

(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name CEFOPERAZONE INJECTION-IP.1.0gm. **Mfg Lic No** [REDACTED]
Submitted By Quality Control Advisor. (MMDSL) Shillong. **Report No** [REDACTED]
Address DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. **Receipt Date** 19-Mar-24
Mfg By N.S. **Report Date** 09-Apr-24
Supplied By N.S. **Ref No** N.S.
Batch No MMDSL/QC-0113 **Mfg. Date** 09/2023 **Exp Date** 08/2025 **Batch Size** N.S. **Sample Qty** 30 VIALS.

RESULT OF ANALYSIS

Date / Period of Performance of test 19/03/2024 to 09/04/2024.
Reference to protocol :- I.P-2022.

Description :- White powder filled in transparent glass vials.

Identification (A) (by HPLC) :- Complies.
(B) :- Complies.

Average fill :- 1.0563gm.
Uniformity of weight :- Within limit.
Clarity of solution :- Complies.
(of Reconstituted solutin)

Bacterial endotoxins :- Less than 0.20EU/mg of Cefoperazone **Limit** NMT- 0.20EU/mg. of Cefoperazone.
Sterility :- Complies with the test for sterility.

pH :- 5.42 **LIMIT** Lower 4.5 Upper 6.5
(Determined in 25%w/v solution)
Water (by KF) :- 4.71%w/w **NMT-5.0 %w/w**
Particulate matter (Of reconstituted solution) :- Complies.

Assay (by HPLC) :- Each vial contains:-
Contents of Cefoperazone Sodium cal.as Anhy.Cefoperazone

Obtained	Claim	Lower	Upper	Method
995.62mg	1000.0mg	900.0mg	1200mg	IP.

NOTE:- SAMPLE CONSUMED IN TESTING.

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

- NOTE :**
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