



2216

## Central Drugs Laboratory, Kolkata 3, Kyd Street Kolkata (India) - 700016 Phone No. 033-22299380.

Email:cdlkol@cdsco.nic.in, cdlkol@gmail.com

Date. 16.07.24

Govt. of

India



## CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

: Subhashini Gouravarapu, Drugs Inspector

**Drugs Control Administration** 

Drugs Inspector, Tirupati-Urban, O/o Assistant Director, D.No. 2-157/5, Bhupal Housing Colony, Ward No. 22, Thimminaidupalem, Karakambadi Road, Tirupati,

Andhra Pradesh, Pin-517507

Mail Sut to
DI on 26/2/24
2. Serial No. and date of Inspector's memorandum

: 02052024/DI/TPT-U/2024, 24-MAY-2024

3. Number of Sample

: Not Mentioned

4. Date of receipt

: 29-MAY-2024

5. Names of drugs purporting to be contained in the sample : Iron Sucrose Injection USP 100mg/5ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/KOL/2024- 25/0319	KOL/LS/2024- 25/575	23 \$10	Dec-2023	Nov-2025	SAI Parenterals Limited,, D1 & D4, Survey No.280,Phase-V IDA,Jeedimetla, Hyderabad, 500055. TS

6. Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing: From 05-Jul-2024 To 11-Jul-2024

COMPOSITION

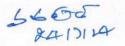
Each 5ml Ampoule contains: Ferric Hydroxide in complex with sucrose

Equivalent to elemental Iron 100 mg

## Protocol Applied: U.S.P.

Sr No.	Test Name	Result	NA NA	
1	Description	Dark brown liquid having characteristic smell supplied in sealed amber color glass ampoule.		
2	Identification (Iron)	Gives positive test for Iron.		
3	Identification (Sucrose)	Gives positive test for Sucrose.	NA	
4	Content of chloride	Passes the test. (Found: 0.0235%)	0.012 to 0.025 %	
5	pH	Passes the test. (Found: 10.52)	10.5 to 11.1 at 20 degree	
6	Alkalinity	Passes the test.	NA	





7	Specific Gravity	Passes the test. (Found 1.1583)	1.135 to 1.165 a 20 degree
8	Particulate Matter In Injections	Complies	NA
9	Bacterial Endotoxins Test	Compiles	NA
10	Sterility	complies	NA
11	Container Content for Injection	Passes the test.	NA
12	Assay (Sucrose)	Passes the test. (Found: 313.002mg/ml)	260 to 340 mg/ml

## Assay

Say		API DI PERINANA DI PERINANA		O/ -f alaim	Limits	Procedure /
Sr.No	Ingredient Name	Found	Claim	% of claim	Lilling	Method
			00 / 1	101.715	95 % to 105 %	U.S.P.
1	Ferric Hydroxide Complex with Sucrose calculated as elemental Iron	20.343 mg/ml	20 mg/ml	101.713		Duran and

In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample conforms to U.S.P. with respect to above tests.

Date: 16-JUL-2024

GOVERNMENT ANALYST

DR. ANJAN PAL
Sr. Scientific Officer (Microbiology)
Central Drugs Laboratory
Govt. of India
3, Kyd Street, Kolkata-16

END OF REPORT