QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	**Risk Assessment No.:**

RISK ASSESSMENT

FOR

MIX-UP & CROSS CONTAMINATION

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FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	**Risk Assessment No.:**

TABLE OF CONTENTS

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

1.0 PRE APPROVAL:

The Author's signature indicates that the document has been prepared in accordance with existing cGMP standards and adequately reflects the tasks and deliverables necessary for Risk Assessment of Process / System / Equipment / Instrument.

Prepared by/ Function	Designation	Signature	Date
Quality Assurance			

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverables necessary for risk assessment of the Process / System / Equipment / Instrument and that the documentation and information included compiles with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head Quality Assurance			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Approved By / Function	Designation	Signature	Date
Quality Assurance			

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FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	**Risk Assessment No.:**

2.0 OVERVIEW:

2.1 Objective

The objective of the risk assessment is to identify different risks involved due to changes , addition, deletion, modification with respect to Mix up and cross contamination and to evaluate the impact of the risk on the quality product / patient, propose the corrective action and preventive action to mitigate / reduce the level of risk.

2.2 Scope

The scope of the risk assessment is to identify risk related to mix up and cross contamination.

3.0 REASON FOR RISK ASSESSMENT

The risk assessment shall be performed for following reason (√)

- New / Modification of Product / Process/ System / Equipment / Instrument
- Inclusion of additional parameters in Risk assessment
- Others (Specify)

  Mix-up and Cross Contamination

  _____

  _____

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

4.0 TEAM MEMBERS

Following team members have been involved in the brain storming session of the risk management of this activity.

Date: _____ **Time: _____** **Venue: _____**

Sr. No.	Name	Designation	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

The details of the discussion of the risk management of the activity, including the process flow of the activity, identification of the risks involved in the activity and corrective action and preventive action of the risk involved in the activity shall be recorded in section 5, 7 & 8.

After implementation of CAPA, the risk shall be recalculated and ensured to be at the acceptable level (Low).

Prepared By : _____ **Date : _____**

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QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

Reviewed By : _____ **Date : _____**

5.0 ACTIVITY: (PROCESS / SYSTEM / EQUIPMENT / INSTRUMENT)

Specify the activities wherein the risk assessment is required. (Tick the appropriate box)

Process	☐
System	☐
Equipment / Instrument	☐
Others: _____	☐

Description:

This document summarizes the quality risk management plan (QRMP) pertaining to Possible mix-ups and cross contamination for the products manufactured at the …….

A formalized risk management approach is applied to the manufacturing facility. This Involved a holistic assessment that identified the potential hazards and risks to product For all products handled in the facility to ensure that appropriate controls are in place to Manufacture these products safety.

Process Flow:

1. **Manufacturing Facility and Processes**

   Non sterile products are manufactured in unit dosage forms (e.g. Capsules and Tablets). No toxic or hazardous substance are used / manufactured in this facility.

2. **Facility Description**

   The walls and ceiling are of clean room partitions. The floor is concrete with epoxy paints, epoxy joints or epoxy coated. All floor and Ceiling joints are coved to avoid any sharp edges thereby eliminating possibility of Dust accumulation.

   To prevent any ingress of air/powder from each process room to the corridors, the Corridors are environmentally controlled and are maintained at positive pressure As compared to the individual rooms. Pressure balancing of each air handling System and overall pressure balancing has been carried out. Each Process Room

is supplied with controlled air through HEPA Filters. Return air Risers are provided in each room and are fitted with 10 micron filters. Dust extraction Systems are installed in the critical processing areas. The air quality in the processing areas complies with the class 8 of ISO 14644 Requirements.

The temperature in the processing areas is maintained below 25°C whereas the

Percentage relative humidity is maintained below 55% or as per requirement of area / product. The required pressure differential of not less than 10 Pascal across the processing area and corridor is maintained and monitored. Minimum 20 numbers of air changes per hour are maintained in the processing area. The processed air from the Air Handling unit is 90% recirculated with 10% addition of the fresh air.

Air filtration level is 10 micron return riser and fresh air intake, which is further filtered

Through pre filter followed by fine filters. All the supply ducts of process area rooms are having terminal EU13 HEPA filters.

Raw Water from MIDC and supplied tanker water, is poured in overhead raw water storage tank (150KL). Water from raw water overhead storage tank is transferred to MGF and UF unit. UF product water is transferred to overhead UF product tank. Water from this overhead UF product tank is supplied to Multi Grade Filter, Ultra Filtration, Softener and Reverse Osmosis (RO) unit. Water from pretreatment system is further supplied to Purified water generation system 1 and 2.

Purified water generation system 1 consists of Reverse Osmosis and Electro De-ionization unit (EDI) unit. Purified water generation system 2 consists of Reverse Osmosis and Septron unit.

3. Process and Manufacturing Equipment Description:

Each equipment system/facility/process is qualified prior to use. Qualification and Validation activities include User Requirement Specifications (URS), Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Re-qualification (RQ) and Supplementary Qualification (SQ).

The process validations are carried out by validation team. As per the cGMP Requirements the four basic types of process validation are as follows.

1. Prospective process validation: for new formula and new process.

2. Concurrent process validation: during actual implementation of the process.

3. Retrospective process validation: for existing products.

4. Re-validation: Any major changes in equipment I process I inputs.

4. Standard Operating Procedures, Personnel, Validation Plans

A well-defined gowning regime comprised of Primary and Secondary Gowning is implemented at site.

Basic training on cGMP, health & hygiene, safety procedure and on the various SOPs pertinent to job function is imparted to all the employees. Additionally, Operator Certification Program is implemented for the operators engaged in the Manufacturing activities to ensure that training on specific job requirements is imparted.

Well defined cleaning procedures are defined for the manufacturing requirement to Address the cleaning requirement between the manufacturing of batches for the same product as well as between the campaigns of two different products.

Risk Assessment

Risk Assessment of the manufacturing activities is performed on the following Guidelines,

1. **Specific Requirements for Handling Product in a Dedicated Facility**:

The Products manufactured at site do not belong to beta lactam, cephalosporin, Hormone, cytotoxic, biological category and hence, there is no specific requirement to manufactures these products in dedicated facility.

