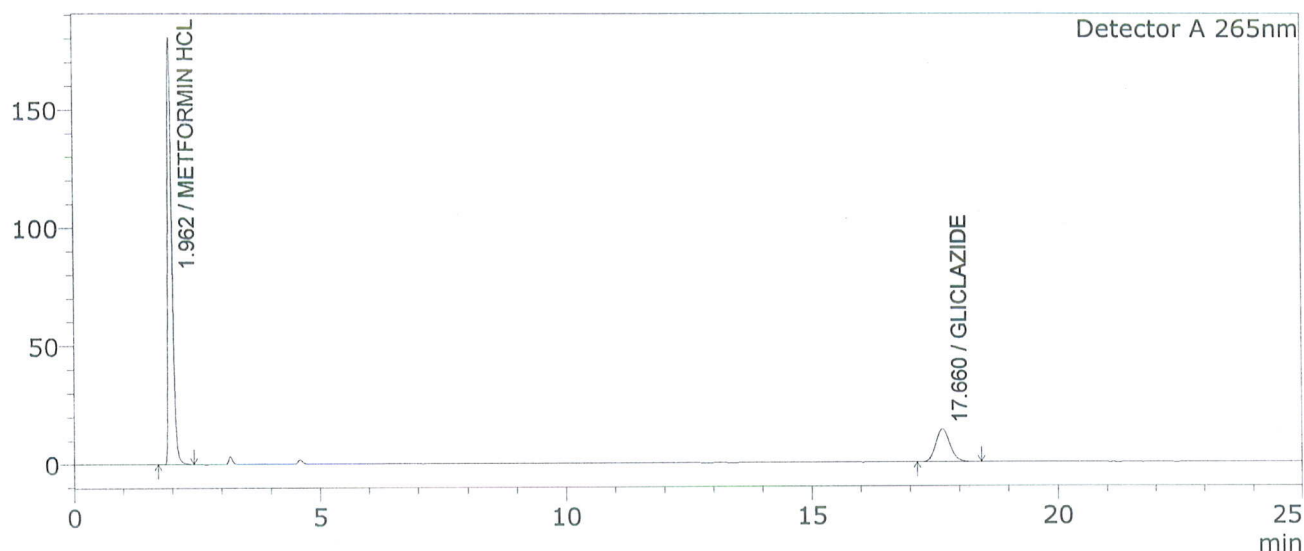
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Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-13.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-11
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 00:33:41
 Date Processed : 14-09-2023 10:03:47

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1121261	79.92	2123	1.477	--	--
2	GLICLAZIDE	17.66	281793	20.08	17766	1.121	44.835	--
Total			1403054	100.00				

14/09/23
 Analysed By

14/09/23
 Checked By



GENERIC HEALTHCARE PVT. LTD.

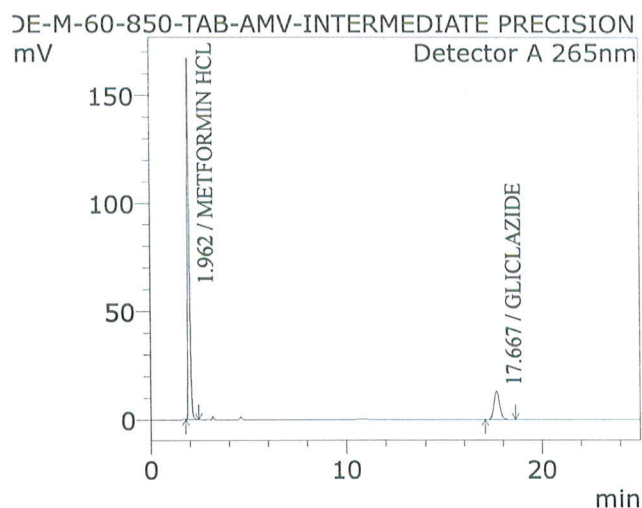
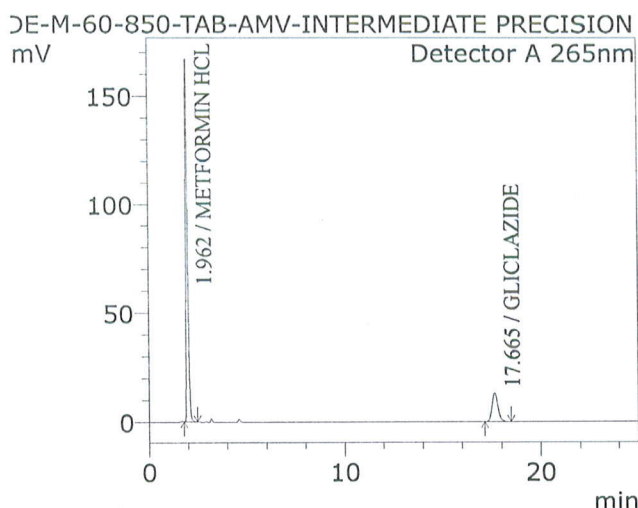
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-850-801-SET4-AS-SPL-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-14.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-15
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 00:59:14
 Date Processed : 14-09-2023 10:04:02

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	AS-SPL-14.lcd	GLIDEM-60-850-801-SET4-AS-SPL-1	1.96	1090056	1930	1.53
15	AS-SPL-15.lcd	GLIDEM-60-850-801-SET4-AS-SPL-2	1.96	1089578	1928	1.53
	Average		1.96	1089817	1929	1.53
	%RSD		0.007	0.031	0.054	0.011

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	AS-SPL-14.lcd	GLIDEM-60-850-801-SET4-AS-SPL-1	17.66	266966	17466	1.13
15	AS-SPL-15.lcd	GLIDEM-60-850-801-SET4-AS-SPL-2	17.67	267163	17436	1.13
	Average		17.67	267065	17451	1.13
	%RSD		0.010	0.052	0.121	0.054

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

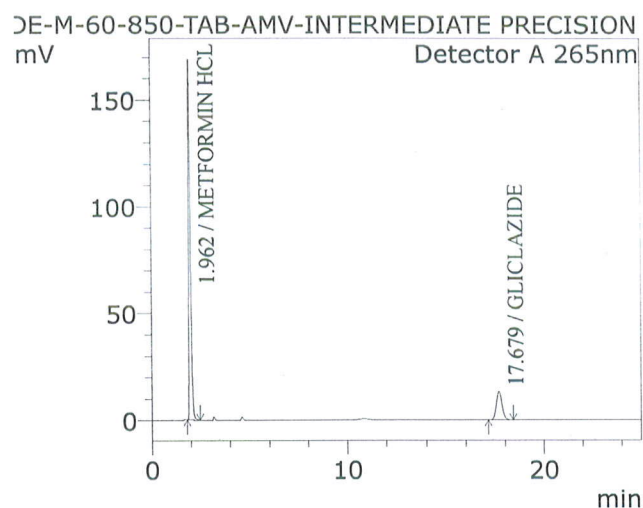
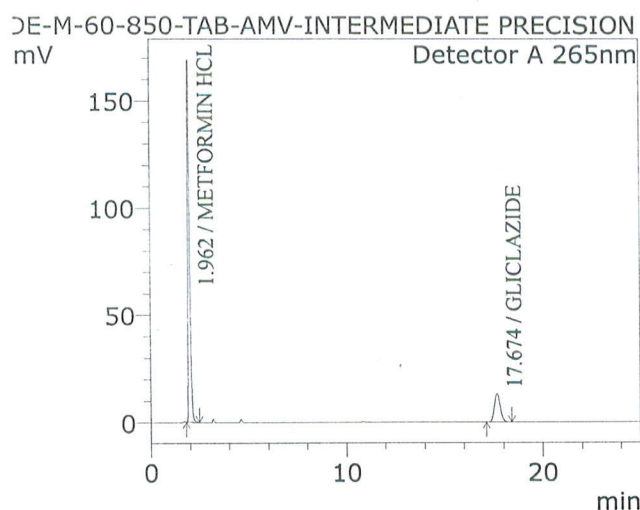
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-850-801-SET5-AS-SPL-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-16.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-16
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 01:50:20
 Date Processed : 14-09-2023 10:04:32

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
16	AS-SPL-16.lcd	GLIDEM-60-850-801-SET5-AS-SPL-1	1.96	1113830	1903	1.53
16	AS-SPL-17.lcd	GLIDEM-60-850-801-SET5-AS-SPL-2	1.96	1114224	1904	1.53
	Average		1.96	1114027	1904	1.53
	%RSD		0.012	0.025	0.050	0.092

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
16	AS-SPL-16.lcd	GLIDEM-60-850-801-SET5-AS-SPL-1	17.67	269911	17427	1.13
16	AS-SPL-17.lcd	GLIDEM-60-850-801-SET5-AS-SPL-2	17.68	268717	17474	1.13
	Average		17.68	269314	17451	1.13
	%RSD		0.020	0.313	0.190	0.042

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

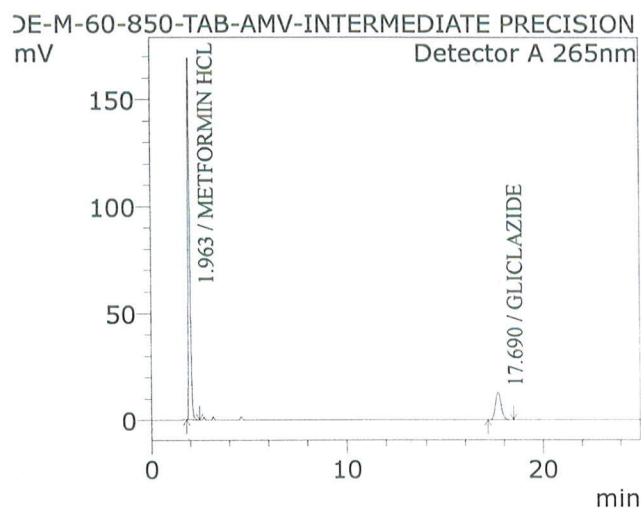
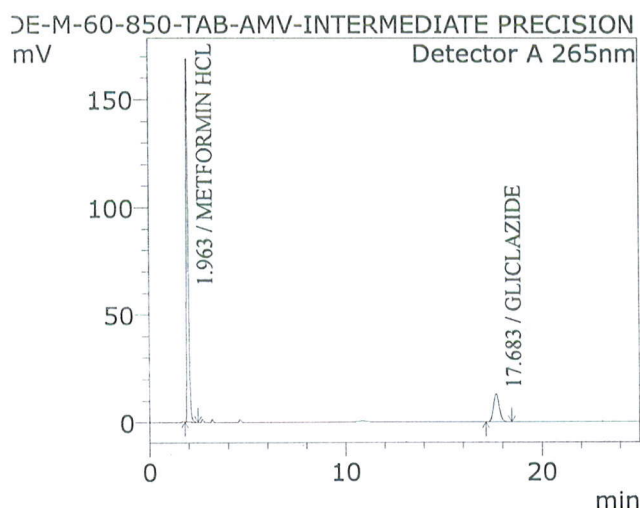
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLIDEM-60-850-801-SET6-AS-SPL-1
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-18.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-17
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 02:41:26
 Date Processed : 14-09-2023 10:05:03

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
17	AS-SPL-18.lcd	GLIDEM-60-850-801-SET6-AS-SPL-1	1.96	1107677	1911	1.52
17	AS-SPL-19.lcd	GLIDEM-60-850-801-SET6-AS-SPL-2	1.96	1107846	1920	1.52
	Average		1.96	1107761	1915	1.52
	%RSD		0.004	0.011	0.323	0.351

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
17	AS-SPL-18.lcd	GLIDEM-60-850-801-SET6-AS-SPL-1	17.68	266365	17423	1.13
17	AS-SPL-19.lcd	GLIDEM-60-850-801-SET6-AS-SPL-2	17.69	265942	17464	1.13
	Average		17.69	266154	17443	1.13
	%RSD		0.027	0.112	0.164	0.036

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

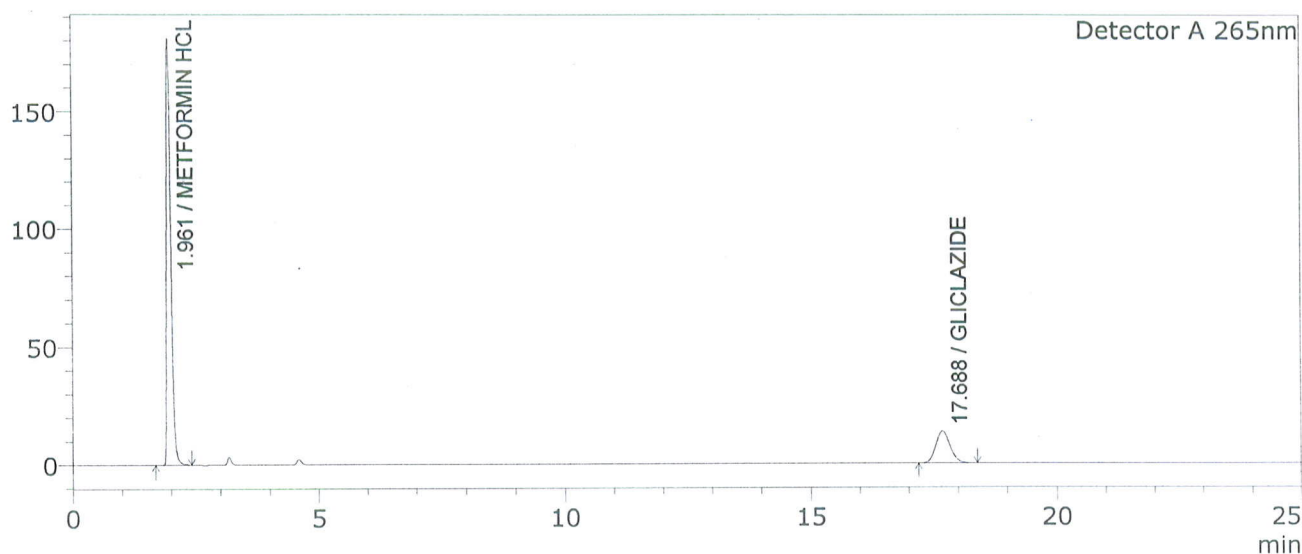
<Sample Information>

Sample Name : INTERMEDIATE PRECISION
 Sample ID : GLICLA+METFORMIN-AS-STD-BKT-2
 Data Filename : 12092023 GLIDE-M-60-850-TAB-AMV-INTERMEDIATE PRECISION-AS-SPL-20.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS_P.lcm
 Batch Filename : 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb
 Vial # : 4-11
 Injection Volume : 20 uL
 Date Acquired : 13-09-2023 03:32:30
 Date Processed : 14-09-2023 10:05:33

Acquired by : C.K.SARAVANAN.
 Processed by : S.GOMATHI

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1122060	80.31	2126	1.480	--	--
2	GLICLAZIDE	17.69	275149	19.69	17813	1.120	44.919	--
Total			1397209	100.00				

14/09/23
Analysed By

14/09/23
Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 12092023 GLIDE-M-60-850-AMV-AS-INTERMEDIATE PRECISION.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
10	4	INTERMEDIATE PRECISION	AS-BLANK	50-500-850-TAB-AS.lcm	ISION-AS-SPL-01.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-02.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-03.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-3	50-500-850-TAB-AS.lcm	ISION-AS-SPL-04.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-4	50-500-850-TAB-AS.lcm	ISION-AS-SPL-05.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLAZIDE+METFORMIN-AS-STD-5	50-500-850-TAB-AS.lcm	ISION-AS-SPL-06.lcd	20.0	QC/CL/23/041
12	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET1-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-07.lcd	20.0	QC/CL/23/041
12	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET1-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-08.lcd	20.0	QC/CL/23/041
13	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET2-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-09.lcd	20.0	QC/CL/23/041
13	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET2-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-10.lcd	20.0	QC/CL/23/041
14	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET3-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-11.lcd	20.0	QC/CL/23/041
14	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET3-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-12.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLA+METFORMIN-AS-STD-BKT-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-13.lcd	20.0	QC/CL/23/041
15	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET4-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-14.lcd	20.0	QC/CL/23/041
15	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET4-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-15.lcd	20.0	QC/CL/23/041
16	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET5-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-16.lcd	20.0	QC/CL/23/041
16	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET5-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-17.lcd	20.0	QC/CL/23/041
17	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET6-AS-SPL-1	50-500-850-TAB-AS.lcm	ISION-AS-SPL-18.lcd	20.0	QC/CL/23/041

