

Title

Certificate of Analysis Finished Product

Product Name	CEFROZONE SB 1.5 Injection	A.R. No.	BD/FP/24/646
Generic Name	Cefoperazone & Sulbactam for Injection 1.5gm	Sampled qty.	45 Vials
Batch No.	B24620B	Sampled by	Rakesh
Batch Size	15,000 Vials	Sampled on	11/02/2025
Mfg. Date	02/2025	Date of Testing	11/02/2025
Exp. Date	01/2027	Date of Release	26/02/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification (By HPLC)	In the Assay, the principal peaks of Cefoperazone & Sulbactam Sodium in the chromatogram obtained with the test solution corresponds to the peak of Cefoperazone & Sulbactam Sodium in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-1.28% & +0.77%
4.	Average weight	Informative.	1652.2 mg
5.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	535/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	4/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
6.	Sterility	No microbial growth should be observed.	Complies
7.	Bacterial Endotoxins	NMT- 0.043 EU/mg of Cefoperazone Sodium & Sulbactam Sodium.	Less than- 0.043 EU/mg of Cefoperazone Sodium & Sulbactam Sodium.

8. Assay:
Each glass vial Contains :

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cefoperazone Sodium (Sterile) IP Eq. to Anhydrous Cefoperazone	1000 mg	1032.28 mg	103.23%	90.0 to 110.0%
Sulbactam Sodium (Sterile) IP Eq. to Anhydrous Sulbactam	500 mg	499.64 mg	99.93%	90.0 to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/IHS.

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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