

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

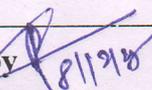
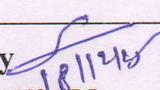
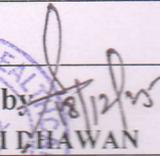
Title

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Certificate of Analysis Finished Product

Product Name	AONE Injection	A.R. No.	ARB/FP/25/019
Generic Name	Ceftriaxone Injection IP 250mg	Sampled qty.	45 Vials
Batch No.	ARB2520A	Sampled by	Anuj Verma
Batch Size	5,000Vials	Sampled on	03/12/2025
Mfg. Date	11/2025	Date of Testing	03/12/2025
Exp. Date	10/2027	Date of Release	18/12/2025

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 I.R	A. The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Ceftriaxone working standard.	Complies
	By HPLC	B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies
	By Chemical	C. It gives the reaction A of sodium salts.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-1.30% & +0.72%
4.	Average weight	Informative $\pm 2\%$.	297.8 mg
5.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.10%
	Sum of all secondary peaks	NMT 5.0%	0.10%
6.	Appearance of solution	A 1.2 percent w/v solution in carbon dioxide-free water is clear and not more intensely coloured than reference solution BY55 or Y55.	Complies
7.	pH	6.0 to 8.0	7.06
8.	Water	NMT 11%w/w	9.20%w/w

Analysis by 
NAME: RAMANJEET SINGHChecked by 
NAME: SUFIYAN ANSARIApproved by 
NAME: MRS. SWATI CHAWAN



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9.	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.	24/vial 0/vial Complies
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.2 EU/mg of Ceftriaxone.	Less than 0.2 EU/mg of Ceftriaxone.
12.	Assay: (By HPLC) Each vial contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone	250 mg	248.70 mg	99.48%	90.0 to 115.0%

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/HHS.

Analysis by NAME: RAMANJEET SINGH	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
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