PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR DOCUMENT ISSUANCE CONTROL

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	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Document issuance control.	• Wrong batch manufacturing. • Wrong batch packing.	• Batch failure.	• Wrong BMR issuance. • Wrong BPR issuance.	• BMR/BPR shall be issued through electronic application (BIMS).	SOP	4	2	3	24	Low Risk category	4	1	3	12
		• Wrong document filling. • Wrong batch manufacturing. • Wrong batch packing. • Wong procedure can be performed.	• Document failure. • Batch failure. • Process failure.	• Wrong SOP issuance.	• Issuance Record of SOPs within Department shall be maintained by user department as per Annexure-VI. • Controlled Copies of SOPs shall be issued to other department as per Annexure-VII. • All specific SOPs shall be distributed by QA to respective departments. • Distribution record shall be maintained by QA as per Annexure-VII and same shall be attached with Master SOP. • All SOP's shall be distributed as per specific SOP's distribution list. • In case of any additional copy of SOPs is requested by any department the same shall be issued as per Annexure-VIII. • Revised SOP shall be distributed only after retrieval copy of Supersede SOP. • All SOPs shall be distributed by QA Department only. • Department wise SOP Index for all Department SOPs shall be maintained by	SOP	4	2	3	24	Low Risk category	4	1	3	12

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR DOCUMENT ISSUANCE CONTROL

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	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
					QA Department as per Annexure-IX. • SOPs Index shall be updated yearly or as and when required and same shall be amended through addendum as per Annexure-X along with the Addendum No. 01,02..and so on. • If the SOP is discontinued through change control, the same SOP No. shall not be allotted to any other SOP. • SOP No. shall not be removed from SOP Index and if the SOP is merged with other SOP then discontinue date, Merged SOP No. and Change Control No. shall be mention in remark column.										
		• Wrong location selected for sampling. • Wrong sample quantity to be collected. • Wrong procedure to be followed. • Wrong equipment/ procedure to be selected.	• Qualification failure. • Process & cleaning validation failure. • Hold time study failure.	• Wrong Protