



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

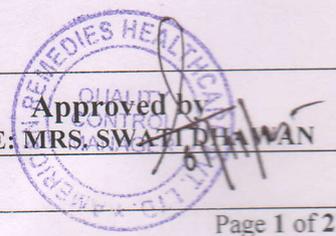
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

## Title : Certificate of Analysis Finished Product

Product Name	AZEECAN 500 Injection	A.R. No.	ARN/FP/25/034
Generic Name	Azithromycin for Injection USP 500mg	Sampled qty.	45 vials
Batch No.	ARN2553A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	10/10/2025
Mfg. Date	10/2025	Date of Testing	11/10/2025
Exp. Date	09/2027	Date of Release	01/11/2025

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)	A. The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies
	(By IR)	B. The Sample exhibits bands at about 900, 995, 1165, 1376, 1456, 1725, and 2936 $\text{cm}^{-1}$ similar to the spectrum from the Standard similarly obtained.	Complies
3.	Uniformity of Dosage units	Average weight $\pm 10\%$	-0.98% & +1.09%
4.	Average weight	Informative $\pm 2\%$	1089.9 mg
5.	pH	6.4 to 6.8	6.64
7.	Impurities		
	Azithromycin N-oxide	NMT 1.0%	Not detected
	Desosamylazithromycin	NMT 0.3%	Not detected
	N-demethylazithromycin	NMT 1.0%	Not detected
	3-(N,N-didemethyl)azithromycin (aminoazithromycin +3(N,N-didemethyl)-3-N-formylazithromycin	NMT 1.0%	Not detected
	3-N-demethyl-3-N-formylazithromycin	NMT 1.0%	Not detected
	3-De(dimethylamino)-3-oxoazithromycin	NMT 1.0%	Not detected
	Any other unspecified impurity	NMT 0.2%	Not detected
	Total impurities	NMT 3.0%	Not detected
8.	Water (By K.F.)	NMT 2.0%w/w	1.51%

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHANWAN
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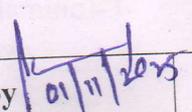
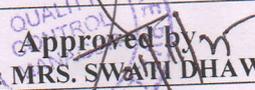
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9.	Particulate Matter A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	116/vial 5/vial  Complies		
10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT 0.7 USP EU/mg of Azithromycin.	Less than 0.7 USP EU/mg of Azithromycin.		
12.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Azithromycin Dihydrate (Sterile) IP Lyophilized Eq. to anhydrous Azithromycin		500 mg	520.93 mg	104.19%	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/HHS.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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