

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Sucrocan Injection (Iron Sucrose Injection USP)		
Batch No.	25AE073A	A.R. No.	PV250473
Batch Size	30100 Ampoules	Sample Quantity	60 Nos
Mfg. Date	05/2025	Date of Testing	21/05/2025
Exp. Date	04/2027	Date of Release	06/06/2025
Reference Batch No	25AE073	MFG. Lic. No.	N-MB-2023/263

Sr. No.	Test	Specification	Observation
1.	Description	A Dark Brown colored Liquid.	Dark Brown colored Liquid
2.	Identification A. iron B. Sucrose C. Molecular weight determination	A. In test sample red Colour is discharged. B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay for Sucrose. C. M W: 34,000–60,000 Da, M N: NLT 24,000 Da, M W/M N: NMT 1.7	Complies
3.	pH	Between 10.50 to 11.1	10.97
4.	Content of chloride	0.012%–0.025%	Complies
5.	Limit of iron [Fe(II)]	NMT 0.4%	Complies
6.	Turbidity	4.4–5.3	Complies
7.	ABSENCE OF LOW-MOLECULAR WEIGHT IRON [FE(II) AND FE(III)] COMPLEXES:	In the polarograms obtained in the test for Limit of Iron [Fe(II)], no additional peaks are found.	Complies
8.	Alkanlinity	0.5–0.8 mL of 0.1 N hydrochloric acid VS is consumed per mL of Injection	Complies
9.	Osmolality and osmolarity	1150–1350 mOsmol/L	Complies
10.	Specific gravity	1.135–1.165 at 20°	Complies
11.	Sucrose	95.0%–105.0%	99.65%
12.	Extractable Volume	NLT 5.0 ml	5.0 ml
13.	Bacterial Endotoxins	NMT 3.7 Endotoxin unit per mg	Less than 3.7 Endotoxin unit per mg



Pacebiotech Pharma (India) Pvt. Ltd.

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

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14.	Particulate Matter (Visible Particles) (Sub Visible Particles) Particles of $\geq 10 \mu\text{m}$ Particles of $\geq 25 \mu\text{m}$	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye. NMT 6000 particles of $10 \mu\text{m}$ NMT 600 particles of $25 \mu\text{m}$	Complies
15.	Sterility	Should be complies	Sterile
16.	Iron	95.0% to 105.0%	101.61%

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 26/06/2025	 06/06/2025	 06/06/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC