

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

Testing Govt. O India Guwahati

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

: SARAH LALDINTLUANGI

ASSISTANT DIRECTOR (FOOD & DRUGS) Sr. CMO OFFICE, SERCHHIP-796181.

SERCHHIP

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

:003/IPA/2024

Date 25/11/2024

3. Number of Sample

:Nil

Date of receipt

:26-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- 25/1503	GUW/LS/2024- 25/1527	SPT-36186	08/2023	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 07-Jan-2025 To 10-Jan-2025

COMPOSITION

Each uncoated dispersible tablet contains:

Cefixime Trihydrate IP

Eq. to Cefixime (Anhydrous)

Protocol Applied: I

Sr No.	Test Name	Result	Limits	
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	0.3004 gm.	NA	
4	Uniformity of weight	Complies.	NA	
5	Uniformity of dispersion	Complies.	NA	
6	Disintegration	Complies (All six units disintegrated within 32 seconds).	NMT 3 minutes	

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cefixime Trihydrate Eq. to Anhydrous Cefixime	215.64 mg/Tablet	200 mg/Tablet	107.82	90 % to 110 %	I.P. 2022

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: 16-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

CDSCO / CDSCO

-- END OF REPORT --