



# 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/25/101
Generic Name	Doxofylline Injection 10ml	Sampled qty.	45 Ampoules
Batch No.	ARN25101A	Sampled by	Anuj Verma
Batch Size	30,000 Ampoules	Sampled on	03/03/2026
Mfg. Date	01/2026	Date of Testing	05/03/2026
Exp. Date	12/2027	Date of Release	19/03/2026

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	5.47
6.	Particulate Matter (A.) Light obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$  (B.) Visual Particle	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.	23/Ampoule 0/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: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Doxofylline IP	10 mg	10.45375 mg	104.54%	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 per IP/BP/USP/IHS.

Qualification : M.Sc. Clinical Microbiology

Registration No. : 50040609593

Approved by

Analysis by	Checked by	Approved by
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