Safetab Life Science

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Certificate of Analysis

(As per Drugs and Cosmetics Act. 1940 and the rules made there under)

Name of the product	: GLIDE-M 60/850	Date of receipt	: 09/06/2020
Batch No	: GD200604	Quantity sampled	: 100 Tablets
Batch size	: 5.0 Lac Tablets	Date of Commencement	: 09/06/2020
Date of Mfg	: JUN' 2020	Date of Completion	: 16/06/2020
Date of Exp	: MAY' 2023	A.R. Number	: SFP/F/00518/2020
Condition	: Finished product	Date of Report	: 16/06/2020

S.No:	Test	Specification	Results
1	Description	White and reddish coloured, bilayered convex, uncoated tablet with break line on reddish layer and plain on white layer.	White and reddish coloured, bilayered convex, uncoated tablet with break line on reddish layer and plain on white layer.
2	Identification a) Gliclazide BP (By HPLC)	The retention time of the one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Gliclazide in the standard preparation as obtained in the assay.	Complies
	b) Metformin Hcl BP (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Metformin Hcl in the standard preparation as obtained in assay.	Complies
3	Average weight of tablet	1360.0 mg ± 5 % (1292.0 mg to 1428.0 mg)	1362.5mg
4	Uniformity of Weight	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.	(-) 1.01% (+) 1.90%
5	Dimension:		
	Length	22.00 mm ± 0.2 mm (20.0mm – 24.0mm)	22.10mm
	Width	9.50 mm ± 0.2 mm (9.30mm – 9.70mm)	9.54mm
6	Thickness	7.10 mm ± 0.30 mm (6.80mm - 7.40mm)	7.00mm
7	Hardness	250-350N	316.26 N
8	Friability	Not more than 1.0%	0.15%
9	**Dissolution:** (i) Gliclazide BP	2nd Hour NMT 25.0% 5th Hour 30.0 – 60.0% 12th Hour NLT 70.0%	Min: 18.1%, Max: 23.3%, Avg: 20.7% Min: 43.6%, Max: 52.8%, Avg: 48.1% Min: 80.4%, Max: 89.2%, Avg: 85.3%
	(ii) Metformin Hcl BP	1st Hour 20.0 – 40.0% 3rd Hour 45.0 – 65.0% 10th Hour NLT 85.0%	Min: 25.1%, Max: 26.1%, Avg: 25.7% Min: 48.7% Max: 49.9%, Avg: 49.6% Min: 98.4%, Max: 102.5%, Avg: 100.1%
10	**Assay: Each uncoated bilayered sustained release tablet contains:**		
	Gliclazide BP 60mg	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg	58.02mg (96.7%)
	Metformin Hydrochloride BP 850mg	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg	836.89mg (98.5%)
11	**Microbial contamination:**		
	i)Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Pseudomonas aeruginosa iii) Salmonella Species iv) Esherichia Coli v) Staphylococcus aureus	 Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent Should be absent Should be absent Should be absent	 40cfu/g Found absent Found absent Found absent Found absent Found absent

In this opinion of the undersigned the sample refered to above is of standard Quality / ~~is not of standard Quality~~ as defined in the Act and the Rules made thereunder for the reason given below:

Observation : The Product complies as per Inhouse Specification with respect to above test.

Note: For Microbiological Parameters test refer Ideal Lab Report No: AR/20/06/11/003

Prepared by	Checked by	Approved by
16/06/2020	16/06/2020	16/06/20
Executive-QC	Assistant Manager-QC	AGM-QC

	Safetab Life Science Puducherry RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850
(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Finished product

Specification No	ROA No	Revision No.	Effective date	Page No:
FGSTSG033-00	ROA/ FGTSG033-00	00	04-06-2020	1 of 3

Batch No.	GD2000604	Sample Quantity	4 Strips
Batch Size	5.01ac	Sampled By /Date	Vinothini/10/06/2020
Mfg. Date	June-2020	Test started on	10/06/2020
Exp. Date	May-2023	Test completed on	16/06/2020
Stage	Finished product	A.R.No	FGF/00425/2020

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
1.0	Description	White and reddish coloured, bilayered convex uncoated tablet with break line on reddish layer and plain on white layer.	White and reddish coloured, bilayered convex, uncoated tablet with break line on reddish layer and plain on white layer.
2.0	***Identification** a) Gliclazide BP (By HPLC)	complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Gliclazide in standard preparation as obtained in assay.
	b) Metformin Hydrochloride BP (By HPLC)	complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Metformin Hydrochloride in standard preparation as obtained in assay.
3.0	Average weight of tablet	1362.4mg	1360.0 mg ± 5 % (1292.0 mg to 1428.0 mg)
4.0	Uniformity of weight	Min (-) : 0.79 %. Max (+) : 1.49 %.	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.

Remarks: The product Complies / ~~Doesn't comply as per~~ IP Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: R.Vinothini Date: 16/06/2020	Sign: Date: 16/06/2020	Sign: Date: 16/06/20

MASTER COPY APPROVAL:	USAGE COPY APPROVAL:
Sign: Date: 02/06/2020	Sign: Date: 05/06/20

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PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
5.0	***Dimension:**		
	Length	22.10 mm	22.00 mm ± 0.2 mm (20.0mm – 24.0mm)
	Width	9.54 mm	9.50 mm ± 0.2 mm (9.30mm – 9.70mm)
6.0	*Thickness	7.00 mm	7.10 mm ± 0.30 mm (6.80mm - 7.40mm)
7.0	*Hardness	316.26 N	250-350N
8.0	Friability	0.17 %	Not more than 1.0%
9.0	***Dissolution** **a) Gliclazide BP** Apparatus II – Paddle with sinker, Medium-900ml, Phosphate buffer pH – 7.4, RPM-100. **b) Metformin Hydrochloride BP** Apparatus II – Paddle with sinker, Medium-1000ml, Phosphate buffer pH-6.8, RPM-100.	Min: Max: Avg: 18.1%, 23.3%, 20.7% 43.6%, 52.8%, 48.1% 80.4%, 89.2%, 85.3% 25.1%, 26.1%, 25.7% 48.7%, 49.9%, 49.6% 98.4%, 102.5%, 100.1%	**a) Gliclazide BP** Time interval / Limit 2nd Hour / NMT 25.0% 5th Hour / Between 30 – 60% 12th Hour / NLT 70% **b) Metformin Hydrochloride BP** Time interval / Limit 1st Hour / Between 20 – 40% 3rd Hour / Between 45 – 65% 10th Hour / NLT 85%

Remarks: The product ~~Complies~~ / ~~Doesn't comply~~ as per IH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: R.Dev Date: 16/06/2020	Sign: Date: 16/06/2020	Sign: Date: 16/6/20

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850
(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Finished product

Specification No	ROA No	Revision No.	Effective date	Page No:
FGSTSG033-00	ROA/ FGTSG033-00	00	04-06-2020	3 of 3

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
10.0	***Assay: Each Uncoated bilayered sustained release tablet contains:**		
	Gliclazide BP 60mg	58.02 mg (96.7 %)	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg
	Metformin Hydrochloride BP 850mg	836.89 mg (98.5 %)	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg
11.0	**Microbial Contamination**		
	i)Total Viable aerobic count		
	a) Total aerobic microbial count	40 cfu/g	Not more than 1000 cfu/g
	b) Total yeast and mould count	Absent	Not more than 100 cfu/g
	ii) Pseudomonas aeruginosa	Absent	Should be absent/g
	iii) Salmonella Species	Absent	Should be absent/10g
	iv) Esherichia Coli	Absent	Should be absent/g
	v) Staphylococcus aureus	Absent	Should be absent/g

Remarks: The product ~~Complies~~ / ~~Doesn't comply~~ as per IH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: R.Dooy	Sign:	Sign:
Date: 16/06/2020	Date: 16/06/2020	Date: 16/6/20

Remarks: The above * marked test results shall be documented as based on Compressed stage report

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Finished product

Batch No/Lot No.	GD200604	A.R.No.	FGF/00425/2020.	
STP No	ROA No	Revision No.	Effective date	Page No:
FGTTSG033-00	ROA/ FGTSG033-00	00	04-06-2020	1 of 5

S.No	TEST / OBSERVATION / LIMIT
1.0	**Description:** White and reddish coloured, bilayered convex, uncoated tablet with break line on reddish layer and plain on white layer. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** R.P.S **Date :** 16/06/2020.
2.0	**Identification:** **Refer:** Compressed tablet report.
3.0	**Average weight:** **Balance ID: ST/QC/EQ/** 030 **Calibration due date:** 04/07/2020.

Number of tablets	Total weight (g)	Average weight of a tablet(g)	Limit (g)
20	27.2486	1.3624	1.2920 – 1.4280

Observation: Conforms: ☑ Does not conform: ☐

Analyst: R.P.S **Date:** 16/06/2020.

4.0	**Uniformity of weight:** **Balance ID: ST/QC/EQ/** 030 **Calibration due date:** 04/07/2020

Checked by : Date : 16/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

Format No: ST/QC/058(R1):A1

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Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Finished product

Batch No/Lot No.	GTD200604	A.R.No.	FQF/100425/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
FGTTSG033-00	ROA/ FGTSG033-00	00	04-06-2020	2 of 5

S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)
1	1.3737	6	1.3604	11	1.3802	16	1.3493
2	1.3513	7	1.3622	12	1.3716	17	1.3582
3	1.3572	8	1.3508	13	1.3695	18	1.3580
4	1.3584	9	1.3612	14	1.3681	19	1.3676
5	1.3569	10	1.3658	15	1.3534	20	1.3754.

Deviation (Mini): { Lowest weight X100} -100
Average weight

$= \{\frac{1.3493}{1.360} \times 100\} - 100$

$= -0.79\ \%$

Deviation (Max): { Highest weight X100} -100
Average weight

$= \{\frac{1.3802}{1.360} \times 100\} - 100$

$= +1.49\ \%$

Limit: Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.

Observation: Conforms: ☒ Does not conform: ☐

Analyst: B.Dey **Date:** 16/06/2020.

5.0 Dimension:

Length:

Refer: Compressed tablet report.

Width:

Refer: Compressed tablet report.

6.0 Thickness:

Refer: Compressed tablet report.

Checked by : Date : 16/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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7.0 Hardness:

Refer: Compressed tablet report.

8.0 Friability:

Balance ID: ST/QC/EQ/ 080	**Calibration due date:** 04/07/2020
Friability ID: ST/QC/EQ/ 010	**Calibration due date:** 07/07/2020.

Weigh 10 tablets and note down the mass in gram up to four decimals (a). Placed weighed tablets in friability test apparatus and operate the friability test apparatus for 100 rotations. After completion of the test collect the tablets from sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in gram up to four decimals (b).

Initial weight (Before friability)	Final weight (After friability)
13.6010	13.5782

$$\% \text{ of Friability} = \frac{13.6010 - 13.5782}{13.6010} \times 100 = \frac{0.17}{\cancel{0.18}}\ \%$$

R.D09 16/06/20

Result: 0.17%.	**Limit:** Not more than 1.0% w/w
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: R.D09	**Date:** 16/06/2020

9.0 Dissolution:

Refer: Compressed tablet report.

10.0 Assay:

Refer: Compressed tablet report.

Checked by : Date : 16/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Finished product

Batch No/Lot No.	GD200604	A.R.No.	FGF/10042 5/2020	
STP No	ROA No	Revision No.	Effective date	Page No:
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11.0 Microbial contamination:

a. Total aerobic microbial count:

Procedure: Proceed as per the current General Analytical Method GAM-035.

b. Total Moulds and yeast count:

Procedure: Proceed as per the current General Analytical Method GAM-036.

Pathogens:

C. Esherichia Coli:

Procedure: Proceed as per the current General Analytical Method GAM-037.

d. Salmonella Species:

Procedure: Proceed as per the current General Analytical Method GAM-038.

e. Pseudomonas aeruginosa:

Procedure: Proceed as per the current General Analytical Method GAM-039.

f. Staphylococcus aureus:

Procedure: Proceed as per the current General Analytical Method GAM-040.

Result:		**Limit:**
i)Total Viable aerobic count:		i)Total Viable aerobic count:
a) Total aerobic microbial count:	40 cfu/g	a) Total aerobic microbial count: Not more than 1000 cfu/g
b) Total yeast and mould count:	Absent	b) Total yeast and mould count: Not more than 100 cfu/g
ii) Pseudomonas aeruginosa:	Absent	ii) Pseudomonas aeruginosa: Should be absent/g
iii) Salmonella Species:	Absent	iii) Salmonella Species: Should be absent/10g
iv) Esherichia Coli:	Absent	iv) Esherichia Coli: Should be absent/g
v) Staphylococcus aureus:	Absent	v) Staphylococcus aureus: Should be absent/g

Note: For Microbiological Parameters test refer Commercial Lab Report No: AR/20/06/11/003

Observation: Conforms: ☑ Does not conform: ☐

Analyst: Ideal Lab **Date:** 16/06/2020

Checked by: Date: 16/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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12.0 ANALYTICAL REPORT VERIFICATION CHECK LIST:

Check the following details and enclosures in the report. If the details are available then put '✓' mark on the remarks column and put '×' mark if the details are not available

S.No:	DETAILS	Remarks:
1	TRF is enclosed with the protocol	☒
2	Product name, B.No, Mfg date, Exp date, A.R.No matches with TRF	☒
3	All the tests are performed as per standard specification	☑
4	All the sheets are page numbered, signed and dated by analyst	☑
5	The protocol is duly filled, no blank place, calculations and entries are ok	☑
6	The printouts of UV-VIS spectrophotometer readings are enclosed	☒
7	The spectrum of IR spectrophotometer is enclosed	☒
8	All HPLC chromatograms are enclosed	☑
9	Other instruments sheets (if applicable, then specify in comments column)	☑
10	Public laboratory reports (if applicable, then specify the reasons below)	☑
11	Comments (if any): weigh balance printout sheet is enclosed "×" mark is not applicable for this product	

Remarks: The report is found to be satisfactory ☑ / not satisfactory ☐

Verifying authority (Sign & date): _____ 16/06/2020

Checked by : _____ Date : 16/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850
(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Specification No	ROA No	Revision No.	Effective date	Page No:
IMSG00130-00	ROA/ IMG00130-00	00	04-06-2020	1 of 3

Batch No.	GD200604	Sample Quantity	100 Tablets
Batch Size	5.0 Lac Tablets	Sampled By /Date	Mani, 09/06/2020
Mfg. Date	June-2020	Test started on	09/06/2020
Exp. Date	May-2023	Test completed on	10/06/2020 MLT 16/06/2020
Stage	Compressed Tablets	A.R.No	SFP/F/00578/2020

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
1.0	Description	White and reddish coloured bilayered convex, uncoated tablet with break line on reddish layer and Plain on white layer	White and reddish coloured, bilayered convex, uncoated tablet with break line on reddish layer and plain on white layer.
2.0	**Identification** a) Gliclazide BP (By HPLC)	Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Gliclazide in standard preparation as obtained in assay.
	b) Metformin Hydrochloride BP (By HPLC)	Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Metformin Hydrochloride in standard preparation as obtained in assay.
3.0	Average weight of tablet	1362.5mg	1360.0 mg ± 5 % (1292.0 mg to 1428.0 mg)
4.0	Uniformity of weight	-1.01% +1.90%	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.

Remarks: The product Complies / ~~Doesn't~~ comply as per IP Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: Date: 10/06/2020	Sign: Date: 11/06/2020	Sign: Date: 11/06/20

MASTER COPY APPROVAL:		USAGE COPY APPROVAL:	
Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850
(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Specification No	ROA No	Revision No.	Effective date	Page No:
IMSG00130-00	ROA/ IMG00130-00	00	04-06-2020	2 of 3

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
5.0	**Dimension:**		
	Length	22.10mm	22.00 mm ± 0.2 mm (20.0mm – 24.0mm)
	Width	9.54mm	9.50 mm ± 0.2 mm (9.30mm – 9.70mm)
6.0	Thickness	7.00 mm	7.10 mm ± 0.30 mm (6.80mm - 7.40mm)
7.0	Hardness	316.26N	250-350N
8.0	Friability	0.15%	Not more than 1.0%
9.0	**Dissolution**	Min: Max: Avg:	
	a) Gliclazide BP Apparatus II – Paddle with sinker, Medium-900ml, Phosphate buffer pH - 7.4, RPM-100.	18.1% 23.3% 20.7% 43.6% 52.8% 48.1% 80.4% 89.2% 85.3%	
	b) Metformin Hydrochloride BP Apparatus II – Paddle with sinker, Medium-1000ml, Phosphate buffer pH-6.8, RPM-100.	25.1% 26.7% 25.7% 48.7% 49.9% 49.6% 98.4% 102.5% 100.1%	

Time interval	Limit
2nd Hour	NMT 25%
5th Hour	Between 30 – 60%
12th Hour	NLT 70%

Time interval	Limit
1st Hour	Between 20 – 40%
3rd Hour	Between 45 – 65%
10th Hour	NLT 85%

Remarks: The product Complies / Doesn't comply as per IH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: Date: 10/06/2020	Sign: Date: 11/06/2020	Sign: Date: 11/6/20

MASTER COPY APPROVAL:		USAGE COPY APPROVAL:	
Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850
(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Specification No	ROA No	Revision No.	Effective date	Page No:
IMSG00130-00	ROA/ IMG00130-00	00	04-06-2020	3 of 3

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
10.0	**Assay: Each Uncoated bilayered sustained release tablet contains:**		
	Gliclazide BP 60mg	58.02mg (96.7%)	90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg
	Metformin Hydrochloride BP 850mg	836.89mg (98.5%)	90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg

Remarks: The product Complies / Does~~n't comply~~ as per IH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: 10/06/2020 Date:	Sign: Date: 11/06/2020	Sign: Date: 11/06/20

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Batch No/Lot No.	GD 200604	A.R.No.	SFP/F /00518 /2020	
STP No	ROA No	Revision No.	Effective date	Page No:
IMTG00130-00	ROA/ IMG00130-00	00	04-06-2020	1 of 19

S.No	TEST / OBSERVATION / LIMIT
1.0	**Description:** White and reddish coloured, bilayered convex, uncoated tablet with break line on reddish layer and plain on white layer. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** R.Dev **Date :** 10/06/2020.
2.0	**Identification:** **a) Gliclazide:** The RT of Gliclazide peak in standard 17.220 min, the RT of principal peak in assay 17.215 min. **b) Metformin Hydrochloride:** The RT of Metformin Hydrochloride peak in standard 1.982 min, the RT of principal peak in assay 1.983 min. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** **Date:** 10.06.2020
3.0	**Average weight of tablet:** **Balance ID: ST/QC/EQ/** 030 **Calibration due date:** 04/07/2020. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** R.Dev **Date:** 10/06/2020.

Number of tablets	Total weight (g)	Average weight of a tablet(g)	Limit (g)
20	27.2499	1.3625	1.2920-1.4280

Checked by : Date : 11/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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4.0 Uniformity of weight:

Balance ID: ST/QC/EQ/ 030 | Calibration due date: 04/07/2020

S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)
1	1.3588	6	1.3578	11	1.3754	16	1.3617
2	1.3712	7	1.3709	12	1.3569	17	1.3591
3	1.3674	8	1.3539	13	1.3618	18	1.3649
4	1.3550	9	1.3727	14	1.3656	19	1.3522
5	1.3589	10	1.3537	15	1.3462	20	1.3858

Deviation (Mini): { Lowest weight X100} -100 / Average weight

$= \{ \frac{1.3462}{1.360} \times 100 \} - 100$

$= -1.01\ \%$

Deviation (Max): { Highest weight X100} -100 / Average weight

$= \{ \frac{1.3858}{1.360} \times 100 \} - 100$

$= +1.90\ \%$

Limit: Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.

Observation: Conforms ☑ Does not conform: ☐

Analyst: [signature] | **Date:** 10/06/2020

5.0 Dimension: (Length)

Vernier caliper ID: ST/QC/EQ/ 008 | Calibration due date: 11/02/2021

1. 22.06	2. 22.15	3. 22.11	4. 22.05	5. 22.10
6. 22.14	7. 22.07	8. 22.08	9. 22.09	10. 22.13

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	Result: 22.10 mm	**Limit:** 22.00 mm ± 0.2 mm (20.0mm – 24.0mm)
	Observation: Conforms: ☑ Does not conform: ☐	
	Analyst: R.Dey	**Date:** 10/06/2020

Width:

Vernier caliper ID: ST/QC/EQ/ 008	**Calibration due date:** 11/02/2021

1. 9.55	2. 9.54	3. 9.55	4. 9.54	5. 9.54
6. 9.54	7. 9.55	8. 9.54	9. 9.54	10. 9.54

Result: 9.54 mm	**Limit:** 9.50 mm ± 0.2 mm (9.30mm – 9.70mm)
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: R.Dey	**Date:** 10/06/2020

6.0 Thickness:

Vernier caliper ID: ST/QC/EQ/ 008	**Calibration due date:** 11/02/2021

1. 7.02	2. 7.00	3. 7.00	4. 6.97	5. 6.99
6. 7.02	7. 6.97	8. 7.00	9. 7.02	10. 7.01

Result: 7.00 mm.	**Limit:** 7.10 mm ± 0.30 mm (6.80mm - 7.40mm)
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: R.Dey	**Date:** 10/06/2020

7.0 Hardness:

Hardness Test ID: ST/QC/EQ/ 035	**Calibration due date:** 07/10/2020

1. 305.55	2. 299.56	3. 330.00	4. 310.03	5. 322.67
6. 317.77	7. 313.52	8. 309.40	9. 340.47	10. 313.65

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	Result: 316.26 N	**Limit:** 250-350N
	Observation: Conforms: ☐ ✓ Does not conform: ☐	
	Analyst: R.Devi	**Date:** 10/06/2020.

8.0 Friability:

Balance ID: ST/QC/EQ/ 030	**Calibration due date:** 04/07/2020
Friability ID: ST/QC/EQ/ 010	**Calibration due date:** 07/07/2020

Weigh 10 tablets and note down the mass in gram up to four decimals (a). Placed weighed tablets in friability test apparatus and operate the friability test apparatus for 100 rotations. After completion of the test collect the tablets from sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in gram up to four decimals (b).

Initial weight (Before friability)	Final weight (After friability)
13.6219	13.6019

$$\% \text{ of Friability} = \frac{13.6219 - 13.6019}{13.6219} \times 100 = 0.15\%$$

Result: 0.15%.	**Limit:** Not more than 1.0%
Observation: Conforms: ☑ ✓ Does not conform: ☐	
Analyst: R.Devi	**Date:** 10/06/2020.

9.0 DISSOLUTION:

Balance ID: ST/QC/EQ/ 041		**Calibration due date:**	04/07/2020
HPLC ID : ST/QC/EQ/ 039		**Calibration due date:**	26/07/2020
Dissolution apparatus ID: ST/QC/EQ/ 027		**Calibration due date:**	08/07/2020
pH meter ID: ST/QC/EQ/ 016		**Calibration due date:**	11/06/2020

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Column ID : QC/CL/ 20/0/14

a) Gliclazide:

Reference: In House

Procedure: By HPLC

Chemicals/Reagents/Standards:

Gliclazide	:	Working standard
Potassium Di-hydrogen orthophosphate	:	AR grade
Dipotassium hydrogen orthophosphate	:	AR grade
Disodium hydrogen orthophosphate	:	AR grade
Orthophosphoric acid	:	AR grade
Methanol	:	HPLC grade
Water	:	Purified
Sodium Hydroxide	:	AR grade
Sodium Chloride	:	AR grade
Acetonitrile	:	HPLC grade

Dissolution parameters:

Apparatus	:	USP Apparatus II (Paddle) with sinker
Volume	:	900 mL
Dissolution medium	:	Phosphate buffer pH 7.4
Speed	:	100 rpm
Temperature	:	37.0±0.5°C
Time	:	2nd, 5th and 12th Hours

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Chromatographic Conditions:

Column	:	Kromasil 100-C18, 250 mm X 4.6 mm, 5µm (or) equivalent
Wave length	:	228 nm
Column Temperature	:	Ambient
Flow Rate	:	1.0 mL/min
Injection Volume	:	20 µL
Run time	:	10 Minutes

Buffer Preparation:

Weigh accurately about 2.96gm of Potassium dihydrogen orthophosphate and 0.54gm of Dipotassium hydrogen orthophosphate in 1000 ml glass beaker. Add about 500 ml of water, shake and sonicate to dissolve completely and finally make the solution 1000 ml with water.

Preparation of Mobile phase:

Mix 550 ml of buffer solution and 450 ml Acetonitrile, adjust the pH 6.85±0.05 using Orthophosphoric acid. Filter through 0.20micron membrane filter, sonicate and degas.

Preparation of Phosphate buffer (pH = 7.4): (Dissolution medium)

Weigh accurately about 23.8 gm of disodium hydrogen orthophosphate, 1.9 gm of Potassium dihydrogen orthophosphate and 80 gm of Sodium Chloride in 500ml with water, shake and sonicate to dissolve completely and finally make the solution to 10 liters of water. Adjust pH to 7.4 using 0.5 M Sodium Hydroxide solution.

Preparation of Standard solution:

Weigh accurately and transfer about 66.0 (66 mg) of Gliclazide working standard (W.S.No. / Valid upto WS/GLIDPIA/19/20/03/2020) into 100 (100ml) volumetric flask. Add about 5 ml of Methanol, sonicate 10 minutes to dissolve and dilute up to mark with dissolution medium and mix. Further dilute 5 (5 ml) of this solution to 50 (50 ml) with dissolution medium and mix well.

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Preparation of Sample solution:

Place the stated volume of dissolution medium of each vessels of the dissolution apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to each vessel. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw 10 ml of aliquot from each specimen. Filter sufficient quantity of this solution through 0.45micron, PVDF syringe filter.

(After withdrawing aliquot at each interval, then add same volume of dissolution medium to maintain 900 ml volume in dissolution vessel)

(Aliquot withdrawal position: - from the mid-way zone between the top surface of dissolution medium and top of rotating paddle and 1 cm away from vessel wall.)

Procedure:

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject equal volumes (20 µl) of solutions as per Sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the System suitability requirements.

Injection sequence:

S. No	Sample Name	No. of injections
1	Blank (Dissolution medium)	1
2	Standard solution	5
3	Sample solution	6
4	Bracketing standard	1 Each after every 6 sample injection

System suitability:

1) The tailing factor for the peak of Gliclazide obtained with standard solution should not more than 2.0.

2) The column efficiency for the peak of Gliclazide obtained in the chromatogram of Standard solution should not less than 2000.

3) The % RSD for the retention time of Gliclazide peak obtained with the replicate injections of standard solution should not more than 1.00

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4) The % RSD for the peak area response of Gliclazide peak obtained with the replicate injections of standard solution should not more than 2.00

5) The % RSD for the retention time of Gliclazide peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 1.00

6) The % RSD for the peak area response of Gliclazide peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00

Calculations:

Calculate % drug release of Gliclazide as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{50} \times \frac{900}{1} \times \frac{P}{100} \times \frac{100}{LC} + D$$

Where,

AT	=	Peak area response of Gliclazide peak obtained with sample solution.
AS	=	Average peak area response of Gliclazide peak obtained with replicate injections of standard solution
WS	=	Weight of Gliclazide working standard in mg.
P	=	Potency of Gliclazide working standard in % on as such basis.
LC	=	Label claim of Gliclazide in mg/tablet.
D	=	Sum of correction factor for all previous time points.

Calculation for correction factor:

Calculate the correction factor (CFn) at each time point by using the following formula.

$$CFn = \frac{Dn}{1000} X10$$

Where,

Dn = % Labeled amount of Gliclazide Dissolved at respective time point.

Calculation for corrected results:

For 2nd Hour = D2
For 5th Hour = D5+CF1
For 12th Hour = D12+CF2+CF1

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Limit: 2nd Hour: NMT 25.0%, 5th Hour: Between 30 – 60%, 12th Hour: NLT 70%

Result: HPLC Graph and validated XL sheet attached.

Observation: Conforms: ☑ Does not conform: ☐

Analyst: [signature] **Date:** 10/06/2020

DISSOLUTION:

Balance ID: ST/QC/EQ/ 041	**Calibration due date:** 04/07/2020.
UV ID : ST/QC/EQ/ 002	**Calibration due date:** 11/06/2020.
Dissolution apparatus ID: ST/QC/EQ/ 037	**Calibration due date:** 17/11/2020

b) Metformin Hydrochloride:

Reference: In House

Procedure: By UV

Chemicals/Reagents/Standards:

Metformin Hydrochloride	:	Working standard
Monobasic potassium phosphate	:	AR grade
Sodium Hydroxide	:	AR grade
Water	:	Purified

Dissolution parameters:

Apparatus	:	USP Apparatus II (Paddle) with sinker
Volume	:	1000 mL
Dissolution medium	:	Phosphate buffer pH 6.8
Speed	:	100 rpm
Temperature	:	37.0±0.5°C
Time	:	1st, 3rd and 10th Hours

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Preparation of Phosphate buffer (pH 6.8):

Weigh accurately about 68 gm of Monobasic potassium phosphate in 500ml with water, shake and sonicate to dissolve completely and finally make the solution to 10 liters of water. Adjust pH to 6.8±0.05 using 0.2 N sodium hydroxide solution.

Preparation of Standard solution:

Weigh accurately and transfer about 42.56 (42.5 mg) of Metformin Hydrochloride Working standard (W.S.No. / Valid upto NS/MET/RP/20/01 / 28/06/2021) into 100 (100ml) volumetric flask. Add about 30 ml of dissolution medium, sonicate to dissolve and dilute up to mark with dissolution medium and mix. Further dilute 5 (5ml) of this solution to 250 (250 ml) with dissolution medium and mix.

Preparation of Sample solution:

Place the stated volume of dissolution medium of each vessels of the dissolution apparatus. Warm the dissolution medium at 37°C ± 0.5°C. Transfer 1 tablet in to each vessel. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw 10 ml of aliquot from each specimen. Filter sufficient quantity of this solution through 0.45micron, PVDF syringe filter.

Further dilute 1 (1ml) of this filtrate to 100 (100 ml) with dissolution medium and Mix.

(After withdrawing aliquot at each interval, then add same volume of dissolution medium to maintain 1000 ml volume in dissolution vessel)

(Aliquot withdrawal position: - from the mid-way zone between the top surface of dissolution medium and top of rotating paddle and 1 cm away from vessel wall.)

Procedure:

Measure the absorbance of resulting Standard solution (5 replicates) and sample solution at 233 nm and calculate % dissolution.

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Calculation:

Calculate the % drug release of Metformin hydrochloride as follows:

$$= \frac{TAB}{SAB} \times \frac{WT}{100} \times \frac{5}{250} \times \frac{1000}{1} \times \frac{100}{1} \times \frac{P}{100} \times \frac{100}{LC} + D$$

Where,

TAB	=	Absorbance of Metformin Hydrochloride in sample solution.
SAB	=	Absorbance of Metformin Hydrochloride in Standard solution.
WT	=	Weight of Metformin Hydrochloride working standard in mg.
P	=	Potency of Metformin Hydrochloride working standard (% on as such basis).
LC	=	Label claim of Metformin Hydrochloride in mg.
D	=	Sum of correction factor for all previous time points.

Calculation for correction factor:

Calculate the correction factor (CFn) at each time point by using the following formula.

$$CFn = \frac{Dn}{1000} X10$$

Where,

Dn = % Labeled amount of Metformin Hydrochloride Dissolved at respective time point.

Calculation for corrected results:

For 1st Hour = D1
For 3rd Hour = D3+CF1
For 10th Hour = D10+CF2+CF1

Limit: 1st Hour: Between 20 – 40%, 3rd Hour: Between 45 – 65%, 10th Hour: NLT 85%

Result: UV Graph and validated XL sheet attached.

Observation: Conforms: ☑ Does not conform: ☐

Analyst: [signature] **Date:** 10/06/2020

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10.0 Assay :

Balance ID: ST/QC/EQ/ 041	**Calibration due date:** 04/07/2020
HPLC ID : ST/QC/EQ/ 039	**Calibration due date:** 26/07/2020
pH meter ID: ST/QC/EQ/ 036	**Calibration due date:** 11/06/2020

Column ID : QC/CL/ 20/H

Reference: In-House

Procedure: By HPLC

Chemicals/Reagents/Standards:

Metformin Hydrochloride	:	Working standard
Gliclazide	:	Working standard
potassium dihydrogen orthophosphate	:	AR grade
Dipotassium hydrogen orthophosphate	:	AR grade
Acetonitrile	:	HPLC grade
Orthophosphoric acid	:	AR grade
Purified water	:	Milli-Q water (or) equivalent

Chromatographic Conditions:

Column	:	Kromasil 100-C18 ,250 mm X 4.6 mm, 5µm (or) equivalent
Wave length	:	265 nm
Column Temperature	:	Ambient
Flow Rate	:	1.0 mL/min
Injection Volume	:	20 µL
Run times	:	25 minutes

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Buffer Preparation:

Weigh accurately about 2.96 gm of potassium dihydrogen orthophosphate and 0.54gm of dipotassium hydrogen orthophosphate in 1000 ml glass beaker. Add about 500 ml of water, shake and sonicate to dissolve completely and finally make the solution 1000 ml with water.

Preparation of Mobile phase:

Mix 550 ml of buffer solution and 450 ml Acetonitrile, adjust the pH 3.0 using Orthophosphoric acid. Filter through 0.20micron membrane filter, sonicate and degas.

Preparation of Standard solution:

Weigh accurately and transfer about 60.15 (60mg) of Gliclazide working standard (W.S.No. / Valid upto WS-GLD014/19 / 20/09/2020) and 850.12 (850mg) of Metformin Hydrochloride working standard (W.S.No. / Valid upto WS/MEF/Dp/20/01/ 28/06/2021) into 100 (100ml) volumetric flask. Add about 50 ml of Mobile phase, sonicate to dissolve and dilute up to mark with Mobile phase and mix. Further dilute 5 (5 ml) of this solution to 25 (25 ml) with mobile phase and mix well.

Preparation of sample powder:

Weigh accurately 20 tablets and make the powder by using mortar and pestle. Use the same for preparation of sample solution. Calculate the average weight by taking weight of 20 tablets taken above and use the same for calculation.

Preparation of Sample solution:

Weigh accurately about 1.3600 (1.360g) of sample powder (eq. to 60mg of gliclazide) into 100 (100 ml) clean and dry volumetric flask. Add about few ml of mobile phase to disperse the sample then add 50ml of mobile phase, sonicate for 20 Minute with intermediate shaking to dissolve, cool and dilute up to the mark with mobile phase and mix. Filter sufficient amount of this solution through 0.45micron syringe filter. Further dilute 5 (5ml) of filtered solution to 25 (25 ml) with mobile phase and mix.

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Procedure:

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject equal volumes (20 µl) of solutions as per Sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the System suitability requirements.

Injection sequence:

S. No	Sample Name	No. of injections
1	Mobile phase (blank)	1
2	Standard solution	5
3	Sample solution	2
4	Bracketing standard	1 Each after every 6 sample injection

System suitability:

1) The tailing factor for the peak of Metformin Hydrochloride and Gliclazide obtained with standard solution should not more than 2.0.

2) The column efficiency for the peak of Metformin Hydrochloride and Gliclazide obtained in the chromatogram of Standard solution should not less than 2000.

3) The % RSD for the retention time of Metformin Hydrochloride and Gliclazide peak obtained with the replicate injections of standard solution should not more than 1.00

4) The % RSD for the peak area response of Metformin Hydrochloride and Gliclazide peak obtained with the replicate injections of standard solution should not more than 2.00

5) The % RSD for the retention time of Metformin Hydrochloride and Gliclazide peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 1.00

6) The % RSD for the peak area response of Metformin Hydrochloride and Gliclazide peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00

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Calculations:

Calculate the assay of Gliclazide in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{25} \times \frac{100}{WT} \times \frac{25}{5} \times \frac{P}{100} \times AW$$

Where,

AT = Average area of peak due to Gliclazide in sample solution.

AS = Average area of peak due to Gliclazide in standard solution.

WS = Weight of Gliclazide working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Gliclazide working standard in % on as such basis.

Calculate the assay of Gliclazide in % as follows:

$$= \frac{\text{mg/tablet}}{LC} \times 100$$

LC = Label claim of Gliclazide in mg/tablet.

System suitability:

Theoretical Plates : 20488 (Not less than 2000)

Tailing factor : 0.987 (Not more than 2.0)

Relative standard deviation : 0.097 (Not more than 2.0%)

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	Safetab Life Science Puducherry RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Batch No/Lot No.	GTD2000604	A.R.No.	SFP/F/00518/2020	
STP No	ROA No	Revision No.	Effective date	Page No:
IMTG00130-00	ROA/ IMG00130-00	00	04-06-2020	16 of 19

Standard and Sample Chromatogram value :

Average peak area of Gliclazide standard preparation: 259885

Area for sample solution:

1. 251483, 2. 250733 Avg.area 251108

Calculate the assay of Gliclazide in mg/tablet as follows :

$$\frac{251108}{259885} \times \frac{60.15}{100} \times \frac{5}{25} \times \frac{100}{1860.01} \times \frac{25}{5} \times \frac{99.65}{100} \times \frac{1860.5}{} = 58.02 \text{ mg}$$

Calculate the assay of Gliclazide in % as follows:

$$= \frac{58.02}{60} \times 100 = 96.7\%$$

Calculate the assay of Metformin Hydrochloride in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{25} \times \frac{100}{WT} \times \frac{25}{5} \times \frac{P}{100} \times AW$$

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Where,

AT = Average area of peak due to Metformin Hydrochloride in sample solution.

AS = Average area of peak due to Metformin Hydrochloride in standard solution.

WS = Weight of Metformin Hydrochloride working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Metformin Hydrochloride working standard in % on as such basis.

Calculate the assay of Metformin Hydrochloride in % as follows:

$$= \frac{\text{mg/tablet}}{\text{LC}} \times 100$$

LC = Label claim of Metformin Hydrochloride in mg/tablet.

System suitability:

Theoretical Plates : 2283 (Not less than 2000)

Tailing factor : 1.212 (Not more than 2.0)

Relative standard deviation : 0.267 (Not more than 2.0%)

Standard and Sample Chromatogram value :

Average peak area of Metformin Hydrochloride standard preparation: 960968

Area for sample solution:

1. 952795, 2. 952145 Avg.area 952470

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	Safetab Life Science Puducherry RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Batch No/Lot No.	GFD2000604	A.R.No.	SPLF/00518/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
IMTG00130-00	ROA/ IMG00130-00	00	04-06-2020	18 of 19

Calculate the assay of Metformin Hydrochloride in mg/tablet as follows :

$$\frac{952470}{960968} \times \frac{850.12}{100} \times \frac{5}{25} \times \frac{100}{1360.01} \times \frac{25}{5} \times \frac{99.14}{100} \times \frac{1362.5}{100} = 836.89 \text{ mg}$$

Calculate the assay of Metformin Hydrochloride in % as follows:

$$= \frac{836.89}{850} \times 100 = 98.5\%$$

Limit: Gliclazide: 90.0% to 110.0% of the labeled claim I.e. 54.0mg to 66.0mg

Metformin Hydrochloride: 90.0% to 110.0% of the labeled claim I.e. 765.0mg to 935.0mg

Observation: Conforms: ☑ Does not conform: ☐

Analyst: [signature] **Date:** 10/06/2020

Checked by : [signature] Date : 11/06/2020

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Sign: [signature]	Date: 02/06/2020	Sign: [signature]	Date: 05/06/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: GLIDE-M 60/850

(Gliclazide 60mg and Metformin Hydrochloride 850mg Sustained Release Tablets)-Compressed Tablets

Batch No/Lot No.	GID2000604	A.R.No.	SFP/F/00518/2020	
STP No	ROA No	Revision No.	Effective date	Page No:
IMTG00130-00	ROA/ IMG00130-00	00	04-06-2020	19 of 19

11.0 ANALYTICAL REPORT VERIFICATION CHECK LIST:

Check the following details and enclosures in the report. If the details are available then put '✓' mark on the remarks column and put '×' mark if the details are not available

S.No:	DETAILS	Remarks:
1	TRF is enclosed with the protocol	☑
2	Product name, B.No, Mfg date, Exp date, A.R.No matches with TRF	☑
3	All the tests are performed as per standard specification	☑
4	All the sheets are page numbered, signed and dated by analyst	☑
5	The protocol is duly filled, no blank place, calculations and entries are ok	☑
6	The printouts of UV-VIS spectrophotometer readings are enclosed	☑
7	The spectrum of IR spectrophotometer is enclosed	☒
8	All HPLC chromatograms are enclosed	☑
9	Other instruments sheets (if applicable, then specify in comments column)	☑
10	Public laboratory reports (if applicable, then specify the reasons below)	☒
11	Comments (if any): Weigh balance printout sheet is enclosed "x" mark is not applicable in this product	

Remarks: The report is found to be satisfactory ☑ / not satisfactory ☐

Verifying authority (Sign & date): _____ 10/06/2020

Checked by : _____ Date : 11/06/2020

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Sign:	Date: 02/06/2020	Sign:	Date: 05/06/20

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	76 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochioride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CD20060A	Mfg.Date:	06/2020	Exp.Date:	05/2023

BMR COPY/QUALITY CONTROL COPY

20.0 TEST REQUEST FORM FOR COMPRESSED TABLETS

From: Manufacturing Department	To: Q.A. Department
To be filled by production Date of Mfg.: 06/2020 Date of exp : 05/2023 Test Request for .: Content TRF raised by R.Raj on date 09/06/20	**To be filled by IPQA** Quantity Sampled : 100 tabl/- Sampled by : M.M on date: 09/06/20 No. of containers : 45 Sample received by : on date: 09/06/20
To be filled by QC TRF received on : 09/06/2020 Sample tested on : 10/06/2020	

Test Results	Limits
Each uncoated bilayered sustained release tablet contains Assay:- metformin Hcl 836.89mg (98.5%) Gliclazide 58.02mg (96.7%) Dissdution:- Gliclazide Min Max Avg 2nd hr 18.1% 23.3% 20.7% 5th hr 43.6% 52.8% 48.1% 12th hr 80.4% 89.2% 85.3% Metformin Hcl Min Max Avg 1st hr 25.1% 26.1% 25.7% 3rd hr 48.7% 49.9% 49.6% 10th hr 98.4% 102.5% 100.1%	
Analytical Reference no.: SFP/F/00518/2020 Reported by Analysed By : on : 10/06/2020	**Space for QC Approval** (Stamping and Signing) APPROVED 10/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	10/06/2020	04.06.2020	09/06/2020	

Safetab Life Science
Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name	**GLIDE M 60/850**	**Batch size :**	**5.0 LAC**
Batch Number	**GD200604**	**Mfg.Date :**	**Jun-20**
Stage	**UNCOATED BILAYERED TABLETS**	**Exp.Date :**	**May-23**

Each 1360mg of Tablets contains
Metformin Hcl BP---------- 850mg
Gliclazide BP---------- 60mg

ASSAY OF METFORMIN HCL

Instrument ID:	ST/QC/EQ/039	**Balance ID:**	ST/QC/EQ/041	**WS No.:**	WS/MEF/BP/20/001	**% Purity (aib)**	99.14

Standard dilution.:	850.12	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-1700.24	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Granule/pow.	mg to --->	100	ml to --->	5	ml to --->	25
Test conc(in ppm)-1696.89	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled claim :	850	mg
Average weight :	1362.5	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
METFORMIN HCL	958247	958715	961043	962443	964392	960968	2568.3	0.267
With Bracketing std.						960968	2568.3	0.267

Sample preparation	Sample Weight taken in mg	Sample Area	Assay in mg/1360mg of tablets	Assay in %
1	1360.01	952470	836.89	98.5

Assay limit : 90.0 - 110.0%

ASSAY OF GLICLAZIDE

						WS No.:	WS-GLD014/19
% Purity (aib)	99.65						
Standard dilution.:	60.15	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-120.3	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	Granule/pow.	mg to --->	100	ml to --->	5	ml to --->	25
Std.conc (in ppm)-119.7806	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled claim :	60	mg
Average weight :	1362.5	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
GLICLAZIDE	259481	259807	259998	260107	260031	259885	251	0.097
With Bracketing std.						259885	251.3	0.097

Sample preparation	Sample Weight taken in mg	Sample Area	Assay in mg/1360mg of tablets	Assay in %
1	1360.01	251108	58.02	96.7

Assay limit : 90.0 - 110.0%

Calculation fomula :

Assay in mg /1360mg of Tablets	Sample area x Std.dilution X Avg.wt x Purity %(aib) x conversion factor / Standard area x sample dilution X 100
Assay in %	Assay in mg /1360mg of tablets x 100 / Labeled claim

Analysed by :	R.VIGNESH	Reported by :	C.K.SARAVANAN	Checked by:	
Date :	10.06.2020	Date :	10.06.2020	Date:	

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M 60/850
Sample ID	: DILUENT-AS
Data Filename	: 09062020 GLIDE M60-850-TAB-604-AS-SPL-01.lcd
Method Filename	: GLIDE M 60-850-TAB-AS_P.lcm
Batch Filename	: 09062020 GLIDE M60-850-TAB-604-AS.lcb
Vial #	: 4-46
Injection Volume	: 20 uL
Date Acquired	: 09/06/2020 21:04:40
Date Processed	: 10/06/2020 09:13:02

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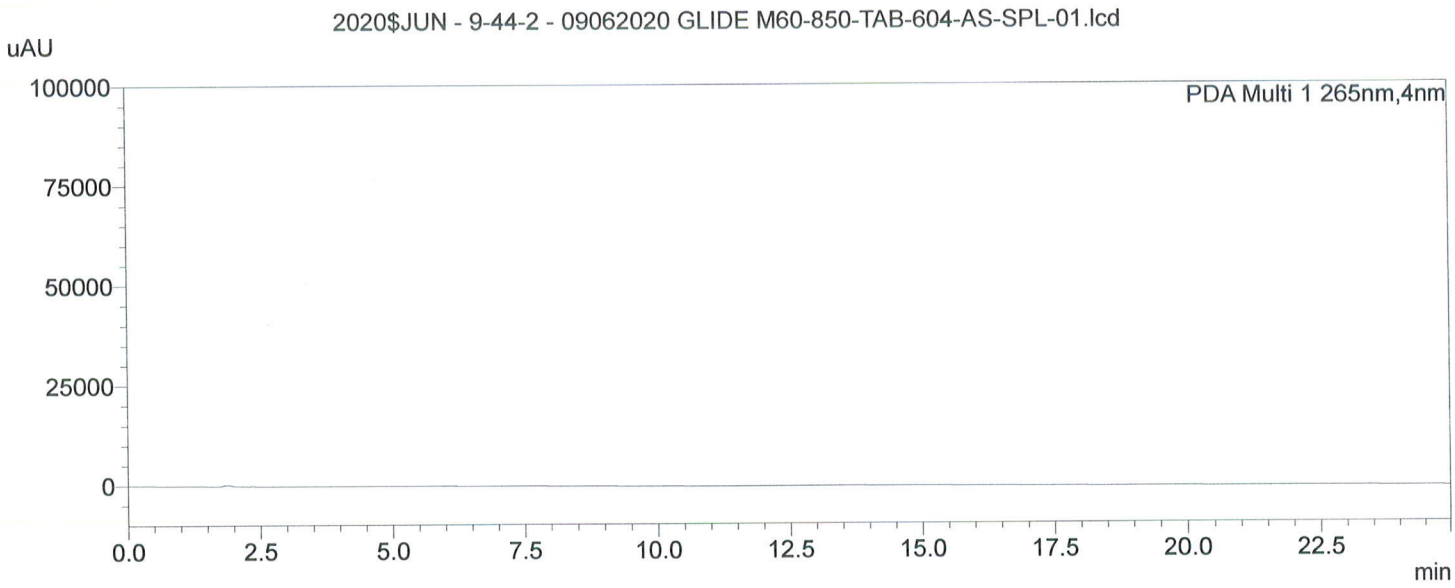

<Peak Table>

PDA Ch1 265nm

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

Analysed By

Date : 10/06/2020

Checked By

Date : 11/06/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M 60/850
Sample ID	: GLICLAZIDE+METFORMIN-AS-STD-01
Tray#	: 4
Vial#	: 47
Injection Volume	: 20
Data File	: 09062020 GLIDE M60-850-TAB-604-AS-SPL-02.lcd
Method File	: GLIDE M 60-850-TAB-AS_P.lcm
Batch File	: 09062020 GLIDE M60-850-TAB-604-AS.lcb
Report Format File	: DEFAULT.lsr
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Date Processed	: 10/06/2020 09:13:03

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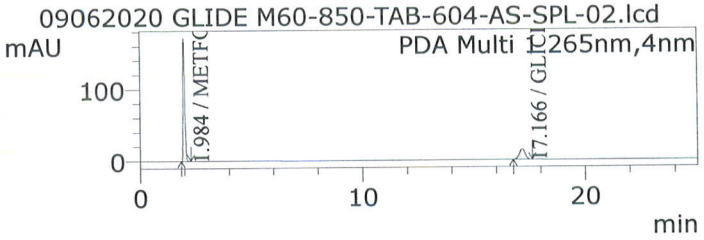

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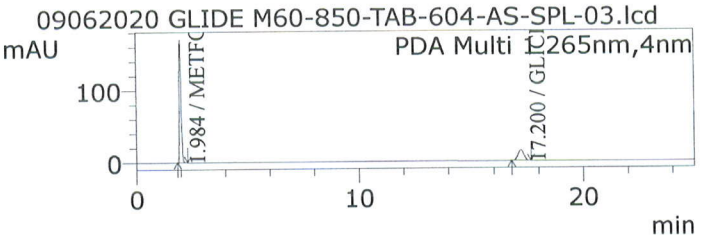

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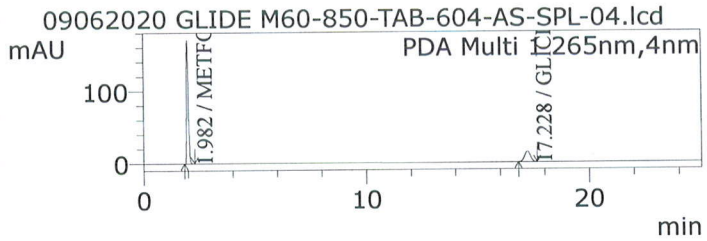

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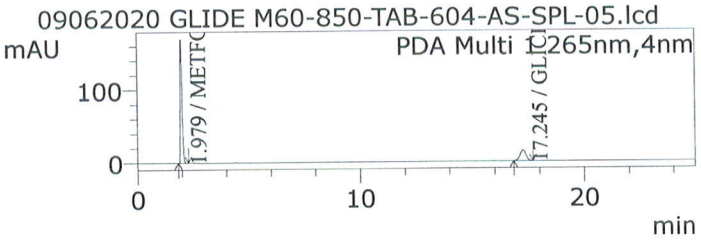

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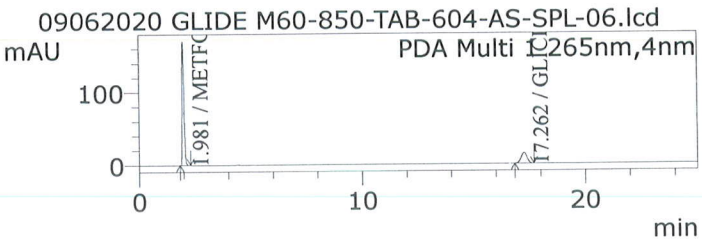

<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
47	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-01	1.984	958247	2317	1.208
47	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-02	1.984	958715	2302	1.212
47	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-03	1.982	961043	2283	1.219
47	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-04	1.979	962443	2251	1.205
47	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-05	1.981	964392	2261	1.215
	Average		1.982	960968	2283	1.212
	%RSD		0.097	0.267	1.199	0.445

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
47	AS-SPL-02.lcd	GLICLAZIDE+METFORMIN-AS-STD-01	17.166	259481	20544	0.988
47	AS-SPL-03.lcd	GLICLAZIDE+METFORMIN-AS-STD-02	17.200	259807	20541	0.989
47	AS-SPL-04.lcd	GLICLAZIDE+METFORMIN-AS-STD-03	17.228	259998	20433	0.986
47	AS-SPL-05.lcd	GLICLAZIDE+METFORMIN-AS-STD-04	17.245	260107	20460	0.986
47	AS-SPL-06.lcd	GLICLAZIDE+METFORMIN-AS-STD-05	17.262	260031	20462	0.986
	Average		17.220	259885	20488	0.987
	%RSD		0.222	0.097	0.249	0.118

Analysed By 10/06/2020

Date :

Checked By

Date : 11/06/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M 60/850
Sample ID	: GLIDE M60/850-TAB-604-AS-SPL-01
Tray#	: 4
Vial#	: 48
Injection Volume	: 20
Data File	: 09062020 GLIDE M60-850-TAB-604-AS-SPL-07.lcd
Method File	: GLIDE M 60-850-TAB-AS_P.lcm
Batch File	: 09062020 GLIDE M60-850-TAB-604-AS.lcb
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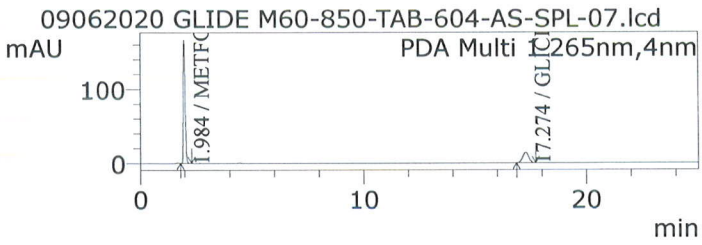

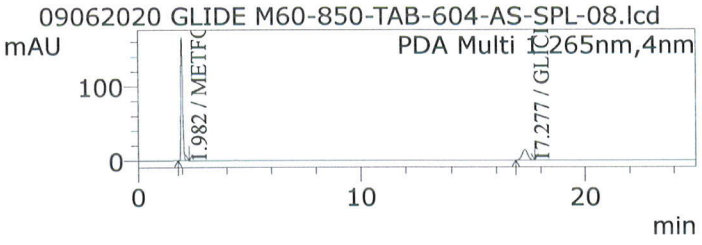

<< PDA >>

ID#1 Compound Name: METFORMIN HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
48	AS-SPL-07.lcd	GLIDE M60/850-TAB-604-AS-SPL-01	1.984	952795	2222	1.221
48	AS-SPL-08.lcd	GLIDE M60/850-TAB-604-AS-SPL-02	1.982	952145	2216	1.226
	Average		1.983	952470	2219	1.224
	%RSD		0.055	0.048	0.195	0.343

ID#2 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
48	AS-SPL-07.lcd	GLIDE M60/850-TAB-604-AS-SPL-01	17.274	251483	20453	0.990
48	AS-SPL-08.lcd	GLIDE M60/850-TAB-604-AS-SPL-02	17.277	250733	20508	0.991
	Average		17.275	251108	20480	0.990
	%RSD		0.012	0.211	0.189	0.055

Analysed By

Date : 10/06/2020

Checked By

Date : 11/06/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name:	GLIDE-60	**Batch size :**	5.0 LAC
Batch Number:	GD200604	**Mfg.Date :**	Jun-20
Stage:	UNCOATED BILAYERED TABLETS	**Exp.Date :**	May-23

DISSOLUTION OF GLICLAZIDE

Instrument ID:	ST/QC/EQ/039	**Balance ID:**	ST/QC/EQ/041	**WS No.:**	WS-GLD014/19	**% Purity (aib)**	99.65

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

Standard dilution.:	66.00	mg to --->	100	ml to --->	5	ml to --->	50
Std.conc (in ppm)-66	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	gm to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-66.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor	1.0000
Labelled claim	60 mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
GLICLAZIDE	2705656	2703730	2698995	2700336	2700417		2701827	2762	0.102
With Bracketing std.	2700730	2696801	2698604				2700659	2840	0.105

2nd Hour — Limit:NMT 25.0%

Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
Unit-1	527498	11.56	19.26	0.21	20.7	18.1
Unit-2	494552	10.83	18.06	0.20		
Unit-3	551751	12.09	20.15	0.22		Maximum %
Unit-4	595328	13.04	21.74	0.24		
Unit-5	637956	13.98	23.29	0.26		23.3
Unit-6	599004	13.12	21.87	0.24		

5th Hour — Limit:Between 30.0-60.0%

Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D4)	Correction Factor (CF2)	Cumulative % (D4+CF1)	Average %	Minimum %
Unit-1	1188203	26.03	43.39	0.482	43.60	48.1	43.6
Unit-2	1222369	26.78	44.63	0.496	44.83		
Unit-3	1258811	27.58	45.96	0.511	46.19		Maximum%
Unit-4	1367176	29.95	49.92	0.555	50.16		
Unit-5	1438079	31.51	52.51	0.583	52.77		52.8
Unit-6	1396013	30.58	50.97	0.566	51.22		

12th Hour — Limit: Not less than 70.0%

Sampling point	Sample Area	Drug release in mg/tablet	Drug Release in % (D12)	Cumulative % (D24+CF1+CF2)	Average %	Minimum %
Unit-1	2181725	47.80	79.66	80.36	85.3	80.4
Unit-2	2304055	50.48	84.13	84.83		
Unit-3	2321495	50.86	84.77	85.50		Maximum %
Unit-4	2309841	50.60	84.34	85.14		
Unit-5	2418767	52.99	88.32	89.16		89.2
Unit-6	2348731	51.46	85.76	86.57		

Calculation formula :

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

Analysed by :	R.VIGNESH	Reported by :	C.K.SARAVANAN	Checked by :	
Date :	10.06.2020	Date :	10.06.2020	Date :	

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: DILUENT-DS
Data Filename	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-01.lcd
Method Filename	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch Filename	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Vial #	: 4-1
Injection Volume	: 20 uL
Date Acquired	: 10/06/2020 05:01:53
Date Processed	: 10/06/2020 10:34:05

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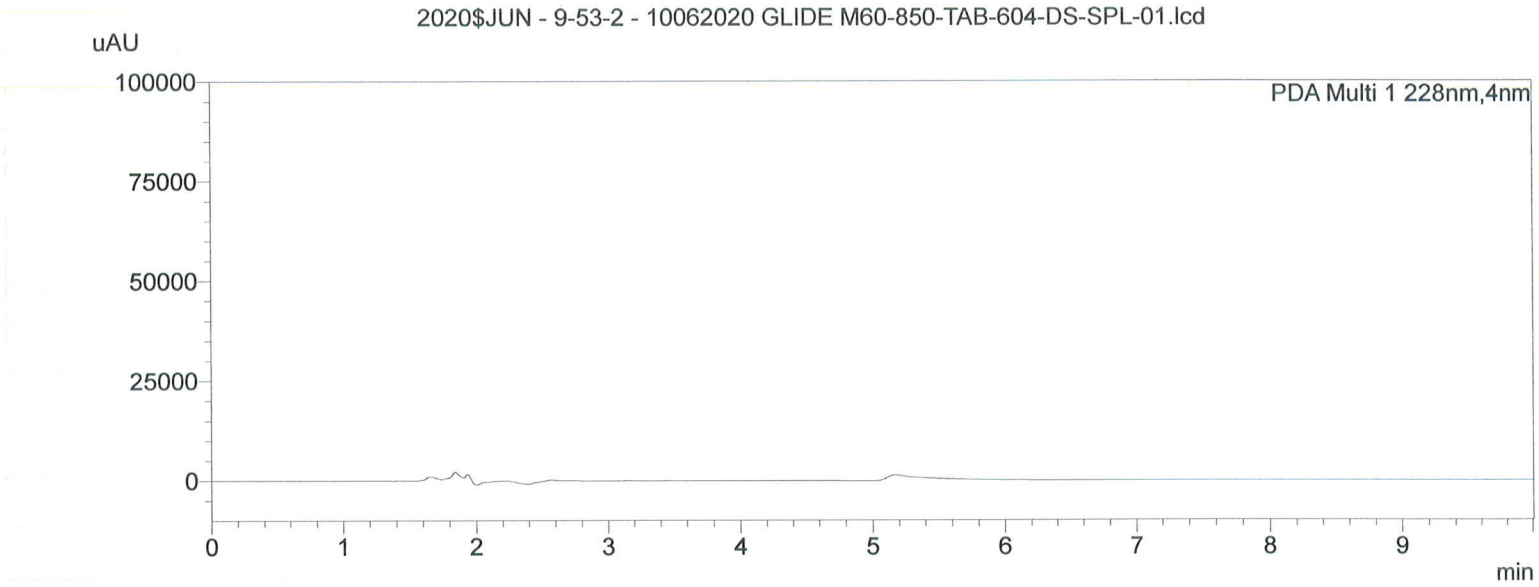

<Peak Table>

PDA Ch1 228nm

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

Analysed By 10/06/2020

Date :

Checked By

Date : 11/06/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLICLAZIDE-DS-STD-01
Tray#	: 4
Vial#	: 2
Injection Volume	: 20
Data File	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-02.lcd
Method File	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch File	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Report Format File	: DEFAULT.lsr
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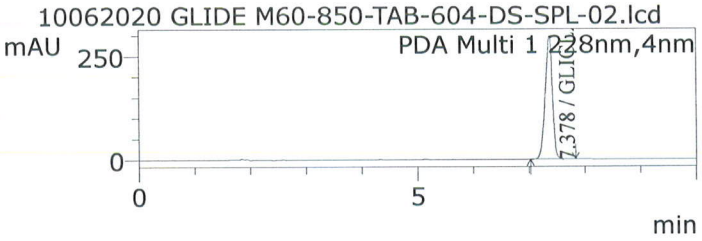
Date Processed	: 10/06/2020 10:34:05

10062020 GLIDE M60-850-TAB-604-DS-SPL-02.lcd



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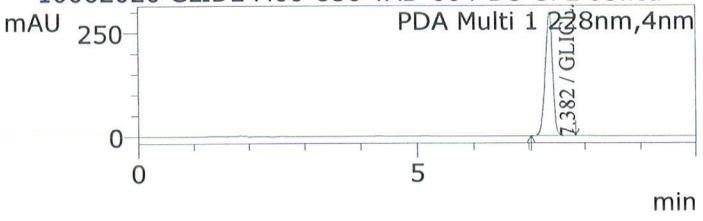

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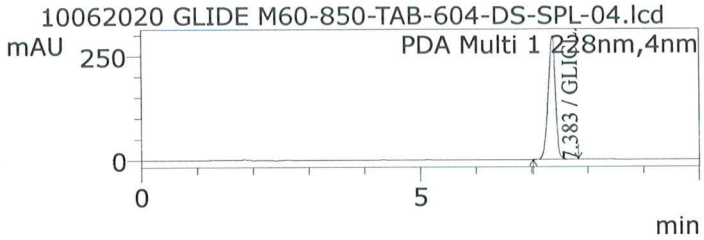

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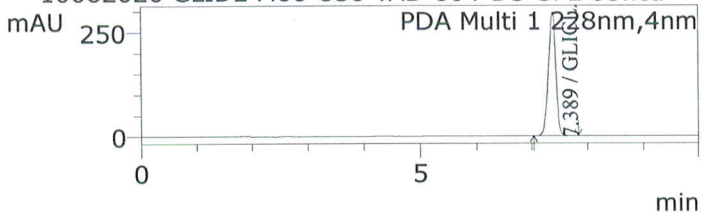

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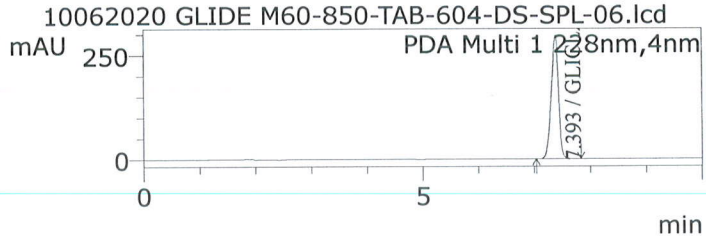

<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	GLICLAZIDE-DS-STD-01	7.378	2705656	13268	0.855
2	DS-SPL-03.lcd	GLICLAZIDE-DS-STD-02	7.382	2703730	13215	0.854
2	DS-SPL-04.lcd	GLICLAZIDE-DS-STD-03	7.383	2698995	13266	0.854
2	DS-SPL-05.lcd	GLICLAZIDE-DS-STD-04	7.389	2700336	13245	0.855
2	DS-SPL-06.lcd	GLICLAZIDE-DS-STD-05	7.393	2700417	13209	0.853
	Average		7.385	2701827	13241	0.854
	%RSD		0.079	0.102	0.208	0.082

Analysed By **Checked By**

Date : 10/06/2020 **Date :** 11/06/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLIDE M60-850-604-2H-DS-SPL-01
Tray#	: 4
Vial#	: 3
Injection Volume	: 20
Data File	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-07.lcd
Method File	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch File	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Report Format File	: DEFAULT.lsr
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Date Processed	: 10/06/2020 10:34:15

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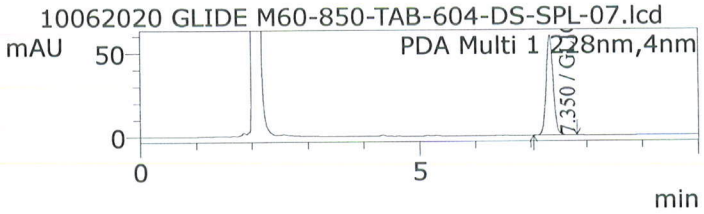

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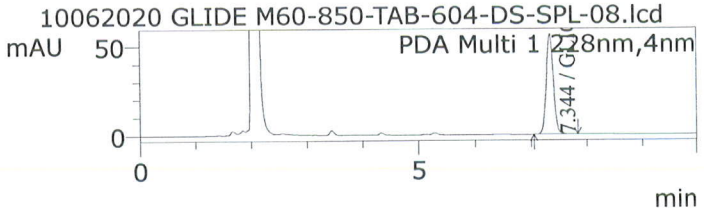

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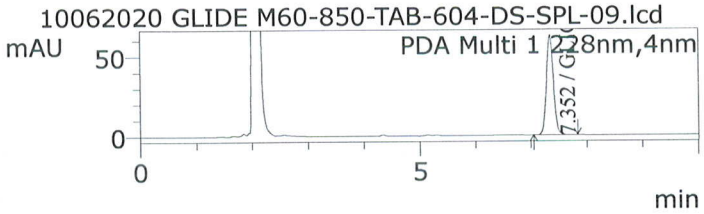

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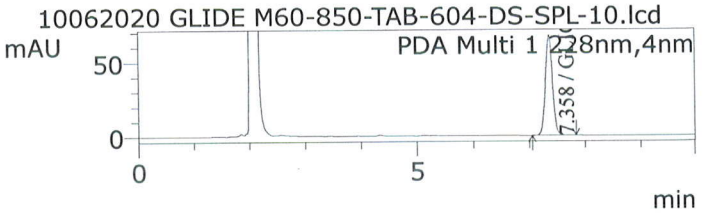

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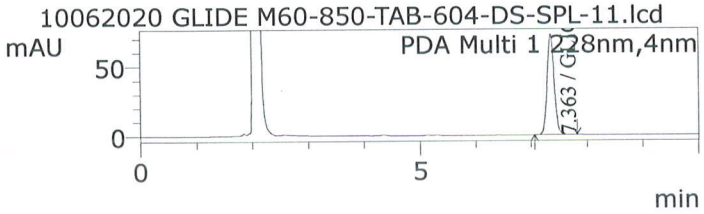

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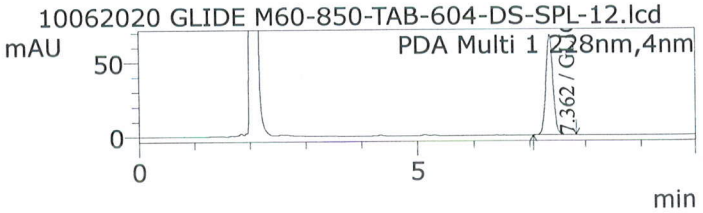

<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	DS-SPL-07.lcd	GLIDE M60-850-604-2H-DS-SPL-01	7.350	527498	14272	1.004
4	DS-SPL-08.lcd	GLIDE M60-850-604-2H-DS-SPL-02	7.344	494552	14238	1.008
5	DS-SPL-09.lcd	GLIDE M60-850-604-2H-DS-SPL-03	7.352	551751	14249	1.001
6	DS-SPL-10.lcd	GLIDE M60-850-604-2H-DS-SPL-04	7.358	595328	14236	0.999
7	DS-SPL-11.lcd	GLIDE M60-850-604-2H-DS-SPL-05	7.363	637956	14244	0.993
8	DS-SPL-12.lcd	GLIDE M60-850-604-2H-DS-SPL-06	7.362	599004	14205	0.996
	Average		7.355	567682	14241	1.000
	%RSD		0.102	9.288	0.154	0.550

Analysed By

Date : 10/06/2020

Checked By

Date : 10/06/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLIDE M60-850-604-5H-DS-SPL-01
Tray#	: 4
Vial#	: 9
Injection Volume	: 20
Data File	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-14.lcd
Method File	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch File	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Report Format File	: DEFAULT.lsr
Date Acquired	: 10/06/2020 07:19:06
Date Processed	: 10/06/2020 10:34:20

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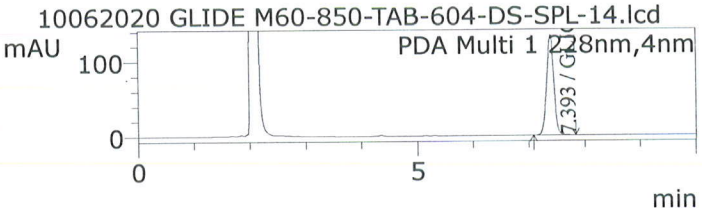

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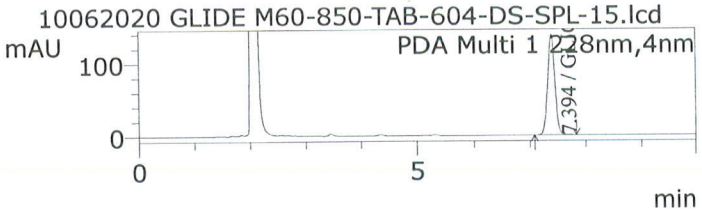
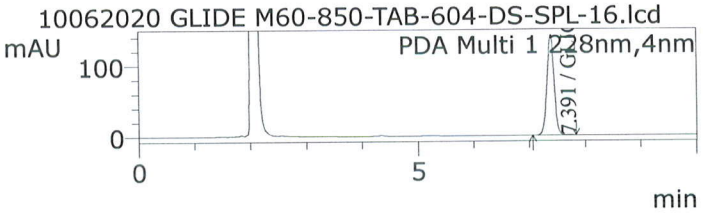


10062020 GLIDE M60-850-TAB-604-DS-SPL-16.lcd



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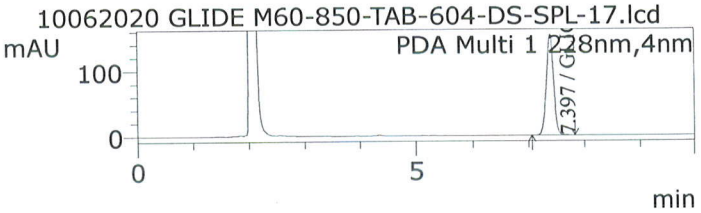

