



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. : GA23L-29A

Mfg. Date : 12/2023

Batch Size : 19925 Ampoules

Exp. Date : 11/2025

Sample Qty. : 50 Ampoules

Analytical Report No.: AFP20230478




Date of Receiving : 26/12/2023

Date of Completion : 07/01/2024

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	10.05 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.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Doxofylline IP		10.0 mg	9.811 mg	98.11 %	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 I.P. and 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:- 07/01/2024	Date:- 07/01/2024	Date:- 07/01/2024

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