



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.	: L24C-03L1	Mfg. Date	: 03/2024
Batch Size	: 24363 Vials	Exp. Date	: 02/2026
Sample Qty.	: 50 Vials	Analytical Report No.:	YFP20240019
Date of Receiving	: 14/03/2024	Date of Completion	: 28/03/2024
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 liquid 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	1.04 ml	
5.	pH	Between (5.0 to 7.50)	6.28	
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	Found	% of labeled amount	Limits % of labeled amount
Triamcinolone acetonide IP	40.00 mg	39.26 mg	98.15 %	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	Approved By QC Manager/In-charge
Signature:- Date:-	Signature:- Date:-	Signature:- Date:-

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