|  |
| --- |
| **Recall Statement** |

**Quality Defect Class:** [ ]  **Class I** [ ]  **Class II** [ ]  **Class III**

**Level of Recall:** [ ]  **Wholesale** [ ]  **Retail**[ ]  **Consumer** [ ]  **Mock Recall Trial**

|  |
| --- |
| **Product Information:** |
| Product name & strength |  |
| Ministry of Health registration number |  |
| Affected batch number (s) |  |
| Manufacturer |  |
| Manufacturing date |  |
| Expiry date |  |
| Packaging details, Stock Keeping Unit (SKU) |  |

**Details of Defect / Reason for Recall:**

Details about the nature of the issue leading to the recall.

Deviation, Nonconformance, and Complaint investigation outputs

**Actions to be taken:**

Instruction to immediately stop prescribing/ dispensing/ distributing or using and quarantine affected stock.

Instruction regarding the return of the affected stock.

Instruction for the local agent to complete the Progress and Final Recall report.

Recall timelines details.

**Document approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Reviewed and approved by:**All Members shall review and approve this document |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |