



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 : K.Lalngilneia, Asst. Director (F and D)
Asst. Director (F&D), CMO Office,,
Mamit Distric: Mamit, Pin- 796441
- Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO (M)/DRUGS/20 , 10-SEP-2024
- Number of Sample : MD08/20
- Date of receipt : 19-SEP-2024
- Names of drugs purporting to be contained in the sample : Ceftriaxone for Injection IP (CAFAGE-1000)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1466	GUW/LS/2024-25/1493	UCD-23145D	Apr-2023	Mar-2025	Ultra Drugs Pvt. Ltd., Manpura, Nalagarh, Distt. Solon-174101 (H.P.)

- 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]

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

Date of Testing : From 04-Nov-2024 To 03-Jan-2025

COMPOSITION : Each vial contains:
 Ceftriaxone Sodium IP (sterile) eq. to Anhydrous Ceftriaxone 1000 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White powder dispensed in transparent colorless sealed glass vials along with water for injection in sealed plastic containers.	NA
2	Identification	Gives positive test for Ceftriaxone sodium.	NA
3	Appearance of solution	Passes the test.	NA
4	Sterility	Passes the test for Ceftriaxone Injection and water for injection.	NA
5	BET	Complies the test for Ceftriaxone Injection and water for injection.	NA
6	pH	Complies, found 6.86	6.0 to 8.0

Assay

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

1	Ceftriaxone Sodium equivalent to Anhydrous Ceftriaxone	968 mg/vial	1000 mg/vial	96.8	90 % to 115 %	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 there under for the reasons given below:-

The sample conforms to claim as per I.P. 2022 in respect of test performed.

Date: 03-JAN-2025

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

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

