

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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FORM 13

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

: K. LaIngilneia

Asst. Director (F&D)

CMO Office, Mamit District: Mamit, Pin- 796441

2. Serial No. and date of Inspector's memorandum

: B.17011/12/09-CMO (M)/DRUGS/22 Date 27th Nov,24

3. Number of Sample

:MD08/22

4. Date of receipt

:09-DEC-2024

5. Names of drugs purporting to be contained in the sample: Cefixime Dispersible Tablets IP (Cefime O 200 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1462	GUW/LS/2024- 25/1488	SPT-36186 ^D	08/2023 ^V /	07/2025	Shervotec Pharmaceuticals, 82/4&82/5,HPSIDC,Baddi, Distt, Solan (H.P)

6. Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the Specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied :Please see below

Date of Testing: From 24-Dec-2024 To 02-Jan-2025

COMPOSITION

Each uncoated dispersible tablet contains:

Cefixime Trihydrate IP

Eq. to Cefixime (Anhydrous)

200 mg.

Sr No.	Test Name	Result				
1	Description	Orange colour, round, bi-convex, uncoated dispersible tablet in aluminum blister pack.				
2	Identification	Gives positive test for Cefixime.	NA			
3	Average weight	0.3019 gm.	NA			
4	Uniformity of weight	Complies.	NA			
5	Uniformity of dispersion	Complies.	NA			
6	Disintegration	Complies (All six units disintegrated within 28 seconds).	NMT 3			

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
		10				

1 0 0	Cefixime Trihydrate Eq. to Anhydrous Cefixime	197.06 mg/Tablet	200 mg/Tablet	98.53	90 % to 110 %	I.P. 2022
\$2500 mg			Year and the			

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 03-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

R.D.T.L., Guwahati-22

----- END OF REPORT -----

