	Safetab Life Science Puducherry			MASTER COPY
	PRODUCT SPECIFICATION			**Market** Export
Name of Product	**GLIDE-M 60/850** (Gliclazide and Metformin Hydrochloride Sustained Release Tablets)			
Specification No.	SPEC-1014-01	**Revision No.**	01	**Product Code:**1014
Supersedes	SPEC-1014-00	**Effective Date:**	21/07/2025	**Page No.:** 1 of 10

S.NO	GENERAL SPECIFICATION (s)	
1	Pharmacopoeial Reference	In House
2	Label claim	Each Uncoated bilayered sustained release tablet contains: Gliclazide BP ---------- 60mg Metformin Hydrochloride BP ---------- 850mg
3	Standard packing	3×10's, Blister packing
4	Shelf Life	36 Months
5	In-Process Sample Quantity	a) In-process Intermediate – Blend, 50g. b) Intermediate compressed tablets –100 tablets
6	Finished Product sample quantity	For Microbial contamination Test : 10 Tablets For Chemical Analysis : 100 Tablets For Control sample : 220 Tablets
7	Stability studies sample quantity	For Accelerated study : 190 tablets For Long term study : 640 tablets For Intermediate study : 310 tablets For Annual study : 520 tablets
8	Storage condition	Store in a cool, dry and dark place.
9	Destructions Instructions	Follow the Standard Operating Procedure: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	19/07/25	19/07/25	21/07/2025

RELEASE SPECIFICATION FOR INTERMEDIATE – BLEND
SPECIFICATION CODE: SPEC-1014-BLD

For Gliclazide:

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Red colour granular powder.
2.0	**Assay: Each 180mg of blend contains:** Gliclazide BP 60mg	57.0mg to 66.0mg (95.0% to 110.0% of the labeled claim)

For Metformin Hydrochloride:

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	A White Colour granular powder.
2.0	**Assay: Each 1180mg of blend contains:** Metformin Hydrochloride BP 850mg	807.5mg to 935.0mg (95.0% to 110.0% of the labeled claim)

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RELEASE SPECIFICATION FOR INTERMEDIATE – COMPRESSED TABLETS
SPECIFICATION CODE: SPEC-1014-COM

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	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)	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)	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	1360.0 mg ± 5 % (1292.0 mg to 1428.0 mg)
4.0	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%.
5.0	**Dimension:**	
	Length	22.00 mm ± 0.2 mm (21.8mm – 22.2mm)
	Width	9.50 mm ± 0.2 mm (9.30mm – 9.70mm)
6.0	Thickness	7.00 mm ± 0.30 mm (6.70mm - 7.30mm)

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S.NO	TEST (s)	SPECIFICATION (s)
7.0	Hardness	Not less than 150N
8.0	Friability	Not more than 1.0% w/w
9.0	**Dissolution:** **a) Gliclazide BP** Apparatus 2 – Paddle with sinker Medium-900ml, Phosphate buffer pH -7.4, RPM-100.	Time interval / Limit 2nd Hour – NMT 25.0% 5th Hour – 30% to 60% 12th Hour – NLT 70%
	b) Metformin Hydrochloride IP Apparatus 2 – Paddle with sinker Medium-1000ml, Phosphate buffer pH-6.8, RPM-100, Time- 1, 3 and 10hrs. 37°C±0.5°C.	Time interval / Limit 1st hour – 20% to 40% 3rd hour – 45% to 65% 10th hour – NLT 85%
10.0	**Assay: Each Uncoated bilayered sustained release tablet contains:** Gliclazide BP 60mg Metformin Hydrochloride BP 850mg	 57.0mg to 66.0mg (95.0% to 110.0% of the labeled claim) 807.5mg to 935.0mg (95.0% to 110.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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	PRODUCT SPECIFICATION			Market: Export
Name of Product	**GLIDE-M 60/850** (Gliclazide and Metformin Hydrochloride Sustained Release Tablets)			
Specification No.	SPEC-1014-01	**Revision No.**	01	**Product Code:**1014
Supersedes	SPEC-1014-00	**Effective Date:**	21/07/2025	**Page No.:** 5 of 10

