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Maharashtra Medical Goods Procurement Authority

Office- 1st Floor, Aarogya Bhawan, Commissionerate of Health Services, Mumbai, D'Mello Road,
St. Georges Hospital Compound, Mumbai 400001

RPD

Contact Number- 022-22611471, 022-22717500 E-mail - maha.mmga2023@gmail.com

O/w. No. /MMGPA/Medicine & Material Sections/2025

314

Date: 04.08.2025

✓To,

Director General
Employees' State Insurance Corporation,
Room No.312 & 314, Hqrs. Office, Panchdeep Bhawan,
C.I.G. Road, New Delhi- 110002



Sub: Regarding drug Inj. Iron Sucrose 20 mg/ml, Batch No. 23IS10, supplied by M/s. Sai Parenterals Ltd., declared as NSQ by Govt. Analyst, CDTL, Mumbai

- Ref:
1. Purchase Order No. 17, dated 07.10.2023, based on ESIC RC No. 146c
 2. 'Certificate of Test or Analysis by Govt. Analyst under section 25(1) of The Drugs and Cosmetics Act, 1940', CDTL, Mumbai, dated 11.02.2025
 3. Approved note of Hon. CEO, MMGPA, Mumbai, dated 31.07.2025

As per Ref. no.1, Purchase Order was issued by this office, for the product 'Inj. Iron Sucrose 20 mg/ml', based on ESIC Rate Contract number 146c (2021-2023).

As per Ref. no. 2, this office is in receipt of 'Certificate of Test or Analysis by Govt. Analyst under section 25(1) of The Drugs and Cosmetics Act, 1940' CDTL, Mumbai, dated 11.02.2025 wherein the batch of the aforesaid drug is reported to be not of standard quality (NSQ). Details of NSQ batch as given below:

Name of item	Name of Manufacturer	Batch No.	Manufacturing Date	Expiry Date
Inj. Iron Sucrose 20 mg/ml	M/s. Sai Parenterals Ltd.	23IS10	12/2023	11/2025

As per the opinion given in the report, "the sample received does not conform to USP 43 with respect to the test for "pH", "Alkalinity", and "Particulate Matter" in injections."

Despite reminders, the firm has failed to replace the stock of NSQ drug as per the testing report of CDTL, Mumbai. The concerned firm has been issued a show cause notice regarding non-replacement of NSQ stock.

As per terms and conditions, clause 22.B.I of the above-mentioned rate contract,

“If single item/.Batch of item is declared NSQ under Category B

- Rate Contract Holder/ Pharmaceutical firm will be debarred for the further supply of the said NSQ item in the currency of the Rate Contract.”

This is for your information and further necessary action.



Dr. Sanjeevkumar Jadhav
General Manager (Technical)
Maharashtra Medical Goods Procurement Authority,
Mumbai



Maharashtra Medical Goods Procurement Authority

A Maharashtra Government Authority

Approval through Government Resolution -Official Gazette, Dated 10th May, 2023
Office- 1st Floor, Aarogya Bhawan, Commissionerate of Health Services, Mumbai, D^o Mello Road,
St. Georges Hospital Compound, Mumbai 411001
Contact Number- 022-22611471, 022-22717500 E-mail- maha.mmgsa2023@gmail.com

Order.No. 17 /MMGPA/Medicine & Material Section/2023, dated 07.10.2023

To,
M/s. SAI PARENTERALS PVT LTD,
8-2-700, Srida Anushka Pride, Road No.12,
Banjara Hills, Hyderabad - 500 034
Mobile/ Tel No: 9885021555/ 040-23097936/9848237131
Email: md.salparenterals@gmail.com saiparenterals@gmail.com

Subject: - Supply of Inj. Iron Sucrose 20mg.

Reference: - (1) Special Permission from Executive Committee, Maharashtra as per Minutes of Meeting Dated 3.10.2023

(2) ESIC Rate Contract No.146c, Valid up to 31.10.2023

(3) Budget Source: Free Drug Initiative, FIP 2023-24 (Sr. No.180),

(4) Sanction of Tender Approval Committee, Meeting Dated 06.10.2023

With reference to the special permission granted under above reference no.1, you have been awarded for the supply of following medicinal product as per valid ESIC Rate Contract w.r.t. reference 2. Accordingly you are requested to supply the following goods to the consignees as per details mentioned below. (Consignee List enclosed separately with this order).

Rate Contract Number & Item No.	Name of the item	Specification of item	Quantity (DHS)	Unit Rate	Total Amount including
146c (2021-2023)	Inj. Iron Sucrose 20mg.	Iron Inj. Each ml to contain: Iron Sucrose 20mg	200150	13.00	2601950.00
Total Amount In Words- Twenty Six Lac One Thousand Nine Hundred Fifty Only					
* GST as applicable will be extra, except for items where no tax has been approved.					

- Packing & Forwarding:** Packing as Per ESIC Rate Contract Terms & Conditions, & Forwarding Free on Road Destination. i.e. door delivery basis
- Delivery Period:** 6 weeks from the date of receipt of order by the supplier to the consignee attached.
- Risk purchase clause:** If the bidder fails to supply the stores within the stipulated delivery period inclusive of period with penalty, the order will stand cancelled. Undersigned shall be entitled to purchase such stores from any other source at such price which ordinarily should not be more than 10% of the tender price, unless otherwise properly satisfied by purchasing officer. The extra expenditure in such cases shall be recovered by Chief Executive Officer, Maharashtra Medical Goods Procurement Authority, Aarogya Bhawan, St.George's Hospital Compound, Mumbai from the Supplier inclusive of recovery by Revenue recovery procedure.
- Payment Terms:** 100 % Payment shall be paid on receipt & acceptance of stores in good conditions by the consignee

ESIC § Rate Contract Purchase 2023-24

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5. **Labeling:** The word "For use of GOVERNMENT OF MAHARASHTRA NOT FOR SALE" should be printed on each unit pack in readable Purple or Green Colours. Bar-coding should be on boxes of Supplied item at Consignee level.
6. **SHELF LIFE** of the supplied drug should not be less than $\frac{1}{4}$ of total shelf life at the time of delivery to the consignee.
7. **Acceptance & Receipt:** In prescribed format enclosed. It should be submitted in Original Certificate copy to the purchasing authority along with triplicate copies of the Invoice.
8. The Consignees upon Receipt of the material should issue acceptance certificate within 7 days of receipt of material in two copies. One copy should handed over to Supplier and One Copy should be sent Maharashtra Medical Goods Procurement Authority, Aarogya Bhavan St.George's Hospital Compound, Mumbai by mail or email. (Email ID- maha.mmppa2023@gmail.com)
9. **Analysis Report:** Manufactures should submit copy of Drugs analysis report to each consignee for each batch supplied with copy of the same along with invoice to Chief Executive Officer, Maharashtra Medical Goods Procurement Authority, Aarogya Bhavan St.George's Hospital Compound, Mumbai
10. **Delivery Challan** - Should be sent in the name of consignee in duplicate. It should specify Name of Drugs/ Mfg. by / Expiry Date / packing & quantity.
11. **Invoice Copy** - Should be sent in triplicate on the Name of Chief Executive Officer, Maharashtra Medical Goods Procurement Authority, Aarogya Bhavan St. George's Hospital Compound, Mumbai.
Other Terms: As per ESIC Rate Contract's terms & conditions will be applicable.
Fall Clause: It is a condition of the contract that all through the currency thereof, the price at which you will the supply stores should not exceed the lowest price charged by you to any customer during the currency of the rate contract and that in the event of the prices going down below the rate contract prices you shall promptly furnish such information to us to enable to amend the contract rates for subsequent supplies.
12. You are requested to submit following within 15 days from receipt of this letter.
 1. Sign and submit the agreement attached herewith on Stamp paper.
13. Submit the Bank Guarantee of Rs.78059/- (3% of the total value of order) from Nationalized /Scheduled commercial bank in favor of Maharashtra Medical Goods Procurement Authority, Aarogya Bhavan St.George's Hospital Compound, Mumbai Validity of the Bank Guarantee should be minimum next 2 months from the date of expiry of warranty or expiry of medicine/item.

Name of Account	Name of Branch Account	No. of Account	IFSC Code
Chief Executive Officer, Maharashtra Medical Goods Procurement Authority, Mumbai	Canara Bank, Nariman Point Branch, Mumbai	120024122310	CNRB0015037

Consignee : As per list enclosed.


 (Dr. Umesh Shirodkar)
 General Manager (Technical)
 Maharashtra Medical Goods Procurement Authority
 Mumbai

- Copy to: 1) Commissioner of Health Services, Mumbai
 2) Director of Health Services, Mumbai
 3) Chief Accounts and Finance Officer, Medical Goods Procurement Authority, Mumbai
 4) Joint Director of Health Services (Procurement Cell) Mumbai
 5) Office File

Copy to Consignee(s):

They should accept Drugs as per order & entry of the said stock is to be taken in stock register as well as in e-Aushadhi system immediately within 24hrs of delivery.

- Copy Submitted to: 1) Addl. Chief Secretary, Public Health Department, Mantralaya, Mumbai
 2) Secretary-2, Public Health Department, Mantralaya, Mumbai

Annexure - C

SCHEDULE FOR PACKING OF DRUGS AND MEDICINES:

I. SCHEDULE FOR PACKAGING OF DRUGS AND MEDICINES GENERAL SPECIFICATIONS

:All drugs should be packed & Supplied in Prescribed packing only & as per standard guidelines of FDA / ISI

1. No corrugate package should weigh more than 15 Kgs. (i.e. product + inner carton + corrugated box).
2. All corrugated boxes should be of 'A' grade paper, i.e. Virgin.
3. All items should be packed only in first hand boxes only.
4. Flute - The corrugated boxes should be of narrow flute.
5. Joint - Every box should be preferably single joint and not more than two joints.
6. Stitching - Every box should be stitched using pairs of metal pins with an interval of two inches Between each pair. The boxes should be stitched and not joined using calico at the corners.
7. Flap - The flaps should uniformly meet but should not overlap each other. The flap when turned by 45 - 60 degree should not crack.
8. Tape - Every box should be sealed with gum tape running along the top and lower opening.
9. Carry strap - Every box should be strapped with two parallel nylon carry straps (they should intersect)
10. Label - Every corrugated box should carry a large outer label clearly indicating that the product is for **GOVERNMENT OF MAHARASHTRA NOT FOR SALE "in readable purple or Green colour.**
11. The product label on the cartoon should be large at least 15 cms * 10 cms dimension. It should carry the correct technical name, strength or the product, date of manufacturing, date of expiry, quantity packed and net weight of the box.
12. Other - No box should contain mixed products or mixed batches of the same product.
13. **Primary Package:** 10 Tablets/Capsules or multiples of 10 should be packed in an Aluminium strip / Aluminium - P V C blister pack
Aluminium strips : Thickness of Aluminium foil : 40 micron with LDPE 25 micron coating/heat seal lacquer
PVC Film : Transparent, clear/amber, food grade, blister forming PVC film, Film gauge - 200 microns, P E coating : 25 microns, PVC coating : 60 gsm
Aluminium foil: Hard tempered Blister foil, VMCH coated, Thickness: 0.025 mm
- Secondary Package:** The strips should be packed in boxes for easy handling, transport and distribution. The box may contain 10 strips. It shall be fabricated from Mainboard/grey board/cardboard with minimum of bursting strength of 400 gsm
- Tertiary Package :** The boxes shall be packed in weather resistant triple walled insulated corrugated 5 ply cartoons, each ply having strength of minimum 150 gsm It should be fabricated from virgin quality 'A' grade material . The overall dimension of the cartoon should be such that the product does not get damaged during transportation and storage. Each international shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores

Bar-coding: - Bar-coding should be on secondary & Tertiary packing only.

