

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	MEFHEAL-SPAS TABLETS		
Generic Name/Dosage Form Strength (mg)	Mefenamic Acid 250 mg and Dicyclomine Hydrochloride 10 mg Tablets IP		
Batch No.	MHP24004	A.R. No.	QC/FG/24/09776
Batch Size	60000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	08/2024	Exp. Date	07/2027
Reference	I.P	Market	Domestic
Sample Received on	19/09/2024	Sample Qty.	1x150 TABLET
Ref. STP No.	WBL/STP/FG/0571 (Current version)	Ref. SPS No.	WBL/FPS/FG/P3/1048
Date of Analysis started on	28/09/2024	Date of Analysis completed on	30/09/2024
Page No.	01 of 03		

S.No.	Test	Specification	Result
1	Description	Light yellow coloured, round, flat faced, beveled edged, uncoated tablet, plain on both sides.	Light yellow coloured, round, flat faced, beveled edged, uncoated tablet, plain on both sides.
2	Identification		
2a.	Mefenamic Acid	In the Assay for mefenamic acid, the test solution shows an absorption maxima and minima at the wavelength as that of reference solution of mefenamic acid.	Complies
2b.	Dicyclomine Hydrochloride	In the Assay for dicyclomine hydrochloride the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution of dicyclomine hydrochloride.	Complies
3	Diameter	11.10 mm to 11.50 mm	Min = 11.27 mm Max = 11.35 mm
4	Thickness	3.70 mm to 4.10 mm	Min = 3.72 mm Max = 3.79 mm
5	Hardness	Not less than 3.0kgf	8.17 kgf
6	Friability	Not more than 1.0% w/w	0.28 % w/w
7	Disintegration Time	Not more than 15 minutes	07 Min 14 Sec
8	Average weight	436.50 to 463.50 mg	451.83 mg

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Vandana Benwal	Kamlesh Upreti	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager-QC	Assistant Manager-QA	G. M.
Date	30/09/2024	30/09/2024	30/09/2024	30/09/2024

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Page No.	02 of 03		

S.No.	Test	Specification	Result
9	Uniformity of weight	Not more than 2 tablets in 20 deviate from the average weight by more than 5%. No tablet deviates from the average weight by more than 10%.	-1.27 to +1.39%
10	Dissolution		
10a.	70% (Q) Mefenamic Acid IP	Not less than 75.0% of the stated amount in 45 minutes	Min-99.8% Max-103.7% Avg-102.0%
10b.	70% (Q) Dicyclomine Hydrochloride IP	Not less than 75.0% of the stated amount in 45 minutes	Min-82.4% Max-93.2% Avg-89.4%
11	Uniformity of dosage unit		
11a.	Uniformity of Dosage Unit (By Content uniformity) Dicyclomine Hydrochloride IP	Acceptance value should be less than 15	13.22
11b.	Uniformity of Dosage Unit (By Weight Variation) Mefenamic Acid IP	Acceptance value should be less than 15	2.30
12	Assay Each uncoated tablet contains:		
12a.	Mefenamic Acid IP...250 mg	90.0 to 110.0%	100.5%
12b.	Dicyclomine Hydrochloride IP...10 mg	90.0 to 110.0%	99.7%

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Page No.	03 of 03		

S.No.	Test	Specification	Result
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Remarks : In the opinion of undersigned the sample refer to above specifications complies with IP

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
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