RISK MANAGEMENT
ANNEXURE III

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1	Recall level not determined correctly - Impacted product could not be withdrawn from Correct level	- SOP – Recall and Product Withdrawal, is available at site.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	

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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

RISK MANAGEMENT
ANNEXURE III

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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	

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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	

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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	