

ASIAN GROUP
Q P S**Asian Pharma**

105-106, katha Baddi, Distt. Solan

Quality control Department

Certificate of Analysis

Product Name	Sucrocan Injection USP		
Batch No	GI014406	AR. No.	AF24- 719
Mfg. Date	06/2024	Batch Size	158.1 Ltr
Exp .Date	05/2026	Sample Qty.	63 Ampoules
		Code. No.	MB/19/1061
Date of Received	25/07/2024	Date of Release	08/08/2024

S No	CHARACTERISTICS	RESULTS	SPECIFICATIONS
1	Description	Dark brown colored liquid filled in amber coloured 5 ml glass ampoule.	Brown to Dark brown colored liquid filled in amber coloured 5 ml glass ampoule.
2	Identification	Positive for iron Sucrose	Should be Comply.
3	Molecular weight Determination	Complies	Should be comply.
4	Average Fill Voloume	5.2 ml	NLT 5 ML
5	Uniformity of Fill Volume	Within limits	The average content of the Ampoules is not less than 91% the nominal volume & not more than 110% of the nominal volume.
6	pH	10.91	Between 10.5 to 11.1
7	Specific Gravity	1.148	Between 1.135 to 1.165.at 20°C
8	Turbidity	Complies	Should be comply.
9	Alkalinity	Complies	Should be comply.
10	Limit of Iron (Fe II)	Less than 0.4%	NMT 0.4%
11	Absence of Low-molecular weight Fe(II) and Fe(III) Complexes	Complies	Should be Comply.
12	Sucrose	Complies	260–340 mg/mL
13	Osmolarity & Osmolality	Within limits	Between 1150 to 1350 mOsmol/lit.
14	Content of chloride	Complies	0.012%–0.025%.
15	Particulate Matter	Reconstituted solution is essentially free from particles of foreign matter that can seen on visual inspection.	Reconstituted solution is essentially free from particles of foreign matter that can seen on visual inspection.
16	Bacterial endotoxins	Less than 3.7 Eu/Mg Of Iron	NMT 3.7 Eu/Mg Of Iron
17	Sterility	Sterile	Must be Sterile
18	Assay : Each ml Contains: Ferric Hydroxide in Complex with Sucrose equivalent to elemental iron ----20 mg	19.885 mg (99.43%)	95.0 % to 105.0% of Iron

Remarks: -The sample complies/does not comply as per IP/BP/USP/IH specification.

	Analysed By	Checked By	Approved By
Sign			
Date	08/08/2024	08/08/2024	08/08/2024