

## **VELLINTON HEALTHCARE**

(Earlier Known as Texus Meditech)
Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

## QUALITY CONTROL DEPARTMENT

## CERTIFICATE OF ANALYSIS

**Product Name** : TRICANORT 40 Triamcinolone acetonide Injection IP Batch No. : L24A-05B Mfg. Date : 01/2024 **Batch Size** : 24235 Vials Exp. Date : 12/2025 Sample Qty. : 50 Vials Analytical Report No.: YFP20240008 Date of Receiving: 06/02/2024 Date of Completion: 20/02/2024

Mfg. License No. : N-MB/18/201

S. No.	Tests	Specifications		Observations				
1.	Description	A white colour liquid suspension filled in transparent glass vial.			A white colour liq id suspension filled in transparent glass vial.			
2.	Identification							
	A. By IR	Compare the spectrum with that obtained with triamcinolone acetonide RS or with the reference spectrum of triamcinolone acetonide.			Complies			
	B. By TLC	The principal spot in the chromatogram obtained with solution (3) appears as a single, compact spot.			Complies			
3.	Uniformity of filled volume	Not less than nominal volume			Min: 1.0 ml Max: 1.1 ml			
4.	Average fill volume	Not less than 1 ml			1.05 ml			
5.	pH	Between (5.0 to 7.50)			7.17			
6.	Related substances							
	The area of any secondary peak	NMT 0.2 %			Not detected			
	The sum of the area of all the secondary peaks	NMT 0.8 %			Not detected			
7.	Sterility	Should be Sterile			Sterile			
8.	Bacterial endotoxins	NMT 4.4 Eu/mg			Less than 4.4 Eu/mg			
9.	Assay : Each ml contains:-							
Composition:		Labeled Claim	LOUIDA 0/ of la		beled amount Limits % of labeled amount			
Triamcinolone acetonide IP		40.00 mg	40.63 mg	10	1.58 %	90.0% to 110%		

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 I.P. and IHS with respect to the above test only.

Analyzed By  QC Officer		Checked By QC Executive		QC Manager/Insquarge
Signature:- Date:-	(M20/02/2024	Signature:- Date:-	Phy 20102/2024	Signature:
Format No.: V	H/SOP/QC-062/FT01-00			