QUALITY RISK ASSESSMENT & MITIGATION PLAN	
FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA	
Reference Document No.:	**Risk Assessment No.:**

QUALITY RISK ASSESSMENT & MITIGATION PLAN

(FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKINGS OF DISPENSING AREAS)

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.:	Risk Assessment No.:

1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk of not having interlocking in dispensing area.

2. **SCOPE:** The scope of this document is limited to interlocking of all Dispensing areas at ……..facility.

3. **RESPONSIBILITY:**

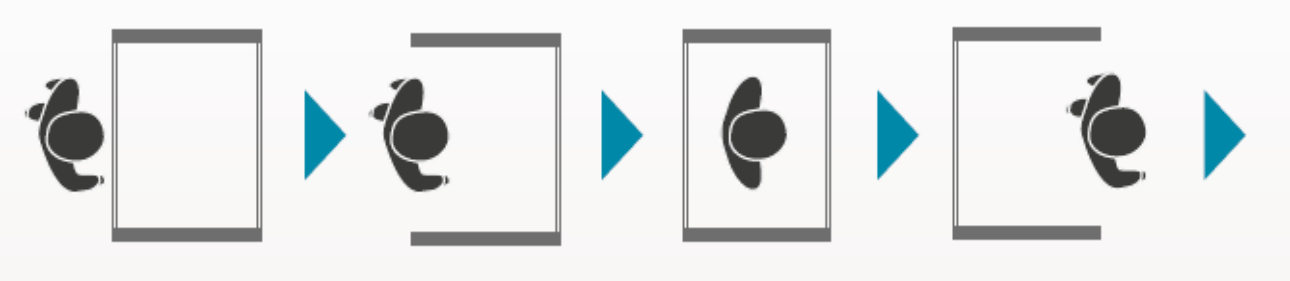
Department	Responsibility
Quality Assurance	• Preparation, Review, and Compilation of FMEA • Post Approval of FMEA
Warehouse	• Review of FMEA

4. **REASON FOR RISK ANALYSIS:**
To mitigate & monitor the risk associated with the absence of interlocking in Dispensing areas.

5. **SITE OF STUDY: ……..**

6. **RISK COMMUNICATION & TRAINING:**
   - The Risk analysis team shall be authorized by the Head-QA or his/her designee.
   - Quality Risk Management Team shall be cross functional team comprised of expert from different areas.
   - Training shall be imparted to the concerned team.

7. **RISK IDENTIFICATION, EVALUATION & MITIGATION:**
In its simplest form, an interlocking system is composed of two doors electronically connected so one cannot open until the other has closed.



Using identification, you enter the first door which must close behind you before the second door opens and allows you to pass through.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.:	Risk Assessment No.:

Airlock I

Airlock II

Airlock III

Encircled areas are the interlocking of all doors of dispensing areas.

Dispensing area is having bubble system, approve area is having low pressure in comparison to Airlock I, while Airlock I is having low pressure in comparison to Airlock II while Dispensing area is having lower pressure then Airlock II. All doors opens at high pressure and consist of door lockers. Doors automatically closed due to high pressure.

Bubble system

Approved Area	Airlock I	Airlock II	Dispensing area
+	++	+++	++

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
• In case of absence or malfunction of interlocking in Dispensing area doors: 1. There may be the chance of cross contamination during pressure differential failure 2. Classified area may got disturbed. 3. Pressure Differential not maintained. 4. HEPA & Return risers got disturbed. 5. Spillage may take place in Approved area. 6. Spillage may take place in Dispensing area.	• Malfunction or absence of interlocking does not have any direct impact on product quality.	• Sufficient controls are in place: 1. Door closures are available. 2. Bubble system is in place to control cross contamination. 3. One door is opened at a time. 4. Dedicated AHU is for each Dispensing area.

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.:	Risk Assessment No.:

5. RISK ASSESSMENT TOOL:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or Instruction for each column is described in the following paragraph.

Column 1	Serial number of Risk Analysis item.
Column 2	Item/Function: Identify the process step or component associated with the risk.
Column 3	Potential Failure Mode: Identify the type of risk associated with the process or component.
Column 4	Effect of Potential Failure/Cause: Verify that whether risk have GMP impact.
Column 5	Potential Cause
Column 6	Risk Mitigation as a Current Control: Write the risk mitigation strategy as considered in design.
Column 7	References
Column 8/9/10/11	Severity/Occurrence/Detection/Risk level/Risk Acceptance: Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 12	Recommended action: Recommended actions should be given for controlling failure occurrence.
Column13/14/15/16	Severity/Occurrence/Detection/Risk level/Risk Acceptance: After recommendation implementations, Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.

Table 1: Instruction for each column given above

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification | **Risk Assessment No.:**

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Interlocking in Dispensing areas | **Quality Risk Assessment Date:**

S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
1.	**Door Interlocking**	• Malfunction in interlocking • No Interlocking	• Cross-contamination • Door will remain open • Pressure differential not maintained • Chocking of HEPA &Riser filter • Air loss occur from Airlocks to adjacent area which leads to contamination.	• Slight opening in door will decrease the pressure differential up to zero resulting into entry of powder from unclassified approved area • Malfunctioned interlocking may result into door opening and disturbed the pressure differential • Opened doors may result into contamination from approved unclassified area which may choke the HEPA & Riser filters. • Door opening may result into air loss which further result into zero pressure	• Bubble system is in place to avoid any cross contamination • Door locks are available, hence failure of interlocking does not have any impact on surrounding areas. • Doors automatically closed as doors opens towards high pressure. • Pressure Differential are monitored after every 4 hour. • Filters are qualified as per planner & risers are cleaned as per schedule. • Filters are cleaned as per schedule • Doors are opened once at a time.	• SOP of Contamination & Cross Contamination • Area Qualification. • Environment monitoring • Preventive maintenance • Building maintenance • Filter cleaning SOP	3	2	1	**6** **Severity** is high as failure of interlocking may result into area failure **Occurrence** is possible **Detectability** is high as failure can be easily detected.	No any recommended action required, as failure shall be corrected immediately	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification | **Risk Assessment No.:**

S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
		• Malfunction in interlocking • No Interlocking	• Two Airlock door can open at a time which leads to disturb in differential pressure • Classified and Non classified area get disturbed • More power consumption • Low RH not maintained • Microbial count increases • Non- Viable particle count increases	differential and result into contamination from the adjacent area. • If interlocks are malfunctioned then two adjacent doors can opens at a time resulting into contamination and disturbance in pressure differential. • Approved area is unclassified while airlocks are classified, hence malfunctioning in interlocking will disturb the area classification. • Leakage in doors will disturb the area ACPH, for compensating the loss AHU's will get overloaded. • Any leakage in doors due to malfunctioned interlocking will	• Dynamic pass box are installed and act as a buffer between classified & unclassified area. • Preventive maintenance schedule is in place. • Building maintenance planner is available. • Dispensing is done under RLAF									

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

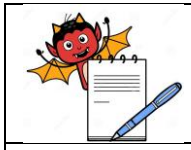
QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification | **Risk Assessment No.:**

S.No.	Item/Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/Mechanism of failure	Current Control	Reference Document No.	S	O	D	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN (SxOxD)
			• In Solvent Dispensing area, fumes may transferred to surrounding area HEPA filters & Return risers may got Chocked	disturb the RH. • As the Dispensing are lock is adjacent to unclassified approved area, so disturbance in pressure disturbance will disturb the Viable & Non- Viable count. • Any leakage (due to interlocking failure) in doors of solvent dispensing will result into transfer of fumes in surrounding areas. • Any spillage in approved area or dispensing area will contaminate the adjacent area if doors are not closed properly.										

Where: S=Severity; O=Occurrence Probability; D=Detection



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification	**Risk Assessment No.:**

Assessment of Severity, Occurrence and Detection:

Severity Effect	Likelihood Occurrence	Likelihood of Detection	Rating
No Effect	Unlikely	Always Detected	1
Moderate Effect	Possible	Might Detect Failure	2
Serious Effect	Almost Certain (Every time)	Lack of Detection Control	3

Evaluation of RPN:

RPN Rating	Category
12 to 27	High
7 to 11	Medium
Upto 6	Low

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	No any recommendation required, any failure in interlocking shall be rectified immediately.		

CAPA (Required/Not Required): Required
If required, mention CAPA No.: ……..

Quality Risk Management Team			Reviewed By Head Operations (Sign & Date)	Approved By Head QA (Sign & Date)
Name	**Department**	**Sign & Date**		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification	**Risk Assessment No.:**

Verification of Recommended Action:

……

……

……

Remarks (if any):

……

……

……

……

……

Verified By
Operating Person QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification	**Risk Assessment No.:**

6. CONCLUSION:……
……
……
……
……
……
……
……
……..
……
……
……

7. REFERENCES:

- Reference SOP of Risk Assessment.
- Related SOP's.

8. DOCUMENTS TO BE ATTACHED:

- Not Applicable

9. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

……
……
……

10. CHANGE CONTROL, IF ANY:

……
……
……..……
……
……
……

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification	**Risk Assessment No.:**

11. ABBREVIATIONS:

FMEA	: Failure Mode Effect Analysis
RPN	: Risk Priority Number
CAPA	: Corrective action preventive action
SOP	: Standard Operating Procedure
QRM	: Quality Risk Management
QA	: Quality Assurance
QMS	: Quality Management System
DP	: Differential Pressure
RH	: Relative Humidity
ID	: Identification

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR INTERLOCKING OF DISPENSING AREA

Reference Document No.: Dispensing Area Qualification	**Risk Assessment No.:**

12. FMEAAPPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING PERSON (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			