

## **VELLINTON HEALTHCARE**

(Earlier Known as Texus Meditech)
Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

## QUALITY CONTROL DEPARTMENT

## CERTIFICATE OF ANALYSIS

: Ascorcan **Product Name** Ascorbic acid Injection IP Batch No. : GL23L-01A Mfg. Date : 12/2023 **Batch Size** : 2080 Vials Exp. Date : 11/2025 Sample Qty. : 50 vials. Analytical Report No.: LFP20230092 Date of Receiving: 02/12/2023 Date of Completion: 16/12/2023

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

S. No.	Tests	Specifications		Observations	a 11 s	
1.	Description		A clear colourless liquid solution filled in 6 ml amber color glass vial.  A clear colourless liquid solution in 6 ml amber color glass vial.		liquid solution filled or glass vial.	
2.	Identification					
	A. By Chemically	A transient blue colour is produced.		Complies	Complies	
	B. By Chemically	The deep blue color appreciably lighter o discharged within 3	r is completely	Complies	Complies	
	C. By flame	An intense yellow color to a nonluminous flame.		Complies	Complies	
3.	Uniformity of filled volume	Not less than nominal volume		Min: 6.0 ml Max: 6.1 ml		
4.	Average fill volume	Not less than 6 ml		6.03 ml	100	
5.	pH	Between (5.50 to 7.0)		5.98		
6.	Oxalic Acid	No turbidity is produced within 1 min.		Complies		
7.	Particulate Matter					
	≥ 10µm	NMT 6000 párticles/container		Less than 6000 pa	Less than 6000 particles/container	
	≥ 25µm	NMT 600 particles/container		The second second	Less than 600 particles/container	
8.	Sterility	Should be Sterile			Sterile	
9.	Bacterial Endotoxin	NMT 1.2 Eu/mg of Ascorbic acid.		- / · · · · · · · · · · · · · · · · · ·	Less than 1.2 Eu/mg	
10.	Assay : Each ml cont					
Composition:		Labeled Claim	Found	% of labeled amount	Limita % of labeles amount	
Ascorbic Acid IP		250.0 mg	245.93 mg	98.37 %	95.0% to 115%	

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:- MG 12 3023	Signature:- Date:- 16 12 2023	Signature:- Date:-