

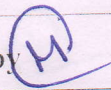
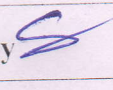
Title : Certificate of Analysis Finished Product

Product Name	L-ORNICAN Infusion	A.R. No.	NL/FP/23/663
Generic Name	L-Ornithine L-Aspartate Infusion 5g/10ml	Sampled qty.	30 Ampoules
Batch No.	A23493B	Sampled by	Arvind
Batch Size	4572 Ampoules	Sampled on	20/01/2024
Mfg. Date	12/2023	Date of Testing	20/01/2024
Exp. Date	11/2025	Date of Release	04/02/2024

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	6.48
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.	71/Ampoule 12/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	5.2080 gm	104.16%	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 