

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	GLYCOHEAL PG 1 SR TABLETS (SALE)		
Generic Name/Dosage Form Strength (mg)	Glimepiride 1 mg, Pioglitazone 15 mg & Metformin Hydrochloride (SR) 500 mg Tablets		
Batch No.	GPR24001	A.R. No.	QC/FG/24/05881
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	05/2024	Exp. Date	04/2026
Reference	IH	Market	Domestic
Sample Received on	15/06/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/0687	Ref. SPS No.	WBL/FPS/FG/6132
Date of Analysis started on	23/06/2024	Date of Analysis completed on	13/07/2024
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S.No.	Test	Specification	Result
1	Description	White to off white & Yellow coloured, elongated, biconvex, bilayered, uncoated tablets, plain on both sides.	White & Yellow coloured, elongated, biconvex, bilayered, uncoated tablets, plain on both sides.
2	Identification		
2a.	For Glimepiride & Pioglitazone	The retention time of the major peak in the chromatogram of the test solution should correspond to that in the chromatogram of the standard solution as obtained in the assay.	Complies
2b.	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	0.18 % w/w
4	Average weight	848.75 to 901.25 mg	884.46 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5%. No tablet deviate from the average weight by more than 10%.	-1.06% to +0.81%
6	Dissolution		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager-QA	G. M.
Date	13/07/2024	13/07/2024	15/07/2024	15/07/2024

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S.No.	Test	Specification	Result	
6a.	1st hour Metformin Hydrochloride IP	25.0 to 50.0%	Min-35.0% Max-39.6% Avg-37.3%	
6b.	3rd hour Metformin Hydrochloride IP	45.0 to 75.0%	Min-65.8% Max-69.7% Avg-68.2%	
6c.	10th hour Metformin Hydrochloride IP	Not less than 80.0%	Min-96.8% Max-98.6% Avg-97.2%	
6d.	Dissolution Glimepiride IP	Not less than 70.0% of labeled amount in 60 minutes	Min-98.2% Max-99.4% Avg- 98.9%	
6e.	Pioglitazone Hydrochloride IP eq. to Pioglitazone	Not less than 70.0% of labeled amount in 45 minutes	Min-95.9% Max-101.5% Avg-98.9%	
7	Uniformity of Dosage Units			
7a.	(By Content Uniformity) Glimepiride IP	Acceptance value should be less than 15	10.5	
7b.	(By Content Uniformity) Pioglitazone Hydrochloride IP eq. to Pioglitazone	Acceptance value should be less than 15	8.27	
7c.	(By Weight Variation) Metformin Hydrochloride IP	Acceptance value should be less than 15	1.00	
8	Assay Each uncoated bilayer tablet contains:			
	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager-QA	G. M.
Date	13/07/2024	13/07/2024	15/07/2024	15/07/2024

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S.No.	Test	Specification	Result
8a.	Glimepiride IP...1mg	90.0 to 110.0%	101.0%
8b.	Pioglitazone Hydrochloride IP eq. to Pioglitazone...15mg	90.0 to 110.0%	100.8%
8c.	Metformin Hydrochloride IP (Prolonged Release form)...500mg	90.0 to 110.0%	100.0%

Remarks : In the opinion of undersigned the sample refer to above specifications complies with IH

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager-QA	G. M.
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