PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Product Recall	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Product Recall.

2.0 SCOPE:

This SOP is applicable to Product Recall of ……..

3.0 RESPONSIBILITY:

3.1 QA (Officer/Executive)

3.1.1 Preparation, Distribution, Revision, Retrieval and Destruction of this SOP.

3.1.2 Issuance of numbering system for product recall and to maintain the Log of Product Recall.

3.2 QA (Manager)

3.2.1 Review, Training and effective implementation of this SOP to all concerned Departments.

3.3 DRA

3.3.1 To share information of Product Recall to Regulatory Agency.

3.4 Warehouse (Manager)

3.4.1 To store the product in segregated area in warehouse.

3.5 PPIC Department

3.5.1 To communicate timely with customer and Site Head QA.

4.0 ACCOUNTABILITY:

4.1 Head QA

4.1.1 Approval, Authorization, ensure Training and Implementation of this SOP

4.1.2 Ensure timely Product Recall initiation.

4.2 Head Operation

4.2.1 To Review and comments for Product Recall Notification.

5.0 DEFINITION:

5.1 Recall: Recall is a firm's removal or correction of marketed products that FDA considers to be violation of the laws it administrates, and against which the agency would initiate legal action.

5.2 Batch Recall: The action of withdrawing a batch from the distribution chain and users. A batch recall may be partial, in that the batch is only withdrawn from selected distributors or users.

5.3 Batch (Lot): A specific quantity of material produced in a process or series of processes so that it

is expected to be homogeneous within specified limits.

5.4 Rapid Alert: An urgent notification from one supervisory authority to other authorities that a Batch recall has been instituted in the country originating the rapid alert. The Procedure for issuing rapid alerts is defined in the Compilation of Community Procedures.

5.5 Voluntary Recall: A recall initiated by the licensee (in case of loan licensee jointly the contract giver and contract acceptor) as a result of abnormal observation in any product quality during periodic review (Internal/External) or investigation of a market complaint or any other failures.

5.6 Statutory Recall: A recall directed by Drug Control Authorities after notifying that product is considered to be in violation of the laws. e.g., declared as Not of Standard Quality by Government Analyst.

6.0 PROCEDURE:

6.1 RECALL CLASSIFICATION:

6.2.1 Recall Classification as per USFDA:

Recall classification is a numerical designation, I, II, or III that is assigned to a particular Product Recall that indicates the relative degree of health hazard.

6.2.1.1 Class I: Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

6.2.1.2 Class II: Class II is situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

6.2.1.3 Class III: Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause any adverse health consequences.

6.2.2 Recall Classification as per "European Medicines Agency (EMA)" :

Recalls are classified with regard to the relative health hazard associated with the use of or exposure to the recalled product. There are three possible classifications:

6.2.2.1 Class I: Defects which are potentially life threatening.

6.2.2.2 Class II: Defects could cause illnesses or mistreatment, but are not class I.

6.2.2.3 Class III: Defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

6.2.3 Recall Classification As Per Drug and Cosmetic Act 1940 and Rules 1945:

6.2.3.1 Recall classification is a numerical designation, I, II, or III that is assigned to a particular Product Recall that indicates the relative degree of health hazard.

6.2.3.2 **Class I:** Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death and as well as banned under 26A of Drugs and Cosmetics Act 1940.

6.2.3.3 **Class II:** Class II is situation in which the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

6.2.3.4 **Class III:** Class III is a situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences.

6.2 TYPES OF RECALL: Voluntary Recall and Statutory Recall.

6.3.1 Voluntary Recall:

6.3.1.1 Voluntary Recall can be triggered by any incident that affects the quality, safety and efficacy of the Batch / Product in question such as, For example:

- If the batch or batches are found to be not complying with the regulatory specifications during the post marketing stability study.
- If the batch is found to be defective during investigation of market complaint.
- During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, mix-up, degradation etc).
- If any unusual observation is noted during visual inspection of retention samples which indicate an impact on quality of the product after investigation.

- If the post marketing surveillance reports /Pharmacovigilance reports indicates that there is serious safety risk associated with the product.

6.3.2 Statutory Recall:

6.3.2.1 Statutory recall can be triggered in response to the direction or mandate by the Drug Regulatory Authorities in one or more of the situations as follows. For example:

- To recall the drug product/batch, considered to be in violation of the laws, it administers such as not of standard quality etc.
- To recall the banned drugs.
- Labeling and/or Promotional materials that are considered to be in violation of law.

6.3 The levels of Recall of a Product/Batch shall be determined based on the recall classification and level to which distribution has taken place. There are three levels of recall such as Consumer/User, Retail and Wholesale.

6.4.1 **Consumer or User Level:** Consumer or User Level which may vary with product, including any intermediate- wholesale or retail level. Consumer or user may include consumers, patients, physicians and hospitals.

6.4.2 **Retailer Level:** Retail Level-Recall to the level immediately preceding consumer or user level. It includes retail groceries, pharmacies, hospital pharmacies, dispensing physicians, institutions such as clinics and nursing homes, etc.

6.4.3 **Wholesaler Level:** Wholesale Level: all distribution levels between the manufacturer and retailer.

6.4.4 All Class I recalls shall be executed to the levels of Wholesaler/Distributors, retail, and consumer. In such cases, public announcements shall be made using print/electronic media aids viz. Newspapers, Television, Radio etc.

6.4.5 All Class II recalls shall be executed up to the level of wholesale and retail.

6.4.6 All Class III recalls shall be executed up to the levels of wholesale.

6.4 TIME LINES FOR EFFECTIVE RECALL SYSTEM AND RAPID ALERT:

6.5.1 The procedure of product recall shall be completed based on the category of risks involved, a within time line of 24 hours up to a maximum of 72 hours for **Class I** Recall,

for **Class II** Recall up to a maximum of 10 days and for **Class III** recall up to a maximum of 30 days respectively from the date of complaint received in case of the product sale in India only.

6.5 PRODUCT RECALL PROCEDURE:

6.6.1 When any critical complaints or critical defects observed during investigation in the major complaints may be classified as per described in Point Number **6.2** of marketed batches of Products, Physician Samples shall be considered for product recall.

6.6.2 QA shall enter the details in the Log as shown in **Annexure-I**, Titled **"Product Recall Log"** and assign a unique recall reference number representing the serial number for a particular year in which the recall has been initiated.

6.6.3 Product Recall shall be numbered as **"PR/YY/NNN"**.

Where,

PR	**:**	Denotes for Product Recall.
/	**:**	Denotes separator
YY	**:**	Denotes for last two Digits of current calendar year
/	**:**	Denotes separator
NNN	**:**	Denotes for serial number, starting from **001**.

Example: PR/21/001; Denotes first Product Recall of .....

6.6.4 Product Recall information shall be given to State Licensing Authority where the Product/Batch is marketed.

6.6.5 If the product is exported, the procedure of product recall shall be initiated by authorized agent of the company or by responsible person established for the respective countries.

6.6.6 Incase the product is exported to European countries; Recall shall also be communicated.

6.6.7 Site Head QA shall inform within 24 hours to Marketing Head/Distribution Head/ Planning Head/Customer/Party by using the fastest mode of communication (Phone, Fax, Email etc.) for stoppage/hold of further sales and distribution of batch(es) of the product based on investigation.

6.6.8 If the defect is Class-I or Class-II Type, as described in Point No. 6.2, Site Head QA shall inform immediately to the General public for alertness, not to consume the

batch(es) of product and return it back to the retailers through media's like newspapers, television and radio. Press statement shall be prepared as per format shown in **Annexure-II**, Titled "**Product Recall–Press Statement".**

6.6.9 Marketing Head / Distribution Head / Planning Head shall immediately inform by fastest mode of communication to C&F agents, Stockist, Distributors, Wholesalers, Customer/party and retailers for stoppage of distribution and sale of the batch(es) of product as per format shown in **Annexure–III**, Titled **"Product Recall Notice to Distributor/Customer/Marketing Company/Stockist/Retailers"**.

6.6.10 Distribution Head shall have all the details (Contact Names/Contact Telephone Numbers in Working Hours/Out of Working Hours) of all key personnel's mentioned as per format shown in **Annexure-IV**, Titled **"Contact Numbers of Key Personnel"** for Immediate Contact.

6.6.11 Distribution Head shall send a report to Head QA regarding the details of distribution for batch (es) of product.

6.6.12 The batch (es) of product shall be kept under hold until the complete investigation.

6.6.13 A detail investigation regarding correctness of reported / identified defects shall be carried out by QA, and Production, supported by Marketing and Distribution team. Opinion of Medical Advisor shall be taken to understand the health hazards.

6.6.14 Head QA /designee shall investigate the distribution of the defective batch (es) of the product and perform the physical inspection of defective batch (es) of the product.

6.6.15 Head QA /designee shall collect the sample from defective batch (es) of the product for investigation and shall also review all the batches that have potential risk of health hazard because of defect.

6.6.16 The decision to recall, if necessary, any of the impacted batches shall be made after product quality assessment.

6.6.17 The investigation of the recalled batch/es shall be conducted to identify the root cause of the failure and Impact assessment shall be conducted on other batches of the concerned product and further extended to batch/es of other product/s, wherever applicable and initiate Corrective Action and Preventive Actions.

6.6.18 If the cause of recall is established to be quality issue associated with any of the raw material used, then the traceability of that material shall be established in all the product/s batches where it has been used.

6.6.19 Alternatively execute the transaction through records to identify the batches / products in which the identified material has been used.

6.6.20 Identify the raw materials traceability in different formulations and its distribution.

6.6.21 List all the raw materials along with batch numbers and the respective quantities used in those batches.

6.6.22 Calculate the total quantity by adding individual quantities used in various products/batches.

6.6.23 Monitoring of the material movement to get the complete overview of stock for that particular material in the plant and extract the information about total quantity received and the balance quantity.

6.6.24 The balance stock, if any in the record shall be verified against the actual physical stock available. QA shall block the remaining available stock.

6.6.25 All the material shall be accounted for after the reconciliation.

6.6.26 The detail investigation shall be completed within 7 working days.

6.6.27 Head QA or his/her authorized nominee shall act as Recall coordinator to initiate the Product Recall Procedure.

6.6.28 Recall coordinator shall conduct the meeting with the concerned people and take approval for recall from Head Operations as per format shown in Annexure-V, Titled “Product Recall Notification”.

6.6.29 Head QA shall send the notification to Marketing Head / Distribution Head / Planning Head as per Annexure-V and copy of the same shall be sent to the Regulatory Authorities including QP/MAH etc. via Drug Regulatory Affairs and Customer/Party for information, Review and approval.

6.6.30 Marketing Head/Distribution Head/Planning Head/Customer/Party shall immediately inform to all C&F agents, Stockist, Distributors, Wholesalers and Retailers to retrieve the batch (es) of product.

6.6.31 All unsold and undistributed stocks including physicians samples of the batch(es), which is not yet dispatched from the warehouse and depot, same shall be retrieved and Quarantine with mark as "RETURNED PRODUCTS" by the concerned In-charge.

6.6.32 The distribution head shall reconcile the total batch quantity received vice-versa dispatches made to various locations and send report to the Head QA.

6.6.33 The recalled batch(es) of product shall be identified and stored separately in secured and segregated area with lock and key in warehouse till final decision on its fate.

