AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title	:	Certificate of Analysis Finished Product

Product Name	**AONE** Injection	**A.R. No.**	ARB/FP/25/001
Generic Name	Ceftriaxone Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	ARB2501A	**Sampled by**	Anuj Verma
Batch Size	50.000 Vials	**Sampled on**	22/07/2025
Mfg. Date	07/2025	**Date of Testing**	23/07/2025
Exp. Date	06/2027	**Date of Release**	06/08/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification By I.R	**A.** Determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with Ceftriaxone sodium IPRS or with the reference spectrum of ceftriaxone sodium.	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 ±10%	-0.67% & +0.96%
4.	Average weight	Informative ±2%.	1209.7 mg
5.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	Not detected
	Sum of all secondary peaks	NMT 5.0%	Not detected
6.	Appearance of solution	1.2 per cent w/v solution in carbon dioxide-free water is clear and not more intensely coloured than reference solution BYS5 or YS5.	Complies
7.	pH	6.0 to 8.0	6.81
8.	Water	NMT 11%w/w	8.68%w/w

Analysis by	Checked by	Approved by
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: SHATI

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9.	Particulate Matter		
	(A.) Light obscuration Particle Count Test		
	(1.) Particles ≥10µm	NMT 6000/vial	84/vial
	(2.) Particles ≥25µm	NMT 600/vial	0/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
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.2 EU/mg of Ceftriaxon.	Less than 0.2 EU/mg of Ceftriaxone.
12.	Assay: (By HPLC) Each glass vial contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Ceftriaxone Sodium IP Eq. to anhydrous Ceftriaxone	1000 mg	1036.88 mg	103.69%	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/IHS~~.

Analysis by	Checked by	Approved by
06/08/2025	06/08/25	06/08/25
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: SWATI CHAWAN

PAONTA SAHIB (H.P.) Quality Control Manager