PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR COLD STORAGE RAW MATERIAL/CONTAINERS EXPOSING AT AMBIENT TEMPERATURE DURING TRANSFER & DISPENSING ACTIVITY

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.	Cold storage raw material /containers exposing at ambient temperature during transfer & dispensing activity.	• May colour change of material. • May impact on quality of material.	• Product failure • Market Complaint.	• Retesting procedure of raw material not available. • Handling of raw materials with special storage conditions not available. • Cleaning and sanitization procedure of cold chamber not available. • Dispensing procedure for cold storage raw material not available • Temperature is not maintained during storage.	• There is procedure for "Retesting of Raw Materials" SOP is in place. During retesting of raw material appearance and potency was verified. • There is procedure for "Handling and Storage of Raw Materials" SOP is in place. In SOP well define procedure for handling of raw materials with special storage conditions. • There is well define procedure for "Operation, Cleaning and Sanitization of Cold Chamber" SOP is in place. • There is procedure for "Dispensing of Raw Materials" SOP is in place. But SOP doesn't have procedure for cold storage raw material dispensing. • Stability data of all material kept at 2 to 8°C have been verified and found that stability study was conducted by vendor at condition long term condition (2 to 8°C up to expiry) & accelerated condition (25°C/65%RH up to 6 month). Hence there is no impact on material quality due	• SOP	5	3	2	30	Risk is medium, SOP to be revised for addition of procedure for cold storage raw material dispensing.	4	3	1	12

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												S	O	D	RPN SxOxD
					to short term excursion during transfer & dispensing activity. • Cold storage raw material/containers exposing at ambient temperature during transfer & dispensing. This activity repeated several time from initial testing to retest period. Further analysis performed as per retest period. Retesting detail of Rabeprazole Sodium IP and Vitamin D3 IP verified and both materials found compiles with specification during retesting, however multiple times dispensing were performed. For reference refer Annexure-I, II, III, IV, V & VI.										

Rating Scale – Severity
1= No Effect
2= Minor Effect
3= Moderate Effect
4= Serious Effect
5= Hazardous Effect

Rating Scale - Occurrence
1= Unlikely
2= Very Rare
3= Possible
4= Likely
5= Almost Certain (every time)

Rating Scale - Detection
1= Always Detected
2= Will Detect Failure
3= Might Detect Failure
4= Almost certain not to Detect Failure
5= Lack of Detection Control

Acceptance Criteria
51 to ≤ 125 = High Categories
26 to 50 = Medium Categories
Upto25 = Low Categories

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

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Remarks:

1.0 For RPN rating ≤ 25, No action plan required, however, for the improvement purpose action plan can be proposed for RPN rating ≤ 25, if required.

2.0 Action plan is required if any of individual Severity and occurrence is high. (Even if RPN is within acceptance criteria).

CONCLUSION: Risk assessment has been performed to cold storage raw material/containers exposing at ambient temperature during transfer & dispensing activity and RPN is found 30, which is in medium category. There are well control strategy defined in the quality system for identified risk like may colour change of material and may impact on potency of material etc. on the basis of risk assessment current control like retest procedure of raw material, handling of raw materials with special storage condition, cleaning and sanitization procedure of cold chamber, dispensing procedure for cold storage raw material, stability data of raw material and detail of raw material (stored in cold storage) was listed out and initial and retest COA was verified and no discrepancy observed from specification. For reference refer Annexure-I, II, III, IV, V & VI. Hence there is no impact on products quality.

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	SOP to be revised for addition of procedure for cold storage raw material dispensing.		

CAPA (Required / not 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**		

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Cold storage raw material/containers exposing at ambient temperature during transfer & dispensing activity.

Verification of Recommended Action:

Remarks (if any):

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)