



Central Drugs Laboratory, Kolkata  
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No. 811

Date: 16-07-24



**FORM 13**  
(See rule 46)  
**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
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

*Mail sent to  
DI on 26/5/24*

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	23IS10	Dec-2023	Nov-2025	SAI Parenterals Limited,, D1 & D4, Survey No.280,Phase-V, IDA,Jeedimetla, Hyderabad, 500055, TS

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector  
[the packet or on portion of sample or container]

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	Limits
1	Description	Dark brown liquid having characteristic smell supplied in sealed amber color glass ampoule.	NA
2	Identification (Iron)	Gives positive test for Iron.	NA
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

*NA Seal*

*5605  
24/7/24*

7	Specific Gravity	Passes the test. (Found 1.1583)	1.135 to 1.165 at 20 degree
8	Particulate Matter In Injections	Complies	NA
9	Bacterial Endotoxins Test	Complies	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**

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ferric Hydroxide Complex with Sucrose calculated as elemental Iron	20.343 mg/ml	20 mg/ml	101.715	95 % to 105 %	U.S.P.

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 -----