

My No: MSD/SCU(S)/Cir/2024
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
19 -12-2024

Circular No: **MSD/Q/P/2024/47**

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 – Calcium Gluconate Injection 10% in 10mL Ampoule.

1. Re-above, details of the Letter No: NMRA/PA3/QF02/2024 dated 12.12.2024 received from CEO/ NMRA, are given below for your information please.

- 1.1) Name of the product/ Item : **Calcium Gluconate injection 10% in 10mL Ampoule.
Calcium Gluconate Injection I.P. 10mL.**
- SR : **00401701**
- 1.2) Batch No : **Product**
- 1.3) Manufacturer : **Coax bioremedies Pvt Ltd, Plot No 83, Sector 27-28,
Industrial area, Hisar, Haryana, India.**
- 1.4) NMQUAL LR No : **39739, 39735, 39670**
- 1.5) Failure/Defect : **Samples are unsatisfactory due to presence of white
particles in the solutions in almost all ampoules.**
- 1.6) SAFRESC Recommendation : **To withdraw the above mentioned product.**
held on 10.12.2024

2. CEO-NMRA Instruction : **To withdraw the above product from use immediately.**

3. Considering above facts, you are requested the following

3.1) **To withdraw the above product (as detailed in 1.1-1.3 above) from use immediately.**

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

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.

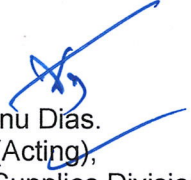
5.2) Please Note: It is the responsibility of all RDHS to ensure that the copies of this circular is circulated among all the heads of the institutions under your preview.

6. Previous Circulars

Circular No
MSD/Q/P/2024/05

Batch
BN423

Decision
Batch Withdraw


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

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

Cc:

1. Auditor General - f.i
2. DGHS-f.i
3. **Chairman/SPC** – Furnish explanation of the manufacturer within 28 days of receiving this letter to CEO/NMRA.
4. DDG(M/S) - f.i.
5. CEO/ NMRA - f.i. & n.a.
6. Secretary/MEC - f.i
7. **D/NMQAL** – f.i.
8. Chief Internal Auditor/ MOH-f.i
9. D/(Stock Verification)/MOH - f.i.
10. DD/MSD - f.i. & n.a.
11. AD (Stores)/MSD - f.i.
12. **Chief Accountant/MSD**- To make arrangements to recover the relevant charges.
13. **Acct(S)MSD** – To make arrangements to recover the relevant charges.
14. AD (Dispatch)/MSD - f.i.
15. AD/ICT Unit - to publish in MSD web site
16. **AD (P)/MSD** – f.i. & n.a.
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 03)**- f.i & n.a.
21. SCO (D/WH 06)-f.i & n.a
22. MSA-WH (06)/MSD - f.i. & n.a.
23. MO (Technical unit)/MOH-f.i & n.a
24. H/Destruction Unit (MSD) - f.i & n.a.