

Sample Name	CEFTRIAXONE INJECTION-IP. 2.0gm.	Mfg Lic No	
Submitted By	Quality Control Advisor. (MMDSL) Shillong.	Report No	
Address	DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya.	Receipt Date	09-Oct-24
Mfg By	N.S.	Report Date	08-Nov-24
Supplied By	N.S.	Ref No	N.S.
Batch No	Mfg. Date	Exp Date	Batch Size
MMDSL/QC-0505	08/2024	07/2027	N.S.
			Sample Qty
			30 VIALS.

TEST RESULTS

Date / Period of Performance of test 09/10/2024 to 08/11/2024.
Reference to protocol :- I.P-2022.

Description :- White powder filled in transparent glass vial.

Identification A (by I.R) :- Complies.
B (by HPLC) :- Complies.
C :- Complies.

Average Net weight :- 2.1882gm
Uniformity of weight :- Within limit
Clarity of solution :- Complies.
(After reconstitution)
Appearance of solution :- Complies.
(After reconstitution)

		Limit	
		Lower	Upper
pH	:- 7.14	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 (Of reconstitution solution)	:- Complies.		
Water	:- 10.15%w/w	-	11.0%w/w

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

			Limit		
	Obtained	Claim	Lower	Upper	Method
Content of Sterile Ceftriaxone Sodium eq. to Anhydrous Ceftriaxone:-	1.983gm	2.0gm	1.8gm	2.3gm	IP.

END OF TEST REPORT

NOTE:- SAMPLE CONSUMED IN TESTING.

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