IV. Case Identification ---- All cases should prominently indicate the following

1. Purchaser's line and code numbers
2. The Generic Name of the product
3. The dosage form (Tablet, Capsule, Ampoule, Syrup, Vial)
4. Date of manufacture and expiry (month and year) (in clear language not code)
5. Expiration dt.(Month & year)
6. Batch Number
7. Quantity per case (Carton containing ----- secondary packages)
8. Special instructions for storage and handling
9. Name and address of manufacture
10. Any additional cautionary statements.

V. Marking: Each packing shall be marked with nomenclature of the Item and shall be labelled in accordance with the requirement of the Drugs and Cosmetics Act, 1940 or relevant standards as applicable

If your company failed to provide barcode on packaging then additional 5% amount on total billing amount will be deducted from your payment.

CONTRACT FORM

THIS AGREEMENT made theday of....., 2023... Between..... (Name of purchaser) of..... (Country of Purchaser) (Hereinafter "the Purchaser") of the one part and..... (Name of Supplier) of..... (City and Country of Supplier) (Hereinafter called "the Supplier") of the other part:

WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz. (Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those goods and services in the sum of..... (Contract Price in Words and Figures) (Hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall be deemed to form and be read and construed as part of this agreement,

viz.:

- (a) The Price List submitted by the Supplier;
 - (b) The Schedule of Requirements;
 - (c) The Technical Specifications;
 - (d) The General Conditions of Contract;
 - (e) The Special Conditions of Contract; and
 - (f) The Purchaser's Notification of Award.
3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the goods and services and to remedy defects therein in conformity in all respects with the provisions of the Contract.
 4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods and services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

Brief particulars of the goods and services which shall be supplied/provided by the Supplier are as under:

SR. NO.	BRIEF DESCRIPTION OF GOODS & SERVICES	QUANTITY TO BE SUPPLIED	UNIT PRICE	TOTAL PRICE	DELIVERY TERMS

TOTAL VALUE:

DELIVERY SCHEDULE:

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the

Said..... (For the Purchaser)

In the presence of:

Signed, Sealed and Delivered by the

Said..... (For the supplier)

In the presence of:

SECURITY DEPOSIT FORM

To, (Name of Purchaser)

WHEREAS..... (Name of Supplier)

Hereinafter called "the Supplier" has undertaken, in pursuance of Contract No..... dated, 200.... to supply.....(Description of Goods and Services) hereinafter called "the Contract".

AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you with a Bank Guarantee by a recognized bank for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the Supplier a Guarantee:

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of..... (Amount of the Guarantee in Words and Figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limit of (Amount of Guarantee) as aforesaid, without your needing to prove or to show ground or reasons for your demand or the sum specified therein.

This guarantee is valid until theday of.....202.....

Signature and Seal of Guarantors

.....
.....
.....

Date.....202.....

Address.....

.....



Central Drugs Testing Laboratory - Mumbai
 CDSCO, DGHS, Ministry of Health & Family Welfare, Govt. Of India, Zonal FDA Bhawan, Belasis Road,
 GMSD Compound Mumbai Central (India) - 400008
 Fax : 022-23099240 Phone No.022-23002309, 022-23002138
 Email:cdtlmumbai@cdsco.nic.in

FORM 13
 (See rule 46)

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

- Name of Inspector from whom received : Mr. Manoj Nilkant Gambhire ,Drugs Inspector
 West Zone -1 Mumbai CDSCO (West Zone-1) 4th Floor
 Zonal FDA Bhawan, GMSD Compound, Bellasis Road,
 Mumbai Central,Mumbai-400008 (India)
- Serial No. and date of Inspector's memorandum : 3-4/MG/CDTL-Mum/WZ/2024/1958 , 26-SEP-2024
- Number of Sample : LS/WZ/MG/2024/37
- Date of receipt : 26-SEP-2024
- Names of drugs purporting to be contained in the sample :Iron Sucrose Injection USP 100 mg/5ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/MUM/2024-25/0639	MUM/LS/2024-25/1026	23IS10	12/2023	11/2025	SAI Parenterals Limited, D1&D4, Survey No.280, Phase-V, IDA,Jeedimetla, Hyderabad-500055, Telangana, India.

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

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

Date of Testing : From 01-Jan-2025 To 04-Feb-2025

COMPOSITION : Each 5 ml Ampoule Contains: Ferric Hydroxide in Complex with Sucrose
 equivalent to elemental Iron 100 mg
 Water for Injection IP q.s.

Protocol Applied : U.S.P. 43

Sr No.	Test Name	Result	Limits
1	Description	Brown coloured solution in sealed amber glass coloured ampoules in plastic tray supplied in paper carton.	NA
2	Identification	Gives positive test for Iron and Sucrose	NA
3	pH	Does not comply (9.84)	10.5 to 11.1
4	Alkalinity	Does not comply (0.357 ml)	0.5 to 0.8 ml
5	Specific Gravity	Complies (1.1508 gm/ml)	1.135 to 1.165 gm/ml



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 : Mr. Manoj Nilkant Gambhire ,Drugs Inspector
West Zone -1 Mumbai CDSCO (West Zone:-1) 4th Floor
Zonal FDA Bhawan, GMSD Compound, Bellasis Road,
Mumbai Central,Mumbai-400008 (India)
2. Serial No. and date of Inspector's memorandum : 3-4/MG/CDTL-Mum/WZ/2024/1958 , 26-SEP-2024
3. Number of Sample : LS/WZ/MG/2024/37
4. Date of receipt : 26-SEP-2024
5. Names of drugs purporting to be contained in the sample : Iron Sucrose Injection USP 100 mg/5ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/MUM/2024- 25/0639	MUM/LS/2024- 25/1026	23IS10	12/2023	11/2025	SAI Parenterals Limited, D1&D4, Survey No.280, Phase-V, IDA,Jeelimetla, Hyderabad-500055, Telangana, India.

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] 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 01-Jan-2025 To 04-Feb-2025

COMPOSITION : Each 5 ml Ampoule Contains: Ferric Hydroxide in Complex with Sucrose
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3	pH	Does not comply (9.84)	10.5 to 11.1
4	Alkalinity	Does not comply (0.357 ml)	0.5 to 0.8 ml
5	Specific Gravity	Complies (1.1508 gm/ml)	1.135 to 1.165 gm/ml

6	Particulate Matter in Injections	Does not comply	NA
7	Bacterial endotoxins test	Complies	NA
8	Sterility	Complies	NA
9	Container Content	Complies	NA

Assay

Sr.No	Ingredient Name	Found	Limits	Procedure / Method
1	Sucrose	285.84 mg/ml	260 mg/ ml to 340 mg/ ml	U.S.P. 43

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample received does not conform to U.S.P. 43 with respect to the test for "pH", "Alkalinity" and "Particulate Matter in Injections".

Note:- i) As per sample label the Batch No. of the sample is "23IS10" where as in the Form- 18 it is stated as "23/S10".
ii) Other test could not be done due to technical reason.

डॉ. एम. व्ही. कुमार / DR. M/V. KUMAR
वरिष्ठ वैज्ञानिक सहायक एवं सरकारी विश्लेषक
SENIOR SCIENTIFIC ASSISTANT & GOVT ANALYST
केंद्रीय औषधि परीक्षण प्रयोगशाला
CENTRAL DRUGS TESTING LABORATORY
मुंबई / MUMBAI

Date: 11-FEB-2025

GOVERNMENT ANALYST

----- END OF REPORT -----