

Pacebiotech Pharma (India) Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	L-ORNICAN INJECTION (L-Ornithine L-Aspartate Infusion)			
Batch No.	25AA007E	A.R. No.	PV250140	
Batch Size	20020 Vials	Sample Quantity	60 Nos	
Mfg. Date	01/2025	Date of Testing	12/01/2025	
Exp. Date	12/2026	Date of Release	27/01/2025	
Reference Batch N	o 25AA007	MFG. Lic. No.	N-MB-2023/263	

Sr.	Test	Specification	Observation	
No.				
1.	Description	A clear, colourless solution.	A clear, colourless solution.	
2.	рН	Between 5.0 to 7.0	6.12	
3.	Extractable Volume	NLT 10.0 ml	10.0 ml	
		Injections that are solutions, when		
4.		examined under suitable conditions		
	Particulate Matter	of visibility, are clear and practically	Complies	
		free from particles that can be		
		observed on visual inspection by the		
		unaided eye.		
5.	Bacterial Endotoxins	NMT 1.67 EU/mg	Complies	
6.	Sterility	Should be complies	Complies	
7.	Assay:			
	Each 10 ml contains :			
	L-Ornithine-L-Aspartate 5 gm	90.0% to 110.0 %	102.82%	
		(4.5 gm to 5.5 gm)	(5.141 gm)	

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

	Prepared By	Checked By	Approved By
Sign/Date	M27/01/2025	24/01/2025	22/01/2025
Name	Manisha Thakur	Vikram Jeet	Bhupinder Navet
Designation	Sr. officer QC	Executive-QC	Head-QC