



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Glycoheal-500	A.R. No.	FG/G/24A0118
Generic Name	Metformin Hydrochloride Tablets IP 500 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40227	Sample Received on	13/02/2024
Batch Size:	7.0 Lac	Analysis Date	13/02/2024
Mfg. Date.	02/2024	Release Date	19/02/2024
Exp. Date	01/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, elongated, biconcave having scored line on one side and other side plain, uncoated tablet.	White colour, elongated, biconcave having scored line on one side and other side plain, uncoated tablet.		
2.	Identification:				
	a) By IR	The IR spectrum of the residue matches with the reference spectrum Metformin hydrochloride or with the spectrum obtained with reference standard or working standard of Metformin hydrochloride.	Complies		
	b) By chemically	An orange-red colour is produced which darkness on keeping.	Complies		
	c) By chemically	A curdy white precipitate is produced.	Complies		
3.	Average weight	630 mg $\pm$ 3.0%.	621.029 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 618.09 mg ; Max: 623.09 mg -0.47% ; +0.33%		
5.	Disintegration	Not more than 15 minutes.	05 minutes 41 seconds.		
6.	Friability	NMT 1.0%w/w	0.50%w/w		
7.	Hardness	Not less than 4.0 Kg/cm ²	12.4 Kg/cm ²		
8.	Dissolution	Not less than 70.00 % (Q) of label claim is dissolved in 45 minutes	Min. = 99.83% Max. = 102.28% Avg. = 101.09%		
9.	Assay :				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Metformin Hydrochloride IP	500 mg	Between 95.0 % to 105.0 % of labeled amount. (Between 475.0 mg to 525.0 mg)	490.24 mg	98.05%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	19/02/2024	19/02/2024	19/02/2024



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10.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	30 cfu/g
ii.	Total yeast and mould count	NMT 100 cfu/g	Less than 10 cfu/g
iii.	Pathogens: Escherichia coli	Should be absent/g	Absent/g

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	DURGESH KUMAR	Gaurav Singh
Designation	Executive	QC Head	Head QA
Signature			
Date	19/02/2024	19/02/2024	19/02/2024