

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

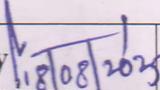
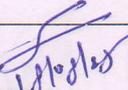
**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	CEFORZONE SB 1.5 Injection	<b>A.R. No.</b>	ARB/FP/25/001
<b>Generic Name</b>	Cefoperazone & Sulbactam for Injection 1.5g	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARB2502A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	15,000 Vials	<b>Sampled on</b>	01/08/2025
<b>Mfg. Date</b>	07/2025	<b>Date of Testing</b>	01/08/2025
<b>Exp. Date</b>	06/2027	<b>Date of Release</b>	18/08/2025

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 $\pm 10\%$	-0.34% & +0.61%
4.	Average weight	Informative $\pm 2\%$ .	1658.4 mg
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.	546/vial 3/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	998.22 mg	99.82%	90.0 to 110.0%
Sulbactam Sodium (Sterile) IP Eq. to Anhydrous Sulbactam	500 mg	517.03 mg	103.41%	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: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DILLON MANAGER
--	---	---