**PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER**

# RISK ASSESSMENT

# REPORT

| | |
|---|---|
| **Product/System/Equipment** | **Tablet and Capsule Sorter (General Block)** |
| **Risk Assessment Report No.** | |
| **Report Date** | |

# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

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# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

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

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

# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

## 1.0 Introduction

The "Tablet and Capsule Sorter" is intended to use for inspection of tablet and capsule. The conveyer motor and vibrator starts vibrating which enables the tablet and capsule move forward, the orientation motor starts rotating and this in turn rotates the tablet and capsule to make it convenient for visibility checking of tablet and capsule with assurance of product safety.

## 2.0 Objective

Objective of this report is to assess the risk associated with the equipment Tablet and Capsule Sorter in pre assessment in the manufacturing facility of General 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 " Tablet and Capsule Sorter " system and define its failure mode at pre assessment in the manufacturing facility 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 ANALYSIS FOR TABLET AND CAPSULE SORTER

**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 "Tablet and Capsule Sorter "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 |

| 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 ANALYSIS FOR TABLET AND CAPSULE SORTER

## 9.0 PRE-RISK ASSESSMENT AS PER FMEA:

Name of facility/Utility/Equipment/Process/Operation: Tablet and Capsule Sorter

| 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) & Air preparation unit not proper for the Tablet and Capsule Sorter. | Area, Air preparation unit 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. | 3 | 54 | Care has to be taken during Area Qualification & equipment 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. | 6 | 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 | 36 | Current control measures are adequate | NA | NA | NA | NA | NA | NA |

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# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

| 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 |
| 3 | Required utilities ( compressed air, electricity ,light facility)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. | 3 | URS is in place for system with all predefined requirement of utility like electricity, compressed air, light facility | 2 | 42 | Current control measures are adequate | | | | | | |
| 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. | 5 | No or less clarity of the machine. | 3 | URS is in place for dimension , capacity and rated output of the of the Tablet and Capsule Sorter | 3 | 45 | Current control measures are adequate | | | | | | |
| 5 | MOC and machine contact parts ,Seals & gaskets not meeting GMP requirement | Not meting GMP requirements and product get affected. | 5 | No or less clarity of the machine contact part and MOC. | 2 | 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 used shall be of food grade rubber. | 2 | 20 | Current control measures are adequate | | | | | | |

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## PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

| 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 |
| 6 | Lubricant used is of no food grade quality | Not meting GMP requirements. | 7 | No or less clarity of the requirement | 4 | FOOD grade lubricant is required defined in URS. | 2 | 56 | Certificate to be received from the vendor for FOOD grade against the supply. This shall be a part of SOP. | QA, Purchase/ Production, \Engineering | | | | | |
| 7 | Equipment not received with the process safety measures. | Accident may happen. | 9 | No or less clarity about equipment safety measures. | 2 | Requirement of Safety measures like Earthing is defined in URS. | 2 | 36 | Current control measures are adequate | | | | | | |
| 8 | Dust collector not provided to suck powder generated | Dusting and congestion occurs | 6 | No or less clarity about equipment safety ,product safety and human safety measures | 2 | URS is in place for dust collector unit for Tablet and Capsule Sorter | 1 | 12 | Current control measures are adequate | | | | | | |

# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

## 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 ANALYSIS FOR TABLET AND CAPSULE SORTER

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

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**(Sign/Date)**

# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

## 11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

**Summary:**……..

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**Conclusion:**

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# PRE RISK ANALYSIS FOR TABLET AND CAPSULE SORTER

## 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** | | | | |