



INNOVA CAPTAB LTD
1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I,
JHARMAJRI, BADDI (HP) INDIA

CERTIFICATE OF ANALYSIS

Product Name: HIFI 200

Generic Name	CEFIXIME DISPERSIBLE TABLETS	Packing Code	C1210056
Batch Log No	24015623	Packing Batch No	C1214134
Bulk Batch No	C1214134	Batch Size	3.0 L
Packing Type	1 x 10 Tablets	Date of Analysis	05/07/2024
A.R. No.	2002FP224001571	Reference	IP
Mfg. Date	07/2024	Exp. Date	06/2026
Specification No	FPS-C121-07	Date of Release	15/07/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Light yellow coloured capsule shape biconvex having break line on one side uncoated dispersible tablets.	Light yellow coloured capsule shape biconvex having break line on one side uncoated dispersible tablets.
2	Identification (By High Performance Liquid Chromatography)	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3	Average weight	500 mg $\pm$ 3%	505.04 mg
4	Uniformity of weight	500.00 $\pm$ 5% (475.00mg to 525.00mg)	%Maximum +ve deviation : 1.4 % %Maximum -ve deviation:-1.8 %
5	Hardness	Not less than 30.0 N	Max : 137.4 N Min:102.5 N
6	Thickness	4.40 $\pm$ 0.20mm	Max : 4.31 mm Min:4.24 mm
7	Friability	Not more than 1.0% w/w	0.21 %w/w
8	Disintegration Time	Not more than 3.0 minutes	Disintegration Time:0.26 Minutes
9	Dispersion	After dispersion the suspension should be passing by 22# mesh i.e. 710 μ mesh.	Complies
10	Water Content	Not more than 10.0% w/w	8.65 %w/w
11	Dissolution	Not less than 75.0% (Q) of labeled amount of Cefixime should be dissolved in buffer solution at 45 minutes.	Min : 94.3 % Max : 96.0 % Average:95.1 %
12	Assay		
12.1	Each uncoated dispersible tablet contains Cefixime IP as Trihydrate Eq. to anhydrous Cefixime...200 mg	180.00 – 220.00 mg [90.0 – 110.0% of Labeled Claim]	Assay % of Label Claim: : 104.0 % Assay:mg/Tab:208.10 mg/tab

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By		Reviewed By	Approved By
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