

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	HEALMARYL MV 1.3 TABLETS		
Generic Name/Dosage Form Strength (mg)	Glimepiride 1 mg, Voglibose 0.3 mg & Metformin Hydrochloride (SR) 500 mg Tablets		
Batch No.	HAK24002	A.R. No.	QC/FG/24/07648
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	07/2024	Exp. Date	06/2026
Reference	IH	Market	Domestic
Sample Received on	30/07/2024	Sample Qty.	1x125 TABLET
Ref. STP No.	WBL/STP/FG/0490	Ref. SPS No.	WBL/FPS/FG/5797
Date of Analysis started on	01/08/2024	Date of Analysis completed on	27/08/2024
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S.No.	Test	Specification	Result
1	Description	White to off white & light Brown colour with mottled appearance, elongated, biconvex, bilayered, uncoated tablets, plain on both sides.	White & light Brown colour with mottled appearance, elongated, biconvex, bilayered, uncoated tablets, plain on both sides.
2	Identification		
2a.	For Glimepiride & Voglibose	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	0.3 % w/w
4	Average weight	800.25 to 849.75 mg	824.56 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%.	-1.46% to +1.29%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Ayushi Sharma	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager-QA	G. M.
Date	27/08/2024	28/08/2024	28/08/2024	28/08/2024

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S.No.	Test	Specification	Result
6	Dissolution		
6a.	1st hour Metformin Hydrochloride IP	25.0 to 50.0%	Min-33.0% Max-35.9% Avg-34.5%
6b.	3rd hour Metformin Hydrochloride IP	45.0 to 75.0%	Min-64.9% Max-68.3% Avg-66.2%
6c.	10th hour Metformin Hydrochloride IP	Not less than 80.0%	Min-98.9% Max-101.9% Avg-100.5%
6d.	Dissolution Glimepiride IP	Not less than 70.0% of labeled amount	Min-93.5% Max-98.8% Avg-96.1%
7	Uniformity of dosage unit		
7a.	(By Content Uniformity) Glimepiride IP	Acceptance value should be less than 15	5.10
7b.	(By content uniformity) Voglibose IP	Acceptance value should be less than 15	11.00
7c.	(By Weight Variation) Metformin Hydrochloride IP	Acceptance value should be less than 15	2.20
8	Assay Each uncoated bilayered tablet contains:		
8a.	Glimepiride IP...1mg	90.0 to 110.0%	101.4%
8b.	Voglibose IP...0.3mg	90.0 to 110.0%	104.7%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
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S.No.	Test	Specification	Result
8c.	Metformin Hydrochloride IP (as sustained release form)...500mg	90.0 to 110.0%	101.4%

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
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