6.6.34 A Copy of all Public Alerts on Newspaper and Video Film of Television shall be sent to the Head QA for record.

6.6.35 After batch(es) recall of the product, Head QA shall decide about the fate of recalled batch(es) of the product. If the recalled batch(es) of the product is to be destroyed, destruction shall be carried out.

6.6.36 Head QA shall inform to Customer/Party to take the decision for destruction of the recalled product.

6.6.37 QA Department shall record all retrievals in Retrieval Record as per format shown in Annexure-I.

6.6.38 After completion of all activity for Product Recall, Head QA shall prepare a summary report as per format shown in Annexure-VI, Titled "Product Recall Summary Report" and same shall be circulated to the all concerned Departments.

6.6.39 Product Recall close out information shall be given to State Licensing Authority (FDA) after completion of recall procedure.

6.6.40 Trend analysis of product recall shall be carried out on half yearly basis to study whether the type of recall was voluntary or statutory and will include the review for effectiveness of CAPA to identify gap analysis in existing CAPA to detect inefficiencies in actions taken or need for reinvestigation to find probable or root cause and subsequent CAPA shall be analyzed and recommended (Refer Annexure-VIII for Trend Analysis of Product Recall)

6.6 Head Operations in consultation with Location Head and QA Head shall conduct a **"Mock Recall"** for retrievability of the information and effectiveness of the procedure required for Product Recall.

6.6.1 Mock Recall shall be carried out for at least one batch of any product, dispatched for sale where maximum distributors and longest distribution chain is involved.

6.6.2 **Frequency of Mock Recall** Once in two years, mock recall can be eliminated if actual product recall performed once in two years and records of mock recall shall be maintained by the Location QA Head.

6.6.3 The complete information shall be available within 48 hours. If not, Location QA Head shall make a report for failure in the system and suggest Corrective Action and Preventive Action accordingly.

6.6.4 For **"Process Flow Chart for Product Recall System"** procedure refer annexure as shown in **Annexure–VII**.

7.0 ABBREVIATIONS:

C & F	Clearing and Forwarding Agent
CQA	Corporate Quality Assurance
DRA	Drug Regulatory Affairs
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
Ltd.	Limited
MAH	Market Authorization Holder
No.	Number
PPIC	Production Planning and Inventory Control
PR	Product Recall
Pvt.	Private
QA	Quality Assurance
QP	Qualified Person
WH	Warehouse

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Product Recall Log	
Annexure-II	Product Recall – Press Statement	
Annexure-III	Product Recall Notice to Distributor/Customer /Marketing Company /Stockist/Retailers	
Annexure-IV	Contact Numbers of Key Personnel	
Annexure-V	Product Recall Notification	
Annexure-VI	Product Recall Summary Report	
Annexure-VII	Process Flow Chart for Product Recall System	
Annexure-VIII	Trend Analysis for Product Recall	

9.0 DISTRIBUTION:

- Controlled Copy No. 01 Head Quality Assurance
- Controlled Copy No. 02 Head Warehouse
- Controlled Copy No. 03 Head PPIC
- Master Copy Quality Assurance Department

10.0 REFERENCES:

- Guidelines in recall and rapid alert system for drugs by Central Drugs Standard Control Organization October 2015.
- European Medicines Agency- Recalls
- 21 CFR Part 7 Subpart C – Recalls
- Drug & Cosmetic Act 1940 & Rules 1945.
- WHO Good Manufacturing Practices for Pharmaceutical Products Annex 2.
- Part 210 -- Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General Section 210.3 Definitions.
- Eudralex (EU legislation in the pharmaceutical sector) Volume 4.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I
PRODUCT RECALL LOG

Year:_____

Recall Ref. No.	Time and Date of Recall Initiation	Recall logged by (Sign & Date)	Product Name	Batch/ Lot No.	Mfg Date	Exp Date	Release Date	Qty. Produced	Classification [Class I,II,III]	Reason for Recall	Quantity Recalled	Closure by QA (Sign & Date)	Remarks

Note: Text in Header Row is only for representation and Text direction (Orientation) in Log shall be in horizontal position (Left to Right).

