

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.	MHP24002	A.R. No.	QC/FG/24/04430
Batch Size	50000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	05/2024	Exp. Date	04/2027
Reference	I.P	Market	Domestic
Sample Received on	09/05/2024	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	10/05/2024	Date of Analysis completed on	27/05/2024
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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 = 11.3 mm Max = 11.34 mm
4	Thickness	3.70 mm to 4.10 mm	Min = 3.84 mm Max = 3.91 mm
5	Hardness	Not less than 3.0kgf	10.31 kgf
6	Friability	Not more than 1.0% w/w	0.22 % w/w
7	Disintegration Time	Not more than 15 minutes	04 Min 04 Sec
8	Average weight	436.50 to 463.50 mg	448.59 mg

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Vandana Benwal	Ravi Kumar	Manoj Gautam	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Sr. Executive	G. M.
Date	27/05/2024	27/05/2024	27/05/2024	27/05/2024

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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%.	deviation -1.89 to +2.10%
10	Dissolution		
10a.	70% (Q) Mefenamic Acid IP	Not less than 75.0% of the stated amount in 45 minutes	Min-95.2% Max-98.7% Avg-97.1%
10b.	70% (Q) Dicyclomine Hydrochloride IP	Not less than 75.0% of the stated amount in 45 minutes	Min-81.4% Max-100.2% Avg-86.1%
11	Uniformity of dosage unit		
11a.	Uniformity of Dosage Unit (By Content uniformity) Dicyclomine Hydrochloride IP	Acceptance value should be less than 15	6.40
11b.	Uniformity of Dosage Unit (By Weight Variation) Mefenamic Acid IP	Acceptance value should be less than 15	2.20
12	Assay Each uncoated tablet contains:		
12a.	Mefenamic Acid IP...250 mg	90.0 to 110.0%	100.4%
12b.	Dicyclomine Hydrochloride IP...10 mg	90.0 to 110.0%	98.3%

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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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