



American Remedies Healthcare Pvt. Ltd.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Sucroheal Injection (Iron Sucrose Injection USP)		
Batch No.	25AR026	A.R. No.	AFP250031
Batch Size	25000 Ampoules	Sample Quantity	60 Nos
Mfg. Date	09/2025	Date of Testing	30/09/2025
Exp. Date	08/2027	Date of Release	16/10/2025
Reference Batch No	25AR026	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.		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	10.68
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%



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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
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.	Each ml contains: Ferric Hydroxide Complex with sucrose Eq. to elemental Iron 20mg	95.0% to 105.0% 19.0 m to 21.0 mg	100.60 % 20.12 mg



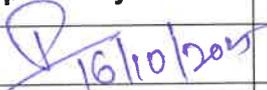
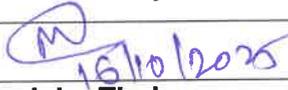
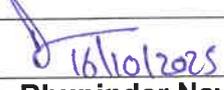
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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 16/10/2025	 16/10/2025	 16/10/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

