



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 -1000	A.R. No.	FG/G/24A0938
Generic Name	Metformin Hydrochloride Prolonged release Tablets IP 1000 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40685	Sample Received on	26/06/2024
Batch Size:	2.0 Lac	Analysis Date	26/06/2024
Mfg. Date.	06/2024	Release Date	01/07/2024
Exp. Date	05/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, elongated, biconvex having scored line on one side and other side plain, uncoated tablet.	White colour, elongated, biconvex having scored line on one side and other side plain, uncoated tablet.		
2.	Identification:				
	A) By IR	The spectrum obtained due to active component in test preparation should correlate with that of reference Metformin Hydrochloride chromatogram.	Complies		
	B) By Chemical	An orange-red colour is produced which darkens on keeping.	Complies		
3.	Average weight	1300.00 mg $\pm$ 3.0%.	1313.69 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 1295.64 mg ; Max: 1324.32 mg - 1.39% ; +0.81%		
5.	Friability	NMT 1.0%w/w	0.14 %w/w		
6.	Hardness	Not less than 4.0 Kg/cm ²	13.25 Kg/cm ²		
7.	Dissolution:				
	1 st Hours	25.0% to 50.0%.	Minimum = 37.45% Maximum = 41.47% Average = 39.74%		
	3 rd Hours	45.0% to 75.0%.	Minimum = 67.79% Maximum = 70.38% Average = 69.08%		
	10 th hours	Not less than 80.0%	Minimum = 98.03% Maximum = 100.85% Average = 99.83%		
8.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Metformin Hydrochloride IP (As sustained release)	1000 mg	Between 90.0 % .to 110.0 % of labeled amount. (Between 900.0 mg to 1100.0 mg)	989.75 mg	98.98%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gaurav Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	01/07/2024	01/07/2024	01/07/2024



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 -1000	A.R. No.	FG/G/24A0938
Generic Name	Metformin Hydrochloride Prolonged release Tablets IP 1000 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40685	Sample Received on	26/06/2024
Batch Size:	2.0 Lac	Analysis Date	26/06/2024
Mfg. Date.	06/2024	Release Date	01/07/2024
Exp. Date	05/2026	Page No.:	Page 2 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
9.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	25 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	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	01/07/2024	01/07/2024	01/07/2024