PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	**Risk Assessment No.:**

RISK ASSESSMENT
FOR
PRODUCT RECALL & WITHDRAWAL

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	**Risk Assessment No.:**

TABLE OF CONTENTS

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

1.0 PRE APPROVAL:

The Author's signature indicates that the document has been prepared in accordance with existing cGMP standards and adequately reflects the tasks and deliverables necessary for Risk Assessment of Process / System / Equipment / Instrument.

Prepared by/ Function	Designation	Signature	Date

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverables necessary for risk assessment of the Process / System / Equipment / Instrument and that the documentation and information included compiles with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head (Initiating Department)			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Approved By / Function	Designation	Signature	Date
Quality Assurance			

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

2.0 OVERVIEW:

2.1 Objective

The objective of the risk assessment is to identify different risks involved in Handling of Product Recall and Withdrawal, and evaluate the impact of the risk on the quality product / patient, propose the corrective action and preventive action to mitigate / reduce the level of risk.

2.2 Scope

The scope of the risk assessment is for handling of Product Recall and Withdrawal.

3.0 REASON FOR RISK ASSESSMENT:

The risk assessment shall be performed for following reason (√)

- New / Modification of Product / Process/ **System** / Equipment / Instrument (√) –

  Product Recall and Withdrawal

- Inclusion of additional parameters in Risk assessment
- Others (Specify)

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

4.0 TEAM MEMBERS:

Following team members have been involved in the brain storming session of the risk management of this activity.

Date: _____ **Time: _____** **Venue: _____**

S.No.	Name	Designation	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			

The details of the discussion of the risk management of the activity, including the process flow of the activity, identification of the risks involved in the activity and corrective action and preventive action of the risk involved in the activity shall be recorded in section 5, 7 & 8.

After implementation of CAPA, the risk shall be recalculated and ensured to be at the acceptable level (Low).

Prepared By : _____ **Date : _____**

Reviewed By : _____ **Date : _____**

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	**Risk Assessment No.:**

5.0 ACTIVITY: (PROCESS / SYSTEM / EQUIPMENT / INSTRUMENT):

Specify the activities wherein the risk assessment is required. (Tick the appropriate box)

Process	
System	√
Equipment / Instrument	
Others: _____	

Description:

SOP is available at site for handling of Product Recall and Withdrawal.

Product Recall –

Product Recall is Defined as 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.

Recall or withdrawal shall be initiated due to complaint pertaining to the product strength, identity, safety, purity or quality of product, 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.

Based on evaluation of data Head –Quality Assurance initiates recall or withdrawal, communication to the concerned personnel and the concerned Regulatory Agency.

Product Recall at site has been classified in following sections, based on possible health hazard –

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.

Class II Recall: Class II is for medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

Class III Recall: Class III defects May not pose a significant hazard to health, but recall may have been initiated for other reasons.

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.

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

- '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.
- '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.
- '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.

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

- Within "THREE" working days, for Class I Recall.
- Within "SEVEN" working days, for Class II Recall.
- Within "FIFTEEN" working days, for Class III Recall

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

Mock Recall:

Mock recall shall be performed on dummy /commercial batch, to check the effectiveness of Recall Procedure.

The frequency of Mock Recall shall be annual or whenever there is change in recall procedure.

Product Withdrawal -

Product Withdrawal is Defined as 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.

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

- Non- conforming result of on-going stability study.
- Investigation of non conforming product.
- Failure to meet product specification.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

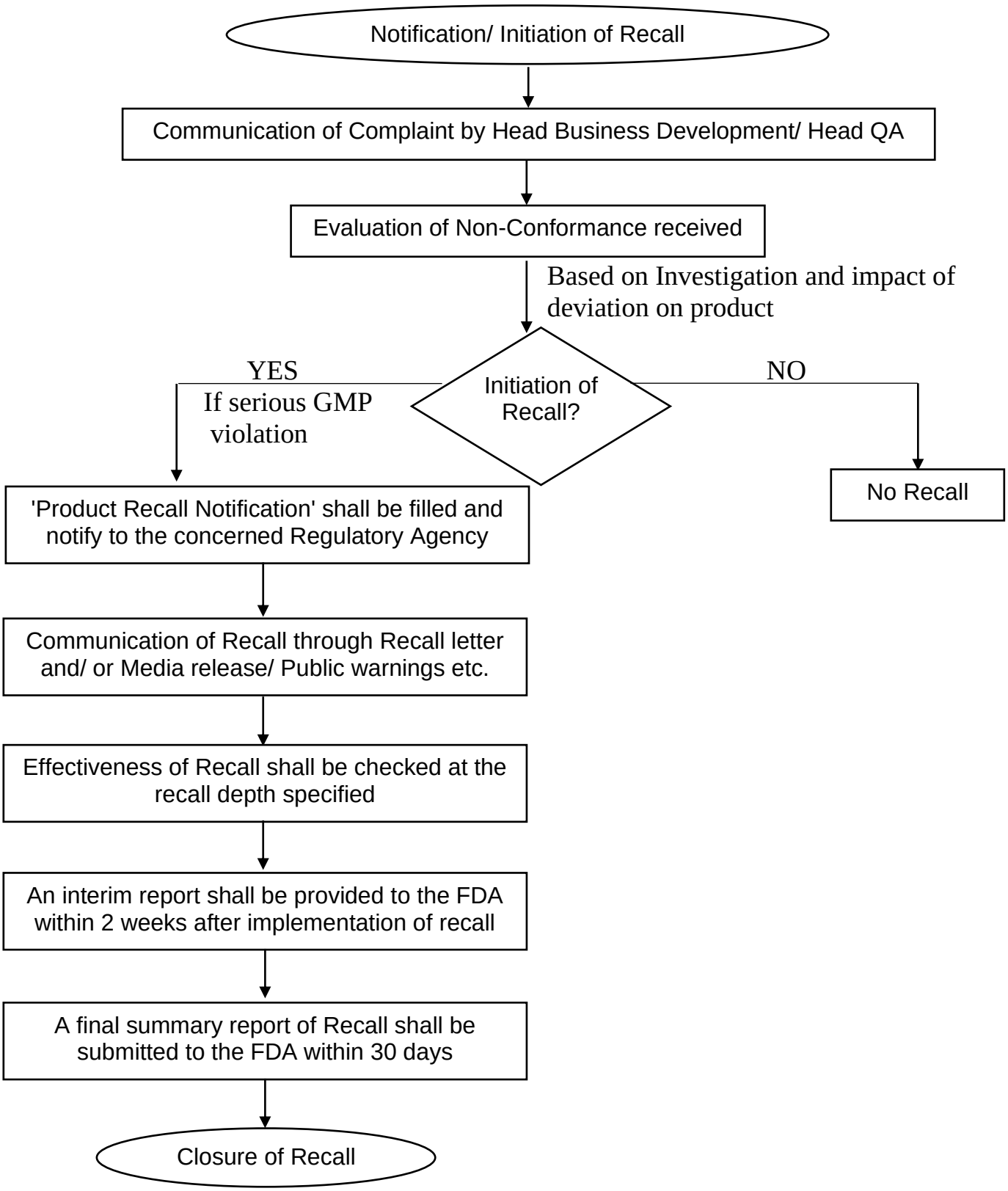
QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

Process Flow:

PRODUCT RECALL FLOWCHART



6.0 DEFINITIONS AND METHODOLOGY:

6.1 Severity of impact:

Identify the severity of impact of the risk on the quality of the product/service. Categorize the severity of impact of risk as Fundamental / High / Moderate / Minor / Insignificant as defined below and put score against each risk at section 7.0.

Category	Description	Score
Fundamental	Very significant and catastrophic impact	5
High	Significant losses and inefficiencies, necessitating timely adressal	4
Moderate	Loss of operating capability, deterioration of efficiency, management intervention required	3
Minor	Impact on operations and efficiency, but not pervasive	2
Insignificant	Limited or no impact on operations and quality of operational efficiency	1

6.2 Occurrence:

Identify the probability of occurrence of risk based on the occurrence frequency and put score against each risk at step 7.0.

Category	Probability of Occurrence	Description	Score
Almost certain	> 90 %	Is expected to occur in most circumstances	5
Likely	60-89 %	Will probably occur in most circumstances	4
Possible	25-59 %	Will probably occur at some time	3
Unlikely	10-24 %	Could occur at some time	2
Rare	< 10 %	May occur in exceptional circumstances	1

6.3 Detection:

Identify the level of detection of risk and give rating as below,

Category	Description	Score
Not aware/ No Control exists	Insufficient information to adequately assess and rate the control	5
Non existent / Very Little chance of detection	No procedural system in place, no risk reduction process procedure in place.	4
Not effective / Likely to be detected	Mitigation plans or risk reduction process & procedures though in place but do not ensure adequate control over risk occurrence / impact as the risk still exists over its acceptance level.	3
Effective / very likely to be detected	Approved Mitigation plans or risk reduction procedures, Checklists are laid down for early detection & immediate corrective actions are taken.	2
Very Effective / 100 % likelihood of detection	Mitigation plans or risk reduction process & procedures involve stringent approval and reporting norms with responsibility duly mapped to various management levels, minimizing possibility of occurrence / optimizing protection in the case of occurrence of the same at very early stage, controlling and reducing the risk.	1

Risk Ranking: Calculate the total score for the particular risk by multiplying the scores of Severity of impact, Occurrence and Detection

Categorize the risk as Low risk, Medium risk or high risk, as follow

RISK LEVEL	OBTAINED SCORE
HIGH RISK	125 to 64
MEDIUM RISK	Below 64 to 27
LOW RISK	Below 27

Upon evaluation of the risk, elaborate the methodology for notification of the risk, responsibility for the handling of risk and Corrective action, Preventive action (CAPA) plan for the identified risk.

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

Note: In addition to RPN No. calculation.

a. If any parameter is having severity as 'Fundamental or High' (i.e. 4 or 5 scale number) then final risk level should be decided as 'High' irrespective of RPN number.

b. If any parameter is having severity as 'Moderate' (i.e. 3 scale number) then final risk level should be decided as at least 'Medium' unless and otherwise the risk is classified as High with RPN greater than 64.

- Criteria 'a' & 'b' are applicable at the stage of identification of risk whereas after mitigation control the final risk level should be confirmed on the basis of RPN number only irrespective of individual severity scale.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	**Risk Assessment No.:**

7.0 IDENTIFICATION OF RISK INVOLVED:

S.No.	Description of Risk	Risk Involved	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Remarks
1	Recall level not determined correctly	Impacted product could not be withdrawn from Correct level	4	3	2	24	High	Risk is Classified as High, as Severity of Impact is scored as 4.
2	Class of Recall not determined correctly	Intensity or level could not be determined correctly	4	3	2	24	High	Risk is Classified as High, as Severity of Impact is scored as 4.
3	Recall initiation not initiated within time frame	Information regarding recall is not Communicated	4	3	2	24	High	Risk is Classified as High, as Severity of Impact is scored as 4.
4	Mock Recall Not Performed	Effectiveness of Recall procedure could not be known	3	3	2	18	Medium	Risk is Classified as Medium, as Severity of Impact is scored as 3.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

S.No.	Description of Risk	Risk Involved	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Remarks
5	Distribution network could not be traced out during Recall	Recall Failure	4	3	2	24	High	Risk is Classified as High, as Severity of Impact is scored as 4.
6	Handling of Recall Stock	Procedure Not Available for Handling of Recalled Stock	3	2	2	12	Medium	Risk is Classified as Medium, as Severity of Impact is scored as 3.

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

8.0 NOTIFICATION AND CAPA:

8.1 NOTIFICATION AND CAPA OF HIGH RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Recall level not determined correctly	Impacted product could not be withdrawn from Correct level	24	Quality Assurance	○ Recall level is determined, depending on the consultation and evidence and/ or experts opinion of the concerned Regulatory Agency.	○ Relevant personnel's involved in the activity are trained on the procedure.	Quality Assurance	
Class of Recall not determined correctly	Intensity or level could not be determined correctly	24	Quality Assurance	○ As per SOP, how to define class of recall has been explained, along with examples. ○ Provision for recording the class of recall has been included in the Product Recall / Withdrawal Notification.	○ Relevant personnel's involved in the activity are trained on the procedure.	Quality Assurance	
Recall initiation not initiated within time frame	Information regarding recall is not Communicated	24	Quality Assurance	As per SOP recall initiation shall be performed, from the date of incidence reporting, within - "THREE" working days, for	○ Relevant personnel's involved in the activity are trained on the procedure.	Quality Assurance	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				Class I Recall. - Within "SEVEN" working days, for Class II Recall. - Within "FIFTEEN" working days, for Class III Recall. o Recall shall be initiated through Recall letter and/or Media Release/ Public Warning. o As per SOP The recall information for the products pertaining to the marketing authorization of products shall be communicated to the Qualified Person or Business Partner. o As per Sop 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 FDA.	o List of contact persons for product recall and withdrawal is available at site to communicate information regarding recall.		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Distribution network could not be traced out during Recall	Recall Failure	24	Business Development / Quality Assurance	○ Product Recall Notification is sent to the Business Development and Corporate Quality Assurance for Anti Retroviral products, which are not distributed through Affiliates. ○ Business Development is responsible for Communicating and Tracing the batches further. ○ Batches which are distributed through Affiliates are tracked by affiliates further.	○ Mock recall is executed to verify the tracing of distribution network on yearly basis.	Business Development / Quality Assurance	

8.2 NOTIFICATION AND CAPA OF MEDIUM RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Mock Recall Not Performed	Effectiveness of Recall procedure could not be known	18	Quality Assurance	○ As per SOP Mock recall shall be performed on dummy /commercial batch ○ The Mock Recall shall be performed separately for the different markets where the products are distributed ○ As per SOP frequency of Mock Recall verification is Annually ○ Learning, if any, as part of product recall or mock recall activity, are implemented by CAPA.	○ The Mock Recall Planner is prepared annually to track the activities. ○ Relevant personnel's involved in the activity are trained on the procedure.	Quality Assurance	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Handling of Recall Stock	Procedure Not Available for Handling of Recalled Stock	12	Quality Assurance, Warehouse	○ Recall stock are handled as per the SOP of 'Handling of Returned Goods'. ○ Based on the assessment and conclusion, recalled stock shall either be destroyed or reworked.	○ Personnel's involved in the activity are trained on the procedure.	Quality Assurance, Warehouse	

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

8.3 NOTIFICATION AND CAPA OF LOW RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

8.4 MITIGATION CONTROL& RE-EVALUATION OF IDENTIFIED RISKS AFTER IMPLEMEMNTATION OF CAPA:

S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
1	Recall level not determined correctly - Impacted product could not be withdrawn from Correct level	- SOP– Recall and Product Withdrawal, is available at site. - Recall level is determined, depending on the consultation and evidence and/ or experts opinion of the concerned Regulatory Agency. - Relevant personnel's involved in the activity are trained on the procedure.	4	2	2	16	Low	
2	Class of Recall not determined correctly – Intensity or level could not be determined correctly	- As per SOP, recall class is defined in SOP. - Provision for recording the class of recall has been included in the Product Recall / Withdrawal Notification. - Relevant personnel's involved in the activity are trained on the procedure.	4	2	2	16	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
3	Recall initiation not initiated within time frame – Information regarding recall is not Communicated	- As per SOP, recall initiation is being performed, from the date of incidence reporting, within - - "THREE" working days, for Class I Recall. - "SEVEN" working days, for Class II Recall. - "FIFTEEN" working days, for Class III Recall. - As per SOP, Recall shall be initiated through Recall letter and/or Media Release/ Public Warning. - As per SOP 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 Sop 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 FDA. - List of contact persons for product recall and withdrawal is available at site to communicate information regarding recall.	4	2	2	16	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
4	Distribution network could not be traced out during Recall – Recall Failure	- As per SOP, Product Recall Notification is sent to the Business Development and Corporate Quality Assurance for Anti Retroviral products, which are not distributed to Affiliates. - Business Development is responsible for Communicating and Tracing the batches further. - Batches which are distributed to Affiliates are tracked by affiliates further. - Mock recall is executed to verify the tracing of distribution network on yearly basis.	4	2	2	16	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
5	Mock Recall Not Performed – Effectiveness of Recall procedure could not be known	- As per SOP Mock recall shall be performed on dummy /commercial batch - The Mock Recall shall be performed separately for the different markets where the products are distributed - As per SOP frequency of Mock Recall verification is Annually - Learning, if any, as part of product recall or mock recall activity, are implemented by CAPA. - The Mock Recall Planner is prepared annually to track the activities. - Relevant personnel's involved in the activity are trained on the procedure.	3	2	2	12	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.: | **Risk Assessment No.:**

S.No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
6	Handling of Recall Stock – Procedure Not Available for Handling of Recalled Stock	- Recall stock are handled as per the SOP of 'Handling of Returned Goods'. - Based on the assessment and conclusion, recalled stock shall either be destroyed or reworked. - Personnel's involved in the activity are trained on the procedure.	3	2	2	12	Low	

9.0 TRAINING AND EVALUATION RECORD:

Date :	Timing : From _____ to_____
Venue :	Name of Trainer :
Title : Risk Assessment	Method of training:

S.No.	Name of Employee	Employee Code	Evaluation Details	
			Signature of Trainee	Remarks

Signature of Trainer (Sign/Date): _____

Comments:

_____

_____

_____

Verified By: _____ Date : _____

10.0 SUMMARY AND CONCLUSION:

10.1 Evaluation of Data:

The Risk Management was conducted for Product Recall and withdrawal, was evaluated for involved risks in the operation and malfunction of critical components.

Risks were categorized on the scores for parameters like severity of impact, likelihood of occurrence and probability of detection and mentioned in Annexure – I.

10.2 Mitigation Plan:

The identified risks attached in Annexure – I were evaluated for the corrective and preventive actions. The corrective and preventive actions are identified for the each identified risk involved in Product Recall and withdrawal process, required reference documents references are provided to mitigate the risk.

All the available controls were found adequate, for the identified risks.

The corrective and preventive actions for the identified risks are identified and attached in Annexure – II.

10.3 Evaluation of Risk Involved after Mitigation Control:

All the identified risks were re-evaluated considering available control and the risk score was identified as Low level risk.

Re categorized identified risks are attached as Annexure – III.

10.4 Summary:

The Risk Management was conducted for Product Recall and withdrawal. Risks were categorized on the scores for parameters like severity of impact, likelihood of occurrence and probability of detection and mentioned in Annexure – I.

The identified risks attached in Annexure – I were evaluated for the available corrective and preventive actions. The corrective and preventive actions are identified for the each identified risk and required reference documents references are provided to mitigate the risk.

The corrective and preventive actions for the identified risks are identified as attached in Annexure – II

Training has been imparted to the personnel's involved in Product Recall and withdrawal.

10.5: Conclusion

On evaluation of data, it can be concluded that the procedures are available to mitigate the involved risk in product recall and withdrawal activity.

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

11.0 REFERENCE DOCUMENTS:

S.No.	Title

Reviewed By : _____ Date : _____

12.0 ABBREVIATION:

S.No.	Abbreviation	Description

Reviewed By : _____ Date : _____

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR PRODUCT RECALL & WITHDRAWAL

Reference Document No.:	Risk Assessment No.:

13.0 ATTACHMENTS:

S.No.	Description

Reviewed By : _____ Date : _____

14.0 COMPLIANCE VERIFICATION:

S.No.	DESCRIPTION	COMPLIANCE (Y/N)	VERIFIED BY

Reviewed By : _____ Date : _____

15.0 POST APPROVAL:

This is hereby certified by the following functionaries, that the risk assessment of the activity in the department stands qualified for its intended purpose.

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverable necessary for risk management and all associated equipment/instruments and systems and that the documentation and information included complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head (Initiating Department)			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory/departmental requirements and current Good Manufacturing Practices.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			