



# Pacebiotech Pharma (India) Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

## CERTIFICATE OF FINISH PRODUCT ANALYSIS

<b>Product Name:</b>	<b>Ascoran Injection (Ascorbic Acid Injection IP 250 mg)</b>		
<b>Batch No.</b>	25VF073D	<b>A.R. No.</b>	FP250156
<b>Batch Size</b>	10020 Vials	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	06/2025	<b>Date of Testing</b>	03/06/2025
<b>Exp. Date</b>	05/2027	<b>Date of Release</b>	18/06/2025
<b>Reference Batch No</b>	25VF073	<b>MFG. Lic. No.</b>	N-MB-2023/263

5

Sr. No.	Test	Specification	Observation
1.	<b>Description</b>	A clear, colourless liquid.	A clear and colorless liquid.
2.	<b>Identification</b>	<p>A. To a volume containing 5 mg of Ascorbic Acid add 0.5 ml of 0.1 M hydrochloric acid and 3 drops of sodium nitroprusside solution followed immediately by 1 ml of 0.1 M sodium hydroxide; a transient blue colour is produced.</p> <p>B. To a volume containing 40 mg of Ascorbic Acid add 4 ml of 0.1 M hydrochloric acid and 4 drops of ethylene blue solution and warm to 40°; the deep blue colour becomes appreciably lighter or is completely discharged within 3 minutes.</p> <p>C. The solution responds to the flame test for sodium salts, when exposed to non-luminous flame, the injection imparts an intense yellow colour.</p>	Complies
3.	<b>pH</b>	Between 5.5 to 7.0.	6.55
4.	<b>Extractable Volume</b>	NLT 6.0 ml	6.0 ml
5.	<b>Oxalic Acid</b>	Any opalescence, after 60 minutes, is not more intense than that produced by treating 5 ml of a solution prepared by dissolving 75 mg of oxalic acid in 500 ml of water in a similar manner (0.3 per cent)	Complies
6.	<b>Particulate Matter</b>	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
7.	<b>Bacterial Endotoxins</b>	NMT 1.2 EU/mg	Less than 1.2 EU/mg
8.	<b>Sterility</b>	Should be complies	Sterile



# Pacebiotech Pharma (India) Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

## CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Ascoran Injection (Ascorbic Acid Injection IP 250 mg)		
Batch No.	25VF073D	A.R. No.	FP250156
Batch Size	10020 Vials	Sample Quantity	60 Nos
Mfg. Date	06/2025	Date of Testing	03/06/2025
Exp. Date	05/2027	Date of Release	18/06/2025
Reference Batch No	25VF073	MFG. Lic. No.	N-MB-2023/263

Assay:		
Each 1ml contains		
9. Sodium Ascorbate IP Eq. to Ascorbic Acid 250mg	95.0 to 115.0 % ( 237.5to 287.5 mg)	102.3 % (255.9 mg)

Remark: The sample is complies as per  IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date			
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-Qc