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
17	4	INTERMEDIATE PRECISION	GLIDEM-60-850-801-SET6-AS-SPL-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-19.lcd	20.0	QC/CL/23/041
11	4	INTERMEDIATE PRECISION	GLICLA+METFORMIN-AS-STD-BKT-2	50-500-850-TAB-AS.lcm	ISION-AS-SPL-20.lcd	20.0	QC/CL/23/041
-1	4	WASH	WASH	THOD-100%-WATER.lcm	ISION-AS-SPL-21.lcd	20.0	QC/CL/23/041
-1	4	WASH	WASH	WASHING METHOD.lcm	ISION-AS-SPL-22.lcd	20.0	QC/CL/23/041
-1	4	SHUTDOWN	SHUTDOWN	ETHOD\SHUTDOWN.lcm	ISION-AS-SPL-23.lcd	20.0	QC/CL/23/041

Analysed By



12/07/23

Checked By



12/09/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF GLICLAZIDE

Instrument ID:	ST/QCLC/009		Balance ID :	ST/QC/EQ/041		WS No.:	ST/WS/22/040	% Purity (aib)	100.0
Standard dilution :	60.05	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-120.1	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 50% Dilution:	31.23	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-62.46	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 100% Dilution:	61.05	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-122.1	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 150% Dilution:	94.06	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-188.12	1	ml to --->	1	ml to --->	1	ml to --->	1		
System suitability	1	2	3	4	5	MEAN	S.D	RSD in %	
Gliclazide	263879	263897	263847	262424	262719	263353	721	0.274	
Standard con. in ppm.	120.1								

Level"s	Injection No.	Observed area	Quantity added in ppm	Quantity Recovered in ppm	% Recovery
I(50%)	1	136424	62.460	62.22	99.61
	2	137249	62.460	62.59	100.21
	3	138173	62.460	63.01	100.88
				MEAN	100.23
				%RSD	0.637
II(100%)	1	270836	122.100	123.51	101.16
	2	269888	122.100	123.08	100.80
	3	269230	122.100	122.78	100.56
				MEAN	100.84
				%RSD	0.299
III(150%)	1	414478	188.120	189.02	100.48
	2	411384	188.120	187.61	99.73
	3	412101	188.120	187.94	99.90
				MEAN	100.04
				%RSD	0.392

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

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

Results:

The % recovery was complies at each levels.

Acceptance criteria:

The mean % recovery at each level should be 98.0 to 102.0.

Analysed by :

E.MEENA

Date :

09-09-2023

Checked by :

Date :

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

Title

ASSAY OF METFORMIN HCL AND GLICLAZIDE IN METFORMIN HCL AND GLICLAZIDE 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

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QCLC/009		Balance ID :	ST/QC/EQ/041		WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
Standard dilution :	850.24	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-1700.48	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 50% Dilution:	450.15	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-900.3	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 100% Dilution:	822.34	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-1644.68	1	ml to --->	1	ml to --->	1	ml to --->	1		
Recovery 150% Dilution:	1185.14	mg to --->	100	ml to --->	5	ml to --->	25		
Std.conc (in ppm)-2370.28	1	ml to --->	1	ml to --->	1	ml to --->	1		
System suitability	1	2	3	4	5	MEAN	S.D	RSD in %	
Metformin Hcl	1124913	1123230	1123263	1124233	1124323	1123992	729	0.065	
Standard con. in ppm.	1700.48								

Level's	Injection No.	Observed area	Quantity added in ppm	Quantity Recovered in ppm	% Recovery
I(50%)	1	598838	900.300	905.98	100.63
	2	599073	900.300	906.33	100.67
	3	598577	900.300	905.58	100.59
				MEAN	100.63
				%RSD	0.041
II(100%)	1	1068860	1644.680	1617.07	98.32
	2	1070738	1644.680	1619.91	98.49
	3	1072260	1644.680	1622.21	98.63
				MEAN	98.48
				%RSD	0.159
III(150%)	1	1543497	2370.280	2335.15	98.52
	2	1543784	2370.280	2335.58	98.54
	3	1543972	2370.280	2335.86	98.55
				MEAN	98.53
				%RSD	0.015

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

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

The % recovery was complies at each levels.

Acceptance criteria:

The mean % recovery at each level should be 98.0 to 102.0.

Analysed by :

E.MEENA

Date :

09-09-2023

09/09/23

Checked by :

Date :

09/09/23



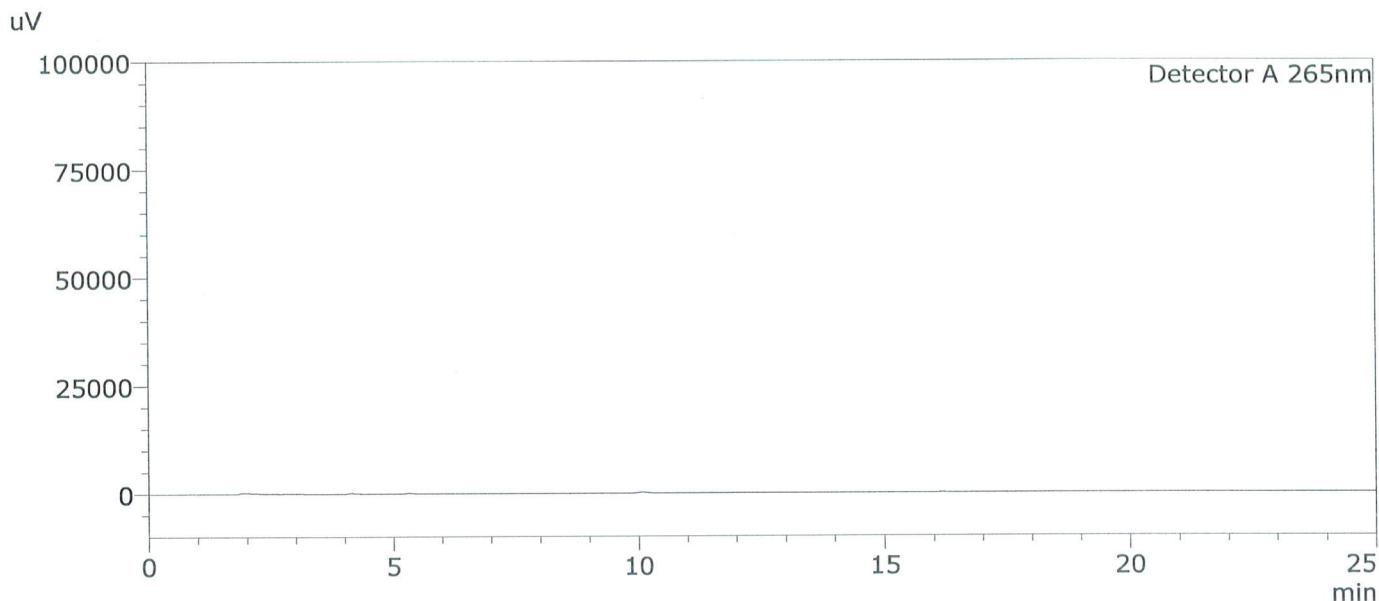
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : RECOVERY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-52.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-11
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 11:31:14
 Date Processed : 09-09-2023 10:29:49
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

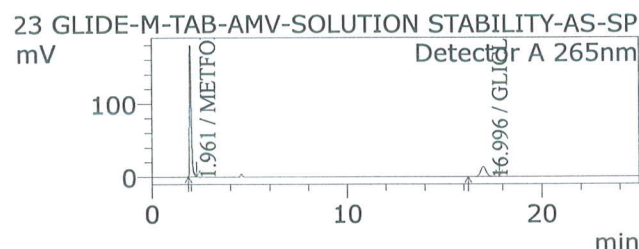
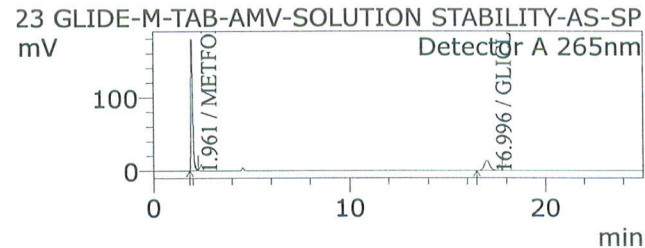
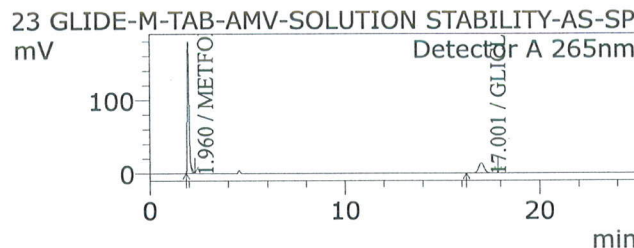
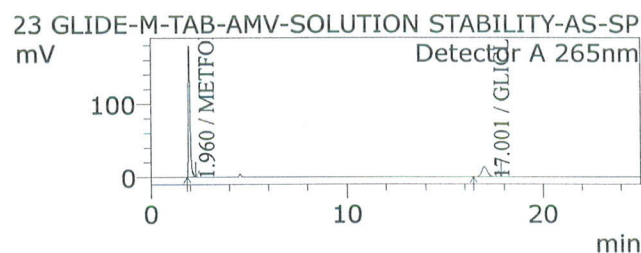
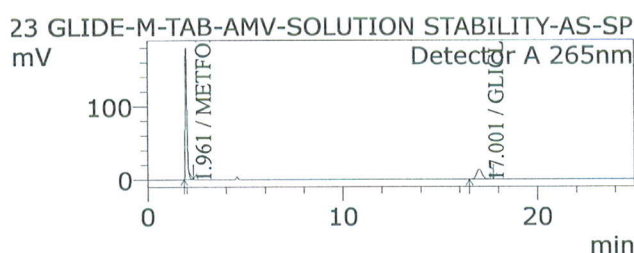
Analysis Report

<Sample Information>

Sample Name : RECOVERY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-53.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-12
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 11:56:47
 Date Processed : 09-09-2023 10:32:43

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	AS-SPL-53.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	1.96	1124913	2061	1.44
12	AS-SPL-54.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	1.96	1123230	2058	1.44
12	AS-SPL-55.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	1.96	1123263	2057	1.44
12	AS-SPL-56.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	1.96	1124233	2064	1.45
12	AS-SPL-57.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	1.96	1124323	2059	1.44
	Average		1.96	1123992	2060	1.44
	%RSD		0.021	0.065	0.139	0.102

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	AS-SPL-53.lcd	GLICLAZIDE+METFORMIN-AS-STD-1	17.00	263879	17888	1.11
12	AS-SPL-54.lcd	GLICLAZIDE+METFORMIN-AS-STD-2	17.00	263897	17868	1.11
12	AS-SPL-55.lcd	GLICLAZIDE+METFORMIN-AS-STD-3	17.00	263847	17861	1.11
12	AS-SPL-56.lcd	GLICLAZIDE+METFORMIN-AS-STD-4	17.00	262424	17845	1.11
12	AS-SPL-57.lcd	GLICLAZIDE+METFORMIN-AS-STD-5	17.00	262719	17800	1.11
	Average		17.00	263353	17852	1.11
	%RSD		0.015	0.274	0.185	0.062

Analysed By


09/09/23

Checked By


09/09/23


GENERIC HEALTHCARE PVT. LTD.

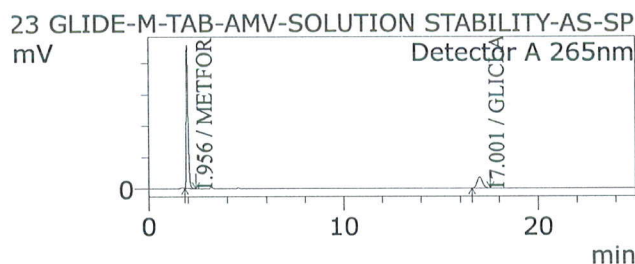
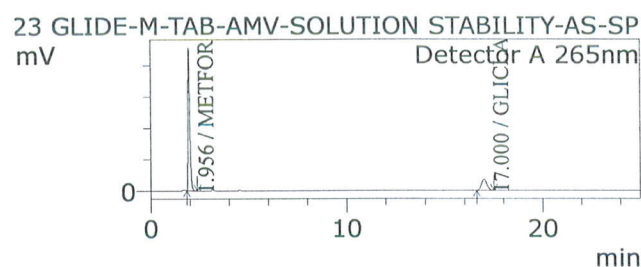
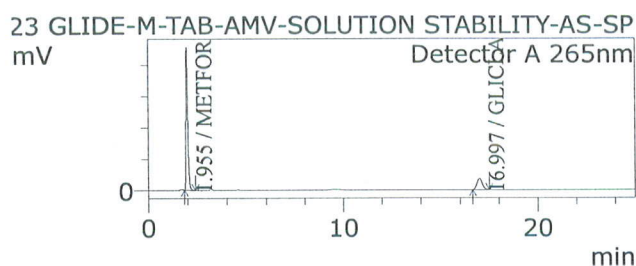
Analysis Report

<Sample Information>

Sample Name : RECOVERY
 Sample ID : GLICLAZIDE+METFOR-50%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-63.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-13
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 16:12:08
 Date Processed : 09-09-2023 17:19:48

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	AS-SPL-63.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-1	1.95	598838	1900	1.50
13	AS-SPL-64.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-2	1.96	599073	1886	1.49
13	AS-SPL-65.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-3	1.96	598577	1901	1.51
	Average		1.96	598829	1896	1.50
	%RSD		0.033	0.041	0.443	0.562

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
13	AS-SPL-63.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-1	17.00	136424	17836	1.13
13	AS-SPL-64.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-2	17.00	137249	17747	1.12
13	AS-SPL-65.lcd	GLICLAZIDE+METFOR-50%-AS-SPL-3	17.00	138173	17668	1.13
	Average		17.00	137282	17750	1.13
	%RSD		0.011	0.637	0.475	0.445

Analysed By

09/09/23

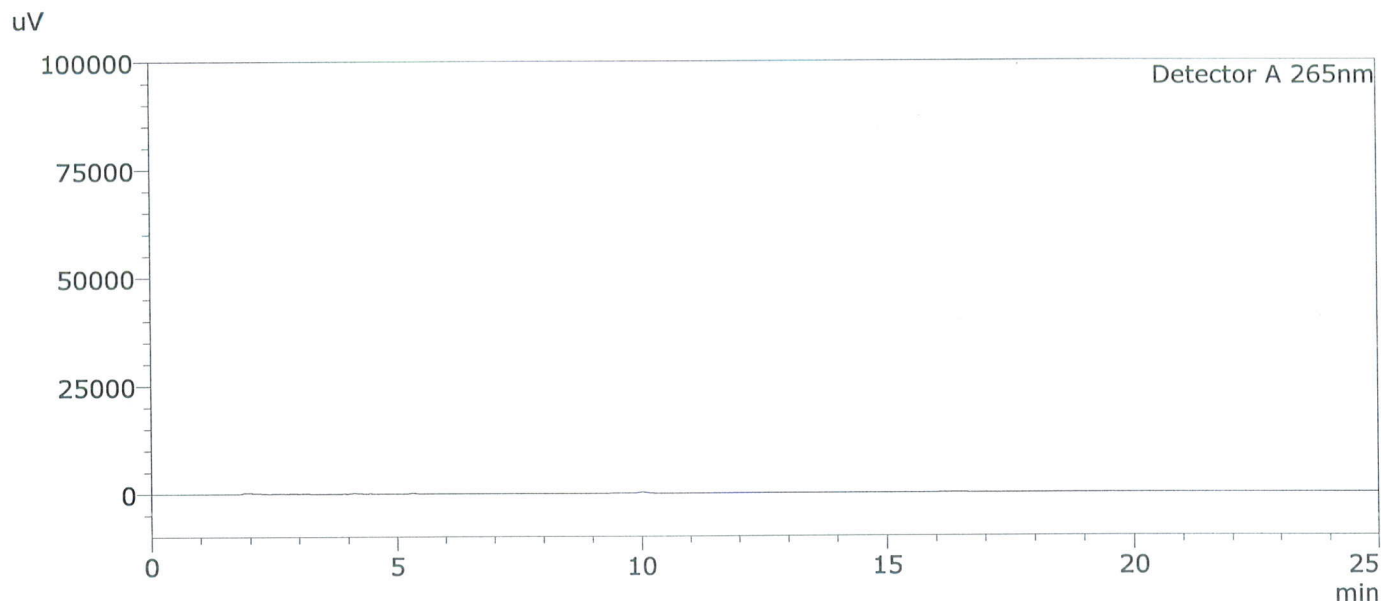
Checked By

09/09/23


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

Sample Name : RECOVERY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-66.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-11
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 17:28:45
 Date Processed : 09-09-2023 10:29:53

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

<Chromatogram>

<Peak Table>

Detector A 265nm

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

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

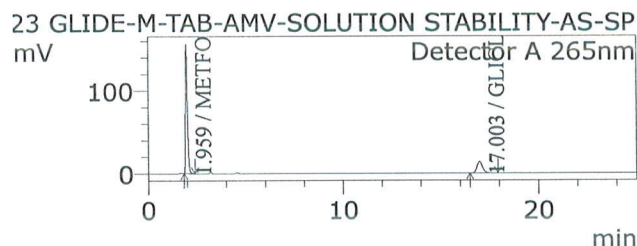
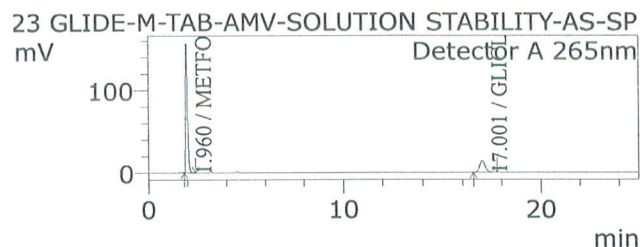
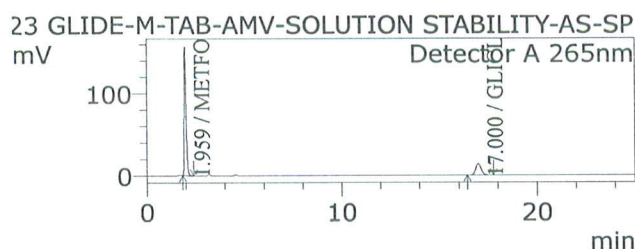
Analysis Report

<Sample Information>

Sample Name : RECOVERY
 Sample ID : GLICLAZIDE+METFOR-100%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-67.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-14
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 17:54:17
 Date Processed : 09-09-2023 10:29:54

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	AS-SPL-67.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-1	1.96	1068860	1792	1.49
14	AS-SPL-68.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-2	1.96	1070738	1772	1.48
14	AS-SPL-69.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-3	1.96	1072260	1756	1.46
	Average		1.96	1070619	1773	1.48
	%RSD		0.012	0.159	1.013	0.858

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
14	AS-SPL-67.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-1	17.00	270836	17439	1.13
14	AS-SPL-68.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-2	17.00	269888	17443	1.13
14	AS-SPL-69.lcd	GLICLAZIDE+METFOR-100%-AS-SPL-3	17.00	269230	17386	1.14
	Average		17.00	269985	17423	1.13
	%RSD		0.011	0.299	0.183	0.196

Analysed By

09/09/23

Checked By

09/09/23



GENERIC HEALTHCARE PVT. LTD.

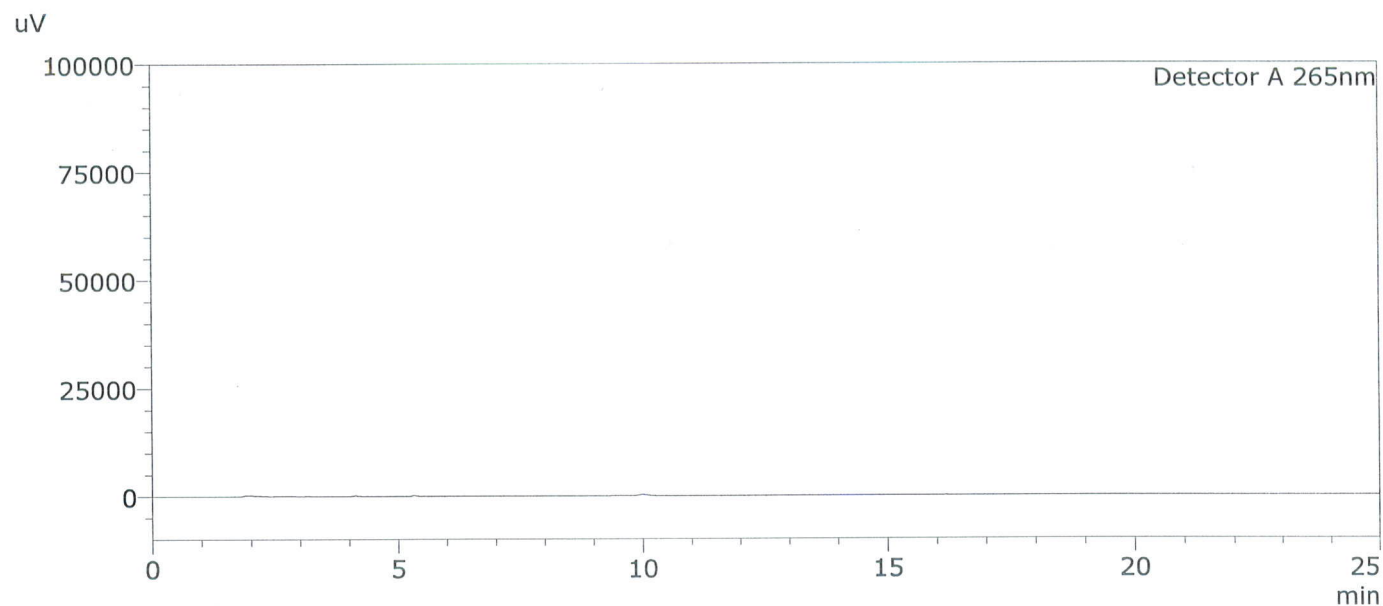
Analysis Report

<Sample Information>

Sample Name : RECOVERY
 Sample ID : AS-BLANK
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-70.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-11
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 19:10:55
 Date Processed : 09-09-2023 10:29:54

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

<Chromatogram>



<Peak Table>

Detector A 265nm

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

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

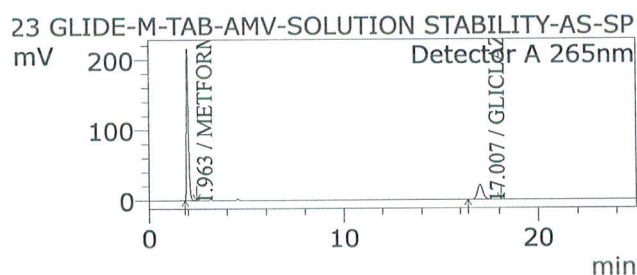
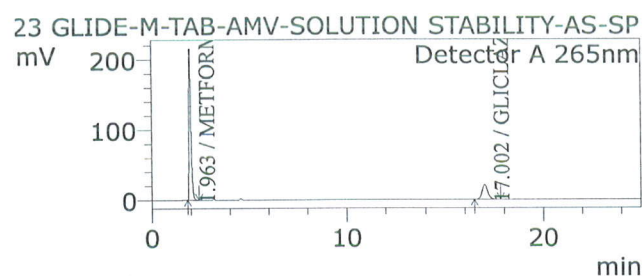
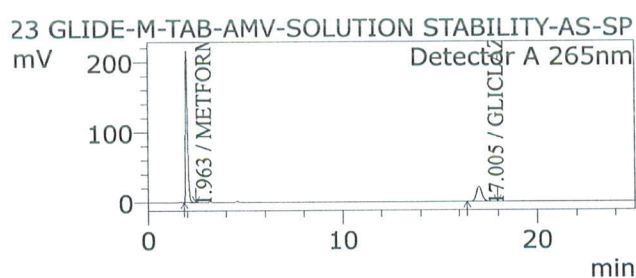
Analysis Report

<Sample Information>

Sample Name : RECOVERY
 Sample ID : GLICLAZIDE+METFOR-150%-AS-SPL-1
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-71.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-15
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 19:36:27
 Date Processed : 09-09-2023 10:29:55

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

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	AS-SPL-71.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-1	1.96	1543497	1644	1.46
15	AS-SPL-72.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-2	1.96	1543784	1638	1.46
15	AS-SPL-73.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-3	1.96	1543972	1640	1.46
	Average		1.96	1543751	1641	1.46
	%RSD		0.012	0.015	0.180	0.117

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	AS-SPL-71.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-1	17.01	414478	17224	1.13
15	AS-SPL-72.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-2	17.00	411384	17205	1.14
15	AS-SPL-73.lcd	GLICLAZIDE+METFOR-150%-AS-SPL-3	17.01	412101	17198	1.14
	Average		17.00	412654	17209	1.14
	%RSD		0.014	0.392	0.080	0.126

Analysed By

09/09/23

Checked By

09/09/23



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Analysis Report

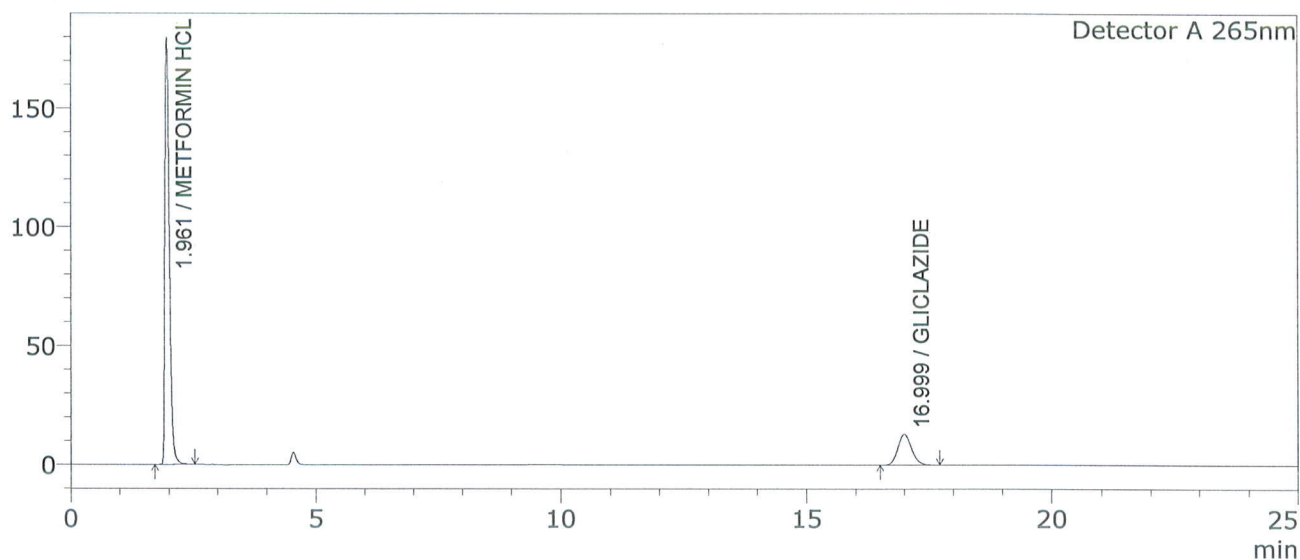
<Sample Information>

Sample Name : RECOVERY
 Sample ID : GLICLAZIDE+METFORMIN-AS-STD-BKT
 Data Filename : 07092023 GLIDE-M-TAB-AMV-SOLUTION STABILITY-AS-SPL-74.lcd
 Method Filename : GLIDE M60-500-850-TAB-AS.lcm
 Batch Filename : 07092023 GLIDE-M-AMV-AS-SOLUTION STABILITY & LINEARITY.lcb
 Vial # : 2-12
 Injection Volume : 20 uL
 Date Acquired : 08-09-2023 20:53:03
 Date Processed : 09-09-2023 10:29:56

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

<Chromatogram>

mV



<Peak Table>

Detector A 265nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	METFORMIN HCL	1.96	1142069	81.98	2034	1.456	--	--
2	GLICLAZIDE	17.00	251081	18.02	17688	1.124	43.896	--
Total			1393151	100.00				

Analysed By

Checked By