PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK MANAGEMENT
ANNEXURE II

NOTIFICATION AND CAPA

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Recall level not determined correctly	Impacted product could not be withdrawn from Correct level	24	Quality Assurance	○ Recall level is determined, depending on the consultation and evidence and/ or experts opinion of the concerned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 Class I Recall. - Within "SEVEN" working days, for Class II Recall. - Within "FIFTEEN" working days, for Class III Recall. ○ Recall shall be initiated through	○ Relevant personnel's involved in the activity are trained on the procedure. ○ List of contact persons for product recall and withdrawal is available at site to communicate	Quality Assurance	

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				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.	information regarding recall.		

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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	

RISK MANAGEMENT
ANNEXURE II

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	

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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** : _____