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** Injection	**A.R. No.**	ARB/FP/26/026
Generic Name	Cefoperazone & Sulbactam for Injection 1.5gm	**Sampled qty.**	45 Vials
Batch No.	ARB2623A	**Sampled by**	Rakesh
Batch Size	19,800 Vials	**Sampled on**	30/09/2026
Mfg. Date	09/2026	**Date of Testing**	01/10/2026
Exp. Date	08/2028	**Date of Release**	15/10/2026

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 ±10%	-0.72% & +0.80%
4.	Average weight	Informative ±2%.	1646.6mg
5.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm	 NMT 6000/vial NMT 600/vial	 517/vial 1/vial
	(B.) Visual Particle	The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	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	1035.1673 mg	103.52%	90.0 to 110.0%
Sulbactam Sodium (Sterile) IP Eq. to Sulbactam	500 mg	496.0373 mg	99.21%	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	Checked by	Approved by
NAME: MOHD. ZAID	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
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