



INNOVA CAPTAB LTD
1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I,
JHARMAJRI, BADDI (HP) INDIA

Certificate of Analysis

Product Name: Glycoheal G 1001

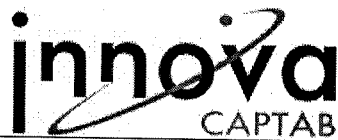
Generic Name	Glimepiride & Metformin Hydrochloride Prolonged Release Tablets IP	Packing Code	GG650001
Batch Log No	32421731	Packing Batch No	GG654001
Bulk Batch No	GG654001	Batch Size	2.0 Lac
Packing Type	20*10 Tablets	Date of Analysis	26/06/2024
A.R. No.	2003FP324003153	Reference	IP
Mfg. Date	05/2024	Exp. Date	04/2026
Specification No	FPS-GG65-00	Date of Release	01/07/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Pink / White coloured, bilayered capsule shaped, biconvex, uncoated tablets having plain on both side.	Pink / White coloured, bilayered capsule shaped, biconvex, uncoated tablets having plain on both side.
2	Metformin Hydrochloride (By UV Spectrophotometer)	In the Assay, the maxima at 232nm obtained with the test solution correspond to that in the maxima obtained with reference solution.	In the Assay, the maxima at 233nm obtained with the test solution correspond to that in the maxima obtained with reference solution.
3	Glimepiride (By High Performance Liquid Chromatography)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution.	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the standard solution.
4	Average weight	1400.0mg $\pm$ 5.0%	1397.47 mg
5	Uniformity of weight	$\pm$ 5.0% of average weight	%Maximum +ve deviation : 0.9 % %Maximum -ve deviation:-0.8 %
6	Hardness	Not less than 50 Newton	Max : 125.8 N Min:103.5 N
7	Friability	Not more than 1.0% w/w	0.35 %w/w
8	1st hour	Not more than 50%	Min : 33.6 % Max : 36.7 % Avg:34.8 %
9	3rd hour	Between 30% and 80%	Min : 64.4 % Max : 67.4 % Avg:65.4 %
10	10th hour	Not less than 70%	Min : 98.0 %

Remarks: APPROVED (Sample conforms to above Specification)

Comments: --

Prepared By	Reviewed By	Approved By
ranjit.nayak(Analyst)	omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
02/07/2024 17:51	02/07/2024 17:55	02/07/2024 17:58
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			Max : 100.1 % Avg:98.7 %
11	For Glimepiride	Not less than 70% (Q) of labeled amount of Glimepiride should be dissolved Phosphate buffer pH 7.8 with SLS, at 90 minutes.	Min : 83.0 % Max : 84.8 % Average:83.6 %
12	Uniformity of content (Glimepiride)	Between 85.0% and 115.0% of average content.	Max : 100.4 % Min:99.7 %
13	Glimepiride IP.....1mg	0.90mg - 1.10mg [90.0% to 110.0% of the labeled claim]	Assay % of Label Claim: : 99.6 % Assay:mg/Tab:1.00 mg/tab
14	Metformin Hydrochloride IP.....1000mg As prolonged-release form)	900.00mg to 1100.00mg (90.0% to 110.0% of Labeled claim)	Assay (I) % : 98.9 % Assay:mg/Tab:988.84 mg/tab
15	Residual Solvents (By GC)#		
15.1	Isopropyl alcohol	Not more than 5000ppm	274.02ppm
16	Microbial Limits Test		
16.1	Total aerobic microbial count	Not more than 10^3 CFU/gm	20 CFU/gm
16.2	Total molds & yeasts count	Not more than 10^2 CFU/gm	<10 CFU/gm
16.3	E.coli	Absent /gm	Absent /gm

Remarks: APPROVED (Sample conforms to above Specification)

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