



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

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

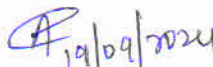

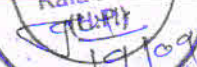
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : THIORIL 4 Thiocolchicoside Injection	
Batch No. : GA24I-36C	Mfg. Date : 09/2024
Batch Size : 35015 Ampoules	Exp. Date : 08/2026
Sample Qty. : 65 Ampoules	Analytical Report No.: UFP20240064
Date of Receiving : 05/09/2024	Date of Completion : 19/09/2024
Mfg. License No. : N-MB/18/201	

S. No.	Tests	Specifications	Observations	
1.	Description	A pale yellow colour liquid solution filled in 2 ml amber colour glass ampoule.	A pale yellow colour liquid solution filled in 2 ml amber colour glass ampoule.	
2.	Identification (By HPLC)	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: 2.0ml Max: 2.1 ml	
4.	Average fill volume	Not less than 2 ml	2.05 ml	
5.	pH	Between (4.50 to 8.0)	5.14	
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 87.5 Eu/ml	Less than 87.5 Eu/ml	
9.	Assay : Each 2ml contains:-			
Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Thiocolchicoside IP	4.0 mg	3.882 mg	97.50 %	90.0% to 110.0 %

Remarks: In the opinion of the undersigned the sample submitted complies/does not complies 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:- 19/09/2024	Date:- 19/09/2024	Date:- 19/09/2024

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

