



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.	: GA24G-23A	Mfg. Date	: 07/2024
Batch Size	: 23225 Ampoules	Exp. Date	: 06/2026
Sample Qty.	: 65 Ampoules	Analytical Report No.:	UFP20240038
Date of Receiving	: 25/07/2024	Date of Completion	: 08/08/2024
Spec No	: FP/TCC/SPC/001	STP No	: FP/TCC/STP/001

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)	4.66	
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	3.98 mg	99.50 %	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:- Date:-	Signature:- Date:-	Signature:- Date:-

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