

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

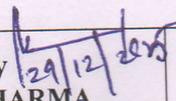
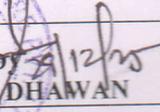
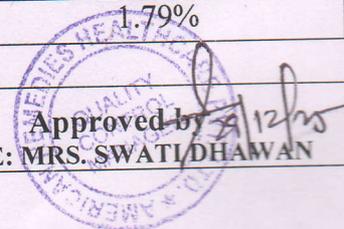
Title

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Certificate of Analysis Finished Product

Product Name	AZEECAN Injection	A.R. No.	ARN/FP/25/074
Generic Name	Azithromycin for Injection USP 500mg	Sampled qty.	45 vials
Batch No.	ARN2578A	Sampled by	Rakesh
Batch Size	14,910 Vials	Sampled on	15/12/2025
Mfg. Date	12/2025	Date of Testing	15/12/2025
Exp. Date	11/2027	Date of Release	29/12/2025

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 HPLC) (By IR)	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
		B. The Sample exhibits bands at about 900, 995, 1165, 1376, 1456, 1725, and 2936 cm^{-1} similar to the spectrum from the Standard similarly obtained.	Complies
3.	Uniformity of Dosage units	Average weight $\pm 10\%$	-0.62% & +0.73%
4.	Average weight	Informative $\pm 2\%$.	1103.2 mg
5.	pH	6.4 to 6.8	6.55
7.	Impurities		
	Azithromycin N-oxide	NMT 1.0%	Not Detected
	Desosaminylazithromycin	NMT 0.3%	Not Detected
	N-demethylazithromycin	NMT 1.0%	Not Detected
	3-(N,N-didemthyl)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	1.79%

Analysis by 
NAME: NIKHIL SHARMAChecked by 
NAME: SUFIYAN ANSARIApproved by 
NAME: MRS. SWATI DHAWAN



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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.	275/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	518.2673mg	103.65%	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/HIS.

Analysis by
NAME: NIKHIL SHARMA

Checked by
NAME: SUFIYAN ANSARI

Approved by
NAME: MRS. SWATI DHAWAN

