



**RISK ASSESSMENT FOR REMOVAL OF EXHAUST FILTERS OF FBP**

**RISK ASSESSMENT STUDY  
(FMEA ANALYSIS)  
FOR  
REMOVAL OF EXHAUST FILTERS OF FBP**

Document No.:.....

Effective From / Approval Date: .....

Risk Review due on:

**Remarks:** Risk assessment is prepared based on change control. The activity for Removal of Exhaust Filters of FBP, through change control procedure and in case in future if again any updation required in FBP same shall be done through change control and risk assessment shall be reviewed through that change control.



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## RISK ASSESSMENT FOR REMOVAL OF EXHAUST FILTERS OF FBP

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### 2.0 Quality Risk Management team:

Following team members were involved during risk identification, assessment & brain storming session. Team nomination was done by the Head of department.

| S.No. | Team Member | Department | Designation | Sign/Date |
|-------|-------------|------------|-------------|-----------|
|       |             |            |             |           |
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### HOD Approval

| Name | Department | Designation | Sign & Date |
|------|------------|-------------|-------------|
|      |            |             |             |



## **RISK ASSESSMENT FOR REMOVAL OF EXHAUST FILTERS OF FBP**

### **3.0 Introduction:**

The facility is producing various ranges of tablets; capsules and oral liquid with the help of required utility & equipment's.

### **4.0 Objective:**

The objective of this protocol is to perform the quality risk assessment study in line with the guidance of the risk management manual of Macleods and ICH Q9 for removal of exhaust filters of FBP.

### **5.0 Scope:**

The purpose of this document is to offer a systematic approach to quality risk management. It serves as a foundation or resource document that is independent of, yet supports other ICH Quality documents and complements existing quality practices, requirements, standards, and guidelines within the manufacturing facility.

This document provides risk assessment study for ICH for removal of exhaust filters of FBP to evaluate the mitigation & acceptance risk associated with it.

### **6.0 Risk assessment approach:**

- ☞ The quality risk assessment has been planned for evaluation on the basis of failure mode effect analysis (FMEA) tool.
- ☞ The evaluation of the risk shall be based on scientific knowledge and ultimately linked to protection of the patient.
- ☞ Various risks associated / anticipated shall be ICH Q9 for removal of exhaust filters of FBP.
- ☞ The impact of the risks shall be evaluated for the potential risks associated with the existing location. Various methodology/ tools of risk analysis shall be used as required.
- ☞ The risk & impact shall be assessed for the mitigation measures in place and / or the measures proposed.
- ☞ Action recommendations shall be given (if required) for mitigation and acceptance of risk.
- ☞ Acceptance of the risk with its mitigating measures shall be decided and endorsed based on the study carried out.
- ☞ The control mechanism and the risk communication shall be enforced / verified in the operating documentation.
- ☞ The quality risk assessment has been planned for evaluation on the basis of failure mode effect analysis (FMEA) tool.



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☞ The following process /steps have been/ will be followed for risk assessment:

### **7.0 Responsibilities:**

**Engineering Department** is responsible for preparation and review of quality risk assessment and coordinate the QRM team members and they shall be take the decisions about quality risk control & action plan.

**Production Department** is responsible for review of quality risk assessment procedure and support to its execution.

**Quality Assurance Department** is responsible for review of quality risk assessment procedure and support to its execution.

**Head Operation** is responsible to check the adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

**Quality Assurance Head** is responsible to check the adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

### **8.0 Reference Documents:**

The relevant Document for monitoring, control is listed below:-

- SOP- Handling of Corrective Action & Preventive actions.
- SOP- Change management system
- SOP- Event management
- SOP- Quality Risk management.
- SOP- Procedure for general maintenance work.
- SOP- Preventive Maintenance of Fluid Bed processor
- SOP- Procedure for work permit.



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## RISK ASSESSMENT FOR REMOVAL OF EXHAUST FILTERS OF FBP

### 9.0 Background:

The facility is producing various ranges of tablets, capsules and oral liquid with the help of required utilities & machineries. At Granulation 01, FBP machines are available, in which exhaust plenum filters are provided at exhaust plenum. In FBP exhaust air is filtered and exhausted to wet scrubber and for FBP exhaust air is filtered and exhausted to outside environment.

**Details of Filters:** Each machine have 03 Nos. of filters

**Rating:** 10 micron

**Size:** 610x610x200 mm

It is proposed to remove the above mentioned Exhaust filters of FBP's as wet scrubber is available and installed at exhaust. Risk assessment study shall be performed to find out potential failure causes for removal of exhaust filters of FBP. Based on the current available process controls, risk severity and probability of occurrence; RPN shall be calculated and risk shall be prioritized. Based on prioritize risk, actions shall be proposed (if any) in order to mitigate the risk.

### 10.0 Risk Ranking Parameters:

#### 10.1 Rating Parameters for Severity:

| Effect      | Scale | Assessment of Severity of Impact (Based on the anticipated negative impact & detrimental effect)  |
|-------------|-------|---|
| No effect   | 1     | No impact to product quality and process robustness   |
| Very Slight | 2     | Very slight effect on product and process performance. The customer may notice non-vital fault. Customer is not annoyed or impacted   |
| Slight      | 3     | Slight effect on performance. Non-vital fault notice most of the time. Customer is slightly annoyed.  |
| Minor       | 4     | Minor effect on product quality and process performance. Fault does not require repair or rectification. Non-vital fault or deficiency always noticed. Customer experiences minor nuisance. |
| Moderate    | 5     | Performance moderately affected. Fault requires repair. Customer experiences some dissatisfaction.  |
| Significant | 6     | Product or Performance hindered but usable /operable and safe. Non-vital part inoperable. Customer experiences discomfort.  |
| Major       | 7     | Product or performance severely affected but functional and safe. Customer dissatisfied.  |
| Extreme     | 8     | Item inoperable but safe. Customer very dissatisfied.   |
| Serious     | 9     | Potential hazardous effect. Able to stop without mishap. Regulatory compliance in jeopardy.   |
| Hazardous   | 10    | Occurrence without warning. Safety related. Regulatory non-compliance.  |



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### 10.2 Rating Parameters for Occurrence:

| Occurrence   | Scale | Parameter  |
|--------------|-------|--|
| Almost never | 1     | Almost impossible probability of occurrence. A failure, which has never been encountered but may be possible theoretically (1 in 15,00,000). |
| Remote       | 2     | Remote, rare number of historical failure(1 in 1,50,000).  |
| Very slight  | 3     | Very few failure likely (1 in 15,000)  |
| Slight       | 4     | Few failure likely (1 in 2,000)  |
| Low          | 5     | Occasional number of failures likely (1 in 400)  |
| Medium       | 6     | Medium number of failures likely (1 in 80)   |
| Moderately   | 7     | Moderately high number of failures likely (1 in 20)  |
| High         | 8     | high number of failures likely (1 in 8)  |
| Very High    | 9     | Very high number of failures likely (1 in 3)   |
| Almost       | 10    | Failure almost certain ( $\geq 1$ in 2)  |

### 10.3 Rating Parameters for Detection Control:

| Detection            | Scale | Parameter  |
|----------------------|-------|--|
| Almost Certain       | 1     | Almost certain that the design control will detect potential cause. Proven detection methods with high reliability.    |
| Very High            | 2     | Very high chance design control will detect potential cause. Proven detection methods available.                       |
| High                 | 3     | High chance design control will detect potential cause. Detection tools have high chance of detecting methods.         |
| Moderately High      | 4     | Moderately high chance design control will detect potential cause. Almost certain not to detect failure.               |
| Moderate             | 5     | Moderate chance design control will detect potential cause. Detection tools have moderate chance of detecting methods. |
| Low                  | 6     | Low chance design control will detect potential cause. Detection tools have a low chance of detecting failure.         |
| Very Low             | 7     | Very low chance design control will detect potential cause. Detection tools may not detect failure.                    |
| Remote               | 8     | Remote chance design control will detect potential cause. Detection tools will probably not detect failure.            |
| Very Remote          | 9     | Very remote chance design control will detect potential cause. Detection tools most likely will not detect failure.    |
| Absolute Uncertainty | 10    | No design control or design control will not detect potential cause. Failure not detected.                             |



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**Note:** Individual contributory factor for each potential failure mode shall be rated. Other scale parameters may also be selected based on the process.

### 11.0 Acceptance Criteria for Risk Assessment by FMEA:

Acceptance criteria for FMEA are as follows:

| Risk Category | Risk Classification (Quantitative) Risk Index | Action Status        |
|---------------|---|----------------------|
| High          | $\geq 500$                                    | CAPA required        |
| Medium        | 126 - 499                                     | CAPA may be required |
| Low           | $\leq 125$                                    | CAPA not required    |





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**12.0 RISK ASSESSMENT AS PER FMEA:**

**Name of facility/Utility/Equipment/Process/Operation:** removal of exhaust filters of FBP.

| S. No. | Potential failure mode                  | Potential failure effects | SEV (S)/REMARKS                                | Potential causes   | OCC (O)/REMARKS                      | Current process controls   | DET (D)/REMARKS                | RPN (SxOxD) | Risk Classification | Actions recommended                            | Responsibility (target date) | Action Results |                 |                 |                 |         |
|--------|---|---------------------------|--|--|--------------------------------------|--|--------------------------------|-------------|---------------------|--|------------------------------|----------------|-----------------|-----------------|-----------------|---------|
|        |   |                           |  |  |                                      |  |                                |             |                     |  |                              | Actions taken  | SEV (S)/REMARKS | OCC (O)/REMARKS | DET (D)/REMARKS | New RPN |
| 1.     | Injury to man during Removal of filters |                           | 5 (Customer experiences some dissatisfaction.) | Unavailability of EHS policy and procedure may cause lack of trained manpower which may leads to the accident. | 4 (Slight probability of occurrence) | -EHS policy is in place as per SOP having tittle "Procedure for work permit".<br>- Procedure for handling of accident and incident is in place as per SOP having tittle "Procedure for accident & incident handling".<br>-Personnel protective equipment's are available which alleviates the risk of health hazard during accident. | 4 (Moderately high detection). | 80          | LOW                 | -EHS work permit shall be initiated as per SOP | Prd/Engg./QA                 |                |                 |                 |                 |         |



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| S. No. | Potential failure mode  | Potential failure effects   | SEV (S)/REMARKS          | Potential causes  | OCC (O)/REMARKS                    | Current process controls  | DET (D)/REMARKS                | RPN (S/Ox/D) | Risk Classification | Actions recommended  | Responsibility (target date) | Action Results |                 |                  |                  |         |
|--------|---|---|--------------------------|---|------------------------------------|---|--------------------------------|--------------|---------------------|--|------------------------------|----------------|-----------------|------------------|------------------|---------|
|        |   |   |                          |   |                                    |   |                                |              |                     |  |                              | Actions taken  | SEV (S)/REMARKS | OCC (O) /REMARKS | DET (D) /REMARKS | New RPN |
| 2.     | Replacement of LED Tube light with multi-color light from top side i.e from service floor side opening.       | Cross contamination<br>Product may contaminate<br>Product failure | 6 (Significant severity) | Area may expose to outer environment during replacement of lights.<br><br>Production activity may not covered properly before execution of work | 4 (Slight probability occurrence). | Area is designed in high pressure with respect to outside environment; with this arrangement air ingress is not feasible in area.<br><br>Production department shall raise work order for replacement of lights.<br><br>Tube light cutouts shall be covered with GI Sheet before opening of light fixtures from production area side. | 4 (Moderately high detection). | 96           | Low                 | - General maintenance work order shall be raised before execution of work as per SOP.<br><br>- It is recommended to perform the fumigation & cleaning of area after replacement of light fixtures from top side. i.e. from service floor side. | Prd./Engg./QA                |                |                 |                  |                  |         |
| 3.     | Replacement of LED Tube light with multi-color light from bottom side i.e. From production area side opening. | Cross contamination<br>Product may contaminate<br>Product failure | 6 (Significant severity) | Area may expose to outer environment during replacement of lights.<br><br>Production activity may not covered properly before execution of work | 4 (Slight probability occurrence). | Area is designed in high pressure with respect to outside environment; with this arrangement air ingress is not feasible in area.<br><br>Production department shall raise work order for replacement of lights.<br><br>Light fixture shall be covered from top side i.e. from service floor side, before execution of the work       | 4 (Moderately high detection). | 96           | Low                 | Area requalification shall be carried out.<br><br>Fumigation and cleaning activity shall be carried out.   | Prd./Engg./QA                |                |                 |                  |                  |         |



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| S. No. | Potential failure mode                               | Potential failure effects | SEV (S)/REMARKS                              | Potential causes  | OCC (O)/REMARKS                         | Current process controls   | DET (D)/REMARKS                | RPN (S/Ox/D) | Risk Classification | Actions recommended  | Responsibility (target date) | Action Results |                 |                  |                  |         |                     |
|--------|--|---------------------------|--|---|---|--|--------------------------------|--------------|---------------------|--|------------------------------|----------------|-----------------|------------------|------------------|---------|---------------------|
|        |  |                           |  |   |   |  |                                |              |                     |  |                              | Actions taken  | SEV (S)/REMARKS | OCC (O) /REMARKS | DET (D) /REMARKS | New RPN | Risk Classification |
| 4.     | Operation of new multicolor lights after replacement | Insufficient luminous     | 5/ Customer experience some dissatisfaction. | New light may not able to provide sufficient required luminous in the areas | 5/ Occasional number of failures likely | These type of multicolor lights are already available in GB2 & GB3 area and also have identical technical specification. | 4 (Moderately high detection). | 100          | Low                 | Lux level shall be monitored   | Prd./Engg./QA                |                |                 |                  |                  |         |                     |
| 5.     | Required Utility not available                       | Operation Failure         | 5/ Customer experience some dissatisfaction  | Equipment cannot be operate without utility                                 | 4/ Few failure likely                   | Electric Connections and required utility supply is available in area for operation of the same                          | 4 (Moderately high detection). | 80           | Low                 | Utility details shall be verified during operation of lights after replacement | Prd./Engg./QA                |                |                 |                  |                  |         |                     |



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| S. No. | Potential failure mode | Potential failure effects   | SEV (S)/REMARKS                              | Potential causes                                | OCC (O)/REMARKS                         | Current process controls  | DET (D)/REMARKS                | RPN (SxOxD) | Risk Classification | Actions recommended            | Responsibility (target date) | Action Results |                 |                  |                  |         |                     |
|--------|------------------------|-----------------------------|--|---|---|---|--------------------------------|-------------|---------------------|--------------------------------|------------------------------|----------------|-----------------|------------------|------------------|---------|---------------------|
|        |                        |                             |  |   |   |   |                                |             |                     |                                |                              | Actions taken  | SEV (S)/REMARKS | OCC (O) /REMARKS | DET (D) /REMARKS | New RPN | Risk Classification |
| 6.     | Documentation          | Failure in GDP requirement. | 5/ Customer experience some dissatisfaction. | History card may not be updated after activity. | 5/ Occasional number of failures likely | Procedure for updation of History card of equipment is in place as per SOP having title | 4 (Moderately high detection). | 100         | Low                 | History card shall be updated, | Prd./Engg./QA                |                |                 |                  |                  |         |                     |



**RISK ASSESSMENT FOR REMOVAL OF EXHAUST FILTERS OF FBP**

**13.0 Risk Control Measures:**

**Investigation / Findings:**

Proposal for replacement of existing LED lights with multicolor lights in manufacturing area and QC micro area reviewed with current process control.

**Corrective Action:**

NA

**14.0 Summary & Conclusion Report for Risk Assessment:**

**Summary:**

Available control measures are sufficient to mitigate the risk of contamination and cross contamination against proposal.

| S.No. | Proposed Action   | Responsible Department | TCD |
|-------|---|------------------------|-----|
| 1.    | Work permit for replacement of existing LED lights          | Production/Engg./QA    |     |
| 2.    | EHS Work permit shall be initiate before execution of work. | Production/Engg./QA    |     |
| 3.    | Area requalification shall be carried out.                  | Production/Engg./QA    |     |
| 4.    | Fumigation activity shall be carried out                    | Production/Engg./QA    |     |
| 5.    | Lux level shall be monitored & recorded                     | Production/Engg./QA    |     |

**Conclusion:**

Based on above risk assessment study it is concluded that risk associated is low as per existing current process control and recommended action to be completed for better control and compliance.

**15.0 Risk categorization:**

(Product, Process, Equipment, System, cross contamination, data integrity, Quality system modules (Change control, CAPA, Event, OOS, Market complaint, Batch release procedure etc.)

Risk is low and detailed risk assessment has been carried out and to be attached in change control PR during risk summarization.

**15.1 Risk related to: Facility**

**15.2 Risk categorization comments:**

Change is related to replacement of existing LED lights at G BLOCK & QC Micro area. Hence risk categorized as related to facility.



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**16.0 Final Report Approval (Pre-Assessment):**

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures taken are documented and have been reviewed and found to be acceptable.

| Responsibility |                   | Name | Signature | Date |
|----------------|-------------------|------|-----------|------|
| Prepared by    | Engineering       |      |           |      |
| Reviewed by    | Engineering       |      |           |      |
|                | Production        |      |           |      |
|                | Store             |      |           |      |
|                | QC                |      |           |      |
| Approved by    | Quality Assurance |      |           |      |
|                | Head - Operation  |      |           |      |
|                | Head - QA         |      |           |      |



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**17.0 Final Report Approval (Post Assessment):**

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures taken are documented and have been reviewed and found to be acceptable.

| Responsibility     |                          | Name | Signature | Date |
|--------------------|--------------------------|------|-----------|------|
| <b>Prepared by</b> | <b>Engineering</b>       |      |           |      |
| <b>Reviewed by</b> | <b>Engineering</b>       |      |           |      |
|                    | <b>Production</b>        |      |           |      |
|                    | <b>Store</b>             |      |           |      |
|                    | <b>QC</b>                |      |           |      |
|                    | <b>Quality Assurance</b> |      |           |      |
| <b>Approved by</b> | <b>Head - Operation</b>  |      |           |      |
|                    | <b>Head - QA</b>         |      |           |      |



## **RISK ASSESSMENT FOR REMOVAL OF EXHAUST FILTERS OF FBP**

### **18.0 Risk Communication:**

The above quality risk assessment is shared with the following process owner and management.

1. Quality Assurance.
2. Production
3. Engineering
4. QC
5. Store

### **19.0 Abbreviation:**

- SOP : Standard Operating Procedure  
FMEA : Failure Mode Effect Analysis  
QRM : Quality Risk Management  
QMS : Quality Management System  
CAPA : Corrective Action and Preventive Action  
RPN : Risk Priority Number  
ICH : International Conference on Harmonization  
RAS : Risk Assessment  
LED : Light emitting diode