



**PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

**RISK ASSESSMENT  
REPORT BY FMEA**

|                                   |                             |
|-----------------------------------|-----------------------------|
| <b>Product/System/Equipment</b>   | <b>TUBE FILLING MACHINE</b> |
| <b>Risk Assessment Report No.</b> |                             |
| <b>Report Date</b>                |                             |



## **PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

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## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

**DOCUMENT APPROVAL:**

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

| Responsibility     | Department        | Name | Signature | Date |
|--------------------|-------------------|------|-----------|------|
| <b>Prepared by</b> | Quality assurance |      |           |      |
| <b>Reviewed by</b> | Production        |      |           |      |
|                    | Quality control   |      |           |      |
|                    | Engineering       |      |           |      |
|                    | Store             |      |           |      |
|                    | Quality assurance |      |           |      |
| <b>Approved by</b> | Head-QA           |      |           |      |



## **PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

### **1.0 Introduction**

The “Tube filling machine “ is intended to fill and seal external preparation like Cream / Ointment /Gel in different tube made of Aluminum, Plastic and HDPE with volumetric filling mechanism along with sealing device by help of heat sealing mechanism with control temperature with assurance of product quality .

### **2.0 Objective**

Objective of this report is to assess the risk associated with the equipment of “tube filling machine” 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 “Tube filling machine” 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



## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

### Background

.....is intended to start manufacturing of external preparation at ..... Risk assessment is a part of corporate quality assurance. Pre Quality Risk assessment of “Tube filling machine” 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                      |



## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

### 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   |
| 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.



## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

### 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.    | $\geq 76$  | Critical     | CAPA Required  |
| 2.    | 51 to 75   | Major        | CAPA Required  |
| 3.    | 26 to 50   | Moderate     | CAPA Required  |
| 4.    | Up to 25   | Minor        | Not applicable |



## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

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

Name of facility/Utility/Equipment/Process/Operation: Tube filling Machine

| 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 handling unit not proper for the Tube filling machine | Area, Air handling 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 with dimensions & required environmental condition                   | 2             | 36              | Care has to be taken during Area Qualification & equipment qualification | Engineering, QA, Production |                |          |            |           |         |
| 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. | 1             | 18              | Current control measures are adequate                                    | NA                          | NA             | NA       | NA         | NA        | NA      |





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

| 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, cooling 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 compressed air. Cooling water, | 1             | 14              | Current control measures are adequate | NA                     | NA             | NA       | NA         | NA        | NA      |
| 4     | Wrong machine selection in terms of Dimension, capacity (speed / min) , design & functionality of machine . | Installation will be affected if dimension is not considered. Output and quality will also get affected if capacity & design are not considered. | 6            | No or less clarity of the machine.   | 2              | URS is in place for dimension , capacity and functionality of the machine .                               | 1             | 12              | Current control measures are adequate | NA                     | NA             | NA       | NA         | NA        | NA      |



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

| S.No. | Potential Failure Mode  | Potential effect (s) of failure                        | Severity (S) | Potential cause/<br>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 |
| 5     | MOC and machine contact parts with products ,Sealer & gaskets, not meeting with GMP requirement | Not meeting 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 non contact parts will be of SS304 and machine contact parts to fulfill GMP requirements. Gasket used shall be of food grade. | 1             | 21              | Current control measures are adequate | NA                     | NA             | NA       | NA         | NA        | NA      |
| 6     | Alignment of tube filling machine with autocartanator is not adequate.                          | Installation and product quality will be affected.     | 6            | No or less clarity of the requirement                   | 2              | URS is in place for alignment of tube filling machine with autocartanator as per predefined requirement .   | 1             | 12              | Current control measures are adequate | NA                     | NA             | NA       | NA         | NA        | NA      |
| 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 interlocking for tube filler with door Emergency stop. Guards for moving parts .  | 1             | 18              | Current control measures are adequate | NA                     | NA             | NA       | NA         | NA        | NA      |



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE

| S.No. | Potential Failure Mode   | Potential effect (s) of failure | Severity (S) | Potential cause/<br>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 |
| 8     | Other accessories (Hopper with stirrer, cassette loader, vacuum pump are not received. | Machine function is not proper  | 6            | No or less clarity about equipment and product safety measures | 2              | Other accessories are part of the filling machine. URS is in place for tube filling machine. | 2             | 24              | Current control measures are adequate | NA                     | NA             | NA       | NA         | NA        | NA      |



**PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

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

| Action Results |          |            |               |     | Remarks |
|----------------|----------|------------|---------------|-----|---------|
| Action Taken   | Severity | Occurrence | Detectability | RPN |         |
|                |          |            |               |     |         |
|                |          |            |               |     |         |
|                |          |            |               |     |         |
|                |          |            |               |     |         |
|                |          |            |               |     |         |



**PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

**10.0 RISK CONTROL MEASURES**

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

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

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**(Sign/Date)**



**PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

**11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT**

**Summary:**

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**Conclusion:**

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**PRE - RISK ASSESSMENT FOR TUBE FILLING MACHINE**

**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           |      |             |           |      |