RELEASE SPECIFICATION – FINISHED PRODUCT
SPECIFICATION CODE: SPEC-1014-FP

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	White and reddish coloured, bilayered convex uncoated tablet with break line on reddish layer and plain on white layer.
2.0	**Identification***	
	b) Gliclazide BP (By HPLC)	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)	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	1360.0 mg ± 5 % (1292.0 mg to 1428.0 mg)
4.0	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%.
5.0	**Dimension*:**	
	Length	22.00 mm ± 0.2 mm (21.8mm – 22.2mm)
	Width	9.50 mm ± 0.2 mm (9.30mm – 9.70mm)
6.0	Thickness*	7.00 mm ± 0.30 mm (6.70mm - 7.30mm)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	19/07/25	19/07/25	21/07/2025

S.NO	TEST (s)	SPECIFICATION (s)
7.0	Hardness*	Not less than 150N
8.0	Friability*	Not more than 1.0% w/w
9.0	**Dissolution:** **a) Gliclazide BP** Apparatus 2 – Paddle with sinker Medium-900ml, Phosphate buffer pH -7.4, RPM-100.	Time interval / Limit: 2nd Hour – NMT 25.0% 5th Hour – 30% – 60% 12th Hour – NLT 70%
	b) Metformin Hydrochloride IP Apparatus 1 – Paddle with sinker Medium-1000ml, Phosphate buffer pH-6.8, RPM-100, Time- 1, 3 and 10hrs. 37°C±0.5°C.	Time interval / Limit: 1st hour – 20% to 40% 3rd hour – 45% to 65% 10th hour – NLT 85%
10.0	**Assay: Each Uncoated bilayered sustained release tablet contains:** Gliclazide BP 60mg Metformin Hydrochloride BP 850mg	57.0mg to 66.0mg (95.0% to 110.0% of the labeled claim) 807.5mg to 935.0mg (95.0% to 110.0% of the labeled claim)

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S.NO	TEST (s)	SPECIFICATION (s)
11.0	**Microbial contamination$**	
	i)Total viable aerobic count	
	a) Total aerobic microbial count	Not more than 1000 cfu/g
	b) Total yeast and mould count	Not more than 100 cfu/g
	ii) Escherichia coli	Should be absent/g
	iii) Salmonella Species	Should be absent/10g
	iv) Pseudomonas aeruginosa	Should be absent/g
	v) Staphylococcus aureus	Should be absent/g

Note: * Marked Test results shall be taken from compressed tablets.

$ - Microbial Limit Test shall be performed for validation batches, first batch of the year and once in every 10th batch (Batch number ends with 1).

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STABILITY SPECIFICATION
SPECIFICATION CODE: SPEC-1014-ST

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	White and reddish coloured, bilayered convex uncoated tablet with break line on reddish layer and plain on white layer.
2.0	Average weight of tablet	1360.0 mg ± 5 % (1292.0 mg to 1428.0 mg)
3.0	**Dissolution:** **a) Gliclazide BP** Apparatus 2 – Paddle with sinker Medium-900ml, Phosphate buffer pH -7.4, RPM-100.	**Time interval** / **Limit** 2nd Hour: NMT 25.0% 5th Hour: 30% to 60% 12th Hour: NLT 70%
	b) Metformin Hydrochloride IP Apparatus 1 – Paddle with sinker Medium-1000ml, Phosphate buffer pH-6.8, RPM-100, Time- 1, 3 and 10hrs. 37°C±0.5°C.	**Time interval** / **Limit** 1st hour: 20% to 40% 3rd hour: 45% to 65% 10th hour: NLT 85%
4.0	**Assay: Each Uncoated bilayered sustained release tablet contains:** Gliclazide BP 60mg Metformin Hydrochloride BP 850mg	 54.0mg to 66.0mg (90.0% to 110.0% of the labeled claim) 765.0mg to 935.0mg (90.0% to 110.0% of the labeled claim)

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Signature			
Date	19/07/25	19/07/25	21/07/2025

S.NO	TEST (s)	SPECIFICATION (s)
5.0	**Microbial contamination#**	
	i)Total viable aerobic count	
	a) Total aerobic microbial count	Not more than 1000 cfu/g
	b) Total yeast and mould count	Not more than 100 cfu/g
	ii) Escherichia coli	Should be absent/g
	iii) Salmonella Species	Should be absent/10g
	iv) Pseudomonas aeruginosa	Should be absent/g
	v) Staphylococcus aureus	Should be absent/g

Mark test will performed on 6th month of Accelerated stability and every 12th month of Long term stability.

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	PRODUCT SPECIFICATION			Market: Export
Name of Product	**GLIDE-M 60/850** (Gliclazide and Metformin Hydrochloride Sustained Release Tablets)			
Specification No.	SPEC-1014-01	**Revision No.**	01	**Product Code:**1014
Supersedes	SPEC-1014-00	**Effective Date:**	21/07/2025	**Page No.:** 10 of 10

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
FGSTSG033-01	Market detail incorporated in Header space of Specification.	ST/CC/21/052	06/08/2021
SPEC-1014-00	(i) Specification numbering Format revised. As per SOP No.ST/QC/058. (ii) Thickness and Hardness test limit has been revised.	ST/CC/24/211	18/07/2024
SPEC-1014-01	There is no change in the Specification and changes made in the STP only.	ST/CC/25/170	21/07/2025

**** END OF THE DOCUMENT ****

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	STANDARD TESTING PROCEDURE			**Market** Export
Name of Product	**GLIDE-M 60/850** (Gliclazide and Metformin Hydrochloride Sustained Release Tablets)			
STP No.	STP-1014-01	**Revision No.**	01	**Product Code:**1014
Supersedes	STP-1014-00	**Effective Date:**	21/07/2025	**Page No.:** 1 of 17

1.0 DESCRIPTION: (By Visual Inspection)

Blend: Spread about 1 to 2 g of sample on a white surface and note the observation.

Tablets: Take 10 tablets on a white background and note the colour, shape, coated or uncoated, embossing and other observations, if any.

2.0 IDENTIFICATION:

a) Gliclazide BP (By HPLC):

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):

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:

Weigh and note down the weight of 20 tablets.

$$\text{Average weight of tablet (in mg)} = \frac{\text{Weight of 20 tablets (g)}}{20} \times 1000$$

4.0 UNIFORMITY OF WEIGHT:

Weigh 20 tablets selected at random and determine the individual weight.

Acceptance criteria:

The average mass of the tablets should comply with the limits specified in the individual specification / monograph.

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Not more than two of the individual masses deviate from the average mass by more than percentage deviation shown in table and none deviate by more than twice that percentage.

Average mass of the tablet	Percentage deviation
80mg or Less than 80mg	± 10
More than 80 mg but Less than 250 mg	± 7.5
250 mg or more	± 5

Calculate the percentage deviation for highest individual weight of tablet as follows:

$$\left[\frac{\text{Highest individual weight of tablet (in g)}}{\text{Average weight of tablet (in g)}} \times 100\right] - 100$$

Calculate the percentage deviation for lowest individual weight of tablet as follows:

$$\left[\frac{\text{Lowest individual weight of tablet (in g)}}{\text{Average weight of tablet (in g)}} \times 100\right] - 100$$

5.0 **LENGTH, WIDTH AND THICKNESS:**

Select randomly 10 tablets and measure the Length, Width and thickness using a suitable Vernier caliper. Record the values. Calculate the average thickness of the tablets as follows:

Average thickness (in mm) = Total thickness of 10 tablets (in mm)/10

Average Length (in mm) = Total Length of 10 tablets (in mm)/10

Average Width (in mm) = Total Width of 10 tablets (in mm)/10

Report the average, minimum and maximum values.

6.0 HARDNESS:

Select randomly 10 tablets and check the hardness using a suitable Hardness tester. Record the values. Calculate the average hardness of the tablets as follows:

Average hardness (in N) = Total hardness of 10 tablets (in N)/10.

7.0 FRIABILITY:

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).

$$\% \text{ of Friability} = \frac{\text{Initial Weight(a) - Final weight (b)}}{\text{Initial Weight (a)}} \times 100$$

8.0 DISSOLUTION:

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

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Orthophosphoric acid	:	AR grade
Methanol	:	HPLC grade
Water	:	Purified
Sodium Hydroxide	:	AR grade
Sodium Chloride	:	AR grade
Acetonitrile	:	HPLC grade

Dissolution parameters:

Apparatus	:	Apparatus 2 (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 12 Hours

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	:	12 Minutes

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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 23.8gm of disodium hydrogen orthophosphate, 1.9gm of Potassium dihydrogen orthophosphate and 80gm 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 mg of Gliclazide working standard into 100ml volumetric flask. Add about 5 ml of Methanol, sonicate to dissolve and dilute up to mark with dissolution medium and mix. Further dilute 5 ml of this solution to 50 ml with dissolution medium and mix well. (**Concentration:** 0.066mg/ml of Gliclazide)

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 and inject. (**Concentration:** 0.066mg/ml of Gliclazide)

(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.

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.

$$CFn = \frac{Dn}{900} X10$$

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

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	:	Apparatus 2 (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

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 using 0.2 N sodium hydroxide solution.

Preparation of Standard solution:

Weigh accurately and transfer about 42.5 mg of Metformin Hydrochloride Working standard into 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 5ml of this solution to 250 ml with dissolution medium and mix. (**Concentration:** 0.0085mg/ml)

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 1ml of this filtrate to 100 ml with dissolution medium and Mix. (**Concentration:** 0.0085mg/ml)

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

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

Procedure:

Measure the absorbance of resulting Standard solution 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

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Date	19/07/25	19/07/25	21/07/2025

9.0 ASSAY:

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 time	:	25 Minutes
Diluent-1	:	Buffer Preparation

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 3.0 using Orthophosphoric acid. Filter through 0.20micron membrane filter, sonicate and degas.

Preparation of Standard solution:

Weigh accurately and transfer about 60mg of Gliclazide working standard and 850mg of Metformin Hydrochloride working standard into 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 ml of this solution to 25 ml with mobile phase and mix well. (**Concentration:**0.12mg/ml of Gliclazide and 1.70mg/ml of Metformin Hydrochloride)

Preparation of Sample solution: (For blend)

Weigh 30g of granules and crush to fine powder. Weigh accurately transfer the sample powder eq.to 60mg of Gliclazide into 100ml clean and dry volumetric flask, add about 45ml of Acetonitrile and sonicate for 10 minutes with intermittent shaking cool and then add 30ml of diluent-1, sonicate for 10 minutes with intermittent shaking cool and dilute upto mark with diluent-1. Filter through 0.45µ syringe filter. Further dilute 5ml of this solution to 25ml with mobile phase and mix well.

Preparation of sample powder: (For Tablets)

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.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	19/07/25	19/07/25	21/07/2025

Preparation of Sample solution:

Weigh accurately and transfer the sample powder eq.to 60mg of Gliclazide into 100ml clean and dry volumetric flask, add about 45ml of Acetonitrile and sonicate for 10 minutes with intermittent shaking cool and then add 30ml of diluent-1, sonicate for 10 minutes with intermittent shaking cool and dilute upto mark with diluent-1. Filter through 0.45µ syringe filter. Further dilute 5ml of this solution to 25ml with mobile phase and mix well. (**Concentration:**0.12mg/ml of Gliclazide and 1.70mg/ml of Metformin Hydrochloride)

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 (Mobile phase)	1
2	Standard solution	5
3	Sample solution	2
4	Bracketing standard (Standard solution)	1 Each after every 6 sample injection

System suitability:

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

2) The column efficiency for the peak of Metformin obtained in the chromatogram of standard solution should not less than 1500 and Gliclazide obtained in the chromatogram of Standard solution should not less than 2000.

3) The % RSD for the retention time of Metformin 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 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 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 and Gliclazide peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00

Calculations:

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

$$= \frac{AT_G}{AS_G} \times \frac{WS_G}{100} \times \frac{5}{25} \times \frac{100}{WT} \times \frac{25}{5} \times \frac{P_G}{100} \times AW$$

Where,

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

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

WS_G = Weight of Gliclazide working standard in mg.

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WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

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

Calculate the assay of Gliclazide in % as follows:

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

LC_G = Label claim of Gliclazide in mg/tablet.

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

$$= \frac{AT_M}{AS_M} \times \frac{WS_M}{100} \times \frac{5}{25} \times \frac{100}{WT} \times \frac{25}{5} \times \frac{P_M}{100} \times AW$$

Where,

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

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

WS_M = Weight of Metformin Hydrochloride working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

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

Calculate the assay of Metformin Hydrochloride in % as follows:

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

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

10.0 MICROBIAL CONTAMINATION:

Total Viable aerobic count and Pathogen test refer as per the current SOP No: ST/MB/011.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Signature			
Date	19/07/25	19/07/25	21/07/2025

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
FGTTSG033-01	Market detail incorporated in Header space of STP.	ST/CC/21/052	06/08/2021
STP-1014-00	(i) STP numbering Format revised. As per SOP No.ST/QC/058. (ii) In Assay, the column efficiency limit for the peak of Metformin has been changed to should not less than 1500 based on Analytical method validation report.	ST/CC/24/211	18/07/2024
STP-1014-01	In the Dissolution test for Metformin Hydrochloride, The Procedure has been changed to **"Measure the absorbance of resulting Standard solution and sample solution at 233 nm and calculate % dissolution"** from "Measure the absorbance of resulting Standard solution(5 replicates) and sample solution at 233 nm and calculate % dissolution"	ST/CC/25/170	21/07/2025

****END OF THE DOCUMENT****

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Date	19/07/25	19/07/25	21/07/2025