PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

1.0 PURPOSE:

1.1 To lay down the procedure for handling of Product Recall and withdrawal.

2.0 SCOPE:

2.1 This procedure shall be applicable for recall or withdrawal identification, initiation, monitoring and follow up, evaluation of root cause and the corrective action plan, responsibilities of personnel involved in the activity, documentation and communication with the management and the concerned Regulatory Agency, in order to ensure its timely and effective implementation.

3.0 RESPONSIBILITY:

3.1 The concerned …… Affiliate/ Business Partner/Business Development is responsible to inform to the Head –Quality Assurance/designee about any complaint pertaining to the product strength, identity, safety, purity or quality of product which is received from the consumer/Business Partner/Regulatory Agency and also responsible for overall co-ordination of the recall and withdrawal actions.

3.2 Head –Quality Assurance/designee is responsible for the evaluation of data / records in order to decide the need for recall or withdrawal, communication to the concerned personnel and the concerned Regulatory Agency and to ensure supportive documentation of recall is maintained and submission of relevant documents to the concerned Regulatory Agency and also responsible for overall co-ordination of the recall actions, in coordination with the concerned …… Affiliate/ Business Partner/Business Development.

3.3 Head-Quality Assurance/designee is responsible to evaluate the potential impact of such issue on product quality, safety and efficacy and communicate the issue to Regional Quality Head who in turn shall communicate the incidence to Global Quality.

4.0 REFERENCES:

4.1 Handling of Complaints.

4.2 Site Interface with the qualified Person, Business Partners and Agencies.

4.3 Handling of Returned goods.

4.4 Field Alert Report (FAR) for the US Market.

4.5 Corrective /Preventive Actions (CAPAS) with Effectiveness Check.

4.6 Incident Report.

4.7 Investigation Report.

5.0 DEFINITIONS:

5.1 **Recall**: A firm's removal or correction of marketed product that the Regulatory Agency considers to be in violation of administrative laws and against which the concerned Regulatory Agency can

initiate a legal action. A recall is a method for removing or correcting a distributed health product, including its labeling, that violates the Act or the Regulations or that may present a risk to the health of the consumer.

5.2 **Withdrawal:** A firm's removal or correction of distributed product which involves a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

5.3 **Product correction:** Repair, modification, adjustment, relabeling, destruction or inspection (including patient monitoring) of a product without its removal to some other location.

6.0 PROCEDURE:

6.1 **Product Recall:** The recall shall be initiated as per the Regulatory Directives. The recall shall be initiated through following Steps,

6.1.1 Notification/ Initiation of the recall :

6.1.2 The Head-Business Development /designee or Quality Assurance personnel of concerned ..... Affiliate/Business Partner shall communicate any complaint pertaining to the product strength, identity, safety, purity or quality of product, to the Head – Quality Assurance of site.

6.1.3 The Head of Quality Assurance / designee shall also evaluate the non-conformance identified due to but not limited to, stability failure, Out of Specification results, Out of Trend results, product mix-up and non-compliance identified during the regulatory audits or audits conducted by the ..... audit team at the material vendor, which can also potentially lead to recall.

6.1.4 A recall shall be initiated based upon the investigation findings, root cause analysis and impact of deviation on product quality, strength, purity, identity or safety of product, if applicable.

6.1.5 Head-Quality Assurance/designee shall evaluate the potential impact of such issue on product quality, safety and efficacy and shall communicate the issue to Regional Quality Head who in turn shall communicate the incidence to Global Quality.

6.1.6 The Regional Head-Quality Assurance shall communicate the incidence to the concerned Qualified Person/Head-Quality Assurance of Affiliate /Business Partner, as applicable, based upon the distribution of potentially affected batch/batches related to subject incidence to these markets.

6.1.7 The investigation of subject complaint shall be performed as per the procedure for 'Handling of Customer Complaints'.

6.1.8 The representatives of Supply Chain management, regulatory affairs and business development shall be part of investigation team, as applicable.

6.1.9 The recall may be necessitated if there is serious cGMP violation noticed either during the regulatory audit or during the ..... Audit of particular API Manufacturer.

6.1.10 The API/s used in the recall batch/s shall be identified, additionally all relevant batches manufactured with this API/s shall be identified.

6.1.11 The investigation shall be extended for the batches as follows-

6.1.11.1 The investigation shall be extended to pre and post batches of the identified batch/s for the recall.

6.1.11.2 The investigation shall be extended to other product batch/batches which could have similar quality problem. Based on the investigation, the need for recall shall be identified

6.1.12 The investigation process shall also include evaluation of the possible counterfeiting.

6.1.13 The decision of recall shall be taken by Head – Quality Assurance/ designee with consultation and agreement with the concerned Regulatory Agency unless and until in case of potential significant health hazard to patients; the Head – Quality Assurance/designee may within 24 hours disseminate information on the recall and shall fill the 'Product Recall / Withdrawal Notification' as per Attachment 01 to notify the concerned Regulatory Agency.

6.1.14 All Competent Authorities of all countries to which products may have been distributed should be informed promptly if products are intended to be recalled because they are, or are suspected of being defective.

6.1.15 QA shall assign a Recall Number as follows
PR/YY/ZZZ.
Where, PR– Denotes Product Recall
YY – represents last two digits of year
ZZZ – represents serial number of Recall in year
For Example- PR/24/001
First Product Recall initiated in year 2024

6.1.16 Manager – QA/designee shall log the details of the product recall in the 'Product Recall Log' as per Attachment 03.

6.1.17 Recall strategy means a planned specific course of action to be taken in conducting specific recall, which addresses the depth of recall, need for public warning, and extent or effectiveness checks for the recall. The Recall Strategy shall be required to initiate by Head – Quality Assurance/designee in consultation with concerned Regulatory Agency by considering the following factors will be developed by recalling that specific product, but not limited to following points -

6.1.17.1 Results of health hazard evaluation

6.1.17.2 Ease in identifying the product

6.1.17.3 Degree to which the product's deficiency is obvious to the consumer or user.

6.1.17.4 Degree to which the product remains unused in the marketplace.

6.1.17.5 Continued availability of essential products.

6.1.18 A copy of 'Product Recall Notification' shall be sent to the Business Development and Corporate Quality Assurance for Anti Retroviral products which are not distributed through any of the ..... Affiliate.

6.1.19 Business Development Department shall coordinate for execution of recall of Anti Retroviral Products which are not distributed through any of the …… Affiliate. The concerned marketing authorization/ANDA holder shall be responsible to execute the recall as per their respective procedure for the recall activity.

6.1.20 The recall information for the products pertaining to the marketing authorization of products shall be communicated to the Qualified Person or Business Partner, as per the SOP for 'Site Interface with the qualified Person, Business Partners and Agencies.

6.1.21 Quality Assurance shall communicate with the Qualified Person within 24 hours of any incidence such as Out of Specification (OOS) as described in the Standard Operating Procedure on 'Site Interface with the qualified Person, Business Partners and Agencies.

6.1.22 Within three (3) working days of incidence as described in the Standard Operating Procedure on 'Field Alert Report (FAR) for the US market', the (A)NDA Holder Quality Management or designate shall file the Field Alert Report (FAR) with the District Office of the Food and Drug Administration (FDA) responsible for the facility involved.

6.1.23 Head-Quality Assurance and Head-Business Development or the concerned designees shall initiate the recall, as per the regulatory directives of the country to which product is marketed.

6.1.24 The relevant steps which shall be followed, but not limited to, following points –

6.1.24.1 Classification of recall based on possible health hazard.: The classification shall be done as follows –

- **Class I Recall**: The Class I Recall is for defective/dangerous /potentially life- threatening medicines that predictably or probably could result into serious health risk/adverse events or even death. Examples are as below which are not limited to,
  - Wrong product (label and contents are different products)
  - Correct product but wrong strength, with serious medical consequences
  - Chemical contamination (cross contamination if life threatening) with serious medical consequences.

- Mix-up of some products (rogues) with more than one container involved.
- Wrong active ingredient in a multi-component product, with serious medical consequences.

- **Class II Recall:** Class II is for medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment. Examples are as below which are not limited to,
  - Mislabeling, e.g. wrong or missing text or figures
  - Missing or incorrect information (leaflets or inserts)
  - Chemical/ physical contamination (significant impurities, cross contamination if not life threatening, Particulates)
  - Mix up of products in containers
  - Non-compliance with specification (e.g. assay, stability, fill/weight)
  - Insecure closure with serious medical consequences (e.g. child resistant containers, potent Products)
- **Class III Recall:** Class III defects May not pose a significant hazard to health, but recall may have been initiated for other reasons. Examples are as below which are not limited to,
  - Faulty packaging, e.g. wrong or missing batch number or expiry date
  - Faulty closure
  - Contamination, e.g. Microbial spoilage, dirt or detritus, particulate matter.
- **Class IV Recall:** The Recall class is applicable for products distributed to the European market. This is also called as '"Caution in Use" This recall is applicable where there is no threat to patients or no serious defect likely to impair product use or efficacy. The recall is generally used for minor defects in packaging or other printed materials.

6.1.25 The required recall level which shall be categorized into Type A, Type B or Type C Recall which are defined as follows:

6.1.25.1 'Type A' recall is designed to reach all suppliers of medicines (all distribution points) i.e. Wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispensers and individual customers or patients through Media Release (radio, television, regional

and national press of the countries where the product batch is distributed) as well as through Recall Letter.

6.1.25.2 'Type B' recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispensers through Recall Letter.

6.1.25.3 'Type C' recall is designed to reach wholesale level and other distribution points (e.g. pharmacies, doctors, hospitals) this can be achieved by means of a representatives calling on wholesalers and/or retail outlets. If it is known where the product in question had been distributed to, specific telephone calls or Recall letter to arrange for the return of the product could be made.

6.1.26 The decision on the Class and Type of recall shall be initiated depending on the consultation and evidence and/ or experts opinion of the concerned Regulatory Agency.

6.1.27 The recall initiation shall be performed, from the date of incidence reporting,

6.1.27.1 Within "THREE" working days, for Class I Recall.

6.1.27.2 Within "SEVEN" working days, for Class II Recall.

6.1.27.3 Within "FIFTEEN" working days, for Class III Recall.

6.2 **Recall Communication:**

6.2.1 The Product Recall shall be initiated through a Recall letter and/or Media Release/ Public Warning.

6.2.2 Public notification through but not limited to recall letter, print media, telecommunication shall be executed based on the Recall Type and Class.

6.2.3 The Recall letter shall include the factual statements of the reasons for the recall of the product, together with the special details are not limited to (Name of product, dosage form, strength, registration number, pack size, batch number(s), expiry date) that allow the product to be easily identified. Prior to dispatch of letter, the text of the Recall letter is required to be approved from concerned Regulatory Agency and this approved letter is required to be dispatch within 24 hours of receiving approval from concerned Regulatory Agency. The Recall communication shall be made on the company's letterhead and signed by the Head – Quality Assurance/designee. The Recall communication shall be marked with the bold red type "URGENT DRUG/ MEDICINE RECALL"

6.2.4 The Recall letter shall include a request to retain the letter in a prominent position for one month in case stock is in transit (where applicable).

6.2.5 Where recalled stock has been distributed to a limited number of hospitals and the recall letter is not to be sent to all hospitals in the province, the letter should include the following:
"If any of the recalled stock could have been transferred from your hospital to another, please let that hospital know or alternatively inform our company so that we can make contact with the hospital supplied from your hospital".

