



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**RISK MANAGEMENT
ANNEXURE I**

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1	Recall level not determined correctly	Impacted product could not be withdrawn from Correct level	4	3	2	24	High	Risk is Classified as High, as Severity of Impact is scored as 4.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.



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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 : _____