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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product	
Product Name	**DOXYCIN** Injection	**A.R. No.**	NB/FP/26/229
Generic Name	Doxycycline for Injection USP 100mg	**Sampled qty.**	45 Vials
Batch No.	N26234A	**Sampled by**	Rakesh
Batch Size	29,340 Vials	**Sampled on**	21/09/2026
Mfg. Date	09/2026	**Date of Testing**	22/09/2026
Exp. Date	08/2028	**Date of Release**	06/10/2026

S. No.	Tests	Specifications	Observations
1	Description	A light yellowish dry powder filled in amber glass vial.	A light yellowish dry powder filled in amber glass vial.
2	Identification (By UV)	**A.** The UV spectrum of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Complies
	(By HPLC)	**B.** The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
3	Uniformity of Weight	Average weight ±10%	-3.24% & +3.59%
4	Average weight	Informative ±2%.	118.6 mg
5	Loss on drying	NMT 4%w/w	1.73%w/w
6	pH	1.8 to 3.3	2.37
7	Organic impurities		
	4-Epidoxycycline	NMT 2.2%	0.003%
	Any individual unspecified impurity	NMT 0.5%	0.070%
	Total impurities	NMT 5.5%	0.075%
8	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	NMT 6000/Vial NMT 600/ Vial	1,636/Vial 13/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 visual inspection.	Complies
9	Constituted Solution: Completeness and clarity of solutions	➢ The Solid dissolves completely, leaving no undissolved matter. ➢ The constituted solution is not significantly less clear than ann equal volume of the diluents or of purified water contained in a similar vessel and examined similarly	Complies

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 5804060[illegible]

Analysis by	Checked by	Approved by
06/10/26	06/10/26	06/10/26
NAME: MOHD.ZAID	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

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		➢ The constituted solution is free from particulate matter that can be observed on visual inspection.	
10	Sterility	No microbial growth should be observed.	Complies
11	Bacterial Endotoxins	NMT1.14 USP EU/mg of Doxycycline.	Less than 1.14 USP EU/mg of Doxycycline.
12	Assay: (By HPLC) Each glass vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Sterile) Doxycycline Hydrochloride IP Eq. to Doxycycline	100 mg	98.3468 mg	98.35%	90.0 to 120.0%

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~~

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registrati...

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NAME: MOHD.ZAID	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN