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** Injection	**A.R. No.**	ARN/FP/26/006
Generic Name	Azithromycin for Injection USP 500mg	**Sampled qty.**	45 vials
Batch No.	ARN2608A	**Sampled by**	Rakesh
Batch Size	15,000 Vials	**Sampled on**	28/04/2026
Mfg. Date	04/2026	**Date of Testing**	29/04/2026
Exp. Date	03/2028	**Date of Release**	26/05/2026

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)	**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 cm^{-1} similar to the spectrum from the Standard similarly obtained.	Complies
3.	Uniformity of Dosage units	Average weight ±10%	-3.20% & +7.62%
4.	Average weight	Informative ±2%.	1101.4mg
5.	pH	6.4 to 6.8	6.67
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)azithro-mycin (aminoazithromycin +3(N,N-didemethyl)-3-N-formylazithromycin	NMT 1.0%	Not Detected
	3-N-demethyl-3-N-formy-lazithromycin	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	1.47%

Analysis by	Checked by	Approved by
26/05/2026	26/05/26	26/05/26
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

Title	:	Certificate of Analysis Finished Product

Product Name	**AZEECAN** Injection	**A.R. No.**	ARN/FP/26/006
Generic Name	Azithromycin for Injection USP 500mg	**Sampled qty.**	45 vials
Batch No.	ARN2608A	**Sampled by**	Rakesh
Batch Size	15,000 Vials	**Sampled on**	28/04/2026
Mfg. Date	04/2026	**Date of Testing**	29/04/2026
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9.	Particulate Matter		
	A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	 NMT 6000/vial NMT 600/vial	 67/vial 2/vial
	(B.) Visual Particle	The 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 0.7 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	502.1974mg	100.44%	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
26/05/2026	26/05/26	26/05/26
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN