

Pace

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Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

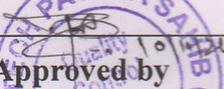
Product Name	L-ORNICAN Infusion	A.R. No.	NL/FP/24/378
Generic Name	L-Ornithine L-Aspartate Infusion 10ml	Sampled qty.	45 Ampoules
Batch No.	A24264C	Sampled by	Boby Kumar
Batch Size	20,000 Ampoules	Sampled on	26/10/2024
Mfg. Date	10/2024	Date of Testing	26/10/2024
Exp. Date	09/2026	Date of Release	10/11/2024

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.		
2.	Identification	Complies as per Assay.	Complies		
3.	Nominal fill volume	NLT-10 ml	10.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	10.1 ml		
5.	pH	5.0 to 7.5	6.05		
6.	Particulate Matter	NMT-6000/Ampoule NMT-600/Ampoule	226/Ampoule 3/Ampoule		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$				
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT- 0.0175 EU/mg of L-Ornithine- L-Aspartate.	Less than- 0.0175 EU/mg of L-Ornithine - L-Aspartate.		
9.	Assay: Each 10ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
L-Ornithine -L-Aspartate		5 gm	5.17762 gm	103.55%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not-complies as per IP/BP/USP/IHS.

Analysis by 
NAME: SUFIYAN ANSARI

Checked by 
NAME: SANDHYA

Approved by 
NAME: P. N. TRIPATHI

