

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title	:	Certificate of Analysis Finished Product	
Product Name	DOFOXO Injection	A.R. No.	ARN/FP/26/012
Generic Name	Doxofylline Injection 10ml	Sampled qty.	45 Ampoules
Batch No.	ARN2621A	Sampled by	Rakesh
Batch Size	30,000 Ampoules	Sampled on	15/05/2026
Mfg. Date	05/2026	Date of Testing	16/05/2026
Exp. Date	04/2028	Date of Release	30/05/2026

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	5.21		
6.	Particulate Matter	NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	31/Ampoule 1/Ampoule Complies		
	(A.) Light obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$				
	(B.) Visual Particle				
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: (By HPLC) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Doxofylline IP		10 mg	10.11706 mg	101.17%	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: SHAHRUKH KHAN	Checked by NAME: RAMANJEET SINGH	Approved by NAME: MRS. SWATI DHAWAN
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