

Sample Name CEFTRIAXONE INJECTION-IP. 1.0gm. **Mfg Lic No** XXXXXXXXXX
Submitted By Quality Control Advisor. (MMDSL) Shillong. **Report No** XXXXXXXXXX
Address DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. **Receipt Date** 29-Apr-24
Mfg By N.S. **Report Date** 17-May-24
Supplied By N.S. **Ref No** N.S.
Batch No MMDSL/QC-0198 **Mfg. Date** 02/2024 **Exp Date** 01/2026 **Batch Size** N.S. **Sample Qty** 30 VIALS.

TEST RESULTS

Date / Period of Performance of test 29/04/2024 to 17/05/2024.

Reference to protocol :- I.P-2022.
 Description :- White powder filled in transparent glass vials.
 Identification A(by I.R) :- Complies.
 B(by HPLC) :- Complies.
 C :- Complies.
 Average Net weight :- 1.1791gm.
 Uniformity of weight :- Within limit.
 Clarity of solution :- Complies.
 (of reconstitution solution)
 Appearance of solution :- Complies.
 (of 1.2%w/v solution)

		Limit	
		Lower	Upper
pH	:- 7.16	6.0	8.0
(10%w/v Of reconstitution solution)			
Related substances(by HPLC)	:- Complies.		
Sterility	:- Complies with the test for Sterility.		
Bacterial Endotoxins	:- Less than 0.2EU/mg of Ceftriaxone	-	0.2EU/mg of Ceftriaxone

Particulate matter	:- Complies.		
(Of reconstitution solution)			
Water(by KF)	:- 8.94%w/w	-	11.0%w/w

Assay (by HPLC) :- Each vial contains:-

Content of	Obtained	Claim	Limit		Method
			Lower	Upper	
Sterile Ceftriaxone Sodium					
eq. to Anhydrous Ceftriaxone:-	991.26mg	1000.0mg	900.0mg	1150.0mg	IP.

NOTE:- SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample referred as defined in the Act and the rules made there under per IP.