

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India) - 781022

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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.Lalngilneia

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/18 Date 10th Sep. 24

3. Number of Sample

: MD08/18

4. Date of receipt

: 19-SEP-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- 25/1 252	GUW/LS/2024- 25/1279	SPT-35562	05/2023	04/2025	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 12-Nov-2024 To 21-Nov-2024

COMPOSITION

Each uncoated dispersible tablet contains:

Cefixime Trihydrate I.P.

Eq. to Cefixime (Anhydrous)

200 mg

Protocol Applied: I.P.202

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	0.3037 gm.	NA	
۷).	Uniformity of weight	Complies.	NA	
5	Uniformity of dispersion	Complies.	NA	
6	Disintegration	Complies (All six units disintegrated within 20 seconds).	NMT 3 minutes	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
		4 4			y .	

1.	Cefixime Trihydrate Eq. to Anhydrous Cefixime	201.2 mg/Tablet	200 mg/Tablet	100.6	90 % to 110 %	I.P.2022
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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 thereunder for the reasons given below:-

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

Date: 26-NOV-2024

GOVERNMENT ANALYST

Dilip Kr. Sarkar Government Analyst R.D.T.L., Guwahati-22

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