6.2.6 The Media Release or Public Warning shall be reserved for the urgent situation (Class I and occasionally Class II Recalls) where other means for preventing use of the recalled product appear inadequate. The text for the media release shall be developed by Head – Quality Assurance/designee in consultation with concerned Regulatory Agency. The media release shall contain sufficient and relevant detail to uniquely define the product, together with clear outline of the problem (without causing unnecessary alarm). A 24-hour access toll free telephone number shall be given for further information.

6.2.7 Regular updates on the progress of an investigation into the cause and conduct of a recall shall be provided to the Agency at no less than weekly intervals. The report shall include a summary reconciliation between the amount of product supplied to the market and the amount returned up to the date of the report.

6.3 **Recall Effectiveness :**

6.3.1 For the US market, the effectiveness of recall communication (through Recall letter or media release or any other means) shall be checked by verifying the all consignees at the recall depth specified by the strategy have received notification about the recall & had taken action. The level of effectiveness checks shall be categorized into Level A, Level B, Level C and Level D which are defined as follows-

6.3.1.1 **Level A:** 100 percent of the total number of consignees to be contacted.

6.3.1.2 **Level B:** Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees.

6.3.1.3 **Level C:** 10 Percent or less of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis; or

6.3.1.4 **Level D:** No effectiveness checks.

6.3.2 A list shall be available at Site with contact details of person/ agency to execute product recall. The list shall be updated periodically in coordination with Business Development and Regulatory Affairs of Contact Persons, as per the format 'List of Contact Persons for Product Recall/ Withdrawal' as per Attachment 05.

6.4 **Post Recall Procedure :**

6.4.1 The Head – Quality Assurance/designee along with Head-Business Development /designee has a legal responsibility for implementing the recall action and for ensuring compliance with the recall procedure. At two weeks after the implementation of the

recall the firm shall provide the interim report on the effectiveness of the recall and within 30 days the final summary report of recall shall be submitted to the FDA, for the product distributed in US market. These reports shall contain the details of investigation, corrective and preventive action proposed and implemented success of the recall (i.e. not limited to quantity of stock returned, corrected, outstanding.) Refer Attachment 06.

6.4.2 The stock of the recalled goods shall be handled as per the SOP for 'Handling of Returned Goods'.

6.4.3 The stock of recalled batch (batches) shall be stored in the secured area, as per prescribed storage conditions, and shall be properly identified.

6.4.4 Reconciliation of stock of the batch manufactured, distributed and subsequently quantity of stock received back, shall be performed.

6.4.5 The stock in transit shall also be considered during the reconciliation procedure.

6.4.6 The recalled stock shall be destroyed or reworked as per the SOP for 'Handling of Returned Goods'.

6.4.7 The entire data of the recall initiation, implementation, monitoring shall be properly compiled and preserved.

6.4.8 Summary Report of Recall as per Attachment 06 shall be prepared by the Quality Assurance Head, Site Head to include, but not limited to, the following points,

6.4.8.1 Product name, strength, name and source of API's

6.4.8.2 Batch numbers, market, mfg. dates and expiry dates Pack size, Batch size of the recalled batches, the reason for recall

6.4.8.3 Date of release, Date of Distribution, Date of recall initiation and completion

6.4.8.4 Total Quantity prior to distribution, Quantity released for distribution prior to recall.

6.4.8.5 Investigation report

6.4.8.6 Indication of Health risk and the reported clinical problems.

6.4.8.7 Quantity manufactured and distributed along with the distribution details

6.4.8.8 Effective checks adopted for the recall

6.4.8.9 Reconciliation of qty. manufactured, distributed and received after the recall.

6.4.8.10 Action taken on the recalled goods with supportive justification.

6.4.8.11 Root cause identification and corrective action taken.

6.4.9 The recall communication and closure shall be performed by the concerned ..... affiliate/Business Partner, as per the applicable laws and regulations, if the affected product is distributed by the firm.

6.5 **Product Withdrawal:**

6.5.1 Product Withdrawal means a firm's removal from further sale or use, or correction of a marketed product that does not violet legislation administered by respective Regulatory Agency. It is not considered to be a recall.

6.5.2 The product withdrawal shall be carried out, but not limited to, following

6.5.2.1 Non- conforming result of on-going stability study.

6.5.2.2 Investigation of non conforming product.

6.5.2.3 Failure to meet product specification.

6.5.3 QA shall assign a Withdrawal Number as follows
PW/YY/ZZZ.
Where, PW– Denotes Product Withdrawal
YY – represents last two digits of year
ZZZ – represents serial number of Withdrawal in year
For Example- PW/24/001
First Product Withdrawal initiated in year 2024

6.5.4 Manager – QA/designee shall log the details of the product withdrawal in the 'Product Withdrawal Log' As per Attachment 02.

6.5.5 A copy of 'Product Withdrawal Notification' shall be sent to concern Regulatory Agency. As per Attachment 01

6.5.6 The Product Withdrawal shall be considered as a recall only if the concern Regulatory Agency regards the product as involving a violation of cGMP.

6.5.7 Summary report shall be submitted to the concern Regulatory Agency.

6.5.8 The required communication, stock reconciliation and its destructed followed by the closure, shall be performed by the concerned ..... affiliate/Business Partner, as per the applicable laws and regulations, if the affected product is distributed by the firm.

6.6 **Mock Recall:**

6.6.1 Mock recall shall be performed on dummy /commercial batch, to check the effectiveness of Recall Procedure, which shall include, but not limited to, following activities –

6.6.1.1 Preparation of protocol/study plan to describe the detail methodology, responsibilities and Procedure.

6.6.1.2 The product batch (batches) distributed to the identified country shall be randomly selected.

6.6.1.3 Batch/s manufactured with single lot of API shall be selected for the study.

6.6.1.4 Proper communication with the customers.

6.6.1.5 Documentation

6.7 The Mock Recall shall be performed separately for the different markets where the products are distributed. The Mock Recall is not essential if the products are supplied through other Business Partner. The product markets for which the Mock Recall shall be performed, are grouped as follows:

6.7.1 Asia

6.7.2 United States of America (USA)

6.7.3 Europe / United Kingdom
6.7.4 Latin America / Brazil
6.7.5 South Africa
6.7.6 African countries
6.7.7 Australia / New Zealand
6.7.8 Others

Note: Supplies to US, Europe/UK, South Africa, Japan, Australia and New Zealand are through business affiliates.

6.8 The frequency of Mock Recall shall be,

6.8.1 Annually & whenever there is change in the procedure of distribution.
6.8.2 Whenever there is change in the Recall Methodology.
6.8.3 The Mock Recall Planner shall be prepared annually and in the month of December for next coming year as per Attachment 09.
6.8.4 Mock recall shall be performed for the continent in which commercial supply has been started.
6.8.5 First mock recall for particular continent shall be executed within first year started from first commercial supply.
6.8.6 Justification shall be provided in case of reschedule of mock recall.
6.8.7 If there is any addition of continent, Mock recall planner shall be updated.

6.9 Mock recall for particular continent is not required if same is executed by other site of ..... India. In such case, the copy of report of mock recall shall be made available at site.

6.10 Mock recall shall not be executed from continent if any actual recall is done from the same continent in same year.

6.11 The learning, if any, as part of product recall or mock recall activity, shall be used to implement Corrective and Preventive Action (CAPA) plan. Corrective and Preventive Actions shall be identified and documented as per the Standard Operating Procedure on 'Corrective and Preventive Actions (CAPA)'.

6.12 The photocopy of entire communication and supportive documents about the recall shall be attached to the relevant Batch Product Record.

