

WINDLAS BIOTECH LIMITED

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.	GPZ24001	A.R. No.	QC/FG/24/05882
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/0421	Ref. SPS No.	WBL/FPS/FG/6139
Date of Analysis started on	23/06/2024	Date of Analysis completed on	15/07/2024
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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
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

	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	15/07/2024	15/07/2024	15/07/2024	15/07/2024

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S.No.	Test	Specification	Result	
3	Friability	Not more than 1.0% w/w	0.21 % w/w	
4	Average weight	848.75 to 901.25 mg	886.58 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%	-1.08% to +1.38%	
6	Dissolution			
6a.	1st hour Metformin Hydrochloride IP	25.0 to 50.0%	Min-35.3% Max-37.1% Avg-36.4%	
6b.	3rd hour Metformin Hydrochloride IP	45.0 to 75.0%	Min-70.2% Max-71.0% Avg-70.6%	
6c.	10th hour Metformin Hydrochloride IP	Not less than 80.0%	Min-96.8% Max-98.9% Avg-97.7%	
6d.	Dissolution Glimepiride IP	Not less than 70.0% of labeled amount in 60 minutes	Min-97.9% Max-99.2% Avg-98.4%	
6e.	Pioglitazone Hydrochloride IP eq. to Pioglitazone	Not less than 70.0% of labeled amount in 45 minutes	Min-94.8% Max-98.9% Avg-97.0%	
7	Uniformity of Dosage Units			
7a.	(By Content Uniformity) Glimepiride IP	Acceptance value should be less than 15	9.28	
	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
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S.No.	Test	Specification	Result
7b.	(By Content Uniformity) Pioglitazone Hydrochloride IP eq. to Pioglitazone	Acceptance value should be less than 15	8.48
7c.	(By Weight Variation) Metformin Hydrochloride IP	Acceptance value should be less than 15	2.10
8	Assay Each uncoated bilayered tablet contains:		
8a.	Glimepiride IP...2mg	90.0 to 110.0%	99.5%
8b.	Pioglitazone Hydrochloride IP eq. to Pioglitazone...15mg	90.0 to 110.0%	102.7%
8c.	Metformin Hydrochloride IP (in sustained 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

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