American Remedies Healthcare Pvt. Ltd.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	**Sucrocan Injection (Iron Sucrose Injection USP 5ml)**		
Batch No.	26AR105	**A.R. No.**	AFP260113
Batch Size	50200 Ampoule	**Sample Quantity**	60 Amps.
Mfg. Date	09/2026	**Date of Testing**	13/09/2026
Exp. Date	08/2028	**Date of Release**	28/09/2026
Reference Batch No	26AR105	**MFG. Lic. No.**	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	**Description**	A Dark Brown colored Liquid filled in amber colour ampoule.	A Dark Brown colored Liquid filled in amber colour ampoule.
2.	**Identification** **A. Iron** **B. By HPLC** **C. Molecular weight Determination**	 Red Colour should be discharged. In the Assay for sucrose, The retention time of the major peak of the Sample solution corresponds to that of the Standard solution. M_W: 34,000–60,000 Da M_N: NLT 24,000 Da M_W/M_N: NMT 1.7	 Complies Complies Complies
3.	**pH**	10.50 to 11.10	10.95
4.	**Content of chloride**	0.012% - 0.025%	0.016%
5.	**Limit of iron [Fe(II)]**	NMT 0.4%	0.09%
6.	**Turbidity**	4.4 - 5.3	4.81
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	0.6 mL
9.	**Osmolality and osmolarity**	1150–1350 Osmol/L	1247 Osmol/L
10.	**Specific gravity**	1.135–1.165 at 20°	1.157
11.	**Sucrose**	260.0 to 340.0 mg/mL	292.0 mg/mL

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12.	**Extractable Volume**	NLT 5.0 ml	5.0 ml
13.	**Bacterial Endotoxins**	NMT 3.7 EU/mg	Less than 3.7 EU/mg
14.	**Particulate Matter (Visible Particles)**	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.	Complies
	(Sub Visible Particles)		
	Particles of ≥10 µm	NMT 6000 particles of 10 µm	742
	Particles of ≥25 µm	NMT 600 particles of 25 µm	63
15.	**Sterility**	Should be Sterile	Sterile
16.	**Each ml Contains:**		
	Ferric Hydoxide complex with sucrose	(95.0 to 105.0%)	(100.26%)
	Eq. to elemental Iron 20 mg	19.0 to 21.0 mg	20.05 mg

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

	Prepared By	Checked By	Approved By
Sign/Date	28/09/2026	28/09/2026	28/09/2026
Name	**Diksha Saini**	**Vinay Kumar**	**Bhupinder Navet**
Designation	**Officer QC**	**Executive-QC**	**Head-QC**

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
Registration No: 12-DVI-103
Pt BD Sharma University of Health Sciences, Rohtak

AMERICAN REMEDIES (I) PVT. LTD. QUALITY CONTROL MANAGER