7.0 ATTACHMENTS:

7.1 **Attachment 01:** Product Recall / Withdrawal Notification,
7.2 **Attachment 02:** Product Withdrawal Log,
7.3 **Attachment 03:** Product Recall Log,
7.4 **Attachment 04:** Product Recall Letter,
7.5 **Attachment 05:** List of Contact Person for Product Recall/Withdrawal,
7.6 **Attachment 06:** Summary Report Of Recall,
7.7 **Attachment 07:** Product Recall Flow Chart,

7.8 **Attachment 08:** Questionnaire For Standard Operating Procedure,

7.9 **Attachment 09:** Mock Recall Planner,

8.0 VERSION HISTORY:

Version	Description of Change	Revised by

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ATTACHMENT 01

	PRODUCT RECALL/ WITHDRAWAL NOTIFICATION

To (Specify the Name and Address of the Regulatory Agency)

Product Recall Class : Class I ☐ Class II ☐ Class III ☐ Class IV ☐

Recall Type : Type A ☐ Type B ☐ Type C ☐

Put tick mark [√] where it is applicable and put cross mark [X] where it is not applicable in the box provided.

Name of the Contact person:
Telephone / Fax / E-mail:

Product Authorization /NDC Number :	**Name of ANDA/NDA/ Manufacturing Authorization Holder:**

Product Details :

Product Name: _____ Name of the API: _____

Vendors of the APIs: _____

B.No: _____ Market : _____

Mfg. Date: _____ Exp. Date: _____

Pack Size: _____ Batch Size: _____

Date of Release: _____ Date of Distribution: _____

Total quantity prior to distribution: _____ Quantity released for distribution: prior to the recall: _____

Source of Complaint: _____ **Date of complaint received:** _____

Details of complaint: _____

Reason for Recall/ Withdrawal (Nature of Defect) : _____

Information on Distribution :

_____

_____

_____

Signature with Date
Head–Quality Assurance

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ATTACHMENT 02

PRODUCT WITHDRAWAL LOG

Withdrawal No.	Reason of Withdrawal	Product Details					Date of Initiation	Investigation Reference No.	CAPA Reference No.	Date of Closure	Remark	Sign/Date
		Name	B.No.	Market	Mfg. Date	Exp. Date						

ATTACHMENT 03

PRODUCT RECALL LOG

Recall No.	Reason of Initiation	Product Details					Date of Recall Initiation	Investigation Reference No	CAPA Reference No	Date of response to Regulatory Agency	Date of Closure	Remark	Sign/Date
		Name	B.No	Market	Mfg. Date	Exp. Date							

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ATTACHMENT 04

	RECALL LETTER
"Urgent Medicine Recall"	
To Name of the Contact person: Telephone / Fax / E-mail:	
Market: Product Recall Class : Class I ☐ Class II ☐ Class III ☐ Class IV ☐ Recall Type : Type A ☐ Type B ☐ Type C ☐ Put tick mark [√] where it is applicable and put cross mark [x] where it is not applicable in the box provided.	
Product Authorization /NDC Number :	Name of ANDA/NDA/ Manufacturing Authorization Holder:
Product Details : Product Name: _____ B.No: _____ Mfg. Date: _____ Exp. Date: _____ Pack Size: _____	
Nature of complaint:_____ Urgency of action:_____ Reason for action:_____ Indication of Health Risk: _____ (Include Side Effects)	
Method of Recovery:_____ Contact Telephone / Fax / E-mail of Matrix:	
Note: 1. *Retain the letter in a prominent position for one month in case stock is in transit (where applicable).* 2. *"If any of the recalled stock could have been transferred from your hospital to another, please let that hospital know or alternatively inform our company so that we can make contact with the hospital supplied from your hospital".*	
Signature with Date Head–Quality Assurance	

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ATTACHMENT 05

		LIST OF CONTACT PERSON FOR PRODUCT RECALL/ WITHDRAWAL	
Sr. No.	**Country/ Agency**	**Name of Contact Person**	**Contact Details**

Prepared By (Sign/Date)	Reviewed By (Sign/Date)	Approved By (Sign/Date)

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ATTACHMENT 06

	SUMMARY REPORT OF RECALL	Page 1 of 2

To (Specify the Name and Address of the Regulatory Agency)

Product Recall Class : Class I ☐ Class II ☐ Class III ☐ Class IV ☐
Recall Type : Type A ☐ Type B ☐ Type C ☐
Effectiveness Level : Level A ☐ Level B ☐ Level C ☐ Level D ☐

Put tick mark [√] where it is applicable and put cross mark [×] where it is not applicable in the box provided.

Marketing Authorization /NDC Number :	**Name of ANDA/NDA/ Manufacturing Authorization Holder:**

Product Details :

Product Name: _____ Name of the API: _____

Vendors of the APIs: _____ Recall Initiation Date: _____

B.No: _____ Market : _____

Mfg. Date: _____ Exp. Date: _____

Pack Size: _____ Batch Size: _____

Date of Release: _____ Date of Distribution: _____

Total quantity prior to distribution: _____ Quantity released for distribution: prior to the recall: _____

Source of Complaint: _____ **Date of complaint received:** _____
Details of complaint: _____

Reason for Recall (Nature of Defect): _____

_____

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ATTACHMENT 06

	SUMMARY REPORT OF RECALL	Page 2 of 2

Detail Investigation Report (Attach separate pages, if required)

_____

_____

Indication of Health Risk and the reported clinical problems: Attach separate pages for details, if required.

Distribution details: Attach the detail lists.

Effectiveness Checks: Attach the supportive lists.

Reconciliation of stock: Attach the details to include the quantity manufactured, quantity distributed, quantity not distributed, Received stock after recall notification.

Disposal Action taken for the returned goods with supportive justification

_____

_____

Root cause for the recall

_____

Corrective actions:

_____

_____

Preventive actions:

_____

_____

Reported by Head –Quality Assurance:
Date: _____

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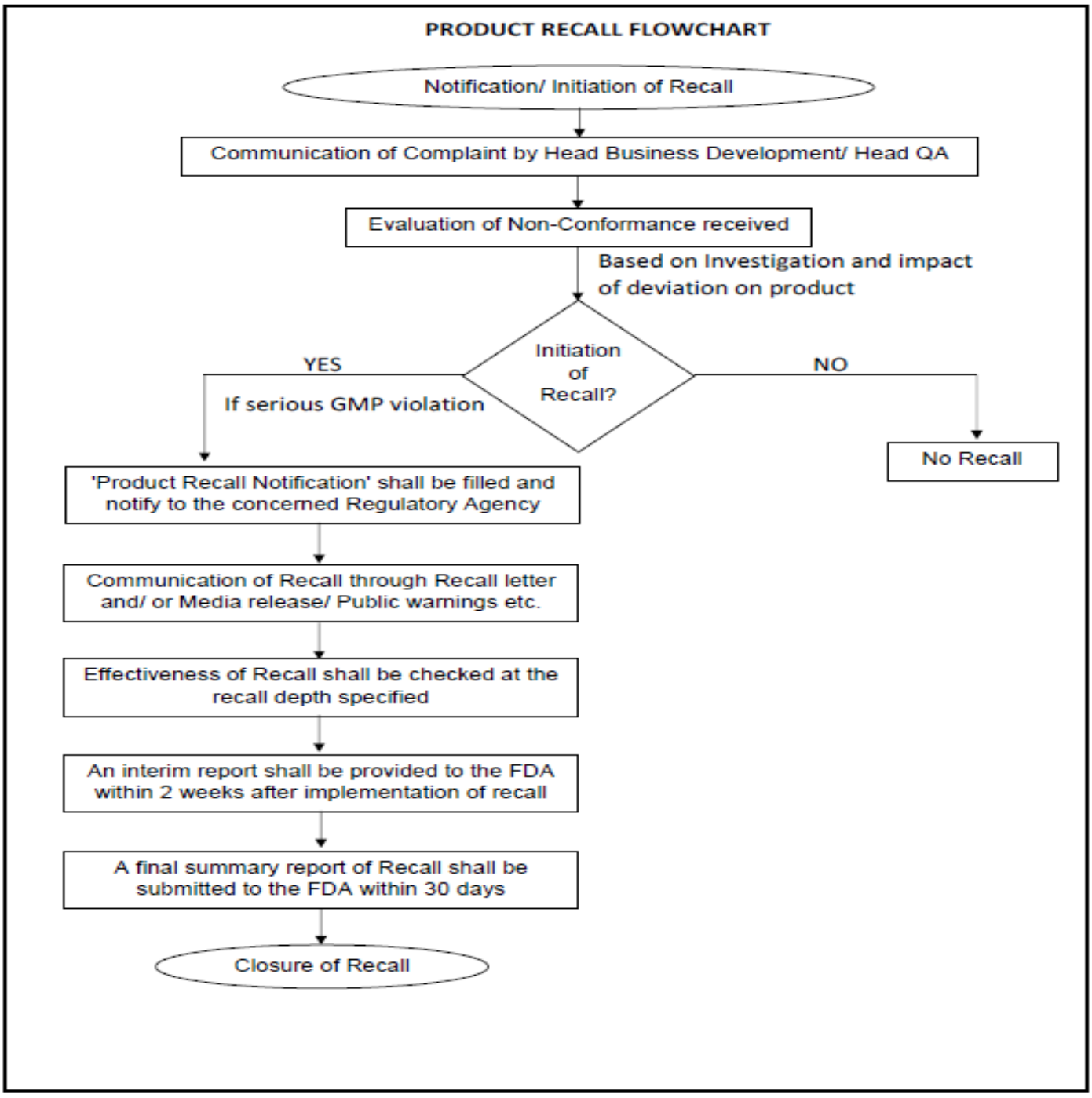
ATTACHMENT 07



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ATTACHMENT 08

	QUESTIONNARIE
SOP Title: PRODUCT RECALL AND WITHDRAWAL	
SOP No.:	
SOP version no. 4.0	

Date :	Department:
Name :	Employee Code:

Select the correct answer and mention in respective box. All questions carry equal marks.

1. Head-Regulatory Affairs/designee shall evaluate the potential impact of such issue on product quality, safety and efficacy and shall communicate the issue to Regional Quality Head who in turn shall communicate the incidence to Global Quality. This statement is -

   a) True b) False ☐

2. QA shall assign a Recall Number as follows,
   PR/YY/ZZZ.
   Where, PR– Denotes Product Recall
   YY – represents month
   ZZZ – represents serial number of Recall in year

   a) True b) False ☐

3. The recall information for the products pertaining to the marketing authorization of products shall be communicated to the Qualified Person or Business Partner.

   a) True b) False ☐

4. Head-Quality Assurance and Head-Business Development or the concerned designees shall initiate the recall, as per the regulatory directives of the country to which product is marketed.

   a) True b) False ☐

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ATTACHMENT 08

	QUESTIONNARIE
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5. Mock Recall shall be performed on ---------- batch. ☐

a) Dummy /commercial
b) Exhibit
c) Scale up / Evaluation
d) Validation

Total marks allocated :	
Total marks obtained :	
Assessment	Excellent (Above 9) ☐ Satisfactory (8-9) ☐ Retraining (Below 8) ☐
Trainer shared correct answer to trainee (if marks between 8 to 10)	Yes ☐ No ☐ Not applicable ☐
Retraining Imparted	Yes ☐ No ☐ Not applicable ☐
Assessment after Retraining	Excellent (Above 9) ☐ Satisfactory (8-9) ☐ Retraining (Below 8) ☐
Evaluated By Name : Sign : Date :	
Acceptance by Trainee: Sign and Date	

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

ATTACHMENT 09

MOCK RECALL PLANNER

YEAR: ----------

Sr. No.	Continents / Markets	Due on	# Rescheduled on	Done on	Sign / Date

Mock recall can be rescheduled if not executed in proposed time but needs to be executed with next commercial supply.

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Monthly Reviewed By												

Prepared By (Sign/date)	Reviewed By (Sign/Date)	Approved By (Sign/Date)