



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : Frasix Frusemide Injection IP.	
Batch No. : GA24I-19A	Mfg. Date : 09/2024
Batch Size : 20450 Ampoules	Exp. Date : 08/2026
Sample Qty. : 50 Ampoules	Analytical Report No.: AFP20240573
Date of Receiving : 21/09/2024	Date of Completion : 05/10/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless or almost colorless solution filled in 4 ml amber colour glass ampoule.	A clear colourless or almost colorless solution filled in 4 ml amber colour glass ampoule.		
2.	Identification A (By UV)	When examined in the range 220 nm to 360 nm, the final solution obtained in the assay shows three absorption maxima at about 228 nm, 271 nm and 333 nm.	Complies		
	B (By Chemically)	A red-violet colour is produced	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 4.0 ml Max: 4.1 ml		
4.	Average fill volume	Not less than 4 ml	4.04 ml		
5.	pH	8.0 to 9.30	8.74		
6.	Related Substances				
	Single impurity	NMT 1.0%	Not Detected		
	Total impurities	NMT 1.50%	Not Detected		
7.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/ Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/ Ampoule		
8.	Sterility	Should be Sterile	Sterile		
9.	Bacterial Endotoxins	NMT 3.5 Eu/mg of furosemide.	Less than 3.5 Eu/mg		
10.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Frusemide IP		10.0 mg	9.759 mg	97.59 %	95.0% to 105%

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:- Date:-	Signature:- Date:-	Signature:- Date:-

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