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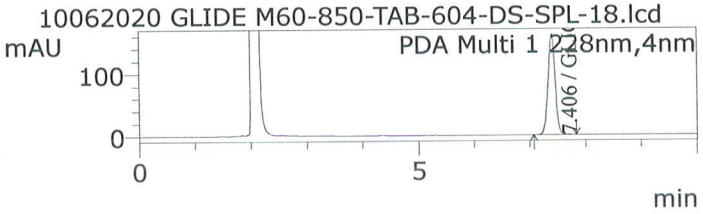
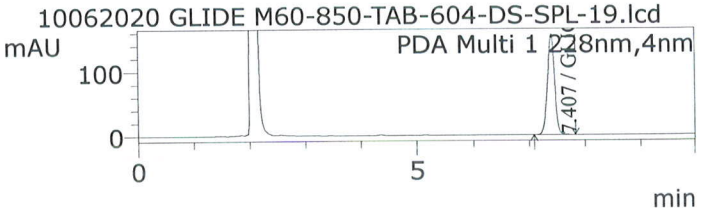


10062020 GLIDE M60-850-TAB-604-DS-SPL-19.lcd



<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	DS-SPL-14.lcd	GLIDE M60-850-604-5H-DS-SPL-01	7.393	1188203	14118	0.948
10	DS-SPL-15.lcd	GLIDE M60-850-604-5H-DS-SPL-02	7.394	1222369	14186	0.948
11	DS-SPL-16.lcd	GLIDE M60-850-604-5H-DS-SPL-03	7.391	1258811	14053	0.943
12	DS-SPL-17.lcd	GLIDE M60-850-604-5H-DS-SPL-04	7.397	1367176	14030	0.934
13	DS-SPL-18.lcd	GLIDE M60-850-604-5H-DS-SPL-05	7.406	1438079	14031	0.928
14	DS-SPL-19.lcd	GLIDE M60-850-604-5H-DS-SPL-06	7.407	1396013	14017	0.930
	Average		7.398	1311775	14072	0.939
	%RSD		0.093	7.788	0.471	0.952

Analysed By

Date : 10/06/2020

Checked By

Date : 11/06/2020

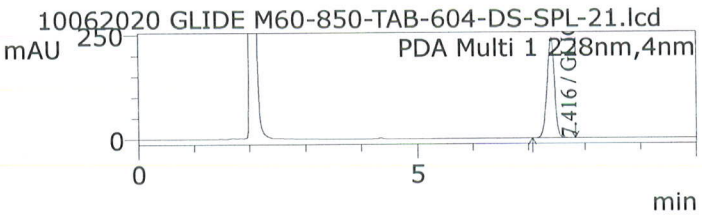
Safetab Life Science

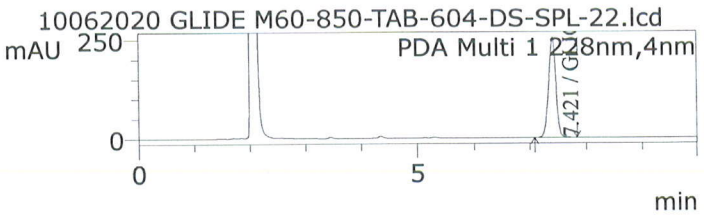
Puducherry- 605 107

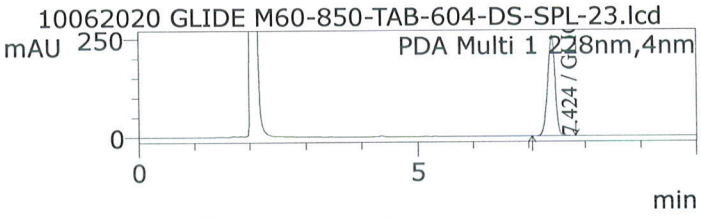
Quality control Department

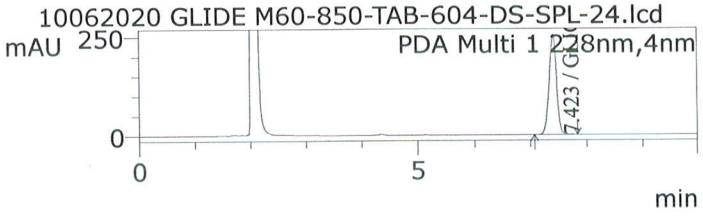
Sample Information

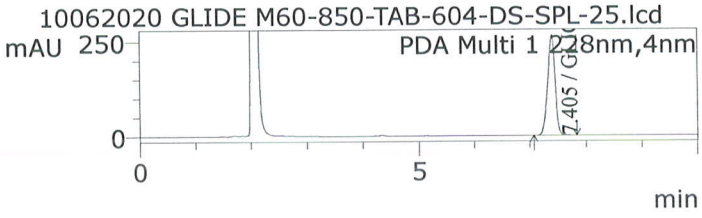
Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLIDE M60-850-604-12H-DS-SPL-01
Tray#	: 4
Vial#	: 15
Injection Volume	: 20
Data File	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-21.lcd
Method File	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch File	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Report Format File	: DEFAULT.lsr
Date Acquired	: 10/06/2020 08:32:58
Date Processed	: 10/06/2020 10:34:24

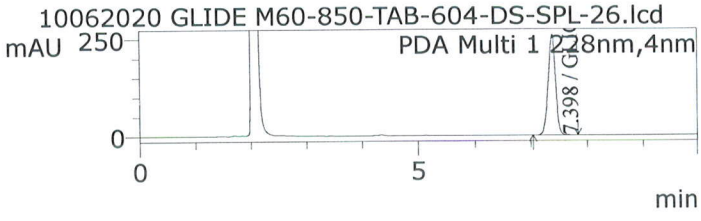












<< PDA >>

ID#1 Compound Name: GLICLAZIDE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
15	DS-SPL-21.lcd	GLIDE M60-850-604-12H-DS-SPL-01	7.416	2181725	13583	0.881
16	DS-SPL-22.lcd	GLIDE M60-850-604-12H-DS-SPL-02	7.421	2304055	13438	0.875
17	DS-SPL-23.lcd	GLIDE M60-850-604-12H-DS-SPL-03	7.424	2321495	13453	0.873
18	DS-SPL-24.lcd	GLIDE M60-850-604-12H-DS-SPL-04	7.423	2309841	13435	0.873
19	DS-SPL-25.lcd	GLIDE M60-850-604-12H-DS-SPL-05	7.405	2418767	13365	0.868
20	DS-SPL-26.lcd	GLIDE M60-850-604-12H-DS-SPL-06	7.398	2348731	13445	0.871
	Average		7.415	2314102	13453	0.873
	%RSD		0.143	3.339	0.529	0.524

Analysed By

Date : 10/06/2020

Checked By

Date : 11/06/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLICLAZIDE-DS-BKT-01
Data Filename	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-13.lcd
Method Filename	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch Filename	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Vial #	: 4-2
Injection Volume	: 20 uL
Date Acquired	: 10/06/2020 07:08:33
Date Processed	: 10/06/2020 10:34:19

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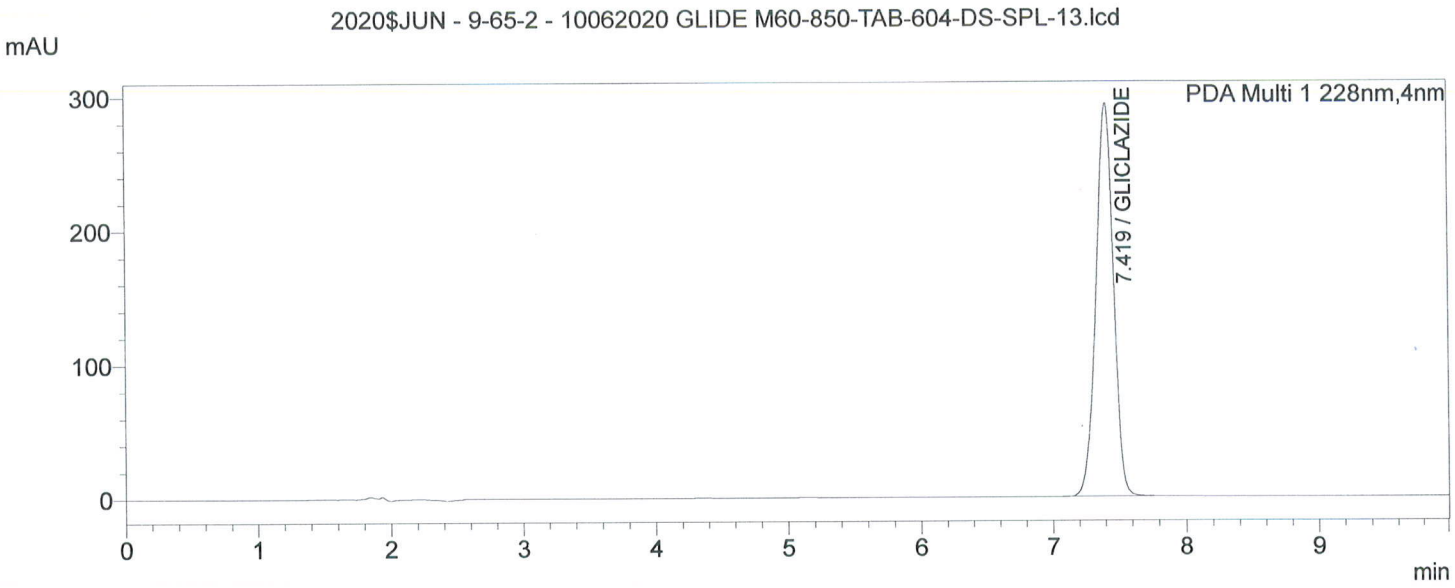

<Peak Table>

PDA Ch1 228nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	7.419	2700730	100.000	13194	0.853	--	--	GLICLAZIDE
Total		2700730	100.000					

Analysed By 10/06/2020

Date :

Checked By 11/06/2020

Date :

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLICLAZIDE-DS-BKT-02
Data Filename	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-20.lcd
Method Filename	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch Filename	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Vial #	: 4-2
Injection Volume	: 20 uL
Date Acquired	: 10/06/2020 08:22:25
Date Processed	: 10/06/2020 10:34:23

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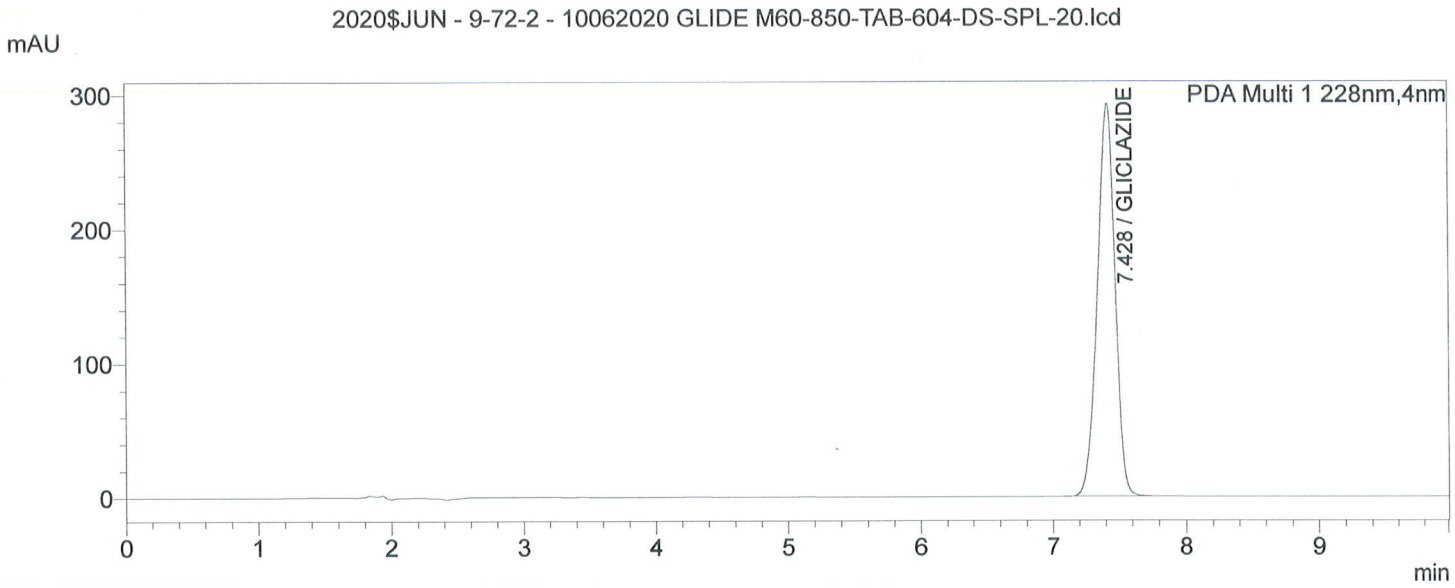

<Peak Table>

PDA Ch1 228nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	7.428	2696801	100.000	13167	0.853	--	--	GLICLAZIDE
Total		2696801	100.000					

Analysed By 10/06/2020

Date :

Checked By 10/06/2020

Date :

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: GLIDE M60-850
Sample ID	: GLICLAZIDE-DS-BKT-03
Data Filename	: 10062020 GLIDE M60-850-TAB-604-DS-SPL-27.lcd
Method Filename	: GLIDE M 60-850-TAB-DS_GLICLAZIDE.lcm
Batch Filename	: 10062020 GLIDE M60-850-TAB-604-GLICLAZIDE-DS.lcb
Vial #	: 4-2
Injection Volume	: 20 uL
Date Acquired	: 10/06/2020 09:36:18
Date Processed	: 10/06/2020 10:34:28

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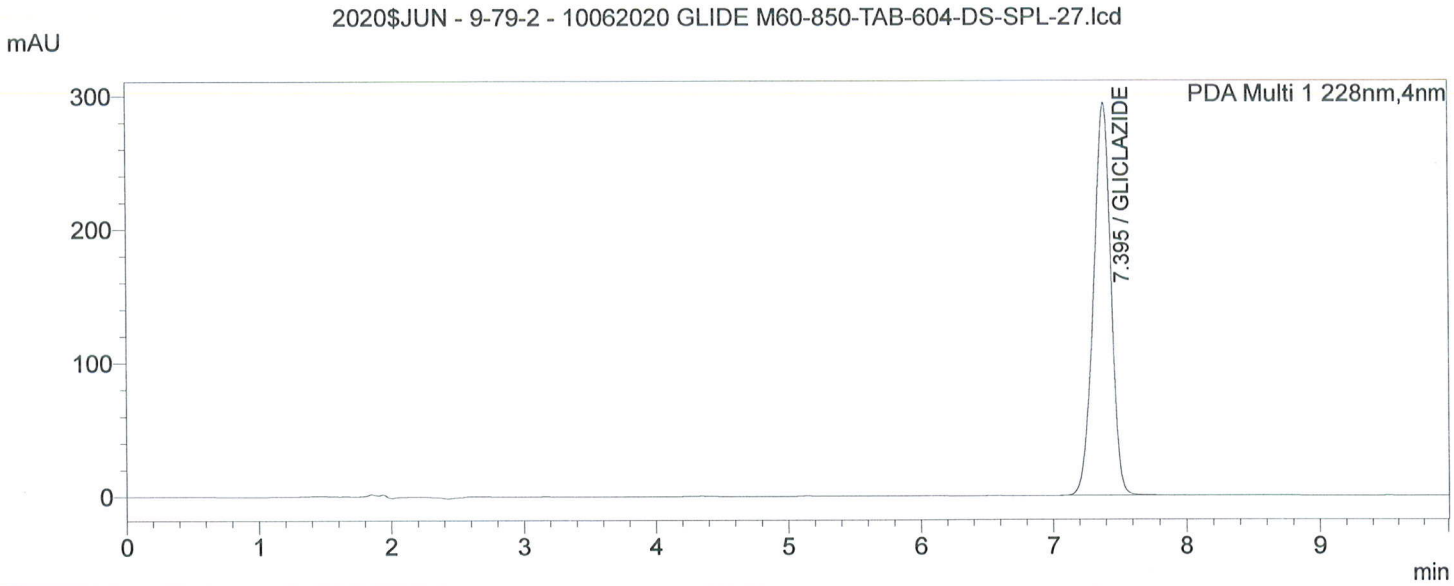

<Peak Table>

PDA Ch1 228nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	7.395	2698604	100.000	13132	0.851	--	--	GLICLAZIDE
Total		2698604	100.000					

Analysed By 10/06/2020

Date :

Checked By

Date : 11/06/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name:	**GLIDE M60 850**	**Batch size :**	**5.0 LAC**
Batch Number:	**GD200604**	**Mfg.Date :**	**Jun-20**
Stage:	**UNCOATED BILAYAR TABLET**	**Exp.Date :**	**May-23**

DISSOLUTION OF METFORMIN HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/037	Balance ID	ST/QC/EQ/041	WS No.:	WS/MEF/BP/20/01	% Purity (aib)	99.14

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

Standard dilution.:	42.56	mg to --->	100	ml to --->	5	ml to --->	250
Std.conc (in ppm)-8.512	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

Standard Absorbance :	0.672

1st Hour — Limit:20-40%

Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D1)	Correction Factor (CF1)	Average %	Minimum %
1	0.173	217.25	25.56	0.26	25.7	25.1
2	0.177	222.27	26.15	0.26		Maximum %
3	0.173	217.25	25.56	0.26		26.1
4	0.177	222.27	26.15	0.26		
5	0.170	213.48	25.12	0.25		
6	0.175	219.76	25.85	0.26		

3nd 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 %
1	0.332	416.92	49.05	0.490	49.30	49.6	48.7
2	0.336	421.94	49.64	0.496	49.90		Maximum%
3	0.335	420.68	49.49	0.495	49.75		49.9
4	0.328	411.89	48.46	0.485	48.72		
5	0.335	420.68	49.49	0.495	49.74		
6	0.336	421.94	49.64	0.496	49.90		

10th Hour — NLT:85.0%

Sampling point	Sample Absorbance	Drug release in mg/Tablet	Drug Release in % (D10)	Cumulative % (D10+CF1+CF2)	Average %	Minimum %
1	0.672	843.88	99.28	100.03	100.1	98.4
2	0.677	850.16	100.02	100.78		Maximum %
3	0.673	845.14	99.43	100.18		102.5
4	0.663	832.58	97.95	98.70		
5	0.661	830.07	97.65	98.40		
6	0.689	865.23	101.79	102.55		

Calculation formula :

Drug release in mg /tablet	Sample absorbance x Std.dilution X Purity %(aib) x conversion factor / Standard absorbance x sample dilution X 100
Drug release in %	Drug release in mg /tablet x 100 / Labeled claim
Correction factor	Drug release % in respective time point / 1000 X 10

Analysed by : VARUNRAJ.E 10/06/2020

DATE : 10-06-2020

Checked by : 11/06/2020

Date :

Safetab Life science

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

Data Information
Filename: \\Qchead\QC PROTOCOLS \UV_DATA_BACKUP\DATA- 2020\JUN-2020\10-06-2020\GLIDE M60-850-TAB-604-DISSOLUTION OF METFORMIN HCL 1ST HR.pho
Title: DISSOLUTION OF METFORMIN HCL
Analyst: VIGNESH R
Date/Time: 10-06-2020 02:19:15 AM
Comments: DISSOLUTION OF METFORMIN HCL

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: 8.500

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		8.500	0.672	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	SPL 1 IN 1	Unknown		2.193	0.173	
2	SPL 1 IN 2	Unknown		2.242	0.177	
3	SPL 1 IN 3	Unknown		2.182	0.173	
4	SPL 1 IN 4	Unknown		2.233	0.177	
5	SPL 1 IN 5	Unknown		2.154	0.170	
6	SPL 1 IN 6	Unknown		2.218	0.175	
7						

Analysed By
Date: 10/06/2020

Checked By
Date: 11/06/20

Safetab Life science

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

Data Information
Filename: \\Qchead\QC PROTOCOLS \UV_DATA_BACKUP\DATA- 2020\JUN-2020\10-06-2020\GLIDE M60-850-TAB-604-DISSOLUTION OF METFORMIN HCL 3RD HR.pho
Title: DISSOLUTION OF METFORMIN HCL
Analyst: VIGNESH R
Date/Time: 10-06-2020 02:22:30 AM
Comments: DISSOLUTION OF METFORMIN HCL

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: 8.500

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		8.500	0.672	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	SPL 3 IN 1	Unknown		4.199	0.332	
2	SPL 3 IN 2	Unknown		4.248	0.336	
3	SPL 3 IN 3	Unknown		4.239	0.335	
4	SPL 3 IN 4	Unknown		4.153	0.328	
5	SPL 3 IN 5	Unknown		4.236	0.335	
6	SPL 3 IN 6	Unknown		4.253	0.336	
7						

Analysed By
Date: 10/06/2020

Checked By
Date: 11/06/2020

Safetab Life science

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

Data Information
Filename: \\Qchead\QC PROTOCOLS \UV_DATA_BACKUP\DATA- 2020\JUN-2020\10-06-2020\GLIDE M60-850-TAB-604-DISSOLUTION OF METFORMIN HCL 10TH HR.pho
Title: DISSOLUTION OF METFORMIN HCL
Analyst: VIGNESH R
Date/Time: 10-06-2020 10:12:47 AM
Comments: DISSOLUTION OF METFORMIN HCL

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: 8.500

Standard Table

	Sample ID	Type	Ex	Conc	WL233.0	Wgt.Factor	Comments
1	STD	Standard		8.500	0.672	1.000	

Sample Table

	Sample ID	Type	Ex	Conc	WL233.0	Comments
1	SPL 10 IN 1	Unknown		8.495	0.672	
2	SPL 10 IN 2	Unknown		8.552	0.677	
3	SPL 10 IN 3	Unknown		8.509	0.673	
4	SPL 10 IN 4	Unknown		8.377	0.663	
5	SPL 10 IN 5	Unknown		8.352	0.661	
6	SPL 10 IN 6	Unknown		8.705	0.689	
7						

Analysed By
Date: 10/06/2020

Checked By
Date: 10/06/2020

518

IDEAL ANALYTICAL AND RESEARCH INSTITUTION

Plot No.1 and 2 (PT),Brindhavanam Nagar,Pazhani samy Nagar, Villianur, Puducherry-605110

CERTIFICATE OF ANALYSIS

Form 39 (Rule 150-E(f))

(As per Drugs & Cosmetics Act, 1940 and the rules made there under) Approval No. :20 30 4332

Analytical Report No. :	AR/20/06/11/003
Date :	16.06.2020

1) Name of the manufacturer from whom sample received with manufacturing license number	Safetab Life Science,Plot No: A-68, PIPDIC Electronic Park, Thirubuvanai, Puducherry - 605 107.	
2) Reference number & date of the sample forwarding letter	**3) Date of receipt of sample**	**4) Name of drug / cosmetics / raw material / final product in bulk / final product (in finished pack) as obtained from the manufacturer**
11.06.2020	11.06.2020	GLIDE M60/850

5) Details of drug / cosmetics / raw material / final product in bulk / final product (in finished pack) as obtained from the manufacturer as follows

a)Original manufacturer's name (in case of raw materials and drugs repacked)	b)Batch No/ Control No.	c)Batch size as represented by sample	d)Date of manufacture, if any	e)Date of expiry, if any	f)Quantity submitted
Safetab Life Science	GD200604	5.0lac	06/2020	05/2023	strips

6) Results of test for analysis: *SAMPLE NOT DRAWN BY US*

PARAMETERS	SPECIFICATIONS	RESULTS
Description		Pink/White colour oblong shaped uncoated tablet scored on one side in the middle and plain on another side.
Microbial Contamination		
1.Total viable aerobic count		
Bacteria	NMT 1000cfu/g	40cfu/g
Fungi	NMT 100cfu/g	Found absent
2.Escherichia coli	Absent/gm	Found absent
3.Salmonella	Absent/10gm	Found absent
4. Staphylococcus aureus	Absent/gm	Found absent
5. Pseudomonas aeruginosa	Absent/gm	Found absent

In the opinion of the undersigned, the sample referred to above is ***of standard quality*** / ~~***is not of standard quality***~~ as defined in the Act and Rules made there under for the reasons given below.

Observation: The sample complies as per IH specifications with respect to above parameters.

Verified by
03/07/2020

Signature of Person-in-charge of testing

(K. Maruthappa Pandian)