



WINDLAS BIOTECH LIMITED

40/1 Mohabewala Industrial Area Dehradun-248110 (Uttarakhand)

Approved by: FDA Uttarakhand, GLP certified Lab

FORM 39 [See rule 150E(f)]

Report of Analysis by Approved Institution

Lic. No.: 1/UA/CTL*/2024

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	GLYCOHEAL PG 2 SR TABLETS (SALE)		
Generic Name/ Dosage Form Strength (mg)	Glimepiride 2 mg, Pioglitazone 15 mg & Metformin Hydrochloride (SR) 500 mg Tablets		
Batch No.	GPZ24002	Booking ID/A.R. No.	QC/FG/24/14381
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	12/2024	Exp. Date	11/2026
Reference	IH	Sample Qty.	1x75 TABLET
Sample Received on	31/12/2024	Manufacturer Lic. No	34/UA/2013,55/UA/SC/P-2013
Protocol/STP No.	WBL/STP/FG/0421	Ref. SPS No.	WBL/FPS/FG/6139
Date of Analysis started on	31/12/2024	Date of Analysis completed on	02/01/2025
Sample Send by and Address	WINDLAS BIOTECH LIMITED (PLANT-2) ,Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun-248110 UK		
Manufactured By	WINDLAS BIOTECH LIMITED (PLANT-2)	Page No.	01 of 04

S.No.	Test	Specification	Result
1	Description	White to off white & Orange coloured, elongated, biconvex, bilayered, uncoated tablets, plain on both sides.	White & Orange coloured, elongated, biconvex, bilayered, uncoated tablets, plain on both sides.
2	Identification		
2a.	For Glimepiride	In the Assay of Glimepiride, the principal peak in the chromatogram obtained with the Test Solution corresponds to the principal peak in the chromatogram obtained with the Standard Solution.	Complies
2b.	For Pioglitazone Hydrochloride	In the Assay of Pioglitazone, the principal peak in the chromatogram obtained with the Test Solution corresponds to the principal peak in the chromatogram obtained with the Standard Solution.	Complies

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
Name	Ayushi Sharma	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager-QA	G. M.
Date	02/01/2025	02/01/2025	02/01/2025	02/01/2025

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S.No.	Test	Specification	Result
2c.	For Metformin Hydrochloride	When examined in the range of 200-300 nm, a 0.001 per cent w/v solution of Metformin Hydrochloride RS and Test Solution, as obtained in the Assay, shows absorption maxima, at about 232 nm.	Complies
3	Friability	Not more than 1.0% w/w	0.2 % w/w
4	Average weight	848.75 to 901.25 mg	871.16 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5%. Not tablet deviate from the average weight by more than 10%	-0.85% to +0.73%
6	Dissolution		
6a.	1st hour Metformin Hydrochloride IP	25.0 to 50.0%	Min-32.1% Max-39.2% Avg-35.9%
6b.	3rd hour Metformin Hydrochloride IP	45.0 to 75.0%	Min-62.7% Max-67.5% Avg-65.5%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
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S.No.	Test	Specification	Result
6c.	10th hour Metformin Hydrochloride IP	Not less than 80.0%	Min-98.2% Max-102.1% Avg-100.4%
6d.	Dissolution Glimepiride IP	Not less than 70.0% of labeled amount in 60 minutes	Min-93.6% Max-99.9% Avg-96.9%
6e.	Pioglitazone Hydrochloride IP eq. to Pioglitazone	Not less than 70.0% of labeled amount in 45 minutes	Min-96.4% Max-100.7% Avg-98.4%
7	Uniformity of Dosage Units		
7a.	(By Content Uniformity) Glimepiride IP	Acceptance value should be less than 15	6.30
7b.	(By Content Uniformity) Pioglitazone Hydrochloride IP eq. to Pioglitazone	Acceptance value should be less than 15	5.70
7c.	(By Weight Variation) Metformin Hydrochloride IP	Acceptance value should be less than 15	1.40
8	Assay Each uncoated bilayered tablet contains:		
8a.	Glimepiride IP...2mg	90.0 to 110.0%	104.3%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
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S.No.	Test	Specification	Result
8b.	Pioglitazone Hydrochloride IP eq. to Pioglitazone...15mg	90.0 to 110.0%	100.5%
8c.	Metformin Hydrochloride IP (in sustained release form)...500mg	90.0 to 110.0%	100.1%

Remarks : The results of analysis relate only to the analysis applied.

In the opinion of the undersigned, the sample referred to above is of standard Quality as defined in the Act and the rules made thereunder for the reason given below.

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
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