

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

Circular No: **MSD/Q/P/2025/20**

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 – Gliclazide Tablet 40mg

MSD ORDER LIST No: 2023/SPM/N/R/P/00012

PA No: 2023/SPM/N/R/P/00012

1. Re-above, details of the letter NMRA/CP/P32/QF30/2021 dated 24.03.2025 received from CEO/NMRA are given below for your information please.

1.1) Name of the product/ Item : **Gliclazide Tablet 40mg**
Gliclazide Tablets BP 40mg

SR : **00700301**

1.2) Manufacturer : State Pharmaceuticals Manufacturing Corporation, No.11, Sri John Kothalawala Mw, Kandawala state, Rathmalana, Sri Lanka

1.3) Batch No. : **HAF03**

1.4) Date of Manufacture : **01.06.2023**

1.5) Dare of Expiry : **31.05.2025**

1.6) NMQUAL LR No : **39843**

1.7) Failure : **Failure to comply with BP specifications with microbial Enumeration test and appearance**

1.8) Recommendation of NMRA : With reference to the decision of the Safety and Risk Evaluation Subcommittee dated 21.03.2025 based on the NMQUAL report 39843

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 NMQUAL.

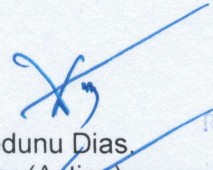
4. Please note: It would be your responsibility,

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

5.2) 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 Number	Batch	Decision
MSD/Q/P/2022/1	HLD04	Withdraw
MSD/Q/P/2022/14	HLE03	Withdraw
MSD/Q/P/2022/20	HLH07	Withdraw
MSD/Q/P/2023/47	Product	Withdraw
MSD/Q/P/2024/2	Product	Revoke the product withdrawal decision and withdraw all batches manufactured on or before 31.05.2023


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 - 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. | | |
| 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. | 13. AD/ICT Unit - to publish in MSD web site | |
| 12. Acct(S)MSD - f.i. & n.a. | 16. AD(Dispatch)/MSD - f.i. | |
| 14. AD(P)/MSD - f.i. & n.a. | 18. SP / MSD - f.i. | 19. HSCO (P1) - f.i. & n.a. |
| 15. AD (Stores)/MSD - f.i. | | |
| 17. All DP/DPDHS - f.i. & n.a. | 22.MSA-WH (07)/MSD - f.i. & n.a. | |
| 20. SCO (S/WH 07) - f.i. & n.a. | 24. H/Destruction Unit (MSD) - f.i & n.a. | |
| 21. SCO (D/WH 07)-f.i & n.a. | | |
| 23. MO (Technical unit)/MOH-f.i & n.a. | | |