



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Title

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	About 42 mg	mg to --->	100	ml to --->	5	ml to --->	250
Std.conc (in ppm)-8.4	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet	mg to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	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	97.77	97.8	Preparation-1	99.34	97.9	99.5
Preparation-2	100.33		Preparation-2	100.84		
Preparation-3	100.74	Maximum	Preparation-3	101.03	Maximum	% RSD
Preparation-4	98.47		Preparation-4	98.38		
Preparation-5	100.17	100.7	Preparation-5	97.93	101.0	1.18
Preparation-6	98.82		Preparation-6	99.78		
Average	99.4	Not applicable	Average	99.6	Not applicable	
% RSD	1.20	Not applicable	% RSD	1.27	Not applicable	

Results:

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

1.20

1.27

1.18

Acceptance criteria:

- 1) % RSD for Dissolution of six preparations should not be more than 5.0.
- 2) Cumulative % RSD for Dissolution of twelve preparations (i.e. method precision and intermediate precision) should not be more than 10.0.

Analysed by :

VIGNESH V

Date :

11-01-2024

V.V
11/01/2024

Checked by :

Date :

A.R
11/01/2024

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	METHOD PRECISION	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.660	0.658	0.659	0.659	0.658	0.659	0.00	0.127

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.199	255.82	30.10	0.30	28.1	26.3
Unit-2	0.185	237.82	27.98	0.28		Maximum %
Unit-3	0.180	231.39	27.22	0.27		
Unit-4	0.174	223.68	26.32	0.26		
Unit-5	0.184	236.53	27.83	0.28		
Unit-6	0.191	245.53	28.89	0.29		30.1

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	446.07	52.48	0.525	52.78	52.5	50.8
Unit-2	0.352	452.50	53.24	0.532	53.51		Maximum%
Unit-3	0.334	429.36	50.51	0.505	50.78		
Unit-4	0.338	434.50	51.12	0.511	51.38		
Unit-5	0.349	448.64	52.78	0.528	53.06		53.5
Unit-6	0.352	452.50	53.24	0.532	53.52		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.641	824.01	96.94	97.77	99.4	97.8	1.20
Unit-2	0.658	845.86	99.51	100.33			
Unit-3	0.661	849.72	99.97	100.74			
Unit-4	0.646	830.44	97.70	98.47			
Unit-5	0.657	844.58	99.36	100.17			
Unit-6	0.648	833.01	98.00	98.82			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V

DATE : 28/12/2023

V.V
28/12/2023

Checked by :

Date :

28/12/2023

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:28:38
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.660	
3	STD 2	Unknown		*****	0.658	
4	STD 3	Unknown		*****	0.659	
5	STD 4	Unknown		*****	0.659	
6	STD 5	Unknown		*****	0.658	
7						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

P.V. 28/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:37:07
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.199	
3	SPL 1 IN 2	Unknown		*****	0.185	
4	SPL 1 IN 3	Unknown		*****	0.180	
5	SPL 1 IN 4	Unknown		*****	0.174	
6	SPL 1 IN 5	Unknown		*****	0.184	
7	SPL 1 IN 6	Unknown		*****	0.191	
8						

N.V. 28/12/2023

Analysed By
Date:

Checked By
Date:

N.V. 28/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:59:18
Comments: 3RD HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.352	
4	SPL 3 IN 3	Unknown		*****	0.334	
5	SPL 3 IN 4	Unknown		*****	0.338	
6	SPL 3 IN 5	Unknown		*****	0.349	
7	SPL 3 IN 6	Unknown		*****	0.352	
8						

N.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

N.V. 28/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:24:13
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.641	
3	SPL 10 IN 2	Unknown		*****	0.658	
4	SPL 10 IN 3	Unknown		*****	0.661	
5	SPL 10 IN 4	Unknown		*****	0.646	
6	SPL 10 IN 5	Unknown		*****	0.657	
7	SPL 10 IN 6	Unknown		*****	0.648	
8						

V.V 28/12/2023
Analysed By
Date:

Checked By
Date:

S.D. 28/12/2023



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	INTERMEDIATE PRECISION	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.14	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.428	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.649	0.648	0.647	0.648	0.650	0.648	0.00	0.176

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.190	247.46	29.11	0.29	28.0	26.4
Unit-2	0.180	234.43	27.58	0.28		Maximum %
Unit-3	0.190	247.46	29.11	0.29		
Unit-4	0.181	235.74	27.73	0.28		
Unit-5	0.172	224.02	26.35	0.26		
Unit-6	0.183	238.34	28.04	0.28		29.1

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.342	445.43	52.40	0.524	52.69	51.9	50.5
Unit-2	0.330	429.80	50.56	0.506	50.84		Maximum%
Unit-3	0.346	450.64	53.02	0.530	53.31		
Unit-4	0.328	427.19	50.26	0.503	50.54		
Unit-5	0.340	442.82	52.10	0.521	52.36		53.3
Unit-6	0.335	436.31	51.33	0.513	51.61		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.643	837.45	98.52	99.34	99.5	97.9	1.27
Unit-2	0.653	850.48	100.06	100.84			
Unit-3	0.654	851.78	100.21	101.03			
Unit-4	0.637	829.64	97.60	98.38			
Unit-5	0.634	825.73	97.14	97.93			
Unit-6	0.646	841.36	98.98	99.78			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : RAGAVAN K
DATE : 11/01/2024

K.P
11/01/2024

Checked by :
Date :

11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSO OF MET HCL--
SYSYSTEM SUITABILITY.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 16:19:04
Comments: SYSYSTEM SUITABILITY

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.649	
3	STD 2	Unknown		*****	0.648	
4	STD 3	Unknown		*****	0.647	
5	STD 4	Unknown		*****	0.648	
6	STD 5	Unknown		*****	0.650	
7						

K. Rg 11/01/2024
Analysed By
Date:

Checked By
Date:

11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSOLUTION OF MET
HCL--1ST HOUR.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 16:41:52
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.190	
3	SPL 1 IN 2	Unknown		*****	0.180	
4	SPL 1 IN 3	Unknown		*****	0.190	
5	SPL 1 IN 4	Unknown		*****	0.181	
6	SPL 1 IN 5	Unknown		*****	0.172	
7	SPL 1 IN 6	Unknown		*****	0.183	
8						

K. R. 11/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24.

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2024\JAN- 2024
\11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 16:59:57
Comments: 3RD HOUR

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.342	
3	SPL 3 IN 2	Unknown		*****	0.330	
4	SPL 3 IN 3	Unknown		*****	0.346	
5	SPL 3 IN 4	Unknown		*****	0.328	
6	SPL 3 IN 5	Unknown		*****	0.340	
7	SPL 3 IN 6	Unknown		*****	0.335	
8						

K. P. 11/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2024\JAN- 2024
\11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 17:28:20
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.643	
3	SPL 10 IN 2	Unknown		*****	0.653	
4	SPL 10 IN 3	Unknown		*****	0.654	
5	SPL 10 IN 4	Unknown		*****	0.637	
6	SPL 10 IN 5	Unknown		*****	0.634	
7	SPL 10 IN 6	Unknown		*****	0.646	
8						

K. R. 11/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No	Absorbance of Metformin Hydrochloride
BLANK	0
1	0.660
2	0.658
3	0.659
4	0.659
5	0.658
Average	0.659
RSD %	0.127

Results :

1) % RSD of absorbance of Metformin Hydrochloride

0.127

Acceptance criteria:

% RSD of absorbance of replicate Standard should not be more than 2.0.

Analysed by :

V.VIGNESH

Date :

28/12/2023

Checked by :

Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:28:38
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.660	
3	STD 2	Unknown		*****	0.658	
4	STD 3	Unknown		*****	0.659	
5	STD 4	Unknown		*****	0.659	
6	STD 5	Unknown		*****	0.658	
7						

V.V. 28/12/2023

Analysed By
Date:

Checked By
Date:

V.V. 28/12/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name : GLIDE-M 60/500 & GLIDE-M 60/850

Batch size : NA

Batch Number : G1722093 & G17230801

Mfg.Date : NA

Parameter : LINEARITY AND RANGE

Exp.Date : NA

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500/850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID: ST/QC/EQ/002 Balance ID : ST/QC/EQ/041 WS No.: WS/MEF/22/01 % Purity (aib) 100.2

Linearity Level-I : 125.02 mg to --- 100 ml to --- 10 ml to --- 100

Std.conc (in ppm)-1.00016 2 ml to --- 250 ml to --- 1 ml to --- 1

Linearity Level-II : 125.02 mg to --- 100 ml to --- 10 ml to --- 100

Std.conc (in ppm)-5.0008 2 ml to --- 50 ml to --- 1 ml to --- 1

Linearity Level-III : 125.02 mg to --- 100 ml to --- 10 ml to --- 100

Std.conc (in ppm)-7.5012 3 ml to --- 50 ml to --- 1 ml to --- 1

Linearity Level-IV : 125.02 mg to --- 100 ml to --- 10 ml to --- 100

Std.conc (in ppm)-10.0016 4 ml to --- 50 ml to --- 1 ml to --- 1

Linearity Level-V : 125.02 mg to --- 100 ml to --- 10 ml to --- 100

Std.conc (in ppm)-12.502 5 ml to --- 50 ml to --- 1 ml to --- 1

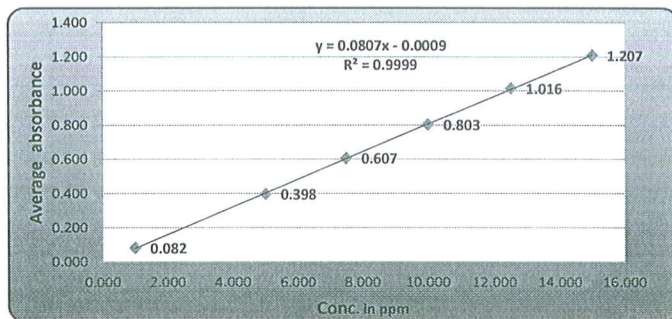
Linearity Level-VI : 125.02 mg to --- 100 ml to --- 10 ml to --- 100

Std.conc (in ppm)-15.0024 6 ml to --- 50 ml to --- 1 ml to --- 1

Level"s	I	II	III	IV	V	VI
S.No.	10%	50%	75%	100%	125%	150%
1	0.082	0.398	0.607	0.804	1.015	1.208
2	0.083	0.399	0.605	0.803	1.016	1.209
3	0.082	0.397	0.608	0.802	1.016	1.205
Average	0.082	0.398	0.607	0.803	1.016	1.207
RSD%	0.701	0.251	0.252	0.125	0.057	0.172

LEVEL"s	Conc. in ppm (X-axis)	Absorbance (Y-axis)
I	1.000	0.082
II	5.001	0.398
III	7.501	0.607
IV	10.002	0.803
V	12.502	1.016
VI	15.002	1.207

LINEARITY GRAPH



Results :

- 1) Squared correlation coefficient of Metformin Hydrochloride **0.999**
- 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 : VIGNESH V

Date : 16/12/2023

Checked by :

Date :

V.V. 16/12/2023

16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
10%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 07:56:54
Comments: LINEARITY 10%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.082	LINEARITY 10%
3	SPL 2	Unknown		*****	0.083	LINEARITY 10%
4	SPL 3	Unknown		*****	0.082	
5						

V.V. 16/12/2023
Analysed By
Date:

Checked By
Date:

V.V. 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
50%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:00:09
Comments: LINEARITY 50%

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.398	
3	SPL 2	Unknown		*****	0.399	
4	SPL 3	Unknown		*****	0.397	
5						

V.V. 16/12/2023

Analysed By
Date:

Checked By
Date:

S. V. D.
16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
75%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:10:09
Comments: LINEARITY 75%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.607	LINEARITY 75%
3	SPL 2	Unknown		*****	0.605	LINEARITY 75%
4	SPL 3	Unknown		*****	0.608	
5						

V.V. 16/12/2023
Analysed By
Date:

Checked By
Date:

S.S. 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
100%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:20:36
Comments: LINEARITY 100%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.804	LINEARITY 100%
3	SPL 2	Unknown		*****	0.803	LINEARITY 100%
4	SPL 3	Unknown		*****	0.802	
5						

V.V 16/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
125%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:23:45
Comments: LINEARITY 125%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	1.015	LINEARITY 125%
3	SPL 2	Unknown		*****	1.016	LINEARITY 125%
4	SPL 3	Unknown		*****	1.016	
5						

V.VA 16/12/2023
Analysed By
Date:

Checked By
Date: / S.D. 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
150%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:28:25
Comments: LINEARITY 150%

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	1.208	LINEARITY 150%
3	SPL 2	Unknown		*****	1.209	LINEARITY 150%
4	SPL 3	Unknown		*****	1.205	
5						

V.VT 16/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 16/12/23

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/500 & GLIDE M-60/850	Batch size :	NA
Batch Number :	G1722093, G17230801	Mfg.Date :	NA
Parameter :	SPECIFICITY	Exp.Date :	NA

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500/850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	50.15	mg to --->	100	ml to --->	5	ml to --->	250
Test.conc (in ppm)-10.03	1	ml to --->	1	ml to --->	1	ml to --->	1

Standard dilution :	42.26	mg to --->	100	ml to --->	5	ml to --->	250
Test.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

Standard dilution :	60.03	mg to --->	1000	ml to --->	2	ml to --->	100
Test.conc (in ppm)-1.2006	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No.	Sample ID.	Compound Name	Absorbance	Peak purity
1	Blank	NA	0	Not applicable
2	WS for Metformin 500 mg	Metformin	0.805	Not applicable
3	WS for Metformin 850 mg	Metformin	0.659	Not applicable
4	Blank	NA	0	Not applicable
5	WS for Gliclazide	Gliclazide	0.001	Not applicable
6	Placebo for Metformin 500mg	NA	0.002	Not applicable
7	Placebo for Metformin 850mg	NA	0.003	Not applicable
8	Placebo for Gliclazide	NA	0.001	Not applicable
9	Placebo+ Gliclazide WS	Gliclazide	0.001	Not applicable
10	Placebo+ Metformin WS 500mg	Metformin	0.801	Not applicable
11	Placebo+ Metformin WS 850mg	Metformin	0.662	Not applicable
12	Metformin 500-Test solution	Metformin	0.779	Not applicable
13	Metformin 850-Test solution	Metformin	0.658	Not applicable

Results :

1) Blank , Placebo solutions are not interfere with Metformin Hydrochloride in test preparation.

Acceptance criteria:

1) Should No significant interference from blank, placebo .

Analysed by : VIGNESH V
Date : 28/12/2023

V.V
28/12/2023

Checked by :
Date :

P.D
28/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-500-850--AMV--
METHOD PRECISION--
SPECIFICITY.pho
Title: SPECIFICITY
Analyst: VIGNESH V
Date/Time: 28-12-2023 15:14:35
Comments:

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD FOR MET 500MG	Unknown		*****	0.805	
3	STD FOR MET 850MG	Unknown		*****	0.659	
4	BLANK.	Unknown		*****	0.000	
5	STD FOR GLICLACIDE	Unknown		*****	0.001	
6	PLACEBO FOR MET 500MG	Unknown		*****	0.002	
7	PLACEBO FOR MET 850MG	Unknown		*****	0.003	
8	PLACEBO FOR GLICLAZIDE	Unknown		*****	0.001	
9	PLACEBO+GLICLAZIDE STD	Unknown		*****	0.001	
10	PLACEBO+STD MET 500MG	Unknown		*****	0.801	
11	PLACEBO+STD MET 850MG	Unknown		*****	0.662	
12	DS TEST SPL FOR MET 500	Unknown		*****	0.779	
13	DS TEST SPL FOR MET 850	Unknown		*****	0.658	
14						

V.VA 28/12/2023
Analysed By
Date:

Checked By
Date: S.V.D. 28/12/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name : GLIDE-M 60/500 & GLIDE M-60/850

Batch size : NA

Batch Number : G1722093, G17230801

Mfg.Date : NA

Parameter : ACCURACY STUDY(RECOVERY)

Exp.Date : NA

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
Standard dilution :	42.52	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.504	1	ml to --->	1	ml to --->	1	ml to --->	1
Recovery 25% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-0.8504	2	ml to --->	200	ml to --->	1	ml to --->	1
Recovery 50% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-4.252	5	ml to --->	100	ml to --->	1	ml to --->	1
Recovery 100% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-8.504	10	ml to --->	100	ml to --->	1	ml to --->	1
Recovery 150% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-12.756	15	ml to --->	100	ml to --->	1	ml to --->	1

System suitability 1

Metformin Hydrochloride 0.802

Standard con. in ppm. 8.504

Level's	Weight taken in mg	Observed Obsorbance	Quantity added in ppm	Quantity Recovered in ppm	% Recovery
I(10%)	42.52	0.084	0.850	0.89	104.74
	42.52	0.081	0.850	0.86	101.00
	42.52	0.082	0.850	0.87	102.24
				MEAN	102.7
				%RSD	1.855
II(50%)	42.52	0.404	4.252	4.28	100.75
	42.52	0.406	4.252	4.31	101.25
	42.52	0.401	4.252	4.25	100.00
				MEAN	100.7
				%RSD	0.623
III(100%)	42.52	0.805	8.504	8.54	100.37
	42.52	0.807	8.504	8.56	100.62
	42.52	0.804	8.504	8.53	100.25
				MEAN	100.4
				%RSD	0.190
III(150%)	42.52	1.209	12.756	12.82	100.50
	42.52	1.207	12.756	12.80	100.33
	42.52	1.208	12.756	12.81	100.42
				MEAN	100.4
				%RSD	0.083

Results:

The % Recovery was complies at each levels.

Acceptance criteria:

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

CALCULATION FORMULA

Quantity added in ppm

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

Quantity recovered in ppm

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

% Recovery

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

Analysed by : VIGNESH. V

Date : 16/12/2023

Checked by :

Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
10%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 10%
Analyst: VIGNESH V
Date/Time: 16-12-2023 13:41:20

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		1.044	0.084	RECOVERY 10%
3	SPL 2	Unknown		1.011	0.081	RECOVERY 10%
4	SPL 3	Unknown		1.023	0.082	
5						

V.VA 16/12/2023
Analysed By
Date:

Checked By
Date:

S.D. 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
50%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 50%
Analyst: VIGNESH V
Date/Time: 16-12-2023 13:50:01

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		5.031	0.404	RECOVERY 50%
3	SPL 2	Unknown		5.060	0.406	RECOVERY 50%
4	SPL 3	Unknown		4.995	0.401	
5						

V.VT 16/12/2023
Analysed By
Date:

Checked By
Date:

P.S. 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
100%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 100%
Analyst: VIGNESH V
Date/Time: 16-12-2023 13:56:28

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		10.035	0.805	RECOVERY 100%
3	SPL 2	Unknown		10.061	0.807	RECOVERY 100%
4	SPL 3	Unknown		10.023	0.804	
5						

V.VT 16/12/2023
Analysed By
Date:

Checked By
Date: 16/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
150%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 150%
Analyst: VIGNESH V
Date/Time: 16-12-2023 14:02:51

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		15.077	1.209	RECOVERY 150%
3	SPL 2	Unknown		15.045	1.207	RECOVERY 150%
4	SPL 3	Unknown		15.066	1.208	
5						

V.V. 16/12/2023
Analysed By
Date:

Checked By
Date:

[Handwritten signature]
16/12/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

Sample dilution :	One tablet	mg to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	850

mg

Standard Absorbance

Metformin Hydrochloride

0.659

Time interval	Metformin Standard Solution Absorbance	Metformin Sample Solution Absorbance	Final time point Dissolution in %	Absolute % difference of Dissolution Sample
Initial	0.659	0.655	99.03	Not applicable
2 Hours	0.660	0.653	98.58	0.46
4 Hours	0.659	0.656	99.18	-0.15
6 Hours	0.659	0.655	99.03	0.00
16 Hours	0.657	0.655	99.33	-0.30
20 Hours	0.659	0.654	98.88	0.15
24 Hours	0.658	0.653	98.88	0.15
28 Hours	0.658	0.654	99.03	0.00
32 Hours	0.657	0.653	99.03	0.00
40 Hours	0.659	0.654	98.88	0.15
44 Hours	0.657	0.652	98.88	0.16
48 Hours	0.656	0.651	98.87	0.16
Average	0.658	0.654	99.0	0.07
% RSD	0.181	0.218	0.189	Not applicable

Results :

Standard solution and Sample solution was stable upto 48 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 :

V.VIGNESH

Date :

30/12/2023

Checked by :

Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--INITIAL
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 14:01:24

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	
3	SPL	Unknown		*****	0.655	
4						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

A.V. 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--2ND HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 16:07:42
Comments: SOLUTION STABILITY--2ND HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.660	2ND HOUR
3	SPL	Unknown		*****	0.653	2ND HOUR
4						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date: P. V. 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--4TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 18:19:54
Comments: SOLUTION STABILITY--4TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	4TH HOUR
3	SPL	Unknown		*****	0.656	4TH HOUR
4						

V.VT 28/12/2023
Analysed By
Date:

Checked By
Date:

C. A. 30/12/2023

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--6TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 20:05:26
Comments: SOLUTION STABILITY--6TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	
3	SPL	Unknown		*****	0.655	
4						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S. J. 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--16TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 06:28:12
Comments: SOLUTION STABILITY--16TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.657	16TH HOUR
3	SPL	Unknown		*****	0.655	
4						

V.V. 29/12/2023
Analysed By
Date:

Checked By
Date:

P.V. 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV DATA BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--20TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 10:17:42
Comments: SOLUTION STABILITY--20TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	20TH HOUR
3	SPL	Unknown		*****	0.654	20TH HOUR
4						

V.V.T 29/12/2023
Analysed By
Date:

Checked By
Date:

S. V. 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--24TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 14:39:19
Comments: SOLUTION STABILITY--24TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.658	24TH HOUR
3	SPL	Unknown		*****	0.653	
4						

V.VA 29/12/2023
Analysed By
Date:

Checked By
Date:

[Signature]
30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--28TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 18:17:55
Comments: SOLUTION STABILITY--28TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.658	28TH HOUR
3	SPL	Unknown		*****	0.654	28TH HOUR
4						

V.VT 29/12/2023
Analysed By
Date:

Checked By
Date:

V.VT 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--32ND HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: CHANDIRARAM P
Date/Time: 29-12-2023 22:02:24
Comments: SOLUTION STABILITY--32ND HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.657	32ND HOUR
3	SPL	Unknown		*****	0.653	32ND HOUR
4						

chaged
Analysed By
Date: 29/12/2023

Checked By
Date: 30/12/2023

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\30-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--40TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 30-12-2023 06:25:22
Comments: SOLUTION STABILITY--40TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	40TH HOUR
3	SPL	Unknown		*****	0.654	
4						

V.V 30/12/2023
Analysed By
Date:

Checked By
Date:

V.V 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\30-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--44TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 30-12-2023 10:10:47
Comments: SOLUTION STABILITY--44TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.657	
3	SPL	Unknown		*****	0.652	
4						

V.V. 30/12/2023
Analysed By
Date:

Checked By
Date:

S. A. 30/12/23

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\30-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--48TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 30-12-2023 14:42:01
Comments: SOLUTION STABILITY--48TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.656	48TH HOUR
3	SPL	Unknown		*****	0.651	
4						

V.VA 30/12/2023

Analysed By
Date:

Checked By
Date:

30/12/23



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	--------------	--------------	---------	--------------	----------------	-------

Standard Dilution :	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

Test Dilution :	One tablet	mg to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	850 mg

Standard Absorbance	
Metformin Hydrochloride	0.659

S.No	Sample Name	Sample Absorbance	Content in mg	Metformin Content in %	% Difference from unfiltered sample
1	Unfiltered sample (Centrifuged)	0.662	850.75	100.1	Not applicable
2	Filter Set-1 (0.45µ PVDF membrane)	0.661	849.46	99.9	0.15
3	Filter Set-2 (0.45µ PVDF membrane)	0.662	850.75	100.1	0.00
4	Filter Set-3 (0.45µ PVDF membrane)	0.659	846.89	99.6	0.46
5	Filter Set-1 (0.45µ Nylon membrane)	0.660	848.18	99.8	0.30
6	Filter Set-2 (0.45µ Nylon membrane)	0.658	845.61	99.5	0.61
7	Filter Set-3 (0.45µ Nylon membrane)	0.658	845.61	99.5	0.61
8	Filter Set-1 (Whatman filter)	0.695	893.15	105.1	-4.75
9	Filter Set-2 (Whatman filter)	0.696	894.44	105.2	-4.89
10	Filter Set-3 (Whatman filter)	0.697	895.72	105.4	-5.02

Results :

The % difference on filtered sample ((0.45µ PvdF ,0.45µ Nylon Membrane) within limit against that of unfiltered (Centrifuged)

Acceptance criteria:

The % difference on filter Solution should not differ ± 2.0 against that of unfiltered (Centrifuged)

Analysed by : V.VIGNESH

Date : 28/12/2023

Checked by :

Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
FILTER PAPER STUDY--PVDF
FILTER.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:35:15

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	CENTRIFUGE SPL	Unknown		*****	0.662	
3	SPL 1	Unknown		*****	0.661	PVDF FILTER
4	SPL 2	Unknown		*****	0.662	
5	SPL 3	Unknown		*****	0.659	
6						

Analysed By
Date:

Checked By
Date:

V.V. 28/12/2023

S.V. 28/12/2023

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
FILTER PAPER STUDY--NYLON
FILTER.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:40:29

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.660	NYLON FILTER
3	SPL 2	Unknown		*****	0.658	NYLON FILTER
4	SPL 3	Unknown		*****	0.658	
5						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 28/12/2023

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
FILTER PAPER STUDY--WHATMAN
FILTER.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:52:44

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.695	WHATMAN FILTER
3	SPL 2	Unknown		*****	0.696	
4	SPL 3	Unknown		*****	0.697	
5						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

V.V. 28/12/23

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

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

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	About 42mg	mg to ---->	100	ml to ---->	5	ml to ---->	250
Std.conc (in ppm)-8.4	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Test solution :	TABLET	mg to ---->	1000	ml to ---->	1	ml to ---->	100
Test.conc (in ppm)-8.5	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Conversion factor :	1.0000
Labelled content :	850

Variation's of Parameters	RSD %	Metformin Dissolution in %	Mean Dissolution value of method precision	% Difference
Low wavelength (231nm)	0.71	99.8	99.4	-0.40
High wavelength (235nm)	1.17	100.1		-0.70
Low Volume(990ml)	1.19	99.1		0.30
High Volume(1010ml)	0.98	98.7		0.00
Low Rpm(96rpm)	1.59	98.9		-0.10
High Rpm(104rpm)	1.34	100.2		-0.80
Low pH(6.6pH)	1.32	99.6		-0.20
High pH(7.0pH)	1.03	99.6		-0.20

Acceptance criteria:

- 1) % Dissolution result shall meet the specification.
- 2) Relative standard deviation of % dissolution results should not be more than 5.0%
- 3) % of dissolution results should not differ by $\pm 5.0\%$ to that of method precision

Analysed by :

VIGNESH V

Date :

10/01/2024

Checked by :

Date :

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW WAVELENGTH 231NM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.643	0.645	0.645	0.644	0.643	0.644	0.00	0.155

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.162	213.04	25.06	0.25	25.6	24.4
Unit-2	0.173	227.50	26.77	0.27		Maximum %
Unit-3	0.161	211.72	24.91	0.25		
Unit-4	0.158	207.78	24.44	0.24		
Unit-5	0.167	219.61	25.84	0.26		
Unit-6	0.171	224.87	26.46	0.26		26.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.324	426.08	50.13	0.501	50.38	50.7	49.3
Unit-2	0.330	433.97	51.05	0.511	51.32		Maximum%
Unit-3	0.338	444.49	52.29	0.523	52.54		
Unit-4	0.325	427.39	50.28	0.503	50.53		
Unit-5	0.321	422.13	49.66	0.497	49.92		52.5
Unit-6	0.317	416.87	49.04	0.490	49.31		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.644	846.89	99.63	100.39	99.8	98.7	0.71
Unit-2	0.639	840.32	98.86	99.64			
Unit-3	0.633	832.42	97.93	98.70			
Unit-4	0.640	841.63	99.02	99.76			
Unit-5	0.646	849.52	99.94	100.70			
Unit-6	0.638	839.00	98.71	99.46			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V

DATE : 28/12/2023

V.V
28/12/2023

Checked by :

Date :

S.V
21/12/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 16:44:30
Comments: SYSTEM SUITABILITY

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.643	
3	STD 2	Unknown		*****	0.645	
4	STD 3	Unknown		*****	0.645	
5	STD 4	Unknown		*****	0.644	
6	STD 5	Unknown		*****	0.643	
7						

V.VT 28/12/2023
Analysed By
Date:

Checked By
Date:

P. D. S.
11/10/24.

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM DISSOLUTION
OF MET HCL--1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 17:07:21
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.162	
3	SPL 1 IN 2	Unknown		*****	0.173	
4	SPL 1 IN 3	Unknown		*****	0.161	
5	SPL 1 IN 4	Unknown		*****	0.158	
6	SPL 1 IN 5	Unknown		*****	0.167	
7	SPL 1 IN 6	Unknown		*****	0.171	
8						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

A.V. 28/12/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM DISSOLUTION
OF MET HCL--3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 17:30:59
Comments: 3RD HOUR

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.324	
3	SPL 3 IN 2	Unknown		*****	0.330	
4	SPL 3 IN 3	Unknown		*****	0.338	
5	SPL 3 IN 4	Unknown		*****	0.325	
6	SPL 3 IN 5	Unknown		*****	0.321	
7	SPL 3 IN 6	Unknown		*****	0.317	
8						

V.VA 28/12/2023
Analysed By
Date:

Checked By
Date:

S.A. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM DISSOLUTION
OF MET HCL--10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 17:55:41
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.644	
3	SPL 10 IN 2	Unknown		*****	0.639	
4	SPL 10 IN 3	Unknown		*****	0.633	
5	SPL 10 IN 4	Unknown		*****	0.640	
6	SPL 10 IN 5	Unknown		*****	0.646	
7	SPL 10 IN 6	Unknown		*****	0.638	
8						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S.A. 28/12/23

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH WAVELENGTH 235NM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3nd and 10th Hours

Standard dilution.:	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.643	0.641	0.641	0.642	0.642	0.642	0.00	0.130

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.161	212.45	24.99	0.25	25.5	24.7
Unit-2	0.163	215.09	25.30	0.25		Maximum %
Unit-3	0.159	209.81	24.68	0.25		
Unit-4	0.162	213.77	25.15	0.25		
Unit-5	0.164	216.41	25.46	0.25		
Unit-6	0.177	233.56	27.48	0.27		27.5

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	457.89	53.87	0.539	54.12	53.0	51.6
Unit-2	0.342	451.29	53.09	0.531	53.35		Maximum%
Unit-3	0.335	442.05	52.01	0.520	52.25		
Unit-4	0.331	436.77	51.39	0.514	51.64		
Unit-5	0.340	448.65	52.78	0.528	53.04		54.1
Unit-6	0.345	455.25	53.56	0.536	53.83		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.637	840.56	98.89	99.68	100.1	98.6	1.17
Unit-2	0.650	857.71	100.91	101.69			
Unit-3	0.638	841.88	99.04	99.81			
Unit-4	0.648	855.07	100.60	101.36			
Unit-5	0.630	831.32	97.80	98.58			
Unit-6	0.637	840.56	98.89	99.70			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 28/12/2023

Checked by :
Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 18:47:25
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.643	
3	STD 2	Unknown		*****	0.641	
4	STD 3	Unknown		*****	0.641	
5	STD 4	Unknown		*****	0.642	
6	STD 5	Unknown		*****	0.642	
7						

V.V 28/12/2023
Analysed By
Date:

Checked By
Date:

S.V 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--DISSO OF MET
HCL--1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 19:12:31
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.161	
3	SPL 1 IN 2	Unknown		*****	0.163	
4	SPL 1 IN 3	Unknown		*****	0.159	
5	SPL 1 IN 4	Unknown		*****	0.162	
6	SPL 1 IN 5	Unknown		*****	0.164	
7	SPL 1 IN 6	Unknown		*****	0.177	
8						

V. V. 28/12/2023
Analysed By
Date:

Checked By
Date: P. V. 11/10/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV DATA BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--DISSO OF MET
HCL--3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 19:28:15
Comments: 3RD HOUR

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.342	
4	SPL 3 IN 3	Unknown		*****	0.335	
5	SPL 3 IN 4	Unknown		*****	0.331	
6	SPL 3 IN 5	Unknown		*****	0.340	
7	SPL 3 IN 6	Unknown		*****	0.345	
8						

V.VT 28/12/2023
Analysed By
Date:

Checked By
Date:

P.V. 11/10/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--DISSO OF MET
HCL--10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 19:46:42
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.637	
3	SPL 10 IN 2	Unknown		*****	0.650	
4	SPL 10 IN 3	Unknown		*****	0.638	
5	SPL 10 IN 4	Unknown		*****	0.648	
6	SPL 10 IN 5	Unknown		*****	0.630	
7	SPL 10 IN 6	Unknown		*****	0.637	
8						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

11/10/24

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW VOLUME 990ML)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	990
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.19	mg to ---->	100	ml to ---->	2	ml to ---->	100
Std.conc (in ppm)-8.438	1	ml to ---->	1	ml to ---->	1	ml to ---->	1
Test dilution .:	One tablet	gm to ---->	1000	ml to ---->	1	ml to ---->	100
Test.conc (in ppm)-8.5	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Conversion factor	1.0000	
Labelled content	850	mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.654	0.654	0.655	0.653	0.654	0.654	0.00	0.108

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.196	253.39	29.81	0.30	28.1	26.6
Unit-2	0.188	243.05	28.59	0.29		Maximum %
Unit-3	0.175	226.24	26.62	0.27		
Unit-4	0.183	236.58	27.83	0.28		
Unit-5	0.182	235.29	27.68	0.28		
Unit-6	0.186	240.46	28.29	0.28		29.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.356	460.23	54.15	0.541	54.44	52.3	50.5
Unit-2	0.343	443.43	52.17	0.522	52.45		Maximum%
Unit-3	0.346	447.31	52.62	0.526	52.89		
Unit-4	0.335	433.09	50.95	0.510	51.23		
Unit-5	0.330	426.62	50.19	0.502	50.47		
Unit-6	0.343	443.43	52.17	0.522	52.45		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.641	828.68	97.49	98.33	99.1	97.4	1.19
Unit-2	0.651	841.61	99.01	99.82			
Unit-3	0.635	820.92	96.58	97.37			
Unit-4	0.652	842.90	99.16	99.95			
Unit-5	0.655	846.78	99.62	100.40			
Unit-6	0.642	829.97	97.64	98.45			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 05/01/2024

V.V.V
05/01/2024

Checked by :
Date :

[Signature]
11/10/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--VOLUME--
SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 15:40:58
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.654	
3	STD 2	Unknown		*****	0.654	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.653	
6	STD 5	Unknown		*****	0.654	
7						

V.V 05/01/2024
Analysed By
Date:

Checked By
Date:

V.V 05/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
105-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
VOLUME 990ML--DISSO OF MET HCL--
1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 16:04:30

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.196	
3	SPL 1 IN 2	Unknown		*****	0.188	
4	SPL 1 IN 3	Unknown		*****	0.175	
5	SPL 1 IN 4	Unknown		*****	0.183	
6	SPL 1 IN 5	Unknown		*****	0.182	
7	SPL 1 IN 6	Unknown		*****	0.186	
8						

V.VT 05/01/2024
Analysed By
Date:

Checked By
Date: S.D. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2024\JAN- 2024
\05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
VOLUME 990ML--DISSO OF MET HCL--
3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 16:26:39

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.356	
3	SPL 3 IN 2	Unknown		*****	0.343	
4	SPL 3 IN 3	Unknown		*****	0.346	
5	SPL 3 IN 4	Unknown		*****	0.335	
6	SPL 3 IN 5	Unknown		*****	0.330	
7	SPL 3 IN 6	Unknown		*****	0.343	
8						

V. V. 05/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
VOLUME 990ML--DISSO OF MET HCL--
10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 16:49:47

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.641	
3	SPL 10 IN 2	Unknown		*****	0.651	
4	SPL 10 IN 3	Unknown		*****	0.635	
5	SPL 10 IN 4	Unknown		*****	0.652	
6	SPL 10 IN 5	Unknown		*****	0.655	
7	SPL 10 IN 6	Unknown		*****	0.642	
8						

V.VT 05/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH VOLUME 1010ML)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1010
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.19	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.438	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.654	0.654	0.655	0.653	0.654	0.654	0.00	0.108

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.174	224.95	26.46	0.26	28.2	26.5
Unit-2	0.185	239.17	28.14	0.28		Maximum %
Unit-3	0.180	232.70	27.38	0.27		
Unit-4	0.194	250.80	29.51	0.30		
Unit-5	0.196	253.39	29.81	0.30		
Unit-6	0.182	235.29	27.68	0.28		29.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.343	443.43	52.17	0.522	52.43	52.7	51.1
Unit-2	0.334	431.79	50.80	0.508	51.08		Maximum%
Unit-3	0.341	440.84	51.86	0.519	52.14		
Unit-4	0.349	451.19	53.08	0.531	53.38		
Unit-5	0.354	457.65	53.84	0.538	54.14		
Unit-6	0.345	446.01	52.47	0.525	52.75		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.643	831.27	97.80	98.58	98.7	97.2	0.98
Unit-2	0.654	845.49	99.47	100.26			
Unit-3	0.634	819.63	96.43	97.22		Maximum %	
Unit-4	0.643	831.27	97.80	98.62			
Unit-5	0.642	829.97	97.64	98.48			
Unit-6	0.644	832.56	97.95	98.75		100.3	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 05/01/2024

Checked by :
Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--VOLUME--
SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 15:40:58
Comments: SYSTEM SUITABIULITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.654	
3	STD 2	Unknown		*****	0.654	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.653	
6	STD 5	Unknown		*****	0.654	
7						

V.V. 05/01/2024
Analysed By
Date:

Checked By
Date: S.D. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH
VOLUME 1010ML--DISSO OF MET
HCL--1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 17:13:34

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.174	
3	SPL 1 IN 2	Unknown		*****	0.185	
4	SPL 1 IN 3	Unknown		*****	0.180	
5	SPL 1 IN 4	Unknown		*****	0.194	
6	SPL 1 IN 5	Unknown		*****	0.196	
7	SPL 1 IN 6	Unknown		*****	0.182	
8						

V. V. 05/01/2024
Analysed By
Date:

Checked By
Date:

S. V. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH
VOLUME 1010ML--DISSO OF MET
HCL--3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 17:27:49

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.343	
3	SPL 3 IN 2	Unknown		*****	0.334	
4	SPL 3 IN 3	Unknown		*****	0.341	
5	SPL 3 IN 4	Unknown		*****	0.349	
6	SPL 3 IN 5	Unknown		*****	0.354	
7	SPL 3 IN 6	Unknown		*****	0.345	
8						

V.V. 05/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH
VOLUME 1010ML--DISSO OF MET
HCL--10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 17:49:59

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: Abs = K1*(Conc) + K0
Zero Interception: Not Selected

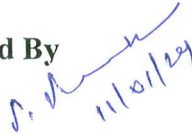
Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.643	
3	SPL 10 IN 2	Unknown		*****	0.654	
4	SPL 10 IN 3	Unknown		*****	0.634	
5	SPL 10 IN 4	Unknown		*****	0.643	
6	SPL 10 IN 5	Unknown		*****	0.642	
7	SPL 10 IN 6	Unknown		*****	0.644	
8						

V. V 05/01/2024
Analysed By
Date:

Checked By
Date:  11/01/24

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW RPM 96RPM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	96RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.10	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.42	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.657	0.654	0.655	0.655	0.656	0.655	0.00	0.174

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.191	245.87	28.93	0.29	28.3	26.2
Unit-2	0.183	235.57	27.71	0.28		Maximum %
Unit-3	0.173	222.70	26.20	0.26		
Unit-4	0.186	239.43	28.17	0.28		
Unit-5	0.191	245.87	28.93	0.29		
Unit-6	0.198	254.88	29.99	0.30		30.0

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	446.69	52.55	0.526	52.84	52.2	50.4
Unit-2	0.339	436.39	51.34	0.513	51.62		Maximum%
Unit-3	0.336	432.53	50.89	0.509	51.15		
Unit-4	0.331	426.09	50.13	0.501	50.41		
Unit-5	0.357	459.56	54.07	0.541	54.36		54.4
Unit-6	0.348	447.97	52.70	0.527	53.00		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.663	853.47	100.41	101.22	98.9	96.8	1.59
Unit-2	0.650	836.73	98.44	99.23			
Unit-3	0.641	825.15	97.08	97.85			
Unit-4	0.634	816.14	96.02	96.80		Maximum %	
Unit-5	0.645	830.30	97.68	98.51			
Unit-6	0.655	843.17	99.20	100.02		101.2	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 04/01/2024

V.V.
04/01/2024

Checked by :
Date :

S. A. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
104-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--LOW RPM--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 18:16:03
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.657	
3	STD 2	Unknown		*****	0.654	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.655	
6	STD 5	Unknown		*****	0.656	
7						

Analysed By
Date: 04/01/2024

Checked By
Date: 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\04-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
RPM--DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 18:36:38

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.191	
3	SPL 2	Unknown		*****	0.183	
4	SPL 3	Unknown		*****	0.173	
5	SPL 4	Unknown		*****	0.186	
6	SPL 5	Unknown		*****	0.191	
7	SPL 6	Unknown		*****	0.198	
8						

V.VT 04/01/2024
Analysed By
Date:

Checked By
Date:

P.D. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information
Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information
Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
04-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
RPM--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 18:49:10

Wavelengths
Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve
Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.339	
4	SPL 3 IN 3	Unknown		*****	0.336	
5	SPL 3 IN 4	Unknown		*****	0.331	
6	SPL 3 IN 5	Unknown		*****	0.357	
7	SPL 3 IN 6	Unknown		*****	0.348	
8						

V. V709/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
04-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
RPM--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 19:10:01

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.663	
3	SPL 10 IN 2	Unknown		*****	0.650	
4	SPL 10 IN 3	Unknown		*****	0.641	
5	SPL 10 IN 4	Unknown		*****	0.634	
6	SPL 10 IN 5	Unknown		*****	0.645	
7	SPL 10 IN 6	Unknown		*****	0.655	
8						

V.V. 04/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH RPM 104RPM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	104RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.36	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.472	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.652	0.651	0.652	0.652	0.652	0.652	0.00	0.069

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.193	251.36	29.57	0.30	28.4	25.7
Unit-2	0.201	261.78	30.80	0.31		Maximum %
Unit-3	0.181	235.73	27.73	0.28		
Unit-4	0.168	218.80	25.74	0.26		
Unit-5	0.178	231.82	27.27	0.27		
Unit-6	0.191	248.76	29.27	0.29		30.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	451.93	53.17	0.532	53.46	51.9	50.2
Unit-2	0.332	432.39	50.87	0.509	51.18		Maximum%
Unit-3	0.326	424.58	49.95	0.500	50.23		
Unit-4	0.341	444.11	52.25	0.522	52.51		
Unit-5	0.350	455.83	53.63	0.536	53.90		53.9
Unit-6	0.327	425.88	50.10	0.501	50.40		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.655	853.06	100.36	101.19	100.2	97.8	1.34
Unit-2	0.644	838.74	98.67	99.49			
Unit-3	0.653	850.46	100.05	100.83			
Unit-4	0.656	854.36	100.51	101.29			
Unit-5	0.633	824.41	96.99	97.80			
Unit-6	0.651	847.85	99.75	100.54			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 10/01/2024

V.V.
10/01/2024

Checked by :
Date :

S. V.
11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:33:44

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.652	
3	STD 2	Unknown		*****	0.651	
4	STD 3	Unknown		*****	0.652	
5	STD 4	Unknown		*****	0.652	
6	STD 5	Unknown		*****	0.652	
7						

V.VT 10/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:45:05

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.193	
3	SPL 1 IN 2	Unknown		*****	0.201	
4	SPL 1 IN 3	Unknown		*****	0.181	
5	SPL 1 IN 4	Unknown		*****	0.168	
6	SPL 1 IN 5	Unknown		*****	0.178	
7	SPL 1 IN 6	Unknown		*****	0.191	
8						

V.VA 10/01/2024
Analysed By
Date:

Checked By
Date: A. D. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:58:00

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.332	
4	SPL 3 IN 3	Unknown		*****	0.326	
5	SPL 3 IN 4	Unknown		*****	0.341	
6	SPL 3 IN 5	Unknown		*****	0.350	
7	SPL 3 IN 6	Unknown		*****	0.327	
8						

V.V. 10/01/2024
Analysed By
Date:

Checked By
Date:

S. S. 11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 20:11:20

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.655	
3	SPL 10 IN 2	Unknown		*****	0.644	
4	SPL 10 IN 3	Unknown		*****	0.653	
5	SPL 10 IN 4	Unknown		*****	0.656	
6	SPL 10 IN 5	Unknown		*****	0.633	
7	SPL 10 IN 6	Unknown		*****	0.651	
8						

26/7
10/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24

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

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW PH 6.6PH)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH 6.6 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.29	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.458	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.655	0.657	0.655	0.655	0.658	0.656	0.00	0.216

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.183	236.42	27.81	0.28	28.1	26.6
Unit-2	0.175	226.08	26.60	0.27		Maximum %
Unit-3	0.178	229.96	27.05	0.27		
Unit-4	0.194	250.63	29.49	0.29		
Unit-5	0.199	257.09	30.25	0.30		30.2
Unit-6	0.181	233.84	27.51	0.28		

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.329	425.04	50.00	0.500	50.28	50.9	48.8
Unit-2	0.338	436.66	51.37	0.514	51.64		Maximum%
Unit-3	0.338	436.66	51.37	0.514	51.64		
Unit-4	0.319	412.12	48.48	0.485	48.78		
Unit-5	0.333	430.21	50.61	0.506	50.91		52.4
Unit-6	0.343	443.12	52.13	0.521	52.41		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.641	828.11	97.43	98.20	99.6	97.7	1.32
Unit-2	0.654	844.91	99.40	100.18			
Unit-3	0.659	851.37	100.16	100.95			
Unit-4	0.638	824.24	96.97	97.75			
Unit-5	0.651	841.03	98.94	99.75			
Unit-6	0.657	848.78	99.86	100.65			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 10/01/2024

Checked by :
Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:00:15
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.655	
3	STD 2	Unknown		*****	0.657	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.655	
6	STD 5	Unknown		*****	0.658	
7						

V.VA 10/01/2024
Analysed By
Date:

Checked By
Date:

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\UV_DATA_BACKUP\2024\JAN- 2024
\10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:12:33

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.183	
3	SPL 1 IN 2	Unknown		*****	0.175	
4	SPL 1 IN 3	Unknown		*****	0.178	
5	SPL 1 IN 4	Unknown		*****	0.194	
6	SPL 1 IN 5	Unknown		*****	0.199	
7	SPL 1 IN 6	Unknown		*****	0.181	
8						

✓✓✓ 10/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:33:11

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.329	
3	SPL 3 IN 2	Unknown		*****	0.338	
4	SPL 3 IN 3	Unknown		*****	0.338	
5	SPL 3 IN 4	Unknown		*****	0.319	
6	SPL 3 IN 5	Unknown		*****	0.333	
7	SPL 3 IN 6	Unknown		*****	0.343	
8						

V.VA 10/01/2024
Analysed By
Date:

Checked By
Date:

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:56:49

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.641	
3	SPL 10 IN 2	Unknown		*****	0.654	
4	SPL 10 IN 3	Unknown		*****	0.659	
5	SPL 10 IN 4	Unknown		*****	0.638	
6	SPL 10 IN 5	Unknown		*****	0.651	
7	SPL 10 IN 6	Unknown		*****	0.657	
8						

V.V. 10/01/2024
Analysed By
Date:

Checked By
Date:

A.D. 11/01/24



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH PH 7.0PH)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH 7.0 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.04	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.408	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.653	0.651	0.653	0.651	0.652	0.652	0.00	0.153

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.193	249.38	29.34	0.29	29.9	28.7
Unit-2	0.200	258.43	30.40	0.30		Maximum %
Unit-3	0.189	244.22	28.73	0.29		
Unit-4	0.203	262.31	30.86	0.31		
Unit-5	0.197	254.55	29.95	0.30		
Unit-6	0.198	255.85	30.10	0.30		30.9

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.348	449.67	52.90	0.529	53.20	52.5	50.8
Unit-2	0.344	444.50	52.29	0.523	52.60		Maximum%
Unit-3	0.335	432.87	50.93	0.509	51.21		
Unit-4	0.353	456.13	53.66	0.537	53.97		
Unit-5	0.332	428.99	50.47	0.505	50.77		54.0
Unit-6	0.349	450.96	53.05	0.531	53.36		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.650	839.90	98.81	99.63	99.6	98.3	1.03
Unit-2	0.660	852.82	100.33	101.16			
Unit-3	0.646	834.73	98.20	99.00			
Unit-4	0.641	828.27	97.44	98.29		Maximum %	
Unit-5	0.654	845.07	99.42	100.22			
Unit-6	0.646	834.73	98.20	99.03		101.2	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 10/01/2024

Checked by :
Date :

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0--SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 18:18:52
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.653	
3	STD 2	Unknown		*****	0.651	
4	STD 3	Unknown		*****	0.653	
5	STD 4	Unknown		*****	0.651	
6	STD 5	Unknown		*****	0.652	
7						

N.R. 10/01/2024
Analysed By
Date:

Checked By
Date:

N.R. 10/01/2024

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0 --DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 18:38:17

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.193	
3	SPL 1 IN 2	Unknown		*****	0.200	
4	SPL 1 IN 3	Unknown		*****	0.189	
5	SPL 1 IN 4	Unknown		*****	0.203	
6	SPL 1 IN 5	Unknown		*****	0.197	
7	SPL 1 IN 6	Unknown		*****	0.198	
8						

V.V. 10/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 18:49:48

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.348	
3	SPL 3 IN 2	Unknown		*****	0.344	
4	SPL 3 IN 3	Unknown		*****	0.335	
5	SPL 3 IN 4	Unknown		*****	0.353	
6	SPL 3 IN 5	Unknown		*****	0.332	
7	SPL 3 IN 6	Unknown		*****	0.349	
8						

V.V.T
10/01/2024
Analysed By
Date:

Checked By
Date:

S.V.T
11/01/24

GENERIC HEALTHCARE PVT. LTD.

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:06:51

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.650	
3	SPL 10 IN 2	Unknown		*****	0.660	
4	SPL 10 IN 3	Unknown		*****	0.646	
5	SPL 10 IN 4	Unknown		*****	0.641	
6	SPL 10 IN 5	Unknown		*****	0.654	
7	SPL 10 IN 6	Unknown		*****	0.646	
8						

V.V.V 10/01/2024
Analysed By
Date:

Checked By
Date:

S.V.V 10/01/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

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

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	About 42mg	mg to ---->	100	ml to ---->	5	ml to ---->	250
Std.conc (in ppm)-8.4	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Test solution :	TABLET	mg to ---->	1000	ml to ---->	1	ml to ---->	100
Test.conc (in ppm)-8.5	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Conversion factor :	1.0000
Labelled content :	850

Variation's of Parameters	RSD %	Metformin Dissolution in %	Mean Dissolution value of method precision	% Difference
Low wavelength (231nm)	0.71	99.8	99.4	-0.40
High wavelength (235nm)	1.17	100.1		-0.70
Low Volume(990ml)	1.19	99.1		0.30
High Volume(1010ml)	0.98	98.7		0.00
Low Rpm(96rpm)	1.59	98.9		-0.10
High Rpm(104rpm)	1.34	100.2		-0.80
Low pH(6.6pH)	1.32	99.6		-0.20
High pH(7.0pH)	1.03	99.6		-0.20

Acceptance criteria:

- 1) % Dissolution result shall meet the specification.
- 2) Relative standard deviation of % dissolution results should not be more than 5.0%
- 3) % of dissolution results should not differ by $\pm 5.0\%$ to that of method precision

Analysed by : VIGNESH V
Date : 10/01/2024

V.V.T
10/01/2024

Checked by :
Date :

11/01/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW WAVELENGTH 231NM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000	
Labelled content	850	mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.643	0.645	0.645	0.644	0.643	0.644	0.00	0.155

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.162	213.04	25.06	0.25	25.6	24.4
Unit-2	0.173	227.50	26.77	0.27		Maximum %
Unit-3	0.161	211.72	24.91	0.25		
Unit-4	0.158	207.78	24.44	0.24		
Unit-5	0.167	219.61	25.84	0.26		
Unit-6	0.171	224.87	26.46	0.26		26.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.324	426.08	50.13	0.501	50.38	50.7	49.3
Unit-2	0.330	433.97	51.05	0.511	51.32		Maximum%
Unit-3	0.338	444.49	52.29	0.523	52.54		
Unit-4	0.325	427.39	50.28	0.503	50.53		
Unit-5	0.321	422.13	49.66	0.497	49.92		
Unit-6	0.317	416.87	49.04	0.490	49.31		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.644	846.89	99.63	100.39	99.8	98.7	0.71
Unit-2	0.639	840.32	98.86	99.64			
Unit-3	0.633	832.42	97.93	98.70			
Unit-4	0.640	841.63	99.02	99.76			
Unit-5	0.646	849.52	99.94	100.70			
Unit-6	0.638	839.00	98.71	99.46			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 28/12/2023

Checked by :
Date :

* For Std Weight prints, Refer Glide M60/850 (System Suitability)
B.NO: G17230801



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 16:44:30
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.643	
3	STD 2	Unknown		*****	0.645	
4	STD 3	Unknown		*****	0.645	
5	STD 4	Unknown		*****	0.644	
6	STD 5	Unknown		*****	0.643	
7						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 11/10/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM DISSOLUTION
OF MET HCL--1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 17:07:21
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

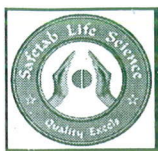
	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.162	
3	SPL 1 IN 2	Unknown		*****	0.173	
4	SPL 1 IN 3	Unknown		*****	0.161	
5	SPL 1 IN 4	Unknown		*****	0.158	
6	SPL 1 IN 5	Unknown		*****	0.167	
7	SPL 1 IN 6	Unknown		*****	0.171	
8						

V.V. 28/12/2023

Analysed By
Date:

Checked By
Date:

P.V. 11/10/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM DISSOLUTION
OF MET HCL--3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 17:30:59
Comments: 3RD HOUR

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

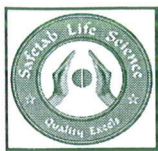
Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.324	
3	SPL 3 IN 2	Unknown		*****	0.330	
4	SPL 3 IN 3	Unknown		*****	0.338	
5	SPL 3 IN 4	Unknown		*****	0.325	
6	SPL 3 IN 5	Unknown		*****	0.321	
7	SPL 3 IN 6	Unknown		*****	0.317	
8						

V. V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S. V. 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--LOW
WAVELENGTH--231NM DISSOLUTION
OF MET HCL--10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 17:55:41
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL231.0
Wavelength: 231.00 nm

Calibration Curve

Column for Cal. Curve: WL231.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL231.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL231.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL231.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.644	
3	SPL 10 IN 2	Unknown		*****	0.639	
4	SPL 10 IN 3	Unknown		*****	0.633	
5	SPL 10 IN 4	Unknown		*****	0.640	
6	SPL 10 IN 5	Unknown		*****	0.646	
7	SPL 10 IN 6	Unknown		*****	0.638	
8						

V.VA_{28/12/2023}
Analysed By
Date:

Checked By
Date:

S.D.
11/01/24



Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH WAVELENGTH 235NM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.643	0.641	0.641	0.642	0.642	0.642	0.00	0.130

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.161	212.45	24.99	0.25	25.5	24.7
Unit-2	0.163	215.09	25.30	0.25		Maximum %
Unit-3	0.159	209.81	24.68	0.25		
Unit-4	0.162	213.77	25.15	0.25		
Unit-5	0.164	216.41	25.46	0.25		
Unit-6	0.177	233.56	27.48	0.27		27.5

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	457.89	53.87	0.539	54.12	53.0	51.6
Unit-2	0.342	451.29	53.09	0.531	53.35		Maximum%
Unit-3	0.335	442.05	52.01	0.520	52.25		
Unit-4	0.331	436.77	51.39	0.514	51.64		
Unit-5	0.340	448.65	52.78	0.528	53.04		
Unit-6	0.345	455.25	53.56	0.536	53.83		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.637	840.56	98.89	99.68	100.1	98.6	1.17
Unit-2	0.650	857.71	100.91	101.69			
Unit-3	0.638	841.88	99.04	99.81		Maximum %	
Unit-4	0.648	855.07	100.60	101.36			
Unit-5	0.630	831.32	97.80	98.58		101.7	
Unit-6	0.637	840.56	98.89	99.70			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 28/12/2023

Checked by :
Date :

* For Std Weight point, Refer Glide M60/850 (System Suitability)
B.No: G17230801



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 18:47:25
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.643	
3	STD 2	Unknown		*****	0.641	
4	STD 3	Unknown		*****	0.641	
5	STD 4	Unknown		*****	0.642	
6	STD 5	Unknown		*****	0.642	
7						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 11/01/24

Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--DISSO OF MET
HCL--1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 19:12:31
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.161	
3	SPL 1 IN 2	Unknown		*****	0.163	
4	SPL 1 IN 3	Unknown		*****	0.159	
5	SPL 1 IN 4	Unknown		*****	0.162	
6	SPL 1 IN 5	Unknown		*****	0.164	
7	SPL 1 IN 6	Unknown		*****	0.177	
8						

V.VA 28/12/2023
Analysed By
Date:

Checked By
Date:

11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--DISSO OF MET
HCL--3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 19:28:15
Comments: 3RD HOUR

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.342	
4	SPL 3 IN 3	Unknown		*****	0.335	
5	SPL 3 IN 4	Unknown		*****	0.331	
6	SPL 3 IN 5	Unknown		*****	0.340	
7	SPL 3 IN 6	Unknown		*****	0.345	
8						

V.V 28/12/2023
Analysed By
Date:

Checked By
Date:

V.V 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--HIGH
WAVELENGTH--235NM--DISSO OF MET
HCL--10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 19:46:42
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL235.0
Wavelength: 235.00 nm

Calibration Curve

Column for Cal. Curve: WL235.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL235.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL235.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL235.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.637	
3	SPL 10 IN 2	Unknown		*****	0.650	
4	SPL 10 IN 3	Unknown		*****	0.638	
5	SPL 10 IN 4	Unknown		*****	0.648	
6	SPL 10 IN 5	Unknown		*****	0.630	
7	SPL 10 IN 6	Unknown		*****	0.637	
8						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 11/01/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW VOLUME 990ML)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	990
Speed	100RPM
Time	1st,3nd and 10th Hours

Standard dilution.:	42.19	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.438	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.654	0.654	0.655	0.653	0.654	0.654	0.00	0.108

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.196	253.39	29.81	0.30	28.1	26.6
Unit-2	0.188	243.05	28.59	0.29		Maximum %
Unit-3	0.175	226.24	26.62	0.27		
Unit-4	0.183	236.58	27.83	0.28		
Unit-5	0.182	235.29	27.68	0.28		
Unit-6	0.186	240.46	28.29	0.28		29.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.356	460.23	54.15	0.541	54.44	52.3	50.5
Unit-2	0.343	443.43	52.17	0.522	52.45		Maximum%
Unit-3	0.346	447.31	52.62	0.526	52.89		
Unit-4	0.335	433.09	50.95	0.510	51.23		
Unit-5	0.330	426.62	50.19	0.502	50.47		
Unit-6	0.343	443.43	52.17	0.522	52.45		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.641	828.68	97.49	98.33	99.1	97.4	1.19
Unit-2	0.651	841.61	99.01	99.82			
Unit-3	0.635	820.92	96.58	97.37		Maximum %	
Unit-4	0.652	842.90	99.16	99.95			
Unit-5	0.655	846.78	99.62	100.40		100.4	
Unit-6	0.642	829.97	97.64	98.45			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 05/01/2024

Checked by :
Date :



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--VOLUME--
SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 15:40:58
Comments: SYSTEM SUITABIULTY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.654	
3	STD 2	Unknown		*****	0.654	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.653	
6	STD 5	Unknown		*****	0.654	
7						

V.VA 05/01/2024
Analysed By
Date:

Checked By
Date:

S. V. 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
VOLUME 990ML--DISSO OF MET HCL--
1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 16:04:30

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.196	
3	SPL 1 IN 2	Unknown		*****	0.188	
4	SPL 1 IN 3	Unknown		*****	0.175	
5	SPL 1 IN 4	Unknown		*****	0.183	
6	SPL 1 IN 5	Unknown		*****	0.182	
7	SPL 1 IN 6	Unknown		*****	0.186	
8						

V. V. 05/01/2024
Analysed By
Date:

Checked By
Date:

S. V. 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
VOLUME 990ML--DISSO OF MET HCL--
3RD HOUR.pho

Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 16:26:39

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

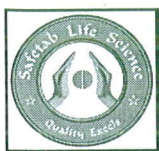
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.356	
3	SPL 3 IN 2	Unknown		*****	0.343	
4	SPL 3 IN 3	Unknown		*****	0.346	
5	SPL 3 IN 4	Unknown		*****	0.335	
6	SPL 3 IN 5	Unknown		*****	0.330	
7	SPL 3 IN 6	Unknown		*****	0.343	
8						

V. V 05/01/2024
Analysed By
Date:

Checked By
Date:

S. V
11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
VOLUME 990ML--DISSO OF MET HCL--
10TH HOUR.pho

Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 16:49:47

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.641	
3	SPL 10 IN 2	Unknown		*****	0.651	
4	SPL 10 IN 3	Unknown		*****	0.635	
5	SPL 10 IN 4	Unknown		*****	0.652	
6	SPL 10 IN 5	Unknown		*****	0.655	
7	SPL 10 IN 6	Unknown		*****	0.642	
8						

V.V. 05/01/2024

Analysed By
Date:

Checked By
Date:

S. J. 11/01/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH VOLUME 1010ML)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1010
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.19	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.438	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.654	0.654	0.655	0.653	0.654	0.654	0.00	0.108

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.174	224.95	26.46	0.26	28.2	26.5
Unit-2	0.185	239.17	28.14	0.28		Maximum %
Unit-3	0.180	232.70	27.38	0.27		
Unit-4	0.194	250.80	29.51	0.30		
Unit-5	0.196	253.39	29.81	0.30		
Unit-6	0.182	235.29	27.68	0.28		29.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.343	443.43	52.17	0.522	52.43	52.7	51.1
Unit-2	0.334	431.79	50.80	0.508	51.08		Maximum%
Unit-3	0.341	440.84	51.86	0.519	52.14		
Unit-4	0.349	451.19	53.08	0.531	53.38		
Unit-5	0.354	457.65	53.84	0.538	54.14		
Unit-6	0.345	446.01	52.47	0.525	52.75		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.643	831.27	97.80	98.58	98.7	97.2	0.98
Unit-2	0.654	845.49	99.47	100.26			
Unit-3	0.634	819.63	96.43	97.22		Maximum %	
Unit-4	0.643	831.27	97.80	98.62			
Unit-5	0.642	829.97	97.64	98.48		100.3	
Unit-6	0.644	832.56	97.95	98.75			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 05/01/2024

V.V.T
05/01/2024

Checked by :
Date :

11/01/24

Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--VOLUME--
SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 15:40:58
Comments: SYSTEM SUITABIULTY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

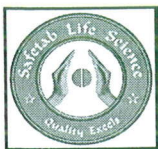
	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.654	
3	STD 2	Unknown		*****	0.654	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.653	
6	STD 5	Unknown		*****	0.654	
7						

Analysed By
Date:

V.V 05/01/2024

Checked By
Date:

P.V 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH
VOLUME 1010ML--DISSO OF MET
HCL--1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 17:13:34

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.174	
3	SPL 1 IN 2	Unknown		*****	0.185	
4	SPL 1 IN 3	Unknown		*****	0.180	
5	SPL 1 IN 4	Unknown		*****	0.194	
6	SPL 1 IN 5	Unknown		*****	0.196	
7	SPL 1 IN 6	Unknown		*****	0.182	
8						

V.V 05/01/2024
Analysed By
Date:

Checked By
Date:

11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH
VOLUME 1010ML--DISSO OF MET
HCL--3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 17:27:49

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

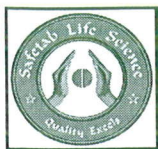
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.343	
3	SPL 3 IN 2	Unknown		*****	0.334	
4	SPL 3 IN 3	Unknown		*****	0.341	
5	SPL 3 IN 4	Unknown		*****	0.349	
6	SPL 3 IN 5	Unknown		*****	0.354	
7	SPL 3 IN 6	Unknown		*****	0.345	
8						

V.V 05/01/2024
Analysed By
Date:

Checked By
Date:

S.S 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
05-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH
VOLUME 1010ML--DISSO OF MET
HCL--10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 05-01-2024 17:49:59

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.643	
3	SPL 10 IN 2	Unknown		*****	0.654	
4	SPL 10 IN 3	Unknown		*****	0.634	
5	SPL 10 IN 4	Unknown		*****	0.643	
6	SPL 10 IN 5	Unknown		*****	0.642	
7	SPL 10 IN 6	Unknown		*****	0.644	
8						

V.VA 05/01/2024
Analysed By
Date:

Checked By
Date:

S. A. 11/01/24



Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW RPM 96RPM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	96RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.10	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.42	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.657	0.654	0.655	0.655	0.656	0.655	0.00	0.174

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.191	245.87	28.93	0.29	28.3	26.2
Unit-2	0.183	235.57	27.71	0.28		Maximum %
Unit-3	0.173	222.70	26.20	0.26		
Unit-4	0.186	239.43	28.17	0.28		
Unit-5	0.191	245.87	28.93	0.29		
Unit-6	0.198	254.88	29.99	0.30		30.0

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	446.69	52.55	0.526	52.84	52.2	50.4
Unit-2	0.339	436.39	51.34	0.513	51.62		Maximum%
Unit-3	0.336	432.53	50.89	0.509	51.15		
Unit-4	0.331	426.09	50.13	0.501	50.41		
Unit-5	0.357	459.56	54.07	0.541	54.36		54.4
Unit-6	0.348	447.97	52.70	0.527	53.00		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.663	853.47	100.41	101.22	98.9	96.8	1.59
Unit-2	0.650	836.73	98.44	99.23		Maximum %	
Unit-3	0.641	825.15	97.08	97.85			
Unit-4	0.634	816.14	96.02	96.80			
Unit-5	0.645	830.30	97.68	98.51			
Unit-6	0.655	843.17	99.20	100.02			

Acceptance criteria:

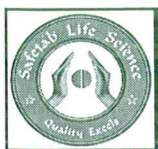
%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 04/01/2024

Checked by :
Date :

VNT
04/01/2024

11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
104-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--LOW RPM--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 18:16:03
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.657	
3	STD 2	Unknown		*****	0.654	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.655	
6	STD 5	Unknown		*****	0.656	
7						

V.A 04/01/2024
Analysed By
Date:

Checked By
Date:

S.D.
11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
V04-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
RPM--DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 18:36:38

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.191	
3	SPL 2	Unknown		*****	0.183	
4	SPL 3	Unknown		*****	0.173	
5	SPL 4	Unknown		*****	0.186	
6	SPL 5	Unknown		*****	0.191	
7	SPL 6	Unknown		*****	0.198	
8						

V.V 04/01/2024
Analysed By
Date:

Checked By
Date:

S.V. 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
04-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
RPM--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 18:49:10

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.339	
4	SPL 3 IN 3	Unknown		*****	0.336	
5	SPL 3 IN 4	Unknown		*****	0.331	
6	SPL 3 IN 5	Unknown		*****	0.357	
7	SPL 3 IN 6	Unknown		*****	0.348	
8						

V.V. 04/01/2024
Analysed By
Date:

Checked By
Date:



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
104-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW
RPM--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 04-01-2024 19:10:01

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.663	
3	SPL 10 IN 2	Unknown		*****	0.650	
4	SPL 10 IN 3	Unknown		*****	0.641	
5	SPL 10 IN 4	Unknown		*****	0.634	
6	SPL 10 IN 5	Unknown		*****	0.645	
7	SPL 10 IN 6	Unknown		*****	0.655	
8						

V.V. 04/01/2024
Analysed By
Date:

Checked By
Date: 11/10/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH RPM 104RPM)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	104RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.36	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.472	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.652	0.651	0.652	0.652	0.652	0.652	0.00	0.069

