# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## QUALITY RISK ASSESSMENT & MITIGATION PLAN

## FAILURE MODE EFFECT ANALYSIS FOR PUNCH SET CHANGE OF PRODUCT

**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 | RPN (SxOxD) | Recommended Actions (if any) | Post Risk Evaluation | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| **1.** | Punch set | •Change control not initiated.<br>•Punch set not available in stock. | •Market complains.<br>•Product fails in FG specification. | •Change control procedure not available.<br>•Negligence of person. | • There is procedure for 'Change Management' SOP is in place. Before taking any change in plant it must recorded through change management.<br>• There is procedure for 'Training of Employees' SOP is in place. Trainings shall be based on job description, organizational structure and working area of employee.On Job Training Matrix for existing employees shall be prepared section wise by department training co-ordinator in consultation with respective department head before start of next calendar year and shall be made master | •SOP | 5 | 2 | 1 | 10 | Risk is low hence no action plan is required | NA | NA | NA | NA |
| **2.** | Batch manufacturing record | •Change control not initiated.<br>•Batch manufacturing record not revised as per change. | •Market complains.<br>•Product fails in FG specification. | •Change control procedure not available.<br>•Negligence of person | • There is procedure for 'Change Management' SOP is in place. Before taking any change in plant it must recorded through change management.<br>• There is procedure for 'Training of Employees' SOP is in place. Trainings shall be based on job description, organizational structure and working area of employee.On Job Training Matrix for existing employees shall be prepared section wise by department training co-ordinator in consultation with respective department head before start of next calendar year and shall be made master | •SOP | 5 | 2 | 1 | 10 | Risk is low hence no action plan is required | NA | NA | NA | NA |
| **3.** | Packing change part | •Change control not initiated.<br>•Packing change part not available in stock. | •Market complains.<br>•Product fails in FG specification. | •Change control procedure not available.<br>•Negligence of person. | • There is procedure for 'Change Management' SOP is in place. Before taking any change in plant it must recorded through change management.<br>• There is procedure for 'Training of Employees' SOP is in place. Trainings shall be based on job description, organizational structure and working area of employee.On Job Training Matrix for existing employees shall be prepared section wise by department training co-ordinator in consultation with | •SOP | 5 | 2 | 1 | 10 | Risk is low hence no action plan is required | NA | NA | NA | NA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN SxOxD |
| | | | | | respective department head before start of next calendar year and shall be made master | | | | | | | | | | |
| **4.** | Product Manufacturing and packing | There may be difference in manufacturing process, environmental conditions and finished product results. | •Market complains.<br>•Product fails in FG specification | Finished product results not identical | • There is no change in manufacturing process of finished product.<br>• There is no change in primary & secondary packing/ containers during processing of batch (During hold time)<br>• There is no change in in process parameters and acceptance limit.<br>• All persons involve in process are qualified and well trained.<br>• Environmental conditions during manufacturing and packing process is as per requirement. | NA | 4 | 2 | 2 | 16 | Risk is low hence no action plan is required | NA | NA | NA | NA |
| **5.** | STS & Specification | •Change control not initiated.<br>•STS & Specification not revised as per change. | •Market complains.<br>•Product fails in FG specification. | •Change control procedure not available.<br>•Negligence of person | • There is procedure for 'Change Management' SOP is in place. Before taking any change in plant it must recorded through change management.<br>• There is procedure for 'Training of Employees' SOP is in place. Trainings shall be based on job description, organizational structure and working area of employee.On Job Training Matrix for existing employees shall be prepared section wise by department training co-ordinator in consultation with respective department head before start of next calendar year and shall be made master | •SOP | 5 | 2 | 1 | 10 | Risk is low hence no action plan is required | NA | NA | NA | NA |
| **6.** | Stability study of Finished Goods | Product may fail during shelf life | •Market complains.<br>•May lead to adverse effect. | Stability data of finished product was not compare and batches not charged for stability | • Three batches of similar composition product charged for Long Term, Real time and Accelerated Stability study.<br>• Data available of 06 month for accelerated stability, 09 month for real time stability and 09 month for long term stability. Reviewed and found satisfactory and attached as annexure-I | NA | 4 | 2 | 2 | 16 | Risk is low hence no action plan is required | 4 | 2 | 2 | 16 |

## QUALITY RISK ASSESSMENT & MITIGATION PLAN

## FAILURE MODE EFFECT ANALYSIS FOR PUNCH SET CHANGE OF PRODUCT

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

| Rating Scale – Severity | Rating Scale - Occurrence | Rating Scale - Detection | Acceptance Criteria |
|---|---|---|---|
| 1= No Effect | 1= Unlikely | 1= Always Detected | 51 to ≤ 125 = High Categories |
| 2= Minor Effect | 2= Very Rare | 2= Will Detect Failure | 26 to 50 = Medium Categories |
| 3= Moderate Effect | 3= Possible | 3= Might Detect Failure | Upto25 = Low Categories |
| 4= Serious Effect | 4= Likely | 4= Almost certain not to Detect Failure | |
| 5= Hazardous Effect | 5= Almost Certain (every time) | 5= Lack of Detection Control | |

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

**CONCLUSION:**

Punch set change of product shall be done with potential failure modes, their consequences, contributory factors and current control measures on risk. The detailed Investigation of the failure mode has been performed.

- Impact analyses have been performed by applying the FMEA tool of QRM approach for the current design control in the system.
- Risk priority numbers have been assigned by evaluating the effectiveness and control of current design control that is being implied to prevent the occurrence of mentioned failure modes.
- Risks ranking also have been done for each contributing factor to decide the priority to address the concern.
- During the assessment, it was found that all the contributing factors are falling under the minor category. Since no risk was identified with high RPN, hence no action plan is required.

Hence based on the risk assessment performed, it is concluded that the Punch set change of product is justified. All the associated risk like Punch set, Batch manufacturing record, Packing change part, Product Manufacturing and packing, STS & Specification and Stability study of Finished Goods were reviewed. Hence there is no risk to Punch set change of product.

## QUALITY RISK ASSESSMENT & MITIGATION PLAN

## FAILURE MODE EFFECT ANALYSIS FOR PUNCH SET CHANGE OF PRODUCT

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

| S.No. | Recommended Action | Responsible Person | Target Date of Completion |
|---|---|---|---|
| 1. | NA | NA | NA |

**CAPA (Required / Not Required):**
**If required, mention CAPA No.:** NA

| Quality Risk Management Team | | | Reviewed By Head Operations (Sign & Date) | Approved By Head QA (Sign & Date) |
|---|---|---|---|---|
| Name | Department | Sign & Date | | |
| | | | | |
| | | | | |
| | | | | |

## QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

**Name of Procedure:** Punch set change of product

**Verification of Recommended Action: NA**

**Remarks (if any): NA**

**Verified By**
**Officer/Executive QA**
**(Sign & Date)**

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