

VELLINTON HEALTHCARE

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name : Ascorcan 1.5g Ascorbic Acid Injection IP Batch No. : GL24I-07A Mfg. Date : 09/2024 **Batch Size** : 5040 Vials Exp. Date : 08/2026 Sample Qty. : 50 vials. Analytical Report No.: LFP20240095 Date of Receiving: 13/09/2024 Date of Completion: 25/09/2024

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

S. No. Tests		Specifications		Observation	Observations		
1. 2	Description	A clear colourless liq 6 ml amber color gla	uid solution filled ir ss vial.	A clear colourle	A clear colourless liquid solution filled in 6 ml amber color glass vial.		
2.	Identification						
	A. By Chemically	A transient blue colo	ur is produced.	Complies	Complies		
	B. By Chemically	The deep blue color appreciably lighter or discharged within 3 r	r is completely	Complies	Complies		
	C. By flame	An intense yellow co	lor to a nonluminou	Complies	Complies		
3.	Uniformity of filled volume	Not less than nominal volume		Min: 6.0 ml Max: 6.1 ml	1,014,000 (Mark Mark Mark Mark Mark Mark Mark Mark		
4.	Average fill volume	Not less than 6 ml		6.05 ml	6.05 ml		
5.	рН	Between (5.50 to 7.0)		6.38	6.38		
6.	Oxalic Acid	No turbidity is produc	ced within 1 min.	Complies	Complies		
7.	Particulate Matter						
	≥ 10µm	NMT 6000 particles/d	container	Less than 6000 particles/container			
3	≥ 25µm	NMT 600 particles/co	ontainer	Less than 600	Less than 600 particles/container		
8.	Sterility	Should be Sterile		232 23	Under analysis		
9.	Bacterial Endotoxin	NMT 1.2 Eu/mg of Ascorbic acid.			Less than 1.2 Eu/mg		
10.	Assay : Each ml cont	3					
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount		
Ascorbic Acid IP		250.0 mg	249.42 mg	99.77 %	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		Checked By		Approved Bymb	
QC Officer		QC Executive		QC Manager/ In-charge	
Signature:- Date:-	Azzloghozy	Signature:- Date:-	Duf og now	Signature:- Date:-	Massay Day

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