

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	DOXYCIN 100MG Injection	A.R. No.	NB/FP/25/386
Generic Name	Doxycycline for Injection USP 100mg	Sampled qty.	45 Vials
Batch No.	N25401E	Sampled by	Anuj Verma
Batch Size	9,504Vials	Sampled on	12/03/2026
Mfg. Date	02/2026	Date of Testing	13/03/2026
Exp. Date	01/2028	Date of Release	29/03/2026

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	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 $\pm 10\%$	-2.53% & +3.70%
4.	Average weight	Informative $\pm 2\%$.	125.1 mg
5.	Loss on drying	NMT 4%w/w	1.79%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	497/Vial
	2. Particles $\geq 25 \mu\text{m}$	NMT 600/ Vial	3 /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	2.22
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: GAGANDEEP SINGH

Checked by
NAME: RAMANJEET SINGH

Approved by
NAME: MRS. SWATI DHAWAN

Mrs. Swati Dhawan

QC HOD

M.Sc. Clinical Microbiology

Registration No.: 53042/2019

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	DOXYCIN 100MG Injection	A.R. No.	NB/FP/25/386
Generic Name	Doxycycline for Injection USP 100mg	Sampled qty.	45 Vials
Batch No.	N25401E	Sampled by	Anuj Verma
Batch Size	9,504Vials	Sampled on	12/03/2026
Mfg. Date	02/2026	Date of Testing	13/03/2026
Exp. Date	01/2028	Date of Release	29/03/2026

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
(Sterile) Doxycycline Hydrochloride IP Eq. to Doxycycline	100 mg	106.4108 mg	106.41%	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/HS.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 5001/2019

Analysis by

NAME: GAGANDEEP SINGH

Checked by

NAME: RAMANJEET SINGH

Approved by

NAME: MRS. SWATI DHAWAN