

Pace

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Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	CARNIVIVE Injection	A.R. No.	NL/FP/25/355
Generic Name	Levocarnitine Injection USP	Sampled qty.	45 Ampoules
Batch No.	A25372J	Sampled by	Anuj Verma
Batch Size	3600 Ampoules	Sampled on	25/02/2026
Mfg. Date	01/2026	Date of Testing	26/02/2026
Exp. Date	12/2027	Date of Release	12/03/2026

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.
2.	Identification (By HPLC) (By colour reaction)	A. The retention time of the Major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay. B. A red violet precipitate should produced.	Complies Complies
3.	Nominal fill volume	NLT 5ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume.	5.1 ml
5.	pH	6.0 to 6.5	6.17
6.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual	NMT 6000/Ampoule NMT 600/Ampoule The solution is free from particles of foreign matter particles that can be observed on visual inspection.	11/Ampoule 1/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 0.1 USP EU/mg of Levocarnitine.	Less than 0.1 USP EU/mg of Levocarnitine.
9.	Assay: (By HPLC) Each 5ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Levocarnitine USP	1000 mg	1000.26267 mg	100.03%	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/HS.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 5102/039593

Analysis by

Checked by

Approved