

POLESTAR POWER INDUSTRIES (PHARMA DIVISION), BAROTIWALA (H.P.)

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product Name	HIFI 400		
Generic Name	Cefixime Dispersible Tablets IP		
Batch No.	T240345B	Mfg. date	09/2024
A. R. No.	FP2412175	Expiry date	08/2026
Pack Size	10×10 Tablets	Type of packaging	Alu-Alu
Date of receiving	20/09/2024	Batch Size	1,00,000 Tablets
Date of preparation	16/10/2024	Page No.	1 of 2

S. No.	Test	Specification	Result
1	Description	A white to off white, oval shaped, uncoated tablet.	Off white, oval shaped, uncoated tablet.
2	Identification By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution should corresponds to the peaks in the chromatogram obtained with the reference solution (a).	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peaks in the chromatogram obtained with the reference solution (a).
3	Average weight	815.00 mg ± 3.0%	812.75 mg
4	Uniformity of weight	±5.00 % of Average weight	Minimum -0.71 % Maximum +0.76 %
5	Thickness*	5.70 ± 0.3mm	Minimum 5.21 mm Maximum 5.27 mm
6	Length	18.80 ± 0.2mm	Minimum 18.79 mm Maximum 18.83 mm
7	Diameter	8.70 mm ± 0.2mm	Minimum 8.61 mm Maximum 8.63 mm
8	Disintegration time	Not more than 3 minutes	00 Minutes 25 second
9	Uniformity of dispersion	Should be 100 % passes through a sieve screen with a nominal mesh aperture of 710 µm.	Complies
10	Friability	Not more than 1.00% w/w	0.62 %
11	Water	Not more than 10.0%	8.92 %
12	Dissolution	Not less than 75.00 % (Q) of the stated amount of Cefixime, C ₁₆ H ₁₅ N ₅ O ₇ S ₂ , in 45 minutes	Minimum 89.09 % Maximum 93.85 % Average 91.24 %

*Under Deviation No. - D/OSD/24/050

	Prepared by	Checked by	Approved by
Name	Sahil Singh	Rajeev Sharma	Charan Singh Yadav
Designation	Trainee Officer-QC	Officer-QC	Manager-QC
Signature			
Date	16/10/2024	16/10/2024	16/10/2024

Format No.: F/QC/024/02/00

Works: Village -Damuwala, Haripur Road, Barotiwala, Tehsil-Baddi, Distt. - Solan, H.P.- 174103

**POLESTAR POWER INDUSTRIES (PHARMA DIVISION), BAROTIWALA (H.P.)
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT**

Product Name	HIFI 400		
Generic Name	Cefixime Dispersible Tablets IP		
Batch No.	T240345B	Mfg. date	09/2024
A. R. No.	FP2412175	Expiry date	08/2026
Pack Size	10×10 Tablets	Type of packaging	Alu-Alu
Date of receiving	20/09/2024	Batch Size	1,00,000 Tablets
Date of preparation	16/10/2024	Page No.	2 of 2

13	Assay		
	Each uncoated dispersible tablet contains:		
	Cefixime Trihydrate IP eq. to Cefixime 400 mg	Not less than 360.00 mg and not more than 440.00 mg of Cefixime, $C_{16}H_{15}N_5O_7S_2$	385.69 mg
		(Not less than 90.00% and not more than 110.00% of the stated amount of Cefixime)	96.42 %

**MOTHER BATCH DETAILS
(FOR RESULTS)**

Batch No.	T240345A	A.R.No.	FP2411997
Stage	Finished Product (After pack)	Sample Qty.	100 Tablets
Date of Receiving	16/09/2024	Type of packaging	Alu-Alu
Start Date of Analysis	23/09/2024	Date of Release	30/09/2024

Remarks: The above sample of finished product **complies** as per specification no. QC/FPS/122/00

	Prepared by	Checked by	Approved by
Name	Sahil Singh	Rajeev Sharma	Charan Singh Yadav
Designation	Trainee Officer-QC	Officer-QC	Manager-QC
Signature			
Date	16/10/2024	16/10/2024	16/10/2024

Format No.: F/QC/024/02/00

Works: Village -Damuwala, Haripur Road, Barotiwala, Tehsil-Baddi, Distt. - Solan, H.P.- 174103