

Pace

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Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	DOFOXO Injection	A.R. No.	NL/FP/25/063
Generic Name	Doxofylline Injection 10ml	Sampled qty.	45 Ampoules
Batch No.	A25038E	Sampled by	Rakesh
Batch Size	15,000 Ampoules	Sampled on	19/05/2025
Mfg. Date	04/2025	Date of Testing	19/05/2025
Exp. Date	03/2027	Date of Release	04/06/2025

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	5.65		
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.	41/Ampoule 2/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	10.168 mg	101.68%	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: NIKHIL SHARMA	Approved by NAME: SWATI DUBOYAN
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