POLICY ON RECALL

INTRODUCTION:

…..…… seeks to maintain its reputation as a firm delivering high quality medicines.

The policy is designed to provide guidance on the manner in which …… shall conduct recall of a batch / product which is non-compliant / or having a potential health hazard to consumers.

SCOPE:

This policy is applicable to drug substances, drug products and medical devices manufactured and distributed by ……...

POLICY DETAILS:

- A rapid, effective and systematic procedure to organise a recall activity shall be established. Recall operation shall be capable of being initiated promptly and at any time.

- The MA holder for the product shall be responsible for carrying out the recall effectively throughout the distribution chain to the appropriate level.

- Where …… is not the MA holder, all relevant information about a non-compliant product shall be communicated to the respective MA holder in a timely manner as per the technical agreement.

- There shall be a recall coordinator for coordinating all activities related to the recall.

- The recall coordinator shall be responsible to receive and further disseminate information in the organization.

- Non compliances in products which have a potential for voluntary recall shall be communicated to the recall coordinator as per defined timelines.

- Incidences for voluntary recall could arise from

  - Non-compliance with regulatory specifications during post market stability studies
  - Investigation of market complaint
  - Any failures that could have impact on already released batch (e.g. contamination, mix-up, degradation etc.)
  - Unusual observation on the retain samples
  - Post market surveillance / pharmacovigilance reports indicates that there is a safety risk associated with the product.

- A thorough investigation including sample evaluation, risk assessment and impact assessment shall be conducted and documented.

- Root cause identification shall be conducted and necessary CAPA shall be implemented.

- Decision for recall shall be taken by the recall committee, comprising of Head Operations Quality, Head Global Quality Compliance and systems, Head Site QA, Cluster Head Unit QA/QC, Product Geographical Quality Head (Responsible Pharmacist for South Africa, North America Quality Head, QP for EU products as applicable), Recall Coordinator and others members of QA/ QC/ CQA/ RA as applicable.

- The distribution records shall be readily available.

- The class and level of recall shall be decided as per defined regulations and procedures. The stocks shall be blocked as per timelines defined in class of recall.

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- ✧ Recalled products shall be identified and stored separately in a secure area while awaiting a decision on their disposal.
- ✧ The progress of recall process shall be recorded and final report issued, including a reconciliation between the delivered and recovered quantity of the product.
- ✧ Communications of recall including information to local authorities and press release shall be made by authorised personnel only, within the time frame defined by regulators
- ✧ If an actual product recall has not been conducted for a period of 1 year for each site, then mock recall shall be conducted by CQA for the respective site. However if all the sites are having actual recall conducted then mock recall shall be conducted for one representative site challenging the full supply chain.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable

ABBREVIATIONS:

CAPA	:	Corrective Action and Preventive Action
IPD	:	Integrated Product Development
MA	:	Marketing Authorization

REFERENCES: Not Applicable