



FORM 13
(See rule 46)

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

- Name of Inspector from whom received : Mrs. C. Ramdinmawii, Assistant Director (Food and Drugs)
State FDA
Champhai-796321 Mizoram
- Serial No. and date of Inspector's memorandum : 035/IPA-CPI/24 , 17-JAN-2025
- Number of Sample : NIL
- Date of receipt : 03-FEB-2025
- Names of drugs purporting to be contained in the sample : Ceftriaxone Injection IP (CEFPY)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0042	GUW/LS/2025-26/49	PTF-2400	Jan-2024 Dec-2025	NA	Park Pharmaceuticals,, Vill. Kalujhanda, Near Nanakpur, Teh. Baddi, Distt. Solan (HP) 174103

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector
[the packet or on portion of sample or container]

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

Date of Testing : From 27-Feb-2025 To 02-Apr-2025

COMPOSITION : Each vial contains: Sterile Ceftriaxone Sodium IP Eq. to Ceftriaxone 1000 mg

Protocol Applied : I.P.2022

Sr No.	Test Name	Result	Limits
1	Description	White amorphous powder filled in colorless sealed glass vials along with sterile water for injection.	NA
2	Identification	Gives positive test for Ceftriaxone.	NA
3	Average filled content	1.0865 g	NA
4	Sterility	Passes the test for Ceftriaxone Injection and water for Injection.	NA
5	Bacterial Endotoxins	Complies the test for Ceftriaxone Injection and water for Injection.	NA
6	Particulate Matter	Passes the test.	NA
7	pH	6.3 .	6.0 to 8.0 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ceftriaxone Sodium equivalent to Ceftriaxone	962.16 mg/vial	1000 mg/vial	96.216	90 % to 115 %	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 conform to claim as per I.P.2022 in respect of test performed.

Date: 07-APR-2025

GOVERNMENT ANALYST

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

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

