| QUALITY RISK ASSESSMENT & MITIGATION PLAN | |
|---|---|
| FAILURE MODE EFFECT ANALYSIS FOR REMOVING OF LOWER IN OINTMENT & ORAL LIQUID SECTION SECONDARY PACKINGAREA | |
| **Reference Document No.:** | **Risk Assessment No.:** |

# QUALITY RISK ASSESSMENT & MITIGATION PLAN (FAILURE MODE EFFECT ANALYSIS FOR REMOVING OF LOWER IN OINTMENT & ORAL LIQUID SECTION SECONDARY PACKING AREA)

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

# QUALITY RISK ASSESSMENT & MITIGATION PLAN

## FAILURE MODE EFFECT ANALYSIS FOR REMOVING OF LOWER IN OINTMENT & ORAL LIQUID SECTION SECONDARY PACKINGAREA

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

1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk in case of "Removing of Lower in Ointment & Oral Liquid Section Secondary Packing Area".

2. **SCOPE:** The Scope of this document is limited to Secondary Packing Gowning in Ointment & Oral Liquid Section at ……..

3. **RESPONSIBILITY:**

| Department | Responsibility |
|---|---|
| Quality Assurance | • Preparation, Review, and Compilation of FMEA<br>• Post Approval of FMEA |
| Production | • Review of FMEA |

4. **REASON FOR RISK ANALYSIS:**

To mitigate & monitor the risk associated with the "Removing of Lower in Ointment & Oral Liquid Section Secondary Packing Area".

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:**

**INTRODUCTION**:

**Gowning:** The Process of wearing special garments in order to control particulate contamination.

**Importance of Gowning:** Correct Gowning Procedure are also of Paramount importance .One of the problem with particulate contamination is that it is largely invisible to the naked eye, any contamination introduced into the clean room on the outer surface of clothing will go unnoticed and so any breakdown in correct gowning procedure will not be immediately apparent. Thus it is vital that operator are well versed and well-practiced in correct gowning procedure .it can be very helpful if a system of mutual help is in place .that is the operators observed each other and in a non-threatening way point out faults that may occur.

**Existing Gowning Procedure:** As per Existing Procedure "Entry and Exit Gowning Procedure for Visitor, Staff, Worker in Ointment & Oral Liquid Section" Personnel Wear firstly Cap, Apron and Lower in Sequence then entry in Secondary Packing Area.

**Reference Guideline:** Schedule M
SOP for Secondary Packing Gowning for Staff

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| RISK IDENTIFICATION | RISK EVALUATION | RISK MITIGATION |
|---|---|---|
| The Process of wearing special garments in order to control particulate contamination.<br>• Contamination of Adjacent Area (Ointment & Lotion De-cartoning Area)<br>• In case of Visitor will come wear only Cap & Apron<br>• Microbial invasion in clean room area<br>• Contamination of Product that was running in Packing Line<br>• In case of Rainy Weather person will enter with wet pant and Salwar | Risk evaluation Depends on the No of RPN ,in this risk assessment RPN found is Low category they are as follows:<br>**Severity**: Severity is high as contamination or cross contamination may leads to product failure.<br>**Occurrence**: Chance of occurrence is low as no complaint received related to contamination & cross contamination<br>**Detectability:** Might detect failure as the Secondary Packing Area is CNC | • Extra Gowning Availability required during rainy weather and same shall be mention in SOP “Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section”<br>• Pictorial Shall be updated and same shall be mention in SOP “Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section” |

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|---|---|

### 8. 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

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

| **Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation:** Removing of Lower in Ointment & Oral Liquid Section Secondary Packing Area | **Quality Risk Assessment Date:** …….. |
|---|---|

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode) | Potential Effect of Failure | Potential Cause/ Mechanism of Failure | Current Control | Reference document No. | S | O | D | Risk Priority Number (SxOxD) | Recommended Actions (if any) | Post Risk Evaluation | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| 1. | Removing Lower in Ointment & Oral Liquid Section Secondary Packing Area | • Contamination of Adjacent Area (Ointment & Lotion Decartoning Area)<br>• Contamination of Product that was running in Packing Line | • Product failure<br>• Market Complaint | • Product Running in Ointment & Lotion Filling Area Contaminate | • Testing procedure is in place After Finish Product Results Complies Batch Release for Market.<br>• SOP for Sampling of In process Bulk ,Semi-finished and finished Product in Oral Solid Dosage ,External Preparation and Oral Liquid is in Place<br>• SOP for Prevention of Contamination, Cross contamination and Mix-up is in place | • Analysis, Approval and Rejection of Bulk /Semi Finished/Finished Sample<br>• Sampling of In process Bulk ,Semi-finished and finished Product in Oral Solid Dosage ,External Preparation and Oral Liquid is in Place<br>• Prevention of Contaminatio | 2 | 2 | 1 | 4<br>**Severity:** Severity is Moderate as contamination in Packing Area is low due to Area is CNC<br>**Occurrence:** Chance of occurrence is low as Removal of Lower in Secondary Packing Area Because this area is CNC so no chance for Contamination | No any recommended action required as the RPN is of low category | NA | NA | NA | NA |

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

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode) | Potential Effect of Failure | Potential Cause/ Mechanism of Failure | Current Control | Reference document No. | S | O | D | Risk Priority Number (SxOxD) | Recommended Actions (if any) | Post Risk Evaluation | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| | | | | | | n, Cross contamination and Mix-up | | | | **Detectability :** Always detect failure as the area is CNC and no Contamination Occurs | | | | | |
| | | • In case of Rainy Weather person will enter with wet pant /Salwar | • Impact on Product Integrity<br>• During Audit Personnel found in Wet Condition<br>• Health issue may Faced Chances of Product Contaminate during handling of Product. | • Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid not in Place | • As per Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid during Rainy Weather Extra Apron and Lower Availability not Mention in SOP. | • Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section | 2 | 2 | 2 | 8<br>**Severity:** Severity is Moderate as Wet Clothes Contaminate the Product<br>**Occurrence:** Chance of occurrence is Possible When Person Enter with wet clothes | Extra Gowning Availability required during rainy weather and same shall be mention in Entry and Exit SOP | 1 | 2 | 2 | 4 |

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

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode) | Potential Effect of Failure | Potential Cause/ Mechanism of Failure | Current Control | Reference document No. | S | O | D | Risk Priority Number (SxOxD) | Recommended Actions (if any) | Post Risk Evaluation | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| | | • In case of Visitor will come wear only Cap & Apron | • Instructions for movement in Secondary Packing Area not Followed | • Gowning for Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid not Available<br>• Pictorial Diagram not Available | • SOP Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section is in Place | • Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section | 2 | 2 | 2 | **Detectability:** Might detection failure as the area is CNC<br>8<br>**Severity:** Severity is Moderate when gowning instruction not followed by Personnel<br>**Occurrence:** Chance of occurrence is Possible When procedure not Followed | Pictorial Shall be updated and same shall be mention in SOP | 1 | 2 | 2 | 4 |

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

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode) | Potential Effect of Failure | Potential Cause/ Mechanism of Failure | Current Control | Reference document No. | S | O | D | Risk Priority Number (SxOxD) | Recommended Actions (if any) | Post Risk Evaluation | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| | | Microbial invasion in clean room area | Area contaminate therefore Product Contaminate | Prevention of Contamination ,cross contamination and mix-up SOP not available | Secondary Packing Area is a CNC Area so no chances of Microbial invasion in respective area. | Prevention of Contamination , Cross contamination and Mix-up | 2 | 2 | 1 | **Detectability:** Might detection failure as gowning instruction no followed<br><br>4<br><br>**Severity:** Severity is Moderate as Microbial invasion in Clean room of Packing Area is low due to Area is CNC<br><br>**Occurrence:** Chance of | No any recommended action required as the RPN is of low category | NA | NA | NA | NA |

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

| S.No. | Item/ Function | Potential Failure Mode (Failure Mode) | Potential Effect of Failure | Potential Cause/ Mechanism of Failure | Current Control | Reference document No. | S | O | D | Risk Priority Number (SxOxD) | Recommended Actions (if any) | Post Risk Evaluation | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| | | | | | | | | | | occurrence is Possible as Microbial invasion in Clean room<br><br>**Detectability:** Always detect failure as the area is CNC | | | | | |

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

**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 |

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

| S.No. | Recommended Action | Responsible Person | Target Date of Completion |
|---|---|---|---|
| 1. | • Extra Gowning Availability required during rainy weather and same shall be mention in SOP "Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section".<br>• Pictorial Shall be updated and same shall be mention in SOP "Entry and Exit Procedure for Visitor, Worker in Ointment & Oral Liquid Section" | | |

**CAPA (Required/Not Required):** Not 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** | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Verification of Recommended Action:**

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

**Remarks (if any):**

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……

……

……

……

**Verified By**
**Operating Person QA**
**(Sign & Date)**

**Approved By**
**Head QA**
**(Sign & Date)**

## QUALITY RISK ASSESSMENT & MITIGATION PLAN

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

**9. CONCLUSION:**……
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……..
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**10. REFERENCES:**

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

**11. DOCUMENTS TO BE ATTACHED:**

- Not Applicable

**12. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:**

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……
……

**13. CHANGE CONTROL, IF ANY:**

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……
……
……

**14. ABBREVIATIONS:**

| | |
|---|---|
| FMEA | : Failure Mode Effect Analysis |
| RPN | : Risk Priority Number |
| CAPA | : Corrective action preventive action |
| SOP | : Standard Operating Procedure |
| QRM | : Quality Risk Management |

## QUALITY RISK ASSESSMENT & MITIGATION PLAN

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|---|---|

### 15. FMEA APPROVAL:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OPERATING PERSON (QUALITY ASSURANCE) | | | |

**REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OPERATING MANAGER (QUALITY ASSURANCE) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |