

Drug Product Recall Information - 2024

| S.No. | Product Name, Batch No. Mfg, expiry date and manufacturer details. | Reason for recall | Remark |
|-------|---|---|--|
| 01 | Ringer lactate USP IV bags of 1000ml (B.No. 2604303), Mfg. date: 04/2023, Expiry date :10/2025 manufactured by Pharmacure plc located in Summit Area, Bole Sub City, Wereda 10, Kebele 16, Addis Ababa | Unknown suspending matter in the IV solution bag with no evidence of leakage during visual inspection of the IV bag. | This recall was voluntarily extended by the manufacturer to include other batches of Ringer Lactate packaged in PVC bags, produced by SA-MED PLC, located in Dukem Town, Oromia Region |
| 02 | Ringer lactate USP IV bags of 1000ml (B.No. 2204302), Mfg. date:04/2023, Expiry date : 10/2025 manufactured by Pharmacure plc located in Summit Area, Bole Sub City, Wereda 10, Kebele 16, Addis Ababa. | Unknown suspending matter in the IV solution bag with no evidence of leakage during visual inspection of the IV bag. | |
| 03 | Carvediol -25mg Batch.No. 27374, Mfg. date: May 2022, Expiry date : May 2025 manufactured by: Denk pharm GmbH& co,kc ,Germany | Based on WHO alert (The dissolution results did not meet the specification limit). | Recall done |
| 04 | Calcium Gluconate injection USP10%w/v Batch.No. XA3KO19, 93H019, 007506, XA3K018, Mfg. date: 05/ 2022, Expiry date: 10/ 2026 manufactured by: Scott Edil Pharmaceuticals, India. | Based on post market surveillance result and Pharmacovigilance report | recall done |
| 05 | Artemether 20 mg & lumefantrine 120 mg (B.No. AR23102),Mfg. Date, Manufactured by Skant Healthcare Ltd,India | Based on PMS result, the product did not comply with dissolution parameter <ul style="list-style-type: none"> i. Artemether (by HPLC) ii. Lumefantrine (by UV) dissolution. | Statutory recall is initiated |
| 06 | Artemether 20 mg & lumefantrine 120 mg,(B.No. 24EY) Manufactured by KPC Pharmaceutical Inc, China | Based on PMS result, the product did not comply with the parameter Assay by HPLC | Statutory recall is initiated |
| 07 | Artemether 20 mg & lumefantrine 120 mg(B.No. PA04254) Manufactured by Ajanta pharma limited,India | Based on PMS result, Lumefantrine does not comply with UV dissolution. | Statutory recall is initiated |
| 08 | Artemether 20 mg & lumefantrine 120 | Based on PMS result, | Statutory recall is |

| | | | |
|--|--|--|-----------|
| | mg(B.No. CHRT24005E) Cachet Manufactured by pharmaceutical PVT. Ltd, India | The product did not comply with the parameter uniformity of dosage unit (Waight variation) Assay by HPLC, and dissolution by UV and HPLC | initiated |
|--|--|--|-----------|