Company Logo	**RISK IDENTIFICATION, ASSESSMENT & MITIGATION TEMPLATE**		
Template No	Effective Date Drafted by Authorised by	Review Date Approved by	Total Page 7

Introduction:

Today the risk management in Pharmaceuticals manufacturing and Control has become important consideration. The cGMP norms require proper identification, assessment, mitigation and prevention of the risk in all areas. Followings are the few potentially risky situations.

1.	Lack of standard operating procedures
2.	Abrupt unwarranted changes in process and analytical methods
3.	Changing the source of raw materials abruptly
4.	Incomplelete specifications of Raw materials/Finished Goods, unwarranted procedures
5.	Unknown personnel disabilities
6.	Employing untrained persons in production/QC/QA
7.	System failures
8.	Inappropriately designed machines and systems
9.	Un-validated Process and methods
10.	Poor maintenance
11.	The management interference **and** ignorance
12.	Missing links in the organization
13.	Low management commitments
14.	Poor man and material flow
15.	Cross contamination in production areas
16.	Undue microbial contamination in Purified water
17.	Inappropriate cleaning procedures
18.	Working in laboratory/production areas in street clothes
19.	Observation of rodent excreta in manufacturing and storage area
20.	Undue filth and microbial contamination
21.	Manufacturing Lactam products and non beta Lactam products side by side Cross contamination issues
22.	Open access to computerized data system
23.	Negligence
24.	Insufficient cleaning of equipments during product changeover
25	Poor vision (disability to see clearly) of final inspection staff
26	Ill health of the personnel in general

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27	Improper validation of EDP system involved in data entry and data maintenance

In addition to manufacturing preclinical studies, bio studies, clinical trials and marketing authorization applications also involve considerable risks.

This SOP is intended to provide a procedure to identify, mitigate and prevent all the risks associated over life history of the pharmaceutical products.

1.0 Responsibilities

Risk management is not a one man show. It requires active involvement of Manufacturing, Quality Control, Quality Assurance and Maintenance department.
Sometimes even the external agencies are involved in the risk management

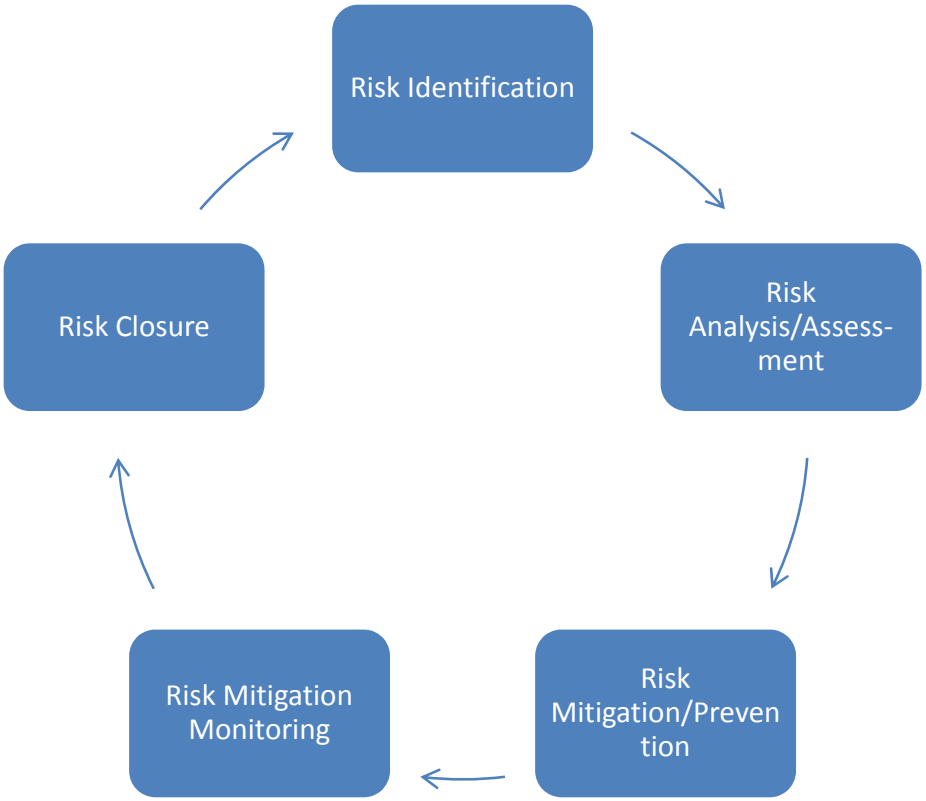
Personnel	Responsibilities
Risk Assessment Officer	To identify the risk
Manufacturing In charge	To report all deviations and unwarranted results in production
Maintenance In charge	To report equipment limitations and deficiencies
Quality Control In charge	To test the products
Quality Assurance	To control the entire process and to mitigate the situation

2.0 Scope

This protocol is applicable to all functions/procedures related to receipt, storage, release, manufacturing, packaging, maintenance, distribution, data handling, documentation, assay, impurity profiling, stability studies and bio studies as performed at pharmaceutical sites.
This SOP will facilitate identification, classification, mitigation and prevention of risk during manufacturing of following products ……..at ……

Procedure

The risk management shall involve the following functions:
Risk identification
Risk Assessment
Risk Mitigation and prevention
Risk closure



3.

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3.1 Risk Identification:

Each and every procedure involved in manufacturing or analysis of the product shall be assessed for the possible risk involved. The particular step of operation which is vulnerable to being wrong shall be identified and controlled
The observations shall be recorded as per follows against each SOP

No	The major system / component/ subsystem /SOP which carries risk.	Probability of risk factor (high ,medium or low)
1		
2		
3		
4		
5		
6		
7		

3.2 **Risk Assessment**

Risk assessment involves assessing the effect of risk on the purity, identity, efficacy, appearance, safety and yield of the product. Theoretically, following are the probabilities if the risk is not controlled

1. The product may not comply with Compendial specifications
2. The product may not withstand the stability
3. The product may lose the identity
4. The colour and appearance of the product may change
5. The product may develop undue impurities
6. The product may develop undue bacterial/viral load
7. The product may not comply with TSE/BSE
8. The product may fail in sterility

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9. The product may carry particulate matter
10. The product may fail in absorption/distribution as intended
11. The product may induce toxic reactions or undue side effects.
12. The product yield may be reduced
13. The product may fail to crystallize in required polymorphic form such as form1, form 2
14. The product may fail in enantiomeric purity

Risk Assessment Table

SOP No: **Title:** **Version No** **Effective Date:** **Review date:**	**SOP Clause No which carries Risk**	**Risk Impact (Critical, Subcritical, medium , Low)**

Identify any other subsystem or subsequent processing steps which may get affected by the risk.

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4. Risk Mitigation

Ideally, the risk mitigation and prevention shall be done till the risk is minimized to zero level. It shall be noted that the risk mitigation is not a onetime process. The new risks are born by changes at site, introduction of new products and updating of the regulation**.**
Following protocol may be followed for risk prevention/mitigation

	Mitigation Plan	Description	Action Taken
1.	**Describe what updating will be required in the process to minimize the risk**		
2.	**Describe the plan/in process tests to monitor the risk**		
3.	**Review the few batches for efficacy of risk control measures**		
4.	**Provide the frequency or exact dates for reviewing the risk control activities**		
5.	**Provide Risk Closing Rationale**		

Conclusion:

The pharmaceutical Manufacturing requires suitable risk management plan over the life history of the products manufactured at the site. The plans shall be live to accommodate changes in regulations, updating in product standards and the changes at the site.

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Notes:
The present protocol is a basic version. The same may be customized as per specific requirements. The readers are invited to post their queries on risk management at guptarmg1952@gmail.com

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