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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/24/127
Generic Name	Azithromycin For Injection USP 500mg	**Sampled qty.**	45 vials
Batch No.	N24055A	**Sampled by**	Aakash
Batch Size	3004 Vials	**Sampled on**	02/08/2024
Mfg. Date	06/2024	**Date of Testing**	02/08/2024
Exp. Date	05/2026	**Date of Conditionally Release**	03/08/2024

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 ±10%	-1.58% & +2.43%
4.	Average weight	Informative.	1111.0 mg
5.	pH	6.4 to 6.8	6.58
6.	Uniformity of Dosage units	Complies as per USP.	Complies
7.	Impurities		
	Limit of Azithromycin N-oxide	Complies as per USP	Under process
	Limit of Aminoazithromycin, formamido Analog	Complies as per USP	Under process
	Any other unspecified impurity	NMT- 0.2%	Under process
	Total Impurities	NMT- 3.0%	Under process
8.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	 NMT-6000/vial NMT-600/vial	 1169/vial 3/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	1.65%w/w
10.	Sterility	No microbial growth should be observed.	Under process
11.	Bacterial Endotoxins	NMT- 0.7 USP EU/mg of Azithromycin.	Under process
12.	Assay: Each glass vial Contains :		

Analysis by	Checked by	Approved by

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Azithromycin Dihydrate (Sterile) IP Lyophilized Eq. to anhydrous Azithromycin	500 mg	516.40 mg	103.28%	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/~~IHS.~~

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

Analysis by	**Checked by**	**Approved by**