

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
03 -09-2024

Circular No: **MSD/Q/P/2024/35**

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 – Lactulose Syr 3g-3.7g/5ml

1. Re-above, details of the Letter No: NMRA/PA3/QF17/2024 dated 29.08.2024 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item : **Lactulose Syr 3g-3.7g/5ml**
Lactulose Solution USP 3.4g/5ml (Laxogen Oral Solution)

SR : **00801302 / 00801304**

1.2) Manufacturer : Newgen Lanka Healthcare Pvt Ltd, Plant A, Andiyagala, Waththala, Othara Road, Elibichchiya, Kurunegala, Sri Lanka.

1.3) Analytical Report : **Sample dose not conform USP specification for the microbial enumeration test and test for specified microorganisms.**

1.4) Recommendation of SAFRESC: **To WITHHOLD THE PRODUCT and withdraw the below mentioned batches from use immediately.**

Batches to be Withdrawn:

Batch Numbers	Manuf. Date	Exp Date	LR Number	Order no	PA Order No
L1524007	APR/2024	MAR/2026	39887/ 39848	2024/MSD/N/R/P/0008	MSD/SB08/LM/107/2024
L1524010			39847/ 39821		
L1524011			39865		
L0424009	MAY/2024	APR/2026	39866	2024/MSD/N/R/P/00019	MSD/SB08/LM/56/2024-C

2. CEO-NMRA Instruction : **To WITHHOLD THE PRODUCT and withdraw the above mentioned batches from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To WITHHOLD THE PRODUCT and withdraw the above mentioned batches 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. 5.1) Please bring the contents of the circular to all concerned in your Province/ Region/ Institution.

- 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. & n.a.
6. Secretary/MEC - f.i
7. **D/NMQAL** - In the event that obtaining samples from 05 different batches is not possible, to inform D/MSD to send samples from available batches.
8. Chief Internal Auditor/ MOH-f.i
9. D/(Stock Verific.)/MOH - f.i.
10. DD/MSD - f.i. & n.a.
11. Chief Accountant/MSD-f.i & n.a
12. AD (Stores)/MSD - f.i.
13. **Acct(S)MSD** - To make arrangement to recover the value of relevant quantity for the supplier from relevant batches.
14. AD (Dispatch)/MSD - f.i.
15. AD/ICT Unit - to publish in MSD web site
16. **AD (P)/MSD** - To ensure that SCO concerned provide the required information to NMQAL
17. All DP/DPDHS - f.i. & n.a
18. SP / MSD - f.i & n.a
19. HSCO (P) - f.i. & n.a.
20. **SCO (S/WH 08)**- To send consignment details, storage condition and other relevant details of above product as per No:08 of NDL Form No:02
21. SCO (D/WH 08)-f.i & n.a
22. MSA-WH (08)/MSD - f.i. & n.a.
23. MO (Technical unit)/MOH-f.i & n.a
22. H/Destruction Unit (MSD) - f.i & n.a