

Circular No: **MSD/Q/P/2025/19**

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
✓-04-2025

To :

DDG/NHSL - Colombo
DDG/NH - Kandy
All Provincial Directors of Health Services,
All Regional Directors of Health Services,
All Directors of Teaching Hospitals,
All Directors of Specialized Campaigns,
Director, N.I.H.S Kalutara,
All MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry

REPORT ON FAILING SAMPLE – Iron Sucrose solution for Injection/Infusion 100mg/5mL Ampoule

MSD ORDER LIST No: 2023/SPC/E/C/P/00167

PA No: LP/DHS/EP/AR/3803/2023

1. Re-above, details of the letter NMRA/PA3/QF07/2025 dated 24.03.2025 received from CEO/NMRA are given below for your information please.

1.1) Name of the product/ Item : **Iron Sucrose solution for Injection/Infusion 100mg/5mL Ampoule**
Iron Sucrose Injection USP 20g/mL

SR : **00400401**

1.2) Manufacturer : Mercury Laboratories Ltd, Unit No.1,2/13-14, Gorwa Industrial Estate, Gorwa, Vadodara-390016, Gujarat, India

1.3) Batch No. : **23362201**

1.4) Date of Manufacture : **01.07.2023**

1.5) Date of Expiry : **30.06.2025**

1.6) NMQAL LR No : **40166, 40163**

1.7) Failure : **Failure to comply with USP specifications with respect to PH test**

1.8) Recommendation of NMRA : With reference to the decision of the Safety and Risk Evaluation Subcommittee dated 21.03.2025 based on the NMQAL reports 40166, 40163

2. CEO-NMRA Instruction : **To withhold the above batch from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withhold the above batch (as detailed 1.1-1.5 above) from use immediately.**

3.2) To inform details of all batches available of this product to D/NMQAL, 120 Norris Canal Road, Colombo 10, to enable them to select samples for further testing and provide sample on request to NMQAL.

4. Please note: It would be your responsibility,

4.1) To follow the instructions given by Secretary of Health, under the circular No: 01/2021 dated 08.12.2021.

5.2) Please Note: It is the responsibility of all RDHS to ensure that the copies of this circular is circulated among all the heads of the institutions under your preview.


Dr. Dedunu Dias.
Director (Acting),
Medical Supplies Division,

Dr. DEDUNU DIAS
Director - (Acting)
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw.
Colombo 10.

Cc:

1. Auditor General - f.i.	2. DGHS-f.i.	3. Chairman/SPC - f.i. & n.a.
4. DDG(M/S) - f.i.	5. CEO/ NMRA - f.i.	6. Secretary/MEC - f.i.
7. D/NMQAL – f.i.	9. D/(Stock Verific.)/MOH - f.i.	10. DD/MSD - f.i. & n.a.
8. Chief Internal Auditor/ MOH-f.i.	13. AD/ICT Unit - to publish in MSD web site	
11. Chief Accountant/MSD-f.i & n.a.	16. AD(Dispatch)/MSD – f.i.	
12. Acct(S)MSD - f.i. & n.a.	18. SP / MSD - f.i.	19. HSCO (P2) - f.i. & n.a.
14. AD(P)/MSD - f.i. & n.a.	22. MSA-WH (06)/MSD - f.i. & n.a.	
15. AD (Stores)/MSD - f.i.	24. H/Destruction Unit (MSD) - f.i & n.a.	
17. All DP/DPDHS - f.i. & n.a.		
20. SCO (S/WH 06)-f.i. & n.a.		
21. SCO (D/WH 06)-f.i & n.a.		
23. MO (Technical unit)/MOH-f.i & n.a.		