

Regional Drugs Testing Laboratory

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India)- 7810225 Fax: 0361-2338555/2330555 Phone No.0361 2338555

Email:rdtlguwahati@cdsco.nic.in

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

: MR. R. VANLALRUATA.

ASSISTANT DIRECTOR (F&D)

OFFICE OF CHIEF MEDICAL OFFICER,

waheti.

AIZAWL, MIZORAM, PIN-769017

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

: MZ/24/A E/19/IPA , Date: 17-DEC-2024

Number of Sample

Date of receipt

: 02-JAN-2025

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.	
LSD/GUW/2024- 25/1588	GUW/LS/2024- 25/1609	SPT-36186	Aug-2023	Jul-2025	Shervotec Phamaceuticals 82/4 & 82/5, HPSIDC, Baddi, Distt. Solan (HP)

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-Jan-2025 To 27-Jan-2025

COMPOSITION

Each uncoated dispersible tablet contains:

CefiximeTrihydrateIP

Eq. to Cefixime (Anhydrous) 200 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Light orange colour, round, uncoated, bi-convex, dispersible tablet in blister strip.	NA
2	Identification	Gives positive test for Cefixime.	NA
3	Average weight	0.30136 g	NA
4	Uniformity of weight	Passes the test.	NA
5	Disintegration	Passes the test. (Time taken for disintegration 01 minute 02 seconds)	NMT 03 minute
6	Uniformity of Dispersion	Complies.	NA

ssay						
Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
		-				* * .
			-	1 1	,	
1	Cefixime Trihydrate	198.96 mg/Tablet	200	99.48	90 % to 110 %	I.P. 2022
	eq. to Cefixime	_	mg/Tablet			
	(Anhydrous)					
	(,,					

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

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

Date: 28-JAN-2025

Amar Jyoti Chamuah
Government Analyst

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

· END OF REPORT -