

Submitted By Quality Control Advisor. (MMDSL) Shillong. Mfg Lic No [REDACTED]
 Address DHS, LaitumkhrahNHM, EastKhasi Hills Meghalaya. Report No [REDACTED]
 Mfg By N.S. Receipt Date 19-Mar-24
 Supplied By N.S. Report Date 08-Apr-24
 Batch No MMDSL/QC-0115 Mfg. Date 09/2023 Exp Date 08/2025 Ref No N.S.
 Batch Size N.S. Sample Qty 30 VIALS.

RESULT OF ANALYSIS

Date / Period of Performance of test 19/03/2024 to 08/04/2024.
 Reference to protocol :- I.P-2022.

Description :- White powder filled in transparent glass vials.
 Identification (by HPLC) :- Complies.
 Average net weight :- 1.6636gm.
 Uniformity of weight :- Within limit.

		LIMIT	
		Lower	Upper
pH ((of 10%w/w soln.)	:- 6.73	4.5	8.0
Sterility	:- Complies with the test for Sterility.		
Related Substances (by HPLC)	:- Complies.		

Bacterial Endotoxins :- Less than 0.2Eu/mg of Ceftriaxone
 NMT-0.2Eu/mg of Ceftriaxone .

Particulate matter (after reconstitution) :- Complies.
 Clarity of solution (after reconstitution) :- Complies.

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

	Obtained	Claim	LIMIT		Method
			Lower	Upper	
Contents of Ceftriaxone Sodium eq. to Ceftriaxone	:- 997.41mg	1000.0mg	900.0mg	1100.0mg	IP.
Sulbactam Sodium eq. to Sulbactam	:- 497.91mg	500.0mg	450.0mg	550.0mg	IP.

NOTE:- SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample r [REDACTED]
 as defined in the Act and the rules made there u [REDACTED]
 per IP.

NOTE: 1. The result listed refer only to the tested samples and applicable parameter. Endorsement of products is neither inferred nor implied.
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