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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**CANAPRIN 25K** Injection	**A.R. No.**	NL/FP/23/825
Generic Name	Heparin Sodium Injection IP 25000IU/5ml	**Sampled qty.**	45Vials
Batch No.	V23129D	**Sampled by**	Arvind
Batch Size	8000 Vials	**Sampled on**	31/03/2024
Mfg. Date	03/2024	**Date of Testing**	31/03/2024
Exp. Date	02/2026	**Date of Release**	16/04/2024

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear glass vial.	A clear colourless solution filled in clear glass vial.
2.	Identification	**A.** It complies with the requirements described under assay. **B.** 1t gives reaction (A) of sodium salts.	Complies Complies
3.	Nominal fill volume	NLT- 5ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	5.1 ml
5.	pH	5.0 to 7.5	6.12
6.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	 NMT-6000/vial NMT-600/vial	 331/vial 1/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.	Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT- 0.03 Endotoxin unit per unit of Heparin.	Less than- 0.03 Endotoxin unit per unit of Heparin.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Heparin Sodium IP (Derived from Porcine mucosa)	5000 IU	4857.76 IU	97.16%	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