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.193	251.36	29.57	0.30	28.4	25.7
Unit-2	0.201	261.78	30.80	0.31		Maximum %
Unit-3	0.181	235.73	27.73	0.28		
Unit-4	0.168	218.80	25.74	0.26		
Unit-5	0.178	231.82	27.27	0.27		
Unit-6	0.191	248.76	29.27	0.29		30.8

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.347	451.93	53.17	0.532	53.46	51.9	50.2
Unit-2	0.332	432.39	50.87	0.509	51.18		Maximum%
Unit-3	0.326	424.58	49.95	0.500	50.23		
Unit-4	0.341	444.11	52.25	0.522	52.51		
Unit-5	0.350	455.83	53.63	0.536	53.90		
Unit-6	0.327	425.88	50.10	0.501	50.40		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.655	853.06	100.36	101.19	100.2	97.8	1.34
Unit-2	0.644	838.74	98.67	99.49			
Unit-3	0.653	850.46	100.05	100.83			
Unit-4	0.656	854.36	100.51	101.29		Maximum %	
Unit-5	0.633	824.41	96.99	97.80			
Unit-6	0.651	847.85	99.75	100.54		101.3	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V V.V
DATE : 10/01/2024 10/01/2024

Checked by :
Date : 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:33:44

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

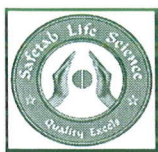
	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.652	
3	STD 2	Unknown		*****	0.651	
4	STD 3	Unknown		*****	0.652	
5	STD 4	Unknown		*****	0.652	
6	STD 5	Unknown		*****	0.652	
7						

V.VT 10/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:45:05

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.193	
3	SPL 1 IN 2	Unknown		*****	0.201	
4	SPL 1 IN 3	Unknown		*****	0.181	
5	SPL 1 IN 4	Unknown		*****	0.168	
6	SPL 1 IN 5	Unknown		*****	0.178	
7	SPL 1 IN 6	Unknown		*****	0.191	
8						

V. V. 10/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:58:00

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.332	
4	SPL 3 IN 3	Unknown		*****	0.326	
5	SPL 3 IN 4	Unknown		*****	0.341	
6	SPL 3 IN 5	Unknown		*****	0.350	
7	SPL 3 IN 6	Unknown		*****	0.327	
8						

V.VT 10/01/2024

Analysed By
Date:

Checked By
Date:

V.VT 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH RPM
104--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 20:11:20

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.655	
3	SPL 10 IN 2	Unknown		*****	0.644	
4	SPL 10 IN 3	Unknown		*****	0.653	
5	SPL 10 IN 4	Unknown		*****	0.656	
6	SPL 10 IN 5	Unknown		*****	0.633	
7	SPL 10 IN 6	Unknown		*****	0.651	
8						

V. V. 10/01/2024
Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (LOW PH 6.6PH)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Dissolution medium :	PH 6.6 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.29	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.458	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.655	0.657	0.655	0.655	0.658	0.656	0.00	0.216

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.183	236.42	27.81	0.28	28.1	26.6
Unit-2	0.175	226.08	26.60	0.27		
Unit-3	0.178	229.96	27.05	0.27		Maximum %
Unit-4	0.194	250.63	29.49	0.29		
Unit-5	0.199	257.09	30.25	0.30		
Unit-6	0.181	233.84	27.51	0.28		30.2

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.329	425.04	50.00	0.500	50.28	50.9	48.8
Unit-2	0.338	436.66	51.37	0.514	51.64		
Unit-3	0.338	436.66	51.37	0.514	51.64		Maximum%
Unit-4	0.319	412.12	48.48	0.485	48.78		
Unit-5	0.333	430.21	50.61	0.506	50.91		
Unit-6	0.343	443.12	52.13	0.521	52.41		52.4

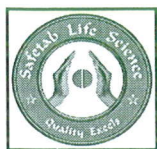
10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.641	828.11	97.43	98.20	99.6	97.7	1.32
Unit-2	0.654	844.91	99.40	100.18			
Unit-3	0.659	851.37	100.16	100.95		Maximum %	
Unit-4	0.638	824.24	96.97	97.75			
Unit-5	0.651	841.03	98.94	99.75			
Unit-6	0.657	848.78	99.86	100.65		100.9	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 10/01/2024

Checked by :
Date : 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:00:15
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

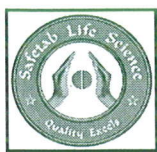
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.655	
3	STD 2	Unknown		*****	0.657	
4	STD 3	Unknown		*****	0.655	
5	STD 4	Unknown		*****	0.655	
6	STD 5	Unknown		*****	0.658	
7						

V.VT 10/01/2024
Analysed By
Date:

Checked By
Date:

A. D. 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:12:33

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.183	
3	SPL 1 IN 2	Unknown		*****	0.175	
4	SPL 1 IN 3	Unknown		*****	0.178	
5	SPL 1 IN 4	Unknown		*****	0.194	
6	SPL 1 IN 5	Unknown		*****	0.199	
7	SPL 1 IN 6	Unknown		*****	0.181	
8						

V.V.T
10/01/2024
Analysed By
Date:

Checked By
Date:

P. D. S.
11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:33:11

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

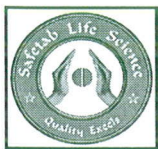
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.329	
3	SPL 3 IN 2	Unknown		*****	0.338	
4	SPL 3 IN 3	Unknown		*****	0.338	
5	SPL 3 IN 4	Unknown		*****	0.319	
6	SPL 3 IN 5	Unknown		*****	0.333	
7	SPL 3 IN 6	Unknown		*****	0.343	
8						

V.VA 10/01/2024
Analysed By
Date:

Checked By
Date:

S.V. 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--LOW PH
6.6--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 17:56:49

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.641	
3	SPL 10 IN 2	Unknown		*****	0.654	
4	SPL 10 IN 3	Unknown		*****	0.659	
5	SPL 10 IN 4	Unknown		*****	0.638	
6	SPL 10 IN 5	Unknown		*****	0.651	
7	SPL 10 IN 6	Unknown		*****	0.657	
8						

N.V.T 10/01/2024

Analysed By
Date:

Checked By
Date:

[Signature]
11/01/24



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	ROBUSTNESS (HIGH PH 7.0PH)	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	PH 7.0 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.04	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.408	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.653	0.651	0.653	0.651	0.652	0.652	0.00	0.153

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.193	249.38	29.34	0.29	29.9	28.7
Unit-2	0.200	258.43	30.40	0.30		Maximum %
Unit-3	0.189	244.22	28.73	0.29		
Unit-4	0.203	262.31	30.86	0.31		
Unit-5	0.197	254.55	29.95	0.30		
Unit-6	0.198	255.85	30.10	0.30		30.9

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.348	449.67	52.90	0.529	53.20	52.5	50.8
Unit-2	0.344	444.50	52.29	0.523	52.60		Maximum%
Unit-3	0.335	432.87	50.93	0.509	51.21		
Unit-4	0.353	456.13	53.66	0.537	53.97		
Unit-5	0.332	428.99	50.47	0.505	50.77		
Unit-6	0.349	450.96	53.05	0.531	53.36		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.650	839.90	98.81	99.63	99.6	98.3	1.03
Unit-2	0.660	852.82	100.33	101.16			
Unit-3	0.646	834.73	98.20	99.00			
Unit-4	0.641	828.27	97.44	98.29			
Unit-5	0.654	845.07	99.42	100.22			
Unit-6	0.646	834.73	98.20	99.03			

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 10/01/2024

Checked by :
Date :

V.V.T
10/01/2024

P.A.
11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0--SYSTEM SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 18:18:52
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.653	
3	STD 2	Unknown		*****	0.651	
4	STD 3	Unknown		*****	0.653	
5	STD 4	Unknown		*****	0.651	
6	STD 5	Unknown		*****	0.652	
7						

V.VA 10/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0 --DISSO OF MET HCL--1ST
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 18:38:17

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.193	
3	SPL 1 IN 2	Unknown		*****	0.200	
4	SPL 1 IN 3	Unknown		*****	0.189	
5	SPL 1 IN 4	Unknown		*****	0.203	
6	SPL 1 IN 5	Unknown		*****	0.197	
7	SPL 1 IN 6	Unknown		*****	0.198	
8						

V.V.T. 10/01/2024
Analysed By
Date:

Checked By
Date: 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 18:49:48

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.348	
3	SPL 3 IN 2	Unknown		*****	0.344	
4	SPL 3 IN 3	Unknown		*****	0.335	
5	SPL 3 IN 4	Unknown		*****	0.353	
6	SPL 3 IN 5	Unknown		*****	0.332	
7	SPL 3 IN 6	Unknown		*****	0.349	
8						

V.V.T
10/01/2024
Analysed By
Date:

Checked By
Date:



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2024\JAN- 2024
\\10-01-2024\GLIDE M60-850--
G17230801--AMV--METHOD
PRECISION--ROBUSTNESS--HIGH PH
7.0--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 10-01-2024 19:06:51

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.650	
3	SPL 10 IN 2	Unknown		*****	0.660	
4	SPL 10 IN 3	Unknown		*****	0.646	
5	SPL 10 IN 4	Unknown		*****	0.641	
6	SPL 10 IN 5	Unknown		*****	0.654	
7	SPL 10 IN 6	Unknown		*****	0.646	
8						

V.V. 10/01/2024
Analysed By
Date:

Checked By
Date: S. V. 11/01/24

**Safetab Life Science ,**

Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Tittle

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	About 42 mg	mg to --->	100	ml to --->	5	ml to --->	250
Std.conc (in ppm)-8.4	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Tablet	mg to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	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	97.77	97.8	Preparation-1	99.34	97.9	99.5
Preparation-2	100.33		Preparation-2	100.84		
Preparation-3	100.74	Maximum	Preparation-3	101.03	Maximum	% RSD
Preparation-4	98.47		Preparation-4	98.38		
Preparation-5	100.17	100.7	Preparation-5	97.93	101.0	1.18
Preparation-6	98.82		Preparation-6	99.78		
Average	99.4	Not applicable	Average	99.6	Not applicable	
% RSD	1.20	Not applicable	% RSD	1.27	Not applicable	

Results:

1) % RSD for Dissolution of six preparations of method precision

1.20

2) % RSD for Dissolution of six preparations of Intermediate precision

1.27

3) Cumulative %RSD for Dissolution of twelve preparations

1.18

Acceptance criteria:

1) % RSD for Dissolution of six preparations should not be more than 5.0.

2) Cumulative % RSD for Dissolution of twelve preparations (i.e. method precision and intermediate precision) should not be more than 10.0.

Analysed by :

VIGNESH V

Date :

11-01-2024

Checked by :

Date :



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	METHOD PRECISION	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3rd and 10th Hours

Standard dilution.:	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850

mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.660	0.658	0.659	0.659	0.658	0.659	0.00	0.127

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.199	255.82	30.10	0.30	28.1	26.3
Unit-2	0.185	237.82	27.98	0.28		Maximum %
Unit-3	0.180	231.39	27.22	0.27		
Unit-4	0.174	223.68	26.32	0.26		
Unit-5	0.184	236.53	27.83	0.28		
Unit-6	0.191	245.53	28.89	0.29		30.1

3rd Hour						Limit:45-65%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Minimum %
Unit-1	0.347	446.07	52.48	0.525	52.78	52.5
Unit-2	0.352	452.50	53.24	0.532	53.51	
Unit-3	0.334	429.36	50.51	0.505	50.78	
Unit-4	0.338	434.50	51.12	0.511	51.38	
Unit-5	0.349	448.64	52.78	0.528	53.06	
Unit-6	0.352	452.50	53.24	0.532	53.52	
						Maximum %
						53.5

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.641	824.01	96.94	97.77	99.4	97.8	1.20
Unit-2	0.658	845.86	99.51	100.33			
Unit-3	0.661	849.72	99.97	100.74			
Unit-4	0.646	830.44	97.70	98.47			
Unit-5	0.657	844.58	99.36	100.17			
Unit-6	0.648	833.01	98.00	98.82			
						Maximum %	
						100.7	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : VIGNESH V
DATE : 28/12/2023

Checked by :
Date :

* For Std Weight point, Refer Glide M60/850 (System Suitability)
B.No: G1722093



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:28:38
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.660	
3	STD 2	Unknown		*****	0.658	
4	STD 3	Unknown		*****	0.659	
5	STD 4	Unknown		*****	0.659	
6	STD 5	Unknown		*****	0.658	
7						

Analysed By
Date:

V.V. 28/12/2023

Checked By
Date:

A.V. 28/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
1ST HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:37:07
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

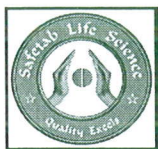
	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.199	
3	SPL 1 IN 2	Unknown		*****	0.185	
4	SPL 1 IN 3	Unknown		*****	0.180	
5	SPL 1 IN 4	Unknown		*****	0.174	
6	SPL 1 IN 5	Unknown		*****	0.184	
7	SPL 1 IN 6	Unknown		*****	0.191	
8						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date: 28/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
3RD HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:59:18
Comments: 3RD HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.347	
3	SPL 3 IN 2	Unknown		*****	0.352	
4	SPL 3 IN 3	Unknown		*****	0.334	
5	SPL 3 IN 4	Unknown		*****	0.338	
6	SPL 3 IN 5	Unknown		*****	0.349	
7	SPL 3 IN 6	Unknown		*****	0.352	
8						

V.VA 28/12/2023
Analysed By
Date:

Checked By
Date:

V.VA 28/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
10TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:24:13
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.641	
3	SPL 10 IN 2	Unknown		*****	0.658	
4	SPL 10 IN 3	Unknown		*****	0.661	
5	SPL 10 IN 4	Unknown		*****	0.646	
6	SPL 10 IN 5	Unknown		*****	0.657	
7	SPL 10 IN 6	Unknown		*****	0.648	
8						

V.V.T 28/12/2023
Analysed By
Date:

Checked By
Date:

[Handwritten signature]
28/12/2023



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M60/850	Batch size :	Not Applicable
Batch Number :	G17230801	Mfg.Date :	Aug-23
Stage:	INTERMEDIATE PRECISION	Exp.Date :	Jul-26

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	------------	--------------	---------	--------------	----------------	-------

Dissolution medium :	PH6.8 Phosphate Buffer
Volume (ml)	1000
Speed	100RPM
Time	1st,3nd and 10th Hours

Standard dilution.:	42.14	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.428	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution.:	One tablet	gm to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled content	850 mg

System suitability	1	2	3	4	5	Mean	SD	RSD%
Standard Absorbance :	0.649	0.648	0.647	0.648	0.650	0.648	0.00	0.176

1st Hour						Limit:20-40%
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	0.190	247.46	29.11	0.29	28.0	26.4
Unit-2	0.180	234.43	27.58	0.28		Maximum %
Unit-3	0.190	247.46	29.11	0.29		
Unit-4	0.181	235.74	27.73	0.28		
Unit-5	0.172	224.02	26.35	0.26		
Unit-6	0.183	238.34	28.04	0.28		29.1

3rd Hour						Limit:45-65%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D3)	Correction Factor (CF2)	Cumulative % (D3+CF1)	Average %	Minimum %
Unit-1	0.342	445.43	52.40	0.524	52.69	51.9	50.5
Unit-2	0.330	429.80	50.56	0.506	50.84		Maximum%
Unit-3	0.346	450.64	53.02	0.530	53.31		
Unit-4	0.328	427.19	50.26	0.503	50.54		
Unit-5	0.340	442.82	52.10	0.521	52.36		53.3
Unit-6	0.335	436.31	51.33	0.513	51.61		

10th Hour						NLT:85.0%	
Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %	% RSD
Unit-1	0.643	837.45	98.52	99.34	99.5	97.9	1.27
Unit-2	0.653	850.48	100.06	100.84			
Unit-3	0.654	851.78	100.21	101.03			
Unit-4	0.637	829.64	97.60	98.38			
Unit-5	0.634	825.73	97.14	97.93			
Unit-6	0.646	841.36	98.98	99.78			
						Maximum %	
						101.0	

Acceptance criteria:

%RSD of drug release six unit of preparations should not be more than 5.0 at final time point and meet the specification limit at individual interval limit.

Analysed by : RAGAVAN K
DATE : 11/01/2024

Checked by :
Date : 11/01/2024



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
\\11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSO OF MET HCL--
SYSYSTEM SUITABILITY.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 16:19:04
Comments: SYSYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

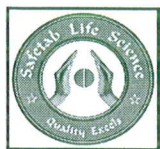
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.649	
3	STD 2	Unknown		*****	0.648	
4	STD 3	Unknown		*****	0.647	
5	STD 4	Unknown		*****	0.648	
6	STD 5	Unknown		*****	0.650	
7						

K. R. 11/01/2024
Analysed By
Date:

Checked By
Date:

A. V. 11/01/24



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
\\11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSOLUTION OF MET
HCL--1ST HOUR.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 16:41:52
Comments: 1ST HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

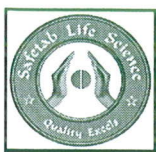
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1 IN 1	Unknown		*****	0.190	
3	SPL 1 IN 2	Unknown		*****	0.180	
4	SPL 1 IN 3	Unknown		*****	0.190	
5	SPL 1 IN 4	Unknown		*****	0.181	
6	SPL 1 IN 5	Unknown		*****	0.172	
7	SPL 1 IN 6	Unknown		*****	0.183	
8						

K. R. 11/01/2024
Analysed By
Date:

Checked By
Date:

11/01/2024



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2024\JAN- 2024
\\11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSO OF MET HCL--3RD
HOUR.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 16:59:57
Comments: 3RD HOUR

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

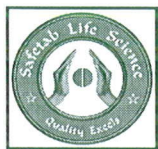
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 3 IN 1	Unknown		*****	0.342	
3	SPL 3 IN 2	Unknown		*****	0.330	
4	SPL 3 IN 3	Unknown		*****	0.346	
5	SPL 3 IN 4	Unknown		*****	0.328	
6	SPL 3 IN 5	Unknown		*****	0.340	
7	SPL 3 IN 6	Unknown		*****	0.335	
8						

K. R. 11/01/2024
Analysed By
Date:

Checked By
Date:

A. V. 11/01/24



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2024\JAN- 2024
11-01-2024\GLIDE M 60-850--
G17230801--AMV--INTERMEDIATE
PRECISION--DISSO OF MET HCL--10TH
HOUR.pho
Title: GLIDE M 60-850--G17230801
Analyst: RAGAVAN K
Date/Time: 11-01-2024 17:28:20
Comments: 10TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 8.400

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 10 IN 1	Unknown		*****	0.643	
3	SPL 10 IN 2	Unknown		*****	0.653	
4	SPL 10 IN 3	Unknown		*****	0.654	
5	SPL 10 IN 4	Unknown		*****	0.637	
6	SPL 10 IN 5	Unknown		*****	0.634	
7	SPL 10 IN 6	Unknown		*****	0.646	
8						

K. R. 11/01/2024
Analysed By
Date:

Checked By
Date:



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard dilution :	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No	Absorbance of Metformin Hydrochloride
BLANK	0
1	0.660
2	0.658
3	0.659
4	0.659
5	0.658
Average	0.659
RSD %	0.127

Results :

1) % RSD of absorbance of Metformin Hydrochloride

0.127

Acceptance criteria:

% RSD of absorbance of replicate Standard should not be more than 2.0.

Analysed by :

V.VIGNESH

Date :

28/12/2023

V.V. 28/12/2023

Checked by :

Date :

V.V. 28/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--SYSTEM
SUITABILITY.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 12:28:38
Comments: SYSTEM SUITABILITY

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD 1	Unknown		*****	0.660	
3	STD 2	Unknown		*****	0.658	
4	STD 3	Unknown		*****	0.659	
5	STD 4	Unknown		*****	0.659	
6	STD 5	Unknown		*****	0.658	
7						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

V.V. 28/12/2023



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/500 & GLIDE-M 60/850	Batch size :	NA
Batch Number :	G1722093 & G17230801	Mfg.Date :	NA
Parameter :	LINEARITY AND RANGE	Exp.Date :	NA

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 500/850 mg

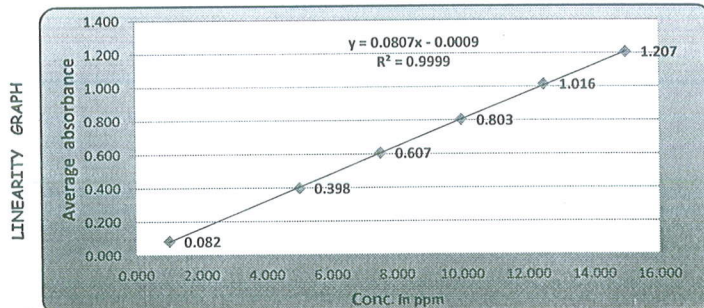
Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
Linearity Level-I :	125.02	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-1.00016	2	ml to --->	250	ml to --->	1	ml to --->	1
Linearity Level-II :	125.02	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-5.0008	2	ml to --->	50	ml to --->	1	ml to --->	1
Linearity Level-III :	125.02	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-7.5012	3	ml to --->	50	ml to --->	1	ml to --->	1
Linearity Level-IV :	125.02	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-10.0016	4	ml to --->	50	ml to --->	1	ml to --->	1
Linearity Level-V :	125.02	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-12.502	5	ml to --->	50	ml to --->	1	ml to --->	1
Linearity Level-VI :	125.02	mg to --->	100	ml to --->	10	ml to --->	100
Std.conc (in ppm)-15.0024	6	ml to --->	50	ml to --->	1	ml to --->	1

Level's	I	II	III	IV	V	VI
S.No.	10%	50%	75%	100%	125%	150%
1	0.082	0.398	0.607	0.804	1.015	1.208
2	0.083	0.399	0.605	0.803	1.016	1.209
3	0.082	0.397	0.608	0.802	1.016	1.205
Average	0.082	0.398	0.607	0.803	1.016	1.207
RSD%	0.701	0.251	0.252	0.125	0.057	0.172

LEVEL's	Conc. in ppm (X-axis)	Absorbance (Y-axis)
I	1.000	0.082
II	5.001	0.398
III	7.501	0.607
IV	10.002	0.803
V	12.502	1.016
VI	15.002	1.207



Results :

- Squared correlation coefficient of Metformin Hydrochloride 0.999
- In Range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels within limits.

Acceptance criteria:

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

Analysed by : VIGNESH V
Date : 16/12/2023

V.V.T
16/12/2023

Checked by :
Date : 16/12/23

* for Std weight point, Refer Glide M60/500 (Linearity)
B.NO: G1722093

Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
10%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 07:56:54
Comments: LINEARITY 10%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.082	LINEARITY 10%
3	SPL 2	Unknown		*****	0.083	LINEARITY 10%
4	SPL 3	Unknown		*****	0.082	
5						

V. V. 16/12/2023
Analysed By
Date:

Checked By
Date: S. S. 16/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
50%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:00:09
Comments: LINEARITY 50%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

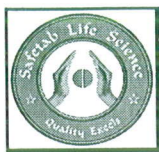
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.398	
3	SPL 2	Unknown		*****	0.399	
4	SPL 3	Unknown		*****	0.397	
5						

V.VA 16/12/2023
Analysed By
Date:

Checked By
Date:

S. S. K.
16/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
75%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:10:09
Comments: LINEARITY 75%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.607	LINEARITY 75%
3	SPL 2	Unknown		*****	0.605	LINEARITY 75%
4	SPL 3	Unknown		*****	0.608	
5						

V.V 16/12/2023

Analysed By
Date:

Checked By
Date:

S.D. 16/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
100%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:20:36
Comments: LINEARITY 100%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.804	LINEARITY 100%
3	SPL 2	Unknown		*****	0.803	LINEARITY 100%
4	SPL 3	Unknown		*****	0.802	
5						

V.VT 16/12/2023

Analysed By
Date:

Checked By
Date:

P. S. D. 16/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
125%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:23:45
Comments: LINEARITY 125%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	1.015	LINEARITY 125%
3	SPL 2	Unknown		*****	1.016	LINEARITY 125%
4	SPL 3	Unknown		*****	1.016	
5						

V.V 16/12/2023

Analysed By
Date:

Checked By
Date:

[Signature]
16/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---LINEARITY
150%.pho
Title: GLIDE M 60-500-850---AMV--METHOD
PRECISION
Analyst: VIGNESH V
Date/Time: 16-12-2023 08:28:25
Comments: LINEARITY 150%

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	1.208	LINEARITY 150%
3	SPL 2	Unknown		*****	1.209	LINEARITY 150%
4	SPL 3	Unknown		*****	1.205	
5						

V. V 16/12/2023
Analysed By
Date:

Checked By
Date:

16/12/23



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET
DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/500 & GLIDE M-60/850	Batch size :	NA
Batch Number :	G1722093, G17230801	Mfg.Date :	NA
Parameter :	SPECIFICITY	Exp.Date :	NA

Each Uncoated bilayered sustained release tablet contains
Metformin HCl BP ----- 500/850 mg
Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
----------------	--------------	--------------	--------------	---------	--------------	----------------	-------

Standard dilution :	50.15	mg to --->	100	ml to --->	5	ml to --->	250
Test.conc (in ppm)-10.03	1	ml to --->	1	ml to --->	1	ml to --->	1

Standard dilution :	42.26	mg to --->	100	ml to --->	5	ml to --->	250
Test.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

Standard dilution :	60.03	mg to --->	1000	ml to --->	2	ml to --->	100
Test.conc (in ppm)-1.2006	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No.	Sample ID.	Compound Name	Absorbance	Peak purity
1	Blank	NA	0	Not applicable
2	WS for Metformin 500 mg	Metformin	0.805	Not applicable
3	WS for Metformin 850 mg	Metformin	0.659	Not applicable
4	Blank	NA	0	Not applicable
5	WS for Gliclazide	Gliclazide	0.001	Not applicable
6	Placebo for Metformin 500mg	NA	0.002	Not applicable
7	Placebo for Metformin 850mg	NA	0.003	Not applicable
8	Placebo for Gliclazide	NA	0.001	Not applicable
9	Placebo+ Gliclazide WS	Gliclazide	0.001	Not applicable
10	Placebo+ Metformin WS 500mg	Metformin	0.801	Not applicable
11	Placebo+ Metformin WS 850mg	Metformin	0.662	Not applicable
12	Metformin 500-Test solution	Metformin	0.779	Not applicable
13	Metformin 850-Test solution	Metformin	0.658	Not applicable

Results :

1) Blank , Placebo solutions are not interfere with Metformin Hydrochloride in test preparation.

Acceptance criteria:

1) Should No significant interference from blank, placebo .

Analysed by :

VIGNESH V

Date :

28/12/2023

V.V.T
28/12/2023

Checked by :

Date :

28/12/23

* For Weight prints , Refer Glide M60/500 (Specifications)

B.NO: G1722093



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-500-850--AMV--
METHOD PRECISION--
SPECIFICITY.pho
Title: SPECIFICITY
Analyst: VIGNESH V
Date/Time: 28-12-2023 15:14:35
Comments:

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD FOR MET 500MG	Unknown		*****	0.805	
3	STD FOR MET 850MG	Unknown		*****	0.659	
4	BLANK.	Unknown		*****	0.000	
5	STD FOR GLICLACIDE	Unknown		*****	0.001	
6	PLACEBO FOR MET 500MG	Unknown		*****	0.002	
7	PLACEBO FOR MET 850MG	Unknown		*****	0.003	
8	PLACEBO FOR GLICLAZIDE	Unknown		*****	0.001	
9	PLACEBO+GLICLAZIDE STD	Unknown		*****	0.001	
10	PLACEBO+STD MET 500MG	Unknown		*****	0.801	
11	PLACEBO+STD MET 850MG	Unknown		*****	0.662	
12	DS TEST SPL FOR MET 500	Unknown		*****	0.779	
13	DS TEST SPL FOR MET 850	Unknown		*****	0.658	
14						

V-V7
Analysed By
Date: 28/12/2023

Checked By
Date: 28/12/23



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

Product Name :	GLIDE-M 60/500 & GLIDE M-60/850	Batch size :	NA
Batch Number :	G1722093, G17230801	Mfg.Date :	NA
Parameter :	ACCURACY STUDY(RECOVERY)	Exp.Date :	NA

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
Standard dilution :	42.52	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.504	1	ml to --->	1	ml to --->	1	ml to --->	1
Recovery 25% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-0.8504	2	ml to --->	200	ml to --->	1	ml to --->	1
Recovery 50% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-4.252	5	ml to --->	100	ml to --->	1	ml to --->	1
Recovery 100% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-8.504	10	ml to --->	100	ml to --->	1	ml to --->	1
Recovery 150% Dilution:	42.52	mg to --->	100	ml to --->	20	ml to --->	100
Std.conc (in ppm)-12.756	15	ml to --->	100	ml to --->	1	ml to --->	1

System suitability 1

Metformin Hydrochloride 0.802

Standard con. in ppm. 8.504

Level's	Weight taken in mg	Observed Obsorbance	Quantity added in ppm	Quantity Recovered in ppm	% Recovery
I(10%)	42.52	0.084	0.850	0.89	104.74
	42.52	0.081	0.850	0.86	101.00
	42.52	0.082	0.850	0.87	102.24
				MEAN	102.7
				%RSD	1.855
II(50%)	42.52	0.404	4.252	4.28	100.75
	42.52	0.406	4.252	4.31	101.25
	42.52	0.401	4.252	4.25	100.00
				MEAN	100.7
				%RSD	0.623
III(100%)	42.52	0.805	8.504	8.54	100.37
	42.52	0.807	8.504	8.56	100.62
	42.52	0.804	8.504	8.53	100.25
				MEAN	100.4
				%RSD	0.190
III(150%)	42.52	1.209	12.756	12.82	100.50
	42.52	1.207	12.756	12.80	100.33
	42.52	1.208	12.756	12.81	100.42
				MEAN	100.4
				%RSD	0.083

Results:

The % Recovery was complies at each levels.

Acceptance criteria:

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

CALCULATION FORMULA

Quantity added in ppm

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

Quantity recovered in ppm

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

% Recovery

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

Analysed by : VIGNESH. V

Date : 16/12/2023

V.V

16/12/2023

Checked by :

Date :

16/12/2023

* For weight prints, Refer Glide M60/500 (Recovery)
B.NO: G1722093



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
10%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 10%
Analyst: VIGNESH V
Date/Time: 16-12-2023 13:41:20

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		1.044	0.084	RECOVERY 10%
3	SPL 2	Unknown		1.011	0.081	RECOVERY 10%
4	SPL 3	Unknown		1.023	0.082	
5						

V.V. 16/12/2023

Analysed By
Date:

Checked By
Date:

V.V. 16/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
50%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 50%
Analyst: VIGNESH V
Date/Time: 16-12-2023 13:50:01

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		5.031	0.404	RECOVERY 50%
3	SPL 2	Unknown		5.060	0.406	RECOVERY 50%
4	SPL 3	Unknown		4.995	0.401	
5						

V. V. 16/12/2023

Analysed By
Date:

Checked By
Date:

V. V. 16/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
100%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 100%
Analyst: VIGNESH V
Date/Time: 16-12-2023 13:56:28

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		10.035	0.805	RECOVERY 100%
3	SPL 2	Unknown		10.061	0.807	RECOVERY 100%
4	SPL 3	Unknown		10.023	0.804	
5						

V.VT 16/12/2023

Analysed By
Date:

Checked By
Date:

V.VT 16/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\16-
12-2023\GLIDE M 60-500-850---AMV--
METHOD PRECISION---DISSOLUTION
OF METFORMIN HCL--RECOVERY
150%.pho
Title: GLIDE M 60-500-850---AMV---
RECOVERY 150%
Analyst: VIGNESH V
Date/Time: 16-12-2023 14:02:51

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Single Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Concentration: 10.000

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		10.000	0.802	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		0.005	0.000	
2	SPL 1	Unknown		15.077	1.209	RECOVERY 150%
3	SPL 2	Unknown		15.045	1.207	RECOVERY 150%
4	SPL 3	Unknown		15.066	1.208	
5						

V.V. 16/12/2023

Analysed By
Date:

Checked By
Date:

16/12/2023



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
Standard dilution :	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1
Sample dilution :	One tablet	mg to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1
Conversion factor :	1.0000						
Labelled claim :	850	mg					

Standard Absorbance

Metformin Hydrochloride 0.659

Time interval	Metformin Standard Solution Absorbance	Metformin Sample Solution Absorbance	Final time point Dissolution in %	Absolute % difference of Dissolution Sample
Initial	0.659	0.655	99.03	Not applicable
2 Hours	0.660	0.653	98.58	0.46
4 Hours	0.659	0.656	99.18	-0.15
6 Hours	0.659	0.655	99.03	0.00
16 Hours	0.657	0.655	99.33	-0.30
20 Hours	0.659	0.654	98.88	0.15
24 Hours	0.658	0.653	98.88	0.15
28 Hours	0.658	0.654	99.03	0.00
32 Hours	0.657	0.653	99.03	0.00
40 Hours	0.659	0.654	98.88	0.15
44 Hours	0.657	0.652	98.88	0.16
48 Hours	0.656	0.651	98.87	0.16
Average	0.658	0.654	99.0	0.07
% RSD	0.181	0.218	0.189	Not applicable

Results :

Standard solution and Sample solution was stable upto 48 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 :

V.VIGNESH

Date :

30/12/2023

V.V. 30/12/2023

Checked by :

Date :

A.V. 30/12/23

* For Std weight point, Refer Glide M60/850 (system suitability)

B.No: G17230801



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--INITIAL
HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 14:01:24

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	
3	SPL	Unknown		*****	0.655	
4						

V.V.A 28/12/2023
Analysed By
Date:

Checked By
Date: S.V.A 30/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--2ND HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 16:07:42
Comments: SOLUTION STABILITY--2ND HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.660	2ND HOUR
3	SPL	Unknown		*****	0.653	2ND HOUR
4						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S. V. 30/12/2023



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--4TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 18:19:54
Comments: SOLUTION STABILITY--4TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	4TH HOUR
3	SPL	Unknown		*****	0.656	4TH HOUR
4						

V. V. 28/12/2023
Analysed By
Date:

Checked By
Date:

A. V. 30/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--6TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 20:05:26
Comments: SOLUTION STABILITY--6TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	
3	SPL	Unknown		*****	0.655	
4						

V.V. 28/12/2023
Analysed By
Date:

Checked By
Date:

S.V. 30/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UVV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--16TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 06:28:12
Comments: SOLUTION STABILITY--16TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.657	16TH HOUR
3	SPL	Unknown		*****	0.655	
4						

V.VT 29/12/2023

Analysed By
Date:

Checked By
Date:

V.VT 30/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--20TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 10:17:42
Comments: SOLUTION STABILITY--20TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

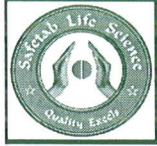
Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	20TH HOUR
3	SPL	Unknown		*****	0.654	20TH HOUR
4						

V.V.T 29/12/2023
Analysed By
Date:

Checked By
Date:

S.V.T
30/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--24TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 14:39:19
Comments: SOLUTION STABILITY--24TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.658	24TH HOUR
3	SPL	Unknown		*****	0.653	
4						

V.V. 29/12/2023

Analysed By
Date:

Checked By
Date:

V.V. 30/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--28TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 29-12-2023 18:17:55
Comments: SOLUTION STABILITY--28TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.658	28TH HOUR
3	SPL	Unknown		*****	0.654	28TH HOUR
4						

V.V. 29/12/2023

Analysed By
Date:

Checked By
Date:

S. V. 30/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\29-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--32ND HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: CHANDIRARAM P
Date/Time: 29-12-2023 22:02:24
Comments: SOLUTION STABILITY--32ND HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.657	32ND HOUR
3	SPL	Unknown		*****	0.653	32ND HOUR
4						

Analysed By
Date:

chand 29/12/2023

Checked By
Date:

S.A. 30/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
\\UV_DATA_BACKUP\2023\DEC-2023\30-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--40TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 30-12-2023 06:25:22
Comments: SOLUTION STABILITY--40TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.659	40TH HOUR
3	SPL	Unknown		*****	0.654	
4						

V.VA 30/12/2023
Analysed By
Date:

Checked By
Date:

S.V.A. 30/12/23



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\30-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--44TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 30-12-2023 10:10:47
Comments: SOLUTION STABILITY--44TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.657	
3	SPL	Unknown		*****	0.652	
4						

V.V.T
30/12/2023
Analysed By
Date:

Checked By
Date:

S.V.
30/12/23



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\30-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
SOLUTION STABILITY--48TH HOUR.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 30-12-2023 14:42:01
Comments: SOLUTION STABILITY--48TH HOUR

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	STD	Unknown		*****	0.656	48TH HOUR
3	SPL	Unknown		*****	0.651	
4						

V-VT
30/12/2023
Analysed By
Date:

Checked By
Date:

S.V.T
30/12/23



Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

DISSOLUTION OF METFORMIN IN GLICLAZIDE AND METFORMIN SUSTAINED RELEASE TABLETS

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

Each Uncoated bilayered sustained release tablet contains

Metformin HCl BP ----- 850 mg

Gliclazide BP ----- 60 mg

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/002	Balance ID :	ST/QC/EQ/041	WS No.:	WS/MEF/22/01	% Purity (aib)	100.2
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Standard Dilution :	42.26	mg to --->	100	ml to --->	2	ml to --->	100
Std.conc (in ppm)-8.452	1	ml to --->	1	ml to --->	1	ml to --->	1

Test Dilution :	One tablet	mg to --->	1000	ml to --->	1	ml to --->	100
Test.conc (in ppm)-8.5	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	850 mg

Standard Absorbance	
Metformin Hydrochloride	0.659

S.No	Sample Name	Sample Absorbance	Content in mg	Metformin Content in %	% Difference from unfiltered sample
1	Unfiltered sample (Centrifuged)	0.662	850.75	100.1	Not applicable
2	Filter Set-1 (0.45µ PVDF membrane)	0.661	849.46	99.9	0.15
3	Filter Set-2 (0.45µ PVDF membrane)	0.662	850.75	100.1	0.00
4	Filter Set-3 (0.45µ PVDF membrane)	0.659	846.89	99.6	0.46
5	Filter Set-1 (0.45µ Nylon membrane)	0.660	848.18	99.8	0.30
6	Filter Set-2 (0.45µ Nylon membrane)	0.658	845.61	99.5	0.61
7	Filter Set-3 (0.45µ Nylon membrane)	0.658	845.61	99.5	0.61
8	Filter Set-1 (Whatman filter)	0.695	893.15	105.1	-4.75
9	Filter Set-2 (Whatman filter)	0.696	894.44	105.2	-4.89
10	Filter Set-3 (Whatman filter)	0.697	895.72	105.4	-5.02

Results :

The % difference on filtered sample ((0.45µ PvdF ,0.45µ Nylon Membrane) within limit against that of unfiltered (Centrifuged)

Acceptance criteria:

The % difference on filter Solution should not differ ± 2.0 against that of unfiltered (Centrifuged)

Analysed by : V.VIGNESH

Date : 28/12/2023

Checked by :

Date :

* For Std weight print, Refer .Glide M60/850 (system Suitability)
Absorbance

B.No: G17230801



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
FILTER PAPER STUDY--PVDF
FILTER.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:35:15

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1*(Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

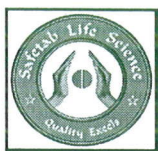
	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	CENTRIFUGE SPL	Unknown		*****	0.662	
3	SPL 1	Unknown		*****	0.661	PVDF FILTER
4	SPL 2	Unknown		*****	0.662	
5	SPL 3	Unknown		*****	0.659	
6						

V.V. 28/12/2023

Analysed By
Date:

Checked By
Date:

V.V. 28/12/2023



Safetab Life science

Software Information

Software Name: UVProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
FILTER PAPER STUDY--NYLON
FILTER.pho

Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:40:29

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.660	NYLON FILTER
3	SPL 2	Unknown		*****	0.658	NYLON FILTER
4	SPL 3	Unknown		*****	0.658	
5						

V.VT
28/12/2023
Analysed By
Date:

Checked By
Date:

V.VT
28/12/2023



Safetab Life science

Software Information

Software Name: UVPProbe
Version: 2.10
Mode: Normal Mode

Data Information

Filename: \\192.168.1.21\qc protocols\QC FILES
UV_DATA_BACKUP\2023\DEC-2023\28-
12-2023\GLIDE M60-850--G17230801--
AMV--METHOD PRECISION--
DISSOLUTION OF METFORMIN HCL--
FILTER PAPER STUDY--WHATMAN
FILTER.pho
Title: GLIDE M60-850--G17230801
Analyst: VIGNESH V
Date/Time: 28-12-2023 13:52:44

Wavelengths

Wavelength Name: WL233.0
Wavelength: 233.00 nm

Calibration Curve

Column for Cal. Curve: WL233.0
Cal. Curve Type: Multi Point
Cal. Curve Unit: mg/l
Selected Wavelength: WL233.0
Calibration Equation: $Abs = K1 * (Conc) + K0$
Zero Interception: Not Selected

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1							

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	BLANK	Unknown		*****	0.000	
2	SPL 1	Unknown		*****	0.695	WHATMAN FILTER
3	SPL 2	Unknown		*****	0.696	
4	SPL 3	Unknown		*****	0.697	
5						

V.VT 28/12/2023
Analysed By
Date:

Checked By
Date: 28/12/2023