PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR QUALITY CONTROL

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Quality Control	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.	**Quality Control**	Sampling of Raw material not in proper manner	Sample cannot represent the results/quality of Complete Batch.	➢ No SOP for Sampling procedure of Raw Material ➢ Unskilled/Untrained person perform the sampling of Raw material ➢ Not maintain environmental condition ➢ Pressure differential not maintain ➢ In addicted procedure of cleaning of sampling tools.	➢ Sampling procedure follow at the time of Raw material sampling, ➢ Procedure for sampling of Raw material is available. ➢ Only Trained person perform the sampling of raw material. ➢ Before the start of raw material sampling, line clearance procedure follow and all checks points verify at the time of line clearance. ➢ Before the environmental condition maintain QA person cannot give the permit to start the sampling.		4	1	3	12	NA	NA	NA	NA	NA
		Analysis Results not in Specification Limit	Product safety will be on risk. Patient safety will be on risk,	➢ Analyst not qualified ➢ Instrument not calibrated ➢ Analytical standards not qualified ➢ Sampling not in proper manner ➢ Manufacturing procedure not follow as per the pre	➢ Analyst qualification of all analyst are done ➢ Calibration of instrument completed as per the scheduled calibration planer. ➢ Analytical standards are qualified with respect to Reference standard. ➢ Skilled and trained person perform the sampling of material as per the standard sampling procedure.	Analyst Qualification Calibration planer	4	2	2	16	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR QUALITY CONTROL

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	
				determine manufacturing procedure/Process	➢ Appropriate manufacturing procedure followed, which are specified in the Batch Manufacturing Record.	Batch Manufacturing Record									
	Quality Control	Raw material not testing as per standard test procedure		➢ Standard test procedure not followed. ➢ UN approved test procedure followed. ➢ Standard test procedure of different Raw material can be followed at the time of testing	➢ STP of all Raw materials is available. ➢ Standard test procedure develops before the indenting of the new upcoming raw material. ➢ After the preparation of Standard Test Procedure and Standard Test Specification QC Head Checked this STP & STS and after that QA Head approved for follow the Standard Test Specification and Standard test Procedure. ➢ Trained and Skilled Person performs the testing as per Standard Test Specification and Standard Test Procedure.	Standard Test Procedure Standard Test Specification	4	2	2	16	NA	NA	NA	NA	NA
		Finished product not testing as per standard test procedure		➢ Standard test procedure not followed. ➢ Unapproved test procedure followed. ➢ Standard test procedure of different Product can be followed at the time of testing	➢ STP of all Finished Good Product is available. ➢ Standard test procedure develops before the indenting of the new upcoming Product. ➢ After the preparation of Standard Test Procedure and Standard Test Specification QC Head Checked this STP & STS and after that QA Head approved for follow the Standard Test Specification and Standard test Procedure.	Standard Test Procedure Standard Test Specification	4	1	2	8	NA	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR QUALITY CONTROL

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	
					➢ Trained and Skilled Person performs the testing as per Standard Test Specification and Standard Test Procedure.										

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

Remarks (if any):

_____

_____

_____

Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR QUALITY CONTROL

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	Quality Control

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