



# VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

## QUALITY CONTROL DEPARTMENT

### CERTIFICATE OF ANALYSIS

Product Name : DOFOXO Doxofylline Injection	
Batch No. : GA24F-64A	Mfg. Date : 06/2024
Batch Size : 20300 Ampoules	Exp. Date : 05/2026
Sample Qty. : 40 Ampoules	Analytical Report No.: AFP20240384
Date of Receiving : 03/07/2024	Date of Completion : 17/07/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in 10 ml clear glass ampoule.	A clear colourless liquid solution filled in 10 ml clear glass ampoule.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in chromatogram obtained with the reference solution.	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 10.0ml Max: 10.1 ml		
4.	Average fill volume	Not less than 10 ml	10.01 ml		
5.	pH	Between (2.50 to 5.0)	3.74		
6.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/ Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/ Ampoule		
7.	Sterility	Should be Sterile	Sterile		
8.	Bacterial endotoxins	NMT 0.20 EU/mg	Less than 0.20 EU/mg		
9.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Doxofylline IP		10.0 mg	10.439 mg	104.39 %	90.0 to 110%

Remarks: In the opinion of the undersigned the sample submitted complies/does not comply with the prescribed standard/not standard of quality, as according to IHS with respect to the above test only

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager in charge
Signature:- 	Signature:- 	Signature:- 
Date:-	Date:-	Date:-

Format No.: VH/SOP/QC-062/FT01-00