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ANNEXURE-II
PRODUCT RECALL-PRESS STATEMENT

Press Statement:

Issued By:

Date:

Time:

…… a pharmaceutical company wise to advise that the Batch Number (s)_____ of the Product _____has shown _____

_____

_____

_____

_____

Patients in possession of this/ these batch number (es) are kindly requested to restrain from using it.

_____

_____

_____

For M/s.

……

……

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ANNEXURE-III

PRODUCT RECALL NOTICE TO DISTRIBUTOR/CUSTOMER/MARKETING COMPANY/STOCKIST/RETAILERS

To:	**Product Recall Circular No.:** **Date:**

Please stop further distribution/sale of below mentioned product/batches with immediate effect. Kindly recall the stocks of these Batch(es) from the market. All unsold goods in the warehouse and recalled goods to be quarantined till further advice.

Product Details (Name/Strength/Dosage/Pack)	**Batch/ Lot No.**	**Mfg. Date**	**Expiry Date**	**Batch Size**	**Quantity released for Sale**

Type of recall: (Tick as appropriate)	**Statutory/Voluntary**
Recall Classification:	**Class I, Class II, Class III**
Extent of Recall : WH/ Depot /Distributors/Retailers/Authorized Exporter (in case of exports) Hospitals/Healthcare Professionals/Consumers Agents in importing countries	
Reason for Recall:	
Location of Manufacturing Site:	
Manufacturing License No.	
Intimation to Warehouse (If applicable) **Comments:**	**(Sign & Date)**
Intimation to Regulatory Affairs (If applicable) **Comments:**	**(Sign & Date)**
Manager QA **(Sign & Date)**	**Head QA** **(Sign & Date)**

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ANNEXURE-IV
CONTACT NUMBERS OF KEY PERSONNEL

S.No.	Name	Designation	Contact Numbers

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ANNEXURE-V

PRODUCT RECALL NOTIFICATION

Product Recall No.: ……..

Details of Product To be Recalled	
Product Name:	**Generic Name:**
Batch No:	**Pack Size:**
Mfg. Date :	**Exp. Date:**
Dosage Forms:	**Strength:**
Product of (Company Name)	**Market:**
Type of recall: (Tick as appropriate)	**Statutory/Voluntary:**
Recall Classification:	**Class I/Class II/Class III:**
Total No. of Units Originally Released:	**Date on which distribution commenced:**
Total No. of Units Distributed:	**Total No. of Units in Stock:**
Source of Complaint:	
Details of Defect and Reason for Recall:	
Comments By PPIC: **Sign & Date :_____**	
Comments By Head Operations: **Sign & Date :_____**	
Comments By Head QA: **Sign & Date :_____**	

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ANNEXURE-VI
PRODUCT RECALL SUMMARY REPORT

Product Recall No.:

Product Recall Circular No.:	**Date:**
Product Name:	**Generic Name:**
Mfg. Date:	**Exp. Date:**
Batch(es) No.:	**Batch Size:**
Medical Advisor's Opinion:	
Quantity Dispatched from Plant:	
Quantity Recalled from Market:	
Quantity Received at Warehouse:	
Feedback from Depots/Distributors/Wholesalers/Customers etc.:	
Action taken for Recalled Products:	
Total Cost incurred due to Product Recall:	
Corrective and Preventive Action taken to prevent Recurrence:	
Prepared By: **Manager QA** **(Sign and Date)**	
Review Comments By: **Head QA** **(Sign & Date)**	

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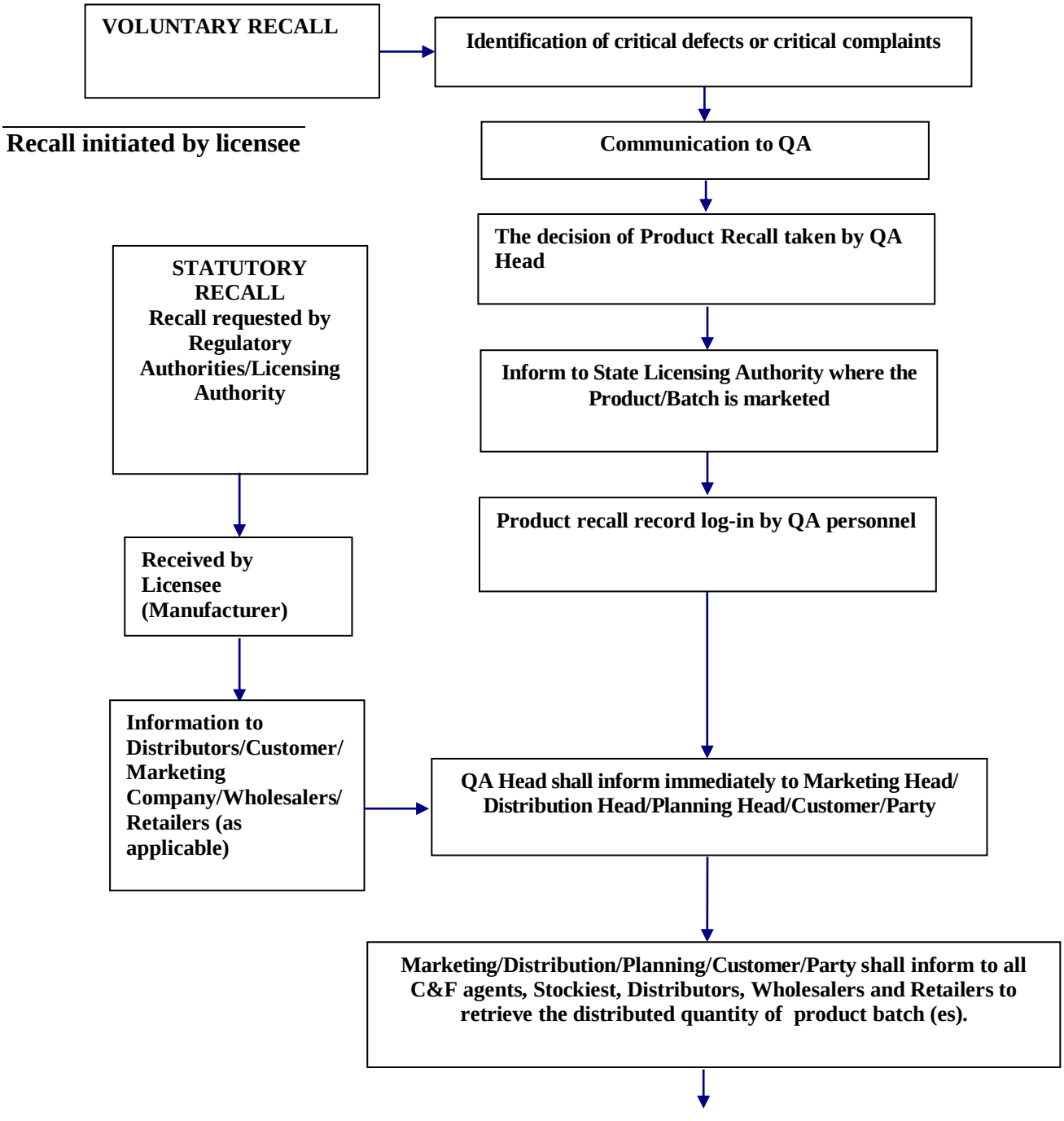
ANNEXURE-VII
PROCESS FLOW CHART FOR PRODUCT RECALL SYSTEM



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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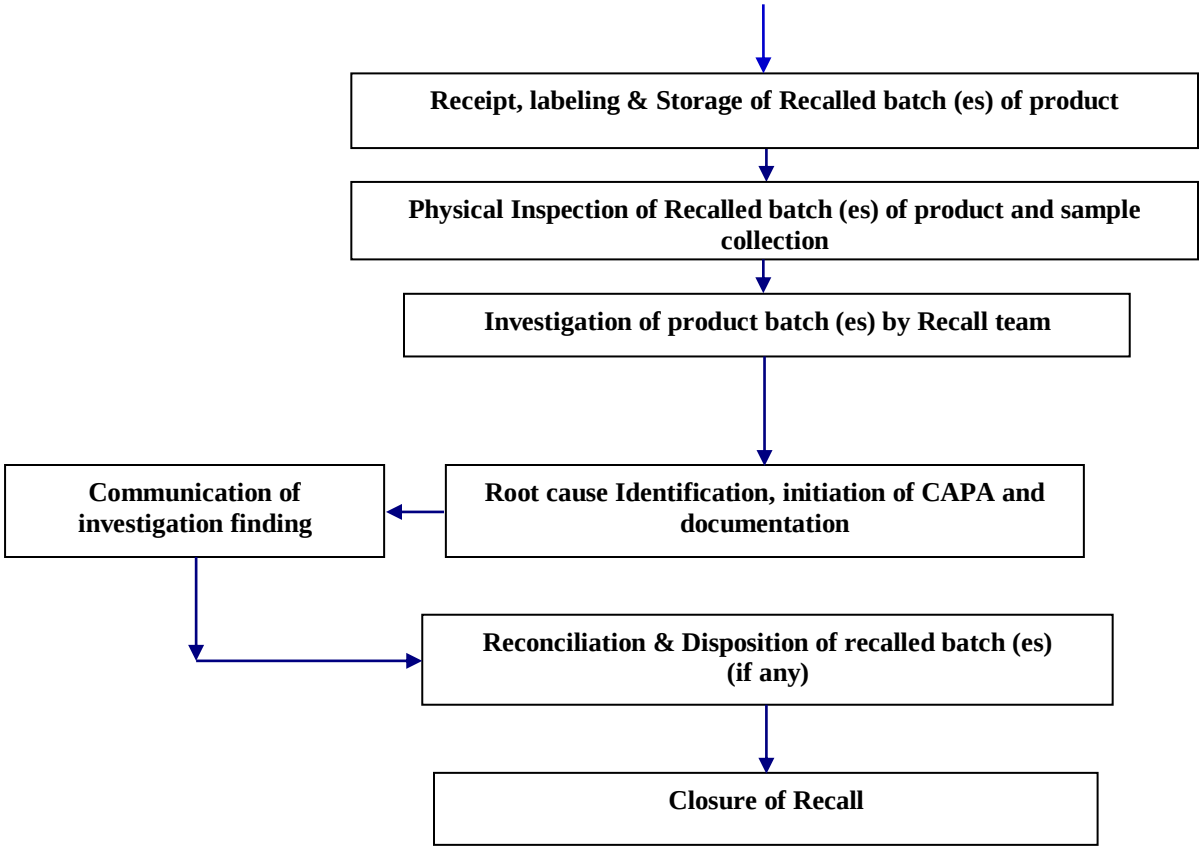

- **Note:** Recall shall be initiated and completed as per timelines of recall classification.

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ANNEXURE-VIII
TREND ANALYSIS OF PRODUCT RECALL

YEAR: **Frequency:** Half Yearly

S.No.	Product Recall No.	Product Name (Mfg. Date/Exp./Date)	Market	Type of Recall	Class of Recall	Reason for Recall	Reference CAPA No.

Total number Product Recalled:

Number of Voluntary Recalls:

Number of Statutory Recalls:

Effectiveness of CAPA:

Gap Analysis to be conducted: (Yes/No)

Prepared by QA:
Sign & Date

Checked by Head QA:
Sign & Date