# PRE RISK ASSESSEMENT FOR COMILL

**RISK ASSESSMENT**

**REPORT BY FMEA**

| | |
|---|---|
| **Product/System/Equipment** | **CO MILL (SUPER MILL) (250 kg & 500 kg)** |
| **Risk Assessment Report No.** | |
| **Report Date** | |

# PRE RISK ASSESSEMENT FOR COMILL

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

# PRE RISK ASSESSEMENT FOR COMILL

**DOCUMENT APPROVAL:**

This risk analysis study for the preapproval of report by following:

| Responsibility | Department | Name | Signature | Date |
|---|---|---|---|---|
| **Prepared by** | Quality assurance | | | |
| **Reviewed by** | Production | | | |
| | Quality control | | | |
| | Engineering | | | |
| | Store | | | |
| | Quality assurance | | | |
| **Approved by** | Head-QA | | | |

# PRE RISK ASSESSEMENT FOR COMILL

## 1.0 Introduction

The "CO MILL" is intended for particle size reduction through rubbing between the rotary blades and screen at variable speeds inside a cylindrical hopper with assurance of product safety. It is necessary to achieve size reduction as well as output of uniform size before subsequent operations.

## 2.0 Objective

Objective of this report is to assess the risk associated with the equipment "CO MILL" in pre assessment in the manufacturing facility of Cepha Block of ……., in line with the guidance of the Risk Management manual of …… and ICH Q9.

## 3.0 Scope

The scope of this document is limited to the design, installation, operation, performance and safety of equipment "CO MILL" system and define its failure mode at pre assessment in the manufacturing facility of Cepha Block at …….

## 4.0 Risk assessment approach

Risk assessment is carried out as per FMEA (Failure mode, effects analysis) method.

## 5.0 Responsibility

Quality Assurance
Engineering
Production
Quality Control
Store

## 6.0 Reference Documents

1. ICH Q9-Quality Risk Management
2. …….guidance on Risk assessment.

# PRE RISK ASSESSEMENT FOR COMILL

**Background**

……is intended to start manufacturing of solid oral facility at ……. Risk assessment is a part of corporate quality assurance. Pre Quality Risk assessment of "CO MILL" is done to check the system is capable of providing quality product throughout the life cycle of the drug product.

## 7.0 RISK RANKING PARAMETERS

### 7.1 Rating parameters for Severity

| Effect | Scale | Description |
|---|---|---|
| **No effect** | 1 | No effect on output |
| **Very slight** | 2 | Customer not annoyed |
| **Slight** | 3 | Slight |
| **Minor** | 4 | Minor effect on performance |
| **Moderate** | 5 | Moderate effect on performance |
| **Significant** | 6 | Partial failure but operable |
| **Major** | 7 | Product performance severely affected, but some operability and safe |
| **Extreme** | 8 | Very dissatisfied, product inoperable but safe |
| **Serious** | 9 | Potentially hazardous effect, time-dependent failure |
| **Hazardous** | 10 | Hazardous effect, safety related sudden failure |

### 7.2 Rating parameters for Occurrence

| Occurrence | Scale | Description |
|---|---|---|
| **Almost never** | 1 | Failure unlikely; history shows no failures |
| **Remote** | 2 | Rare number of historical failure |
| **Very Slight** | 3 | Very few failures likely |
| **Slight** | 4 | Few failures likely |
| **Low** | 5 | Occasional number of failures likely |
| **Medium** | 6 | Medium number of failures likely |
| **Moderately High** | 7 | Moderately high number of failures likely |

# PRE RISK ASSESSEMENT FOR COMILL

| Occurrence | Scale | Description |
|---|---|---|
| **High** | 8 | High number of failures likely |
| **Very High** | 9 | Very high number of failures likely |
| **Almost certain** | 10 | Failure almost certain |

### 7.3 Rating parameters for Detection control

| Detection | Scale | Description |
|---|---|---|
| **Almost certain** | 1 | Proven detection methods with high reliability |
| **Very High** | 2 | Proven detection methods available |
| **High** | 3 | Detection tools have high chance of detecting methods |
| **Moderately High** | 4 | Almost certain not to detect failure |
| **Medium** | 5 | Detection tools have moderate chance of detecting defect |
| **Low** | 6 | Detection tools have a low chance of detecting failure |
| **Slight** | 7 | Detection tools may not detect failure |
| **Very Slight** | 8 | Detection tools will probably not detect failure |
| **Remote** | 9 | Detection tools most likely will not detect failure |
| **Impossible** | 10 | Failure not detected |

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

## 8.0 ACCEPTANCE CRITERIA FOR RISK ASSESSMENT BY FMEA

Acceptance criteria for FMEA are as follows:

| S.No. | RPN Rating | RPN Category | Action Status |
|---|---|---|---|
| 1. | ≥ 76 | Critical | CAPA Required |
| 2. | 51 to 75 | Major | CAPA Required |
| 3. | 26 to 50 | Moderate | CAPA Required |
| 4. | Up to 25 | Minor | Not applicable |

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# PRE RISK ASSESSEMENT FOR COMILL

**9.0 PRE-RISK ASSESSMENT AS PER FMEA:**

Name of facility/Utility/Equipment/Process/Operation: CO MILL (SUPER MILL)

| S.No. | Potential Failure Mode | Potential effect (s) of failure | Severity (S) | Potential cause/ Mechanism of failure | Occurrence (O) | Current Control | Detection (D) | RPN(S x O x D) | Recommended action | Responsibility and TCD | Action Results | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN |
| 1 | Required Area (floor, Temperature, RH, Differential pressure) not proper for the CO MILL. | Area will not be suitable for proper functioning of Equipment. | 6 | No or less clarity of the product requirement and machine functionality. | 3 | Approved layout is in place with dimensions & required environmental condition | 3 | 54 | Care has to be taken during Area Qualification | Engineering ,QA, Production | NA | NA | NA | NA | NA |
| 2 | Required parameter not defined in URS. URS not proper for system | Systems not receive suitable for proper output of quality with all parameter as per specification. Affect the product quality. | 4 | No or less clarity of the product requirement and machine functionality. | 3 | Preparation of URS before procurement of equipment is in place with all pre-specified parameter. | 2 | 24 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |
| 3 | Required utilities (compressed air, purified water, electricity)are not available | Machine will not function as expected. | 7 | No or less clarity of the product requirement and machine functionality with respect to utility requirement. | 2 | URS is in place for system with all predefined requirement of utility like electricity, compressed air, light facility . | 1 | 14 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |

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# PRE RISK ASSESSEMENT FOR COMILL

| S.No. | Potential Failure Mode | Potential effect (s) of failure | Severity (S) | Potential cause/ Mechanism of failure | Occurrence (O) | Current Control | Detection (D) | RPN(S x O x D) | Recommended action | Responsibility and TCD | Action Results | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN |
| 4 | Wrong machine selection in terms of Dimension, capacity and output. | Installation will be affected if dimension is not considered. Output will also get affected if capacity is not considered. | 6 | No or less clarity of the machine. | 2 | URS is in place for dimension , capacity and rated output of the of the Tablet and Capsule Sorter | 1 | 12 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |
| 5 | MOC and machine contact parts , not meeting GMP requirement | Not meting GMP requirements and product get affected. | 7 | No or less clarity of the machine contact part and MOC. | 3 | URS is in place for MOC ( contact part should be of SS316 or 316L and food grade material and non contact parts will be of SS304 and machine contact parts to fulfill GMP requirements. Gasket/rubber used shall be of food grade rubber.. | 1 | 21 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |
| 6 | Equipment not provided with castor wheel with lock arrangement | Accident may happen. | 10 | No or less clarity about equipment safety measures. | 2 | FOOD grade lubricant is required defined in URS. | 1 | 20 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |

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# PRE RISK ASSESSEMENT FOR COMILL

| S.No. | Potential Failure Mode | Potential effect (s) of failure | Severity (S) | Potential cause/ Mechanism of failure | Occurrence (O) | Current Control | Detection (D) | RPN(S x O x D) | Recommended action | Responsibility and TCD | Action Results | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN |
| 7 | Equipment not received with the process safety measures. | Accident may happen. | 10 | No or less clarity about equipment safety measures. | 2 | Preparation of URS before procurement of equipment is in place for Requirement of Safety measures like interlocking, ,discharge port, Earthing, Emergency stop, castor wheel with lock arrangement. | 1 | 20 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |
| 8 | Dust collector not provided to suck powder generated | Dusting and congestion occurs | 4 | No or less clarity about equipment safety measures. | 2 | Approved layout is in place. | 1 | 8 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |

# PRE RISK ASSESSEMENT FOR COMILL

## 9.1 REVIEW OF RISK ASSESSMENT AS PER FMEA AFTER ACTION TAKEN:

| Action Results | | | | | Remarks |
|---|---|---|---|---|---|
| Action Taken | Severity | Occurrence | Detectability | RPN | |
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## 10.0 RISK CONTROL MEASURES

**Investigation/ findings:** *(an extra sheet can be used if space is insufficient)*

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# PRE RISK ASSESSEMENT FOR COMILL

**Corrective Action:** *(an extra sheet can be used if space is insufficient)*

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**(Sign/Date)**

# PRE RISK ASSESSEMENT FOR COMILL

## 11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

**Summary:**

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**Conclusion:**……

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# PRE RISK ASSESSEMENT FOR COMILL

**12.0 FINAL REPORT APPROVAL:**

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.

| Department | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **Quality assurance** | | | | |
| **Production** | | | | |
| **Quality control** | | | | |
| **Engineering** | | | | |
| **Store** | | | | |
| **Head-QA** | | | | |