

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	CARNIVIVE Injection	A.R. No.	NL/FP/25/122
Generic Name	Levocarnitine Injection USP 1g/5ml	Sampled qty.	45 Ampoules
Batch No.	A25137B	Sampled by	Rakesh
Batch Size	10,000 Ampoules	Sampled on	15/07/2025
Mfg. Date	07/2025	Date of Testing	15/07/2025
Exp. Date	06/2027	Date of Release	30/07/2025

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	6.28		
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 Particle	NMT 6000/Ampoule NMT 600/Ampoule The solution is free from particles of foreign matter particles that can be observed on visual inspection.	69/Ampoule 0/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		1.0 gm	1.086554gm	108.66%	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: SYAHEEDHAWAN

