MAYA BIOTECH PRIVATE LIMITED

Works: Village- Kondi, P.O.- Thana, Baddi, Distt.- Solan, (H.P.)-173205
Corp. Office: Plot No-46/A, First Floor, Industrial Area Phase-2, Chandigarh-160002

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs and cosmetics Act 1940 and the rules there under)

Generic Name	**Cefoperazone & Sulbactam for Injection 1.5 gm**		
Product Name	**Cefrazo Plus 1.5 gm Injection**	A. R. No.	F-02/11/23
Batch No.	DX084	Date of Receipt	26/11/2023
Mfg. Date	11/2023	Batch Size	10200 Vials
Exp. Date	10/2025	Sample Qty.	40 Vials

S. No.	Test	Specification	Result
1.	Description	A white to off white powder filled in clear glass vials.	A off white powder filled in clear glass vials.
2.	Nominal fill weight	1612 mg	1612.89 mg
3.	Uniformity fill weight	±10%	Complies
4.	Identification (By HPLC)	The Principal peak of Cefoperazone Sodium & Sulbactam Sodium in reference chromatogram corresponds to sample chromatogram respectively as in assay.	Complies
5.	pH	4.0 to 7.0	5.92
6.	Water	NMT 6.0%	4.98 %
7.	Particulate matter	When Examined under suitable conditions of visibility of reconstituted solution are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
8.	Constituted solution	The solution should be clear & no residue left.	Complies
9.	Assay (By HPLC) Each vial contains Cefoperazone Sodium I.P. Eq to Anhydrous Cefoperazone 1000 mg	NLT 900 mg to NMT 1100 mg (90.0% to 110.0 %)	996.43 mg (99.64%)
	Sulbactam Sodium USP Eq. to Sulbactam 500 mg	NLT 450 mg to NMT 550 mg (90.0% to 110.0%)	501.01 mg (100.20%)
10.	Sterility	Should be sterile	Sterile

Remarks: The product referred to above complies / ~~does not comply~~ / with ~~I.P. / BP / USP~~ / In-House Specifications.

MAYA BIOTECH PVT. LTD. QA APPROVED

	Prepared By	Checked By	Approved By
Sign & Date	10/12/2023	10/12/2023	10/12/2023