



**RISK MANAGEMENT  
ANNEXURE IV**

**SUMMARY AND CONCLUSION:**

**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.

**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.

**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.

**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.



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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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.

**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** : \_\_\_\_\_

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