

Circular No: **MSD/Q/P/2025/4**

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10
Tel: (011)2694114/13
N -01-2025

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 – Cyclophosphamide for Injection 200mg Vial
MSD ORDER LIST No: 2022/SPC/X/R/P/00586 PA No: DHS/ICL/PS/383/2022

1. Re-above, details of the Letter No: NMRA/PA3/QF02/2025 dated 06.01.2025 received from CEO/ NMRA, are given below for your information please.

1.1) Name of the product/ Item : **Cyclophosphamide for Injection 200mg Vial**
Cyclophosphamide for Injection USP 200mg

SR : **01200303**

1.2) Manufacturer : GLS Pharma Limited, Plot No:10, Phase I, IDA, Jeedimetla Hyderabad-500055, Telangana State, India

1.3) Batch No. : **CYPA2306G**

1.4) Date of Manufacture : **01.03.2023**

1.5) Date of Expiry : **28.02.2025**

1.6) NMQAL LR No : **39507**

1.7) Failure : **Samples are unsatisfactory due to presence of dark orange colour melted stains at the bottom of vial**

1.8) Recommendation of NMRA : With reference to the decision of the Safety and Risk Evaluation Subcommittee dated 02.01.2025 based on the NMQAL report LR 39507

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

3. Considering above facts, you are requested the following

3.1) **To withdraw the above batches (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. 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: