

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	DOXYCIN Injection	A.R. No.	NB/FP/25/265
Generic Name	Doxycycline for Injection USP 100 mg	Sampled qty.	45 Vials
Batch No.	N25279E	Sampled by	Anuj Verma
Batch Size	7,536 Vials	Sampled on	27/11/2025
Mfg. Date	11/2025	Date of Testing	28/11/2025
Exp. Date	10/2027	Date of Release	12/12/2025

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	Nominally 1mg/ml of Doxycycline in methanol pass through suitable filter, and use the Filtrate, passes the test I Tetracycline's.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-2.38% & +3.44%
4.	Average weight	Informative $\pm 2\%$.	130.4mg
5.	Loss on drying	NMT 4%w/w	2.23%w/w
6.	Organic impurities		
	4-Epidoxycycline	NMT 2.2%	Not Detected
	Any individual unspecified impurity	NMT 0.5%	Not Detected
	Total impurities	NMT 5.5%	Not Detected
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	1. Particles $\geq 10\mu\text{m}$	NMT 6000/Vial	1341/Vial
	2. Particles $\geq 25\mu\text{m}$	NMT 600/ Vial	5 /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
8.	pH	1.8 to 3.3	2.12
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 1.14 USP EU/mg of Doxycycline.	Less than 1.14 USP EU/mg of Doxycycline.
11.	Assay: (By HPLC) Each glass vial contains:		

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. FSD/39593

Approved by
NAME: MRS. SWATI DHAWAN

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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Sterile) Doxycycline Hydrochloride IP Eq. to Doxycycline	100 mg	105.99mg	105.99%	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.~~

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Name : Mrs. Swati Dhawan Designation : QC HOD Qualification : M. Sc. Medical Microbiology Registration No. : 80100039593 NAME: MRS. SWATI DHAWAN Punjab Technical University, Jalandhar
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