



Safetab Life Science

**Plot No. A-67 to 72, PIPDIC
Electronic Park, Thirubuvanaï,
Puducherry-605107**

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CERTIFICATE OF ANALYSIS

Product Name	:	GLIDE–M 60/850 (Gliclazide and Metformin Hydrochloride Sustained Release Tablets)			
Batch No.	:	G17250526	Batch Size	:	5.0LAC
Mfg. Date	:	MAY'2025	Exp. Date	:	APR'2028
Sampling Date	:	22/05/2025	Sample Quantity	:	4X10'S
Analysis Date	:	23/05/2025	Specification No.	:	SPEC-1014-00
Release Date	:	29/05/2025	A.R. No.		SFP250880

Sr. 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 (By HPLC)		
	A. Metformin HCl BP	The retention time of one of the major Peak in the chromatogram of sample preparation corresponds to the peak due to Metformin in standard preparation as obtained in assay.	Complies
	B. Gliclazide BP	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.	Complies
3.	Average Weight of Tablet	1360.0 mg \pm 5.0% (1292.0 mg to 1428.0 mg)	1367.8mg
4.	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than \pm 5.0% and none deviate by more than \pm 10%	(-): 1.23% (+): 2.72%
5.	Length	22.00 mm \pm 0.2 mm (21.8 to 22.2 mm)	22.10mm

Particulars	Prepared By	Reviewed By	Approved By
Name	S.PALANICHAMY	C.K.SARAVANAN	M.VIJAYAKUMAR
Designation	Asst.Manager - QC	Asst.Manager - QC	GM - QC
Signature/Date			



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6.	Width	9.50 mm \pm 0.2 mm (9.30 to 9.70 mm)	9.54mm
7.	Thickness	7.00 mm \pm 0.3 mm (6.70 to 7.30 mm)	6.88mm
8.	Hardness	Not less than 150 N	205.4N
9.	Friability	Not more than 1.0%	0.16%
10.	Dissolution		
	Gliclazide:		
	2 nd hour	Not more than 25.0%	Min: 13.7%; Max: 24.4%; Avg: 19.4%
	5 th hour	Between 30.0% to 60.0%	Min: 31.1%; Max: 59.9%; Avg: 47.7%
	12 th hour	Not less than 70.0%	Min: 81.5%; Max: 97.9%; Avg: 91.7%
	Metformin Hydrochloride:		
	1 st hour	Between 20.0% to 40.0%	Min: 21.1%; Max: 23.7%; Avg: 22.1%
	3 rd hour	Between 45.0% to 65.0%	Min: 46.9%; Max: 49.4%; Avg: 48.0%
	10 th hour	Not less than 85.0%	Min: 98.8%; Max: 101.1%; Avg: 99.9%

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11.	Assay: Each Uncoated Bilayered Sustained Released Tablet Contains		
	Gliclazide BP.....60 mg	Not less than 90.0% and not more than 110.0% of labeled claim	62.88mg (104.8%)
	Metformin Hydrochloride BP.....850 mg	Not less than 90.0% and not more than 110.0% of labeled claim	829.40mg (97.6%)
12.	Microbial Limit Test:		
	Total aerobic microbial count	Not more than 1000 cfu/g	<10cfu/g
	Total Yeast & Mould count	Not more than 100 cfu/g	<10cfu/g
	E. Coli	Should be Absent/g	Absent
	Salmonella	Should be Absent/10 g	Absent
	P. aeruginosa	Should be Absent/g	Absent
	S. aureus	Should be Absent/g	Absent

Remarks: The sample Complies/Does not Complies as per BP / USP / In-House specification..

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