

# Pace

Add Pace To Health

# Pace Biotech

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

Title

Certificate of Analysis Finished Product

Product Name	DOFOXO Injection	A.R. No.	NL/FP/24/469
Generic Name	Doxofylline Injection 10ml	Sampled qty.	45 Ampoules
Batch No.	A24329D	Sampled by	Vineet
Batch Size	20,000 Ampoules	Sampled on	03/01/2025
Mfg. Date	12/2024	Date of Testing	03/01/2025
Exp. Date	11/2026	Date of Release	18/01/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber colour ampoule.	A clear colourless solution filled in amber colour ampoule.
2.	Identification (By HPLC)	In the Assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the peaks in the chromatogram obtained with the reference solution.	Complies
3.	Nominal fill volume	NLT- 10ml	10.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	10.1 ml
5.	pH	5.0 to 6.0	5.44
6.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$  (b.) Visual	NMT-6000/ Ampoule NMT-600/ Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	121/ Ampoule 3/ Ampoule  Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT- 0.291 EU/mg of Doxofylline.	Less than- 0.291 EU/mg of Doxofylline.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Doxofylline IP	10 mg	10.56 mg	105.60%	90.0% 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.

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: P. N. TRIPATHI