

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

Certificate of Analysis Finished Product

Product Name	CEFORZONE SB -1.5 gm Injection	A.R. No.	ARB/FP/25/017
Generic Name	Cefoperazone & Sulbactam for Injection	Sampled qty.	45 Vials
Batch No.	ARB2519A	Sampled by	Aakash
Batch Size	20,000Vials	Sampled on	28/11/2025
Mfg. Date	11/2025	Date of Testing	29/11/2025
Exp. Date	10/2027	Date of Release	15/12/2025

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 $\pm 10\%$	-2.00% & +1.84%
4.	Average weight	Informative $\pm 2\%$.	1664.1mg
5.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	75/vial 1/vial 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: (By HPLC) 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	1088.24 mg	108.82%	90.0 to 110.0%
Sulbactam Sodium (Sterile) IP Eq. to Sulbactam	500 mg	486.15 mg	97.23%	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/FP/USP/IHS.~~

Analysis by
NAME: NIKHIL SHARMAChecked by
NAME: SUFIYAN ANSARIApproved by
NAME: MRS. SWATI DHAWAN