PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR VENDOR EVALUATION

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Vendor evaluation	**Date Of Quality Risk Assessment:**

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure				Recommended Actions (if any)	Risk after control measure			RPN (S*O*D)
							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
1.	**Vendor Evaluation**	Risk of Low potent/out of specification results of material receiving from the vendor.	Physical Description and assay not get within specification	• Vendor not qualified. • Approved lab and approved chemist not available at raw material manufacturing site. • Approved testing procedure not available at Raw material manufacturing site • Without testing material dispatch from vendor site. • Appropriate/ Validated	• All selected vendors for materials are qualified. Vendor qualification is done at the time of selection of vendor through questioners, vendor audits and joint analysis. • At the time of vendor audit all checks point covers as per check list like approval of lab, chemist and training program of all manufacturing chemist. • Approved Standard testing procedure and standard testing specification are available. • All raw materials which are come from the vendor side not received without Certificate of Analysis (COA)	**Vendor qualification report** **Analysis Results** **Standard testing specification,** **Standard testing Procedure** **Stability testing Report** **Vendor evaluation report,** **Analysis**	4	2	4	32	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Vendor evaluation			procedure not followed at a time of Raw material manufacturing • Vendor evaluation not performs as per annual scheduled time.	• Stability report of Raw material is available • Method validation of Raw material is available. • Material receiving procedure followed. • Vendor evaluation of Raw material, excipients materials, and Packing material has been completed.	**Results** **Standard material receiving procedure**									
			PH and water analysis results not get within specification	• Fail in Container closer integrity	• Container closer integrity test is performed and validated. • Analysis results of Raw material are observed within the acceptance criteria.	Validation Protocol COA of Raw Materials.	4	1	4	16	NA	NA	NA	NA	NA
		Packing material variation	Shade card not match with received consignment of packing material	• Color variation	• Without Certificate of Analysis (COA) Consignment of packing material not received. • Packing material receiving procedure followed. • Without verification of material consignment not accepted/ received.	Approved Shade Card Approved Standard testing specification, And Standard testing Procedure									

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					• Approved shade card is available at vendor site • Also for cross verification shade card is available at our site.	Packing material Receiving procedure.									

Remarks (if any):

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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 Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	Vendor Evaluation

S. No.	Recommended Action	Responsible Person	Target Date of Completion

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):

_____

_____

_____

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date