

Pace

Add Pace To Health

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/24/321
Generic Name	L-Ornithine L-Aspartate Infusion 10ml	Sampled qty.	45 Ampoules
Batch No.	A24178A	Sampled by	Vineet
Batch Size	10,000 Ampoules	Sampled on	20/09/2024
Mfg. Date	08/2024	Date of Testing	20/09/2024
Exp. Date	07/2026	Date of Release	05/10/2024

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	6.00		
6.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/Ampoule NMT-600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	143/Ampoule 6/Ampoule 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	5.2277 gm	104.55%	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

Checked by

Approved by