2. **Appropriate criteria to support cleaning**:

Proper utilization of equipment and facilities requires knowledge of the potential for retention of carryover from one product to another. This is a characteristic based on the chemical and physical nature of the compound and the design and materials of constructions of the equipment. The acceptable level of retention or carryover should be determined, on a case-by-case basis, taking into account the hazard(s) presented by the product and the nature and route of administration of the product that will next be processed in the equipment, unit, of facility.

3**. Route of cross contamination**:

3.1 **Mix ups**: Mix- up refers to the contamination at unsafe levels of one Product with another. The highest risks from mix-up normally stem from Low-tech GxP failures due to basic human error (e.g., failure to follow Procedure) or system weakness (e.g., poor material labeling).

3.2 **Retention**: It is defined as carryover of material on product contact Surface from one product to another in the same equipment used in a Sequential or campaign manner. The factors affecting retention relate to the effectiveness of the cleaning procedure and its application by Operating personnel following completion of a campaign, and include cleaning bi-products or cleaning material residues, as well as product Residues.

3.3 **Mechanical Transfer**: Mechanical transfer includes all routes all routes by which material can be transferred from contaminated non-product surfaces into the product. This includes product contact surface contaminated by contact with contaminated surface (e.g., in cleaning areas), inadvertent or transient contact with other contaminated non-designated product contact areas and direct contact of the product with such surfaces as operator apparels and gloves, is the lack of control of contaminated items. The risk of mechanical transfer can occur with the co-location of the process with contaminated equipment or items, e.g. operators wearing contaminated clothing or contact between processes Equipment contaminated with different materials.

3.4 **Airborne Transfer**: Factors to be considered when assessing whether the airborne transfer criteria is met include:

1) Open processing activities at both source and receiving points.

2) The transfer process of blend is through usage of Vacuum Transfer System to avoid process equipment with pressure driving forces to promote undesired transfer, e.g., positive pressure equipment at Source and/or negative pressure at receiving material positions the repeated transfer of material.

3) The transfer of in process material/blend is carried out transfer the Material from the in process bins/containers into another equipment installed in the same area and thereby avoiding cross contamination.

Facility - are there other GxP issues that might introduce risk? For example, would movement of personnel or materials within the facility or inadequate differential pressures between manufacturing zones give cause of concern? Are materials and personnel airlocks provided? If so, are they adequate at controlling airborne transfer?

If these factors can all be addressed satisfactorily, then the use of multi-product facility may be a viable option for the processing or manufacture of the material or product under consideration. If the answer is "no" or "not easily" to any of the above questions, then some element of dedication should be considered.

4**. Probability of Occurrence:**

The following are possible examples where the probability of failure or error May be enhanced, and these also should be considered as part of any review.

4.1 **Production Process Activities**

4.1.1 Operational Status - Set-Up, operation, cleaning:

The product manufacturing involves following activities -

1. Set up
2. Operation
3. Intervention for correction, end point determination, equipment failure
4. Disassembly
5. Cleaning

Each process step is evaluated to ensure that there are adequate procedural controls it does not provide a significant potential for exposure. The review of each of these items should ensure that the necessary actions can be performed and transfer of tools, material, and components to perform the tasks, can be done without significant or unacceptable exposure or carry over.

4.1.2 **Process and Exposures** - A specific process will have a Number of features, all of which may a greater or lesser impact on the risk of cross- contamination by one or more of the following routes.

1. Milling
2. Compaction
3. Blending

4. Fluidization

5. Compression

The dust generation inherent to above process is controlled through dust extraction systems. The manufacturing activities of only one product are performed in the particular processing area. Further, in view of the manual interface, the adequacy of training is ensured through the Operation Certification Program.

4.2 **Non-Processing Activities**:

4.2.1 **Waste Handling**: The risk analysis should cover all aspects of waste handling to ensure that items such as soiled clothing, disposable items (e.g., masks, gloves),and material/product waste streams are appropriately handled to avoid the potential for cross-contamination. Shared areas, e.g., common cleaning rooms, potentially containing simultaneously booth "dirty" and "clean" equipment from different process streams should be carefully considered.

4.2.2 **Planned and Unplanned Maintenance**: All planned maintenance activities should be review in sufficient detail to identify potential routes for cross contamination. The planned preventive maintenance shall take place outside of normal operating hours and by personnel other than those involved with the batch manufacture.

4.2.3 **Changeovers**: The changeover between one product and the next is an important aspect to be reviewed. The changeover activities are appropriately documented as part of a procedure and clearly indicate the sequence of the changeover work. Changeover between products may require that equipment change

Parts have to be removed from the line for one product and be replaced with change parts for the second product.

4.2.4 **Cleaning:** Cleaning can in itself create a potential risk of cross contamination if not performed properly. The cleaning procedures are reviewed and validated to ensure that they are sufficiently detailed for personnel to be able to follow them consistently and correctly.

5. Adequacy of Controls:

The procedural controls which are defined and are in place to mitigate the Possibility of mix up and cross contamination are reviewed for adequacy while performing the risk assessment activity. The review of the procedural Controls is detailed.

Further, various protocol based studies are carried out to verify the adequacy and effectiveness of procedural controls which are summarized below-

1. Cleaning verification / validation - To evaluate the effectiveness of equipment cleaning procedures.
2. Qualification, annual assessment requalification of equipment.
3. HVAC Qualification - Particle count generated in the area, recovery, air Flow pattern, pressure differential across the process areas, environmental Monitoring.
4. Purified Water system - Trending of key attribution of Water System
5. Study to find out possible contamination of process corridor due to man / material movement in the process areas.
6. Study to find out contamination level due to powder accumulation during manufacturing activities on the secondary gowning.
7. Study to verify effectiveness of linen washing procedure.
8. Study to fine out contamination level due to waste movement inside the process areas.

6.0 DEFINITIONS AND METHODOLOGY:

6.1 Severity of impact:

Identify the severity of impact of the risk on the quality of the product/service. Categorize the severity of impact of risk as Fundamental / High / Moderate / Minor / Insignificant as defined below and put score against each risk at section 7.0.

Category	Description	Score
Fundamental	Very significant and catastrophic impact	5
High	Significant losses and inefficiencies, necessitating timely adressal	4
Moderate	Loss of operating capability, deterioration of efficiency, management intervention required	3
Minor	Impact on operations and efficiency, but not pervasive	2
Insignificant	Limited or no impact on operations and quality of operational efficiency	1

6.2 Occurrence:

Identify the probability of occurrence of risk based on the occurrence frequency and put score against each risk at step 7.0.

Category	Probability of Occurrence	Description	Score
Almost certain	> 90 %	Is expected to occur in most circumstances	5
Likely	60-89 %	Will probably occur in most circumstances	4
Possible	25-59 %	Will probably occur at some time	3
Unlikely	10-24 %	Could occur at some time	2
Rare	< 10 %	May occur in exceptional circumstances	1

6.3 Detection:

Identify the level of detection of risk and give rating as below,

Category	Description	Score
Not aware/ No Control exists	Insufficient information to adequately assess and rate the control	5
Non existent / Very Little chance of detection	No procedural system in place, no risk reduction process procedure in place.	4
Not effective / Likely to be detected	Mitigation plans or risk reduction process & procedures though in place but do not ensure adequate control over risk occurrence / impact as the risk still exists over its acceptance level.	3
Effective / very likely to be detected	Approved Mitigation plans or risk reduction procedures, Checklists are laid down for early detection & immediate corrective actions are taken.	2
Very Effective / 100 % likelihood of detection	Mitigation plans or risk reduction process & procedures involve stringent approval and reporting norms with responsibility duly mapped to various management levels, minimizing possibility of occurrence / optimizing protection in the case of occurrence of the same at very early stage, controlling and reducing the risk.	1

Risk Ranking: Calculate the total score for the particular risk by multiplying the scores of Severity of impact, Occurrence and Detection

Categorize the risk as Low risk, Medium risk or high risk, as follow

RISK LEVEL	OBTAINED SCORE
HIGH RISK	125 to 64
MEDIUM RISK	Below 64 to 27
LOW RISK	Below 27

Upon evaluation of the risk, elaborate the methodology for notification of the risk, responsibility for the handling of risk and Corrective action, Preventive action (CAPA) plan for the identified risk.

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

Note: In addition to RPN No. calculation.

a. If any parameter is having severity as 'Fundamental or High' (i.e. 4 or 5 scale number) then final risk level should be decided as 'High' irrespective of RPN number.

b. If any parameter is having severity as 'Moderate' (i.e. 3 scale number) then final risk level should be decided as at least 'Medium' unless and otherwise the risk is classified as High with RPN greater than 64.

- Criteria 'a' & 'b' are applicable at the stage of identification of risk whereas after mitigation control the final risk level should be confirmed on the basis of RPN number only irrespective of individual severity scale.

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QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

7.0 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	**Mix up**							
1.1	Identification and status labeling/ controls of materials and products.	Mix -Up	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
1.2	Status Labeling/ controls of equipment and facilities	Mix -Up	4	2	2	16	High	Risk is classified as High as Severity of Impact is classified as “4”
1.3	Receipt and controls of materials and product	Mix -Up	5	2	1	10	High	Risk is classified as High as Severity of Impact is classified as “5”
1.4	Physical segregation, process flow and security during material and product handling, storage and staging.	Mix -Up	4	2	2	16	High	Risk is classified as High as Severity of Impact is classified as “4”
1.5	Inadequate line clearance between products.	Mix -Up	5	3	3	45	High	Risk is classified as High as Severity of Impact is classified as “5”
1.6	The accidental use of dirty equipment	Mix -Up	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
1.7	Introduction of rogue product during sampling	Mix -Up	5	1	2	10	High	Risk is classified as High as Severity of Impact is classified as “5”

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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
1.8	Incorporation of the wrong starting material or excipients.	Mix -Up	5	1	1	5	High	Risk is classified as High as Severity of Impact is classified as “5”
1.9	Mislabeling of equipment and /or materials	Mix -Up	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
1.10	Unintended transfer of materials or product from one vessel to another containing different product/ materials.	Mix -Up	5	1	1	5	High	Risk is classified as High as Severity of Impact is classified as “5”
1.11	Operator training and understanding of process requirements.	Mix -Up	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
1.12	Overlapping process flows and transit routes	Mix -Up	5	3	3	45	High	Risk is classified as High as Severity of Impact is classified as “5”
1.13	Common dispensary areas	Mix -Up	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
1.14	Common storage areas for change parts.	Mix -Up	5	3	2	30	High	Risk is classified as High as Severity of Impact is classified as “5”
2	**Retention**							
2.1	Use of processes requiring equipment with large surface areas for potential product contact	Cross Contamination	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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
2.2	Frequency of change over and cleaning	Cross Contamination	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
2.3	Any crevices or ledges where product can accumulate	Cross contamination	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
2.4	Drains	Cross contamination	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
2.5	Process creating sticky or “caked on” solids that may be difficult to clean	Cross contamination	5	2	3	30	High	Risk is classified as High as Severity of Impact is classified as “5”
2.6	The use of materials with poor solubility or wettability with the cleaning materials available	Cross contamination	5	2	3	30	High	Risk is classified as High as Severity of Impact is classified as “5”
3	**Mechanical Transfer**							
3.1	Usage of common accessories	Cross contamination	5	2	3	30	High	Risk is classified as High as Severity of Impact is classified as “5”
3.2	Release of the materials from the contaminated surface to the product	Cross contamination	5	2	3	30	High	Risk is classified as High as Severity of Impact is classified as “5”
3.3	Use of common gowning regimes	Cross contamination	5	2	4	40	High	Risk is classified as High as Severity of Impact is classified as “5”

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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
3.4	Use of common equipment, e.g. hand tools or change parts between different processes	Cross contamination	5	2	3	30	High	Risk is classified as High as Severity of Impact is classified as “5”
3.5	Manual, uncontained/ open processes	Cross contamination	5	2	3	30	High	Risk is classified as High as Severity of Impact is classified as “5”
4	**Airborne Transfer**							
4.1	Open processing activities in the area	Cross contamination	5	2	2	20	High	Risk is classified as High as Severity of Impact is classified as “5”
4.2	The transfer process of blend is through usage of vacuum Transfer System	Cross contamination	4	2	3	24	High	Risk is classified as High as Severity of Impact is classified as “4”
4.3	The transfer of in-process material/blend from the in process bins/ containers into another equipment installed in the same area	Cross contamination	4	2	3	24	High	Risk is classified as High as Severity of Impact is classified as “4”
4.4	The transfer of in-process material/blend from one area to another area	Cross contamination	4	2	2	16	High	Risk is classified as High as Severity of Impact is classified as “4”
4.5	Movement of personnel or material within the facility, inadequate differential pressures between manufacturing zone, materials and personnel airlocks.	Cross contamination	5	3	3	45	High	Risk is classified as High as Severity of Impact is classified as “5”
4.6	Contamination through Air Handling System	Cross contamination	5	2	4	40	High	Risk is classified as High as Severity of Impact is classified as “5”

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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
4.7	Contamination through Compressed Air System	Cross contamination	5	1	2	10	High	Risk is classified as High as Severity of Impact is classified as “5”

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Reviewed By : _____ **Date** : _____

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

8.0 NOTIFICATION AND CAPA:

8.1 NOTIFICATION AND CAPA OF HIGH RISK*:*

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ Date : _____

Reviewed By : _____ Date : _____

8.2 NOTIFICATION AND CAPA OF HIGH RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Identification and status labeling/ controls of materials and products.	Mix -Up	20	QA	Following SOP are available at plant for controlling the status labelling of materials and products 1. Status Labeling 2. Label Control	Personnel's working in the production are trained on the relevant procedures. Activities in the production shop floor are monitored by In Process Quality Assurance.	Respective department & QA	Nil
Status Labeling/ controls of equipment and facilities	Mix -Up	16	QA	Following SOP are available at plant for controlling the status labelling of materials and products 1. Status Labeling 2. Label Control Cause specific corrective actions are taken based upon investigation findings.	Personnel's working in the production are trained on the relevant procedures. Activities in the production shop floor are monitored by In Process Quality Assurance.	Respective department & QA	Nil
Receipt and controls of materials and product	Mix -Up	10	QA	Following SOP are available at plant for controlling the status of materials and products 1. Receipt and Storage of Raw Materials 2. Receipt and Storage of Packaging Materials 3. Storage and Transfer of Solvents 4. Handling, Storage of Rejected Raw and Packing Materials 5. Dispensing of Raw Materials 6. Receipt and Storage of Returned Finished Product.	Personnel's working in the production are trained on the relevant procedures. Materials are kept at required storage condition for the material in warehouse and production floor.	Respective department & QA	Nil
Physical segregation,	Mix -Up	16	QA	Cause specific corrective actions are	Process Flow diagrams are	Respective	Nil

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
process flow and security during material and product handling, storage and staging.				taken based upon investigation findings.	available in plant, which include Man Movement, Material movement, and waste movement. Storage of Raw Materials and Packing materials is done in warehouse area, maintaining storage conditions required by material. In process stores and Dispensed Raw Material holding areas are available to store the material at their required storage condition. Segregation of material is ensured through Line clearance system, labeling, pressure differentials and container closure systems.	department & QA	
Inadequate line clearance between products.	Mix -Up	45	QA	SOP on Line clearance is available at site to follow the line clearance procedure.	All persons involved in line clearance activity are trained on the procedure. Effectiveness check monitoring of Line clearance procedure is routinely checked as per the SOP of Line Clearance.	Respective department & QA	Nil
The accidental use of dirty equipment	Mix -Up	20	QA	Individual cleaning SOP are available for each production equipment. Usage and Cleaning details for each	Production and QA Personnel's involved in the activity are trained on the relevant SOP. Dirty equipment hold time has	Respective department & QA	Nil

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				equipment are recorded on the cleaning checklist and equipment log card. Hold time of equipment after Type A, B and C cleaning is defined in the SOP of Procedure for Storage and usage of equipment and accessories before and after cleaning.	been established as per protocol of Dirty Equipment Hold Time. Hold time of equipment is verified during the line clearance activity of equipment.		
Introduction of rogue product during sampling	Mix -Up	10	QA	Following SOP are available to control the error during sampling 1.In process and finished product sampling 2. In process Control	Production and QA Personnel's involved in the activity are trained on the relevant SOP.	Respective department & QA	Nil
Incorporation of the wrong starting material or excipients.	Mix -Up	5	QA	Dispensing of material of materials is done based on Process Order generated from SAP, based on the recipe. Dispensing of material is done as per SOP Dispensing of Materials. As per SOP of Dispensing of Raw Material, all materials are verified for identification based on Material code, Batch Number and quantity.	Procedure for Receipt and Verification of Dispensed Raw Material, is available to verify the material after dispensing. Procedure for line clearance is available to verify the each activity before starting.	Respective department & QA	Nil
Mislabeling of equipment and /or materials	Mix -Up	20	QA	Following SOP are available at plant for controlling the status labelling of materials and products 1. Status Labeling 2. Label Control.	Personnel's working in the production are trained on the relevant procedures. Activities in the production shop	Respective department & QA	Nil

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
					floor are monitored by In Process Quality Assurance		
Unintended transfer of materials or product from one vessel to another containing different product/ materials.	Mix -Up	5	QA	Only one type of material or product is handled in the processing area at one time. Each Step of manufacturing is carried out as per the instruction defined in the Batch Manufacturing Record.	Every stage and step of material processing is labeled as per respective SOP. All the personnel's working in the area are trained on the cGMP practices every year. In-process and finished product testing is done as per approved specification in Quality Control Laboratory. Any unintended results are investigated as per Procedure for the Investigation and Disposition of Aberrant test results	Respective department & QA	
Operator training and understanding of process requirements.	Mix -Up	20	QA	Every operator in the facility is trained as per SOP of – 1. Training. 2. Analyst Certification	Each Step of manufacturing is carried out as per the instruction defined in the Batch Manufacturing Record. Every activity done, is being checked by a different second personnel. In process Control checks are carried out by production supervisor and QA personnel as	Respective department & QA	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
					per SOP In process Control. All the personnel's working in the area are trained on the cGMP practices every year.		
Overlapping process flows and transit routes	Mix -Up	45	QA	Cause specific corrective actions are taken based upon investigation findings.	Process Flow diagrams are available in plant, which include Man Movement, Material movement, and waste movement. Segregation of material is ensured through Line clearance system, labeling, pressure differentials and container closure systems.	Respective department & QA	
Common dispensary areas	Mix -Up	20	QA	Dispensing of material is done as per SOP Dispensing of Materials. As per SOP of Dispensing of Raw Material, all materials are verified for identification based on Material code, Batch Number and quantity. Dedicated product specific dispensed label is attached to each material after dispensing.	Procedure for Receipt and Verification of Dispensed Raw Material, is available to verify the material after dispensing. Procedure for line clearance is available to verify the each activity before starting. Cleaning of Dispensary areas is being done as per SOP Dispensing of Materials, after every material change over.	Respective department & QA	
Common storage areas for change parts.	Mix -Up	30	QA	Change parts used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of	All the change parts are cleaned after use as per respective SOP. All the change parts are labeled, segregated and wrapped to avoid	Respective department & QA	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				Accessories 3. Procedure for Issue, Cleaning, and Storage of Tablet Tooling. 4. Handling of Hose Pipes/ /Marprene Tubes / Silicon Tubes. 5. Procedure for procurement, receipt, inspection, issuance and storage of Packaging change parts.	the mixup.		
Use of processes requiring equipment with large surface areas for potential product contact	Cross Contamination	20	QA	Each equipment in production area is having an SOP of operation and cleaning. Cleaning of equipment is verified and validated for product as per the SOP Cleaning Validation.	Validated cleaning procedures are revivified at periodic frequency, as per SOP of Cleaning Validation. SOP of Line Clearance is available for ensuring equipment cleaning before start of the activity.	Respective department & QA	
Frequency of change over and cleaning	Cross Contamination	20	QA	Individual cleaning SOP are available for each production equipment. Frequency of cleaning is defined in the operation and cleaning procedure of each equipment. Hold time of equipment after Type A, B and C cleaning is defined in the SOP of Procedure for Storage and usage of equipment and accessories before and after cleaning. Usage and Cleaning details for each equipment are recorded on the	Production and QA Personnel's involved in the activity are trained on the relevant SOP. Dirty equipment hold time and Clean equipment hold time has been established as per protocol. Hold time of equipment is verified during the line clearance activity of equipment.	Respective department & QA	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				cleaning checklist and equipment log card.			
Any crevices or ledges where product can accumulate	Cross contaminati on	20	QA	Individual cleaning SOP are available for each production equipment. Manufacturing and process areas are cleaned as per SOP of Cleaning and Sanitization of Process Room / Other Manufacturing Areas. Hard to clean areas of each equipment are identified during evaluation of equipment as per SOP of Cleaning Validation	Cleaning procedures used for equipment cleaning are verified and validated as per procedure of Cleaning Validation SOP of Line Clearance is available for ensuring equipment cleaning before start of the activity.	Respective department & QA	
Drains	Cross contaminati on	20	QA	SOP Cleaning and Sanitization of drains is available at site to clean the drains at periodic frequency.	Drains available in area are of Air brake design.	Respective department & QA	
Process creating sticky or “caked on” solids that may be difficult to clean	Cross contaminati on	30	QA	Individual cleaning SOP are available for each production equipment. Manufacturing and process areas are cleaned as per SOP of Cleaning and Sanitization of Process Room / Other Manufacturing Areas. Hard to clean areas of each equipment are identified during evaluation of equipment as per SOP	Cleaning procedures used for equipment cleaning are verified and validated as per procedure of Cleaning Validation. SOP of Line Clearance is available for ensuring equipment cleaning before start of the activity.	Respective department & QA	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				of Cleaning Validation			
The use of materials with poor solubility or wettability with the cleaning materials available	Cross contaminati on	30	QA	Every product before introduction is evaluated as per SOP of Cleaning Validation, for LD50 and Solubility.	Based on the Solubility Worst case products are identified and validated as per SOP Cleaning Validation	Respective department & QA	
Mechanical Transfer							
Usage of common accessories	Cross contaminati on	30	QA	Accessories used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2.Cleaning and Storage of Accessories 3.Handling of Hose Pipes / Marprene Tubes / Silicon Tubes.	Cleaning procedure of accessories has been verified as per protocol for cleaning verification of dispensing, sampling tools and production accessories.	Respective department & QA	
Release of the materials from the contaminated surface to the product	Cross contaminati on	30	QA	Change parts used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of Accessories 3. Procedure for Issue, Cleaning, and Storage of Tablet Tooling. 4. Handling of Hose Pipes/ /Marprene Tubes / Silicon Tubes. 5. Procedure for procurement, receipt, inspection, issuance and storage of Packaging change parts.	All the change parts and accessories are cleaned after use as per respective SOP.	Respective department & QA	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
				6. Procedure for cleaning of Pallets.			
Use of common gowning regimes	Cross contamination	40	QA	All employees working in production area are required to follow the SOP of Entry and Exit inn Solid Dosage As per SOP Persons other than performing the activities in the process room if they stay for more than 15 minute in the process room then the person has to discard the secondary gown, hand gloves and wear fresh over gown, booties, mask and hand gloves before entering into another process room.	All the employees in production are trained on the SOP of Entry and Exit in Solid Dosage. Study for gowning contamination has been done as per protocol for Contamination Study for Personnel Movement.	Respective department & QA	
Use of common equipment, e.g. hand tools or change parts between different processes	Cross contamination	30	QA	Change parts used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of Accessories 3. Procedure for Issue, Cleaning, and Storage of Tablet Tooling. 4. Handling of Hose Pipes/ /Marprene Tubes / Silicon Tubes. 5. Procedure for procurement, receipt, inspection, issuance and storage of Packaging change parts. 6. Procedure for cleaning of Pallets.	All the change parts and accessories are cleaned after use as per respective SOP. Cleaning procedure of accessories has been verified as per protocol for cleaning verification of dispensing, sampling tools and production accessories.	Respective department & QA	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Manual, uncontained/ open processes	Cross contaminati on	30	QA	Wherever possible closed equipment's are used in the production. Vacuum transfer systems are available in production area (Granulation and compression) to transfer the material in closed condition.	Cleaning procedure for area and equipment and accessories are available to handle dust generation for open process. Only one product in processed in the processing area at one time. Pressure differentials are maintained between process area and corridor so that process dust is contained in the processing area only. Terminal HEPA filters are installed in processing areas. Dust extraction systems are available in process area to handle high dust generating areas.	Respective department & QA	
Airborne Transfer							
Open processing activities in the area	Cross contaminati on	20	QA	Wherever possible closed equipment's are used in the production. Vacuum transfer systems are available in production area (Granulation and compression) to transfer the material in closed	Cleaning procedure for area and equipment and accessories are available to handle dust generation for open process. Only one product in processed in the processing area at one time.	Respective department & QA	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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				condition.	Pressure differentials are maintained between process area and corridor so that process dust is contained in the processing area only. Terminal HEPA filters are installed in processing areas. Dust extraction systems are available in process area to handle high dust generating areas like granulation, and compression.		
The transfer process of blend is through usage of vacuum Transfer System	Cross contamination	24	QA	Vacuum transfer systems are available in production area (Granulation and compression) to transfer the material in closed condition.	Cleaning procedures are available to clean the vacuum transfer systems.	Respective department & QA	
The transfer of in-process material/blend from the in process bins/ containers into another equipment installed in the same area	Cross contamination	24	QA	Were ever possible Vacuum transfer systems are used in the production area. (Granulation and Compression)	Cleaning procedures are available to clean the vacuum transfer systems. Dust extraction systems are available in process area to handle high dust generating areas like granulation, and compression. Pressure differentials are maintained between process area and corridor so that process dust is contained in the processing area only.	Respective department & QA	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
					Cleaning procedure for area and equipment and accessories are available to handle dust generation for open process. Only one product in processed in the processing area at one time.		
The transfer of in-process material/blend from one area to another area	Cross contamination	16	QA	SOP Handling of In Process Materials is available, to handle the transfer of materials / blend from one area to another area.	All the personnel's involved in the activity are trained on the SOP of handling of In Process materials.	Respective department & QA	
Movement of personnel or material within the facility, inadequate differential pressures between manufacturing zone, materials and personnel airlocks.	Cross contamination	45	QA	Schematic for Material and Man movement is available in the production area. Pressure Differential in the area is checked as per the SOP Environmental Monitoring.	Production areas are designed considering the positive corridors and negative process rooms. Personnel's working in the area are trained on the SOP of Environmental Monitoring.	Respective department & QA	
Contamination through Air Handling System	Cross contamination	40	QA	Air Handling Units in the process areas are installed with Terminal HEPA Filters. Areas were common AHU are catering, a contamination study as per protocol of Contamination Study of Same AHU has been performed.	Air Handling units installed are validated before use. Routine requalification of AHU systems is done as per SOP Periodic revalidation of HVAC system. AHU designing has been done considering the corridors positive with respect to process areas.	Respective department & QA	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks
Contamination through Compressed Air System	Cross contaminati on	10	QA	0.2 Micron terminal cartridge filters are available at terminal of compressed air system.	Compressed air system qualified before usage as per approved protocols. Routine periodic revalidation of Compressed air system is being done as per SOP.	Respective department & QA	

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

8.3 NOTIFICATION AND CAPA OF LOW RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

8.4 MITIGATION CONYROL& 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	**Mix up**							
1.1	Identification and status labeling/ controls of materials and products	Following SOP are available at plant for controlling the status labelling of materials and products • Status Labeling • Label Control Personnel's working in the production are trained on the relevant procedures. Activities in the production shop floor are monitored by In Process Quality Assurance.	5	2	1	10	Low	
1.2	Status Labeling/ controls of equipment and facilities	Following SOP are available at plant for controlling the status labelling of materials and products • Status Labelling • Label Control Personnel's working in the production are trained on the relevant procedures. Activities in the production shop floor are monitored by In Process Quality Assurance	4	2	1	8	Low	
1.3	Receipt and controls of materials and product	Following SOP are available at plant for controlling the status of materials and products • Receipt and Storage of Raw Materials • Receipt and Storage of Packaging Materials • Storage and Transfer of Solvents • Handling, Storage of Rejected Raw and Packing Materials • Dispensing of Raw Materials • Receipt and Storage of Returned Finished Product • Personnel's working in the production are trained on the	5	2	1	10	Low	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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		relevant procedures. Materials are kept at required storage condition for the material in warehouse and production floor.						
1.4	Physical segregation, process flow and security during material and product handling, storage and staging.	Cause specific corrective actions are taken based upon investigation findings. Process Flow diagrams are available in plant, which include Man Movement, Material movement, and waste movement. Storage of Raw Materials and Packing materials is done in warehouse area, maintaining storage conditions required by material. In process stores and Dispensed Raw Material holding areas are available to store the material at their required storage condition. Segregation of material is ensured through Line clearance system, labeling, pressure differentials and container closure systems.	4	2	1	8	Low	
1.5	Inadequate line clearance between products.	SOP on Line clearance is available at site to follow the line clearance procedure. All persons involved in line clearance activity are trained on the procedure. Effectiveness check monitoring of Line clearance procedure is routinely checked as per the SOP of Line Clearance.	5	3	1	15	Low	
1.6	The accidental use of dirty equipment	Individual cleaning SOP are available for each production equipment. Usage and Cleaning details for each equipment are recorded on the cleaning checklist and equipment log card. Hold time of equipment after Type A, B and C cleaning is defined in the SOP of Procedure for Storage and usage of equipment and	5	2	1	10	Low	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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		accessories before and after cleaning Production and QA Personnel's involved in the activity are trained on the relevant SOP. Dirty equipment hold time has been established as per protocol of Dirty Equipment Hold Time. Hold time of equipment is verified during the line clearance activity of equipment.						
1.7	Introduction of rogue product during sampling	Following SOP are available to control the error during sampling 1.In process and finished product sampling 2. In process Control Production and QA Personnel's involved in the activity are trained on the relevant SOP.	5	1	1	5	Low	
1.8	Incorporation of the wrong starting material or excipients.	Dispensing of material of materials is done based on Process Order generated from SAP, based on the recipe. Dispensing of material is done as per SOP Dispensing of Materials. As per SOP of Dispensing of Raw Material, all materials are verified for identification based on Material code, Batch Number and quantity. Procedure for Receipt and Verification of Dispensed Raw Material, is available to verify the material after dispensing. Procedure for line clearance is available to verify the each activity before starting.	5	1	1	5	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
1.9	Mislabeling of equipment and /or materials	Following SOP are available at plant for controlling the status labelling of materials and products 1. Status Labelling. 3. Label Control. Personnel's working in the production are trained on the relevant procedures. Activities in the production shop floor are monitored by In Process Quality Assurance	5	2	1	10	Low	
1.10	Unintended transfer of materials or product from one vessel to another containing different product/ materials.	Only one type of material or product is handled in the processing area at one time. Each Step of manufacturing is carried out as per the instruction defined in the Batch Manufacturing Record. Every stage and step of material processing is labeled as per respective SOP. All the personnel's working in the area are trained on the cGMP practices every year. In-process and finished product testing is done as per approved specification in Quality Control Laboratory. Any unintended results are investigated as per Procedure for the Investigation and Disposition of Aberrant test results.	5	1	1	5	Low	
1.11	Operator training and understanding of process requirements.	Every operator in the facility is trained as per SOP of – 1. Training. 2. Analyst Certification.	5	2	1	10	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
		Each Step of manufacturing is carried out as per the instruction defined in the Batch Manufacturing Record. Every activity done, is being checked by a different second personnel. In process Control checks are carried out by production supervisor and QA personnel as per SOP In process Control. All the personnel's working in the area are trained on the cGMP practices every year						
1.12	Overlapping process flows and transit routes	Cause specific corrective actions are taken based upon investigation findings. Process Flow diagrams are available in plant, which include Man Movement, Material movement, and waste movement. Segregation of material is ensured through Line clearance system, labeling, pressure differentials and container closure systems.	5	3	1	15	Low	
1.13	Common dispensary areas	Dispensing of material is done as per SOP of Dispensing of Materials. As per SOP of Dispensing of Raw Material, all materials are verified for identification based on Material code, Batch Number and quantity. Dedicated product specific dispensed label is attached to each material after dispensing. Procedure for Receipt and Verification of Dispensed Raw Material, is available to verify the material after dispensing.	5	2	1	10	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
		Procedure for line clearance is available to verify the each activity before starting. Cleaning of Dispensary areas is being done as per SOP – Dispensing of Materials, after every material change over.						
1.14	Common storage areas for change parts.	Change parts used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of Accessories 3. Procedure for Issue, Cleaning, and Storage of Tablet Tooling. 4. Handling of Hose Pipes/ /Marprene Tubes / Silicon Tubes. 5. Procedure for procurement, receipt, inspection, issuance and storage of Packaging change parts. All the change parts are cleaned after use as per respective SOP. All the change parts are labeled, segregated and wrapped to avoid the mixup.	5	3	1	15	Low	
2	**Retention**							
2.1	Use of processes requiring equipment with large surface areas for potential product contact	Each equipment in production area is having an SOP of operation and cleaning. Cleaning of equipment is verified and validated for product as per the SOP Cleaning Validation. Validated cleaning procedures are revivified at periodic frequency, as per SOP of Cleaning Validation.	5	2	1	10	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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		SOP of Line Clearance is available for ensuring equipment cleaning before start of the activity.						
2.2	Frequency of change over and cleaning	Individual cleaning SOP are available for each production equipment. Frequency of cleaning is defined in the operation and cleaning procedure of each equipment. Hold time of equipment after Type A, B and C cleaning is defined in the SOP of Procedure for Storage and usage of equipment and accessories before and after cleaning. Usage and Cleaning details for each equipment are recorded on the cleaning checklist and equipment log card. Production and QA Personnel's involved in the activity are trained on the relevant SOP. Dirty equipment hold time and Clean equipment hold time has been established as per protocol. Hold time of equipment is verified during the line clearance activity of equipment available for each production equipment.	5	2	1	10	Low	
2.3	Any crevices or ledges where product can accumulate	Manufacturing and process areas are cleaned as per SOP of Cleaning and Sanitization of Process Room / Other Manufacturing Areas. Hard to clean areas of each equipment are identified during evaluation of equipment as per SOP of Cleaning Validation – Cleaning procedures used for equipment cleaning are verified and validated as per procedure of Cleaning Validation.	5	2	1	10	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
		SOP of Line Clearance is available for ensuring equipment cleaning before start of the activity.						
2.4	Drains	SOP Cleaning and Sanitization of drains is available at site to clean the drains at periodic frequency. Drains available in area are of Air brake design.	5	2	1	10	Low	
2.5	Process creating sticky or “caked on” solids that may be difficult to clean	Individual cleaning SOP are available for each production equipment. Manufacturing and process areas are cleaned as per SOP of Cleaning and Sanitization of Process Room / Other Manufacturing Areas. Hard to clean areas of each equipment are identified during evaluation of equipment as per SOP of Cleaning Validation Cleaning procedures used for equipment cleaning are verified and validated as per procedure of Cleaning Validation. SOP of Line Clearance is available for ensuring equipment cleaning before start of the activity.	5	2	1	10	Low	
2.6	The use of materials with poor solubility or wettability with the cleaning materials available	Every product before introduction is evaluated as per SOP of Cleaning Validation, for LD50 and Solubility. Based on the Solubility Worst case products are identified and validated as per SOP Cleaning Validation.	5	2	1	10	Low	
3	**Mechanical Transfer**							

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
3.1	Usage of common accessories	Accessories used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of Accessories 3. Handling of Hose Pipes / Marprene Tubes / Silicon Tubes. Cleaning procedure of accessories has been verified as per protocol for cleaning verification of dispensing, sampling tools and production accessories.	5	2	1	10	Low	
3.2	Release of the materials from the contaminated surface to the product	Change parts used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of Accessories 3. Procedure for Issue, Cleaning, and Storage of Tablet Tooling. 4. Handling of Hose Pipes/ /Marprene Tubes / Silicon Tubes. 5. Procedure for procurement, receipt, inspection, issuance and storage of Packaging change parts. 6. Procedure for cleaning of Pallets. All the change parts and accessories are cleaned after use as per respective SOP.	5	2	1	10	Low	
3.3	Use of common gowning regimes	All employees working in production area are required to follow the SOP of Entry and Exit inn Solid Dosage As per SOP Persons other than performing the activities in the process room if they stay for more than 15 minute in the process room then the person has to discard the secondary gown, hand gloves and wear fresh over gown, booties, mask and hand gloves before entering into another	5	2	1	10	Low	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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		process room. All the employees in production are trained on the SOP of Entry and Exit in Solid Dosage. Study for gowning contamination has been done as per protocol for Contamination Study for Personnel Movement.						
3.4	Use of common equipment, e.g. hand tools or change parts between different processes	Change parts used production activities are maintained as per respective defined procedure – 1. Handling of Sieves and Screens 2. Cleaning and Storage of Accessories 3. Procedure for Issue, Cleaning, and Storage of Tablet Tooling. 4. Handling of Hose Pipes/ /Marprene Tubes / Silicon Tubes. 5. Procedure for procurement, receipt, inspection, issuance and storage of Packaging change parts. 6. Procedure for cleaning of Pallets. All the change parts and accessories are cleaned after use as per respective SOP. Cleaning procedure of accessories has been verified as per protocol for cleaning verification of dispensing, sampling tools and production accessories.	5	2	1	10	Low	
3.5	Manual, uncontained/ open processes	Wherever possible closed equipment's are used in the production. Vacuum transfer systems are available in production area (Granulation and compression) to transfer the material in closed condition. Cleaning procedure for area and equipment and accessories are available to handle dust generation for open process.	5	2	1	10	Low	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
		Only one product in processed in the processing area at one time. Pressure differentials are maintained between process area and corridor so that process dust is contained in the processing area only. Terminal HEPA filters are installed in processing areas. Dust extraction systems are available in process area to handle high dust generating areas.						
4	**Airborne Transfer**							
4.1	Open processing activities in the area	Wherever possible closed equipment's are used in the production. Vacuum transfer systems are available in production area (Granulation and compression) to transfer the material in closed condition. Cleaning procedure for area and equipment and accessories are available to handle dust generation for open process. Only one product in processed in the processing area at one time. Pressure differentials are maintained between process area and corridor so that process dust is contained in the processing area only. Terminal HEPA filters are installed in processing areas. Dust extraction systems are available in process area to handle high dust generating areas like granulation, and compression.	5	2	1	10	Low	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.: | **Risk Assessment No.:**

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)
4.2	The transfer process of blend is through usage of vacuum Transfer System	Vacuum transfer systems are available in production area (Granulation and compression) to transfer the material in closed condition. Cleaning procedures are available to clean the vacuum transfer systems.	4	2	1	8	Low	
4.3	The transfer of in-process material/blend from the in process bins/ containers into another equipment installed in the same area	Were ever possible Vacuum transfer systems are used in the production area. (Granulation and Compression) Cleaning procedures are available to clean the vacuum transfer systems. Dust extraction systems are available in process area to handle high dust generating areas like granulation, and compression. Pressure differentials are maintained between process area and corridor so that process dust is contained in the processing area only. Cleaning procedure for area and equipment and accessories are available to handle dust generation for open process. Only one product in processed in the processing area at one time.	4	2	1	8	Low	
4.4	The transfer of in-process material/blend from one area to another area	SOP Handling of In Process Materials is available, to handle the transfer of materials / blend from one area to another area. All the personnel's involved in the activity are trained on the SOP of handling of In Process materials.	4	2	1	8	Low	
4.5	Movement of personnel or material within the facility, inadequate differential pressures between	Schematic for Material and Man movement is available in the production area.	5	3	1	15	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)
	manufacturing zone, materials and personnel airlocks.	Pressure Differential in the area is checked as per the SOP for Environmental Monitoring. Production areas are designed considering the positive corridors and negative process rooms. Personnel's working in the area are trained on the SOP of Environmental Monitoring.						
4.6	Contamination through Air Handling System	Air Handling Units in the process areas are installed with Terminal HEPA Filters. Areas were common AHU are catering, a contamination study as per protocol of Contamination Study of Same AHU has been performed. Air Handling units installed are validated before use. Routine requalification of AHU systems is done as per SOP for Periodic revalidation of HVAC system. AHU designing has been done considering the corridors positive with respect to process areas.	5	2	1	10	Low	
4.7	Contamination through Compressed Air System	0.2 Micron terminal cartridge filters are available at terminal of compressed air system. Compressed air system qualified before usage as per approved protocols. Routine periodic revalidation of Compressed air system is being done as per SOP.	5	1	1	5	Low	

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	**Risk Assessment No.:**

9.0 TRAINING AND EVALUATION RECORD:

Date :	Timing : From _____ to_____
Venue :	Name of Trainer :
Title : Risk Assessment	Method of training:

S. No.	Name of Employee	Employee Code	Evaluation Details	
			Signature of Trainee	Remarks

Signature of Trainer (Sign/Date): _____

Comments:

_____

_____

_____

Verified By: _____ Date : _____

10.0 SUMMARY AND CONCLUSION:

10.1 Evaluation of Data:

During risk identification all the process / ways / methods / systems are considered for evaluation and identification of ways for mix up and contamination.

10.2 Mitigation Plan:

The adequacy and effectiveness of laid down systems and procedures is evaluated, for the identified risk and appropriate CAPA plan available in system has been identified and enlisted.

10.3 Evaluation of Risk Involved after Mitigation Control:

All the procedural controls found in place as mitigation control for the identified risk. After assessment of the mitigation control risk level found to be reduced to low level.

10.4 Summary:

The Risk Management activity for cross contamination and mix up is carried out. The possible pathways which could contribute to cross contamination or mix up during the product manufacturing activity are identified and mitigation plan comprised of training of employees, procedural controls as well the detection mechanism to identify Mechanism to identify incidents is reviewed as part of risk assessment and found Satisfactory.

10.5: Conclusion

Based upon the Risk management activities it is concluded that well defined systems and procedures are in place controls mitigate possible mix up and cross Contamination.

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

11.0 REFERENCE DOCUMENTS:

S.No.	Title

Reviewed By : _____ Date : _____

12.0 ABBREVIATION:

S.No.	Abbreviation	Description

Reviewed By : _____ Date : _____

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MIX-UP & CROSS CONTAMINATION

Reference Document No.:	Risk Assessment No.:

13.0 ATTACHMENTS:

S.No.	Description

Reviewed By : _____ Date : _____

14.0 COMPLIANCE VERIFICATION:

S.No.	DESCRIPTION	COMPLIANCE (Y/N)	VERIFIED BY

Reviewed By : _____ Date : _____

15.0 POST APPROVAL:

This is hereby certified by the following functionaries, that the risk assessment of the activity in the department stands qualified for its intended purpose.

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverable necessary for risk management and all associated equipment/instruments and systems and that the documentation and information included complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head Quality Assurance			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			