Regional Drugs Testing Laboratory
Directorate General of Health Services, Guwahati (India) - 781022
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Regional Drugs Testing Laboratory Govt. of India Guwahati-22

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 and D)
   Asst. Director (F&D), CMO Office,,
   Mamit Distric: Mamit, Pin- 796441
2. **Serial No. and date of Inspector's memorandum** : B.17011/12/09-CMO (M)/DRUGS/19 , 10-SEP-2024
3. **Number of Sample** : MD08/19
4. **Date of receipt** : 19-SEP-2024
5. **Names of drugs purporting to be contained in the sample** : Ceftriaxone Injection IP (CPCEF)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1374	GUW/LS/2024-25/1413	B23415G	Sep-2023	Aug-2025	Pace Biotech, Surajpur, Paunta Sahib, Dist. - Sirmour (H.P.)-173001

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 29-Oct-2024 To 14-Nov-2024

COMPOSITION : Each vial contains:
Sterile Ceftriaxone Sodium I.P. eq. to anhydrous Ceftriaxone 500 mg

Protocol Applied : I.P. 2022

Sr.No.	Test Name	Result	Limits
1	Description	White powder filled in transparent colorless sealed glass vials along with sterile water for injection, supplied in paper carton.	NA
2	Identification	Gives positive test for Ceftriaxone Sodium.	NA
3	Sterility	Passes the test for Ceftriaxone injection and water for injection.	NA
4	BET	Complies the test for Ceftriaxone injection and water for injection.	NA
5	pH	Complies, found 7.59	6.0 to 8.0 .

Assay

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

1	Ceftriaxone Sodium equivalent to Anhydrous Ceftriaxone	464.15 mg/vial	500 mg/vial	92.83	90 % of Claim to 115 % of Claim	I.P. 2022

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 claim as per I.P. 2022 in respect of test performed.

Date: 18-DEC-2024

GOVERNMENT ANALYST

Rinku Kalita
Government Analyst
R.D.T.L., Guwahati-22

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