

# Pace

Add Pace To Health

# Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

Product Name	AZEECAN 500 Injection	A.R. No.	NB/FP/23/440
Generic Name	Azithromycin For Injection USP 500mg	Sampled qty.	45 vials
Batch No.	N23405B	Sampled by	Arvind
Batch Size	7056 Vials	Sampled on	14/03/2024
Mfg. Date	02/2024	Date of Testing	14/03/2024
Exp. Date	01/2026	Date of Release	29/03/2024

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	In the chromatogram obtained the retention time of major peak in test solution is correspondence with RT of major peak in working standard solution.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-1.14% & +1.46%
4.	Average weight	Informative.	1109.12 mg
5.	pH	6.4 to 6.8	6.42
6.	Uniformity of Dosage units	Complies as per USP.	Complies
7.	Impurities		
	Limit of Azithromycin N-oxide	Complies as per USP.	Complies
	Limit of Aminoazithromycin, formamido Analog	Complies as per USP.	Complies
	Any other unspecified impurity	NMT- 0.2%	Complies
	Total Impurities	NMT- 3.0%	Complies
8.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$	NMT-6000/vial NMT-600/vial	1087/vial 2/vial
	(B.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies
9.	Water	NMT- 2.0% w/w	1.72%w/w
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 Azithromycin.
12.	Assay: Each glass vial Contains :		

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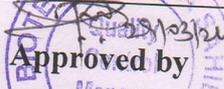
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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Azithromycin Dihydrate (Sterile) (Lyophilized) I.P Eq. to anhydrous Azithromycin	500 mg	491.26 mg	98.25%	90.0.0% to 110.0%

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  Checked by  Approved by   
Manager

