

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title**:****Certificate of Analysis Finished Product**

Product Name	CARNIVIVE Injection	A.R. No.	ARN/FP/26/038
Generic Name	Levocarnitine Injection USP 5ml	Sampled qty.	45 Ampoules
Batch No.	ARN2636A	Sampled by	Rakesh
Batch Size	20,250 Ampoules	Sampled on	20/07/2026
Mfg. Date	07/2026	Date of Testing	20/07/2026
Exp. Date	06/2028	Date of Release	03/08/2026

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	6.45
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.	72/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	1072.00631 mg	107.20%	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/WHO.

Analysis by

NAME: FIROJ KHAN

Checked by

NAME: SURJEET KAUR

Approved by

NAME: MRS. SWATI DHAWAN