OM BIOMEDIC PVT LTD

PLOT NO : 68,69,82 & 83,SECTOR 6A,IIE,SIDCUL,HARIDWAR-249403
REG.OFF.: 134/5 H.T.M ROAD NEAR SECTOR 1&4,RAIPUR LANE-HISAR HARYANA PIN-125001,HISAR-
C.I.No..: U85110HR2005PTC040863

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : SUCROCAN INJECTION 5 ML. AMERICAN REMEDIES
Packing : 5 ML
Generic Name : IRON SUCROSE INJECTION USP

Product Code : SUCR02
Batch No. : II24-30
Actual Batch Size : 161 LTR (31568 AMP)
Packing Batch Size : 161 LTR
Sample Size : 50.000 AMP
Released Qty : 161.000 LTR (31568 AMP)

Mfg. Dt. : 09/2024
Exp. Dt. : 08/2026
Test Packing : 1 AMP
Mfg. Lic No. : 138/UA/SC/P2007
Test As Per : USP

Remarks :

A.R. No. : OMFPLI241148
Rel. Dt. : 20-09-2024
T.R. Slip No. : FTRLIQ4298
T.R. Slip Dt. : 06-09-2024
Analysis Date : 06-09-2024

Location : HARIDWAR
Make : OMBPL

Sr.	Test	Result	Specification
1	DESCRIPTION	Dark brown colour solution filled in amber coloured glass ampoule. Properly sealed & labeled.	Dark brown colour solution filled in amber coloured glass ampoule. Properly sealed & labeled.
2	IDENTIFICATION	A) Complies. B) Complies. C) Mw: 42154 Da Mn: 29548 Da Mw/Mn: 1.22.	A) Iron: The red colour is dicharged. B) By HPLC: 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) Molecular Weight Mw: 34000 - 60000 Da Mn: NLT 24000 Da Mw/Mn: NMT 1.7
3	PH	10.68	10.50 - 11.10 at 20°.
4	NOMINAL VOLUME	5.00ml	5.00ml
5	EXTRACTABLE VOLUME	5.06ml	NLT 5.00ml
6	PARTICULATE MATTER	No any particle observed by unaided eye.	No any particle observed by unaided eye.
7	CONTENT OF CHLORIDE	0.018%.	0.012% - 0.025%
8	LIMIT OF IRON [FE(II)]	0.17%.	NMT 0.4%.
9	TURBIDITY	5.01	4.40 - 5.30
10	ABSENCE OF LOW-MOLECULAR WEIGHT IRON [FE(II) AND FE(III)] COMPLEXES	Complies.	No additional peaks are found.
11	ALKALINITY	0.6ml	0.5ml - 0.8ml of 0.1 N hydrochloric acid VS is consumed/ml of Injection.
12	OSMOLARITY & OSMOLALITY	1216 mOsmol/L.	1150 - 1350 mOsmol/L
13	SPECIFIC GRAVITY	1.142gm/ml	1.135 - 1.165 at 20°.

Conclusion : The above sample complies as per USP
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By

Approved By

OM BIOMEDIC PVT LTD

PLOT NO : 68,69,82 & 83,SECTOR 6A,IIE,SIDCUL,HARIDWAR-249403
REG.OFF.: 134/5 H.T.M ROAD NEAR SECTOR 1&4,RAIPUR LANE-HISAR HARYANA PIN-125001,HISAR-
C.I.No. : U85110HR2005PTC040863

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : SUCROCAN INJECTION 5 ML. AMERICAN REMEDIES
Packing : 5 ML
Generic Name : IRON SUCROSE INJECTION USP

Product Code : SUCR02 **Mfg. Dt.** : 09/2024
Batch No. : II24-30 **Exp. Dt.** : 08/2026
Actual Batch Size : 161 LTR (31568 AMP) **Test Packing** : 1 AMP
Packing Batch Size : 161 LTR **Mfg. Lic No.** : 138/UA/SC/P2007
Sample Size : 50.000 AMP
Released Qty : 161.000 LTR (31568 AMP) **Test As Per** : USP
Remarks :

A.R. No. : OMFPLI241148
Rel. Dt. : 20-09-2024
T.R. Slip No. : FTRLIQ4298
T.R. Slip Dt. : 06-09-2024
Analysis Date : 06-09-2024

Location : HARIDWAR
Make : OMBPL

Sr.	Test	Result	Specification
14	BACTERIAL ENDOTOXIN	Less than 3.7 USP EU/mg.	NMT 3.7 USP EU/mg.
15	STERILITY	Complies.	Should Comply.
16	SUCROSE	328.16mg	260 - 340mg/ml
17	ASSAY	19.85mg (99.24%)	Each ml Contains: Ferric Hydroxide in Complex with Sucrose Eq. to Elemental Iron 20.0mg [Limit: 19.0mg - 21.0mg][95.0% - 105.0%]

Conclusion : The above sample complies as per USP
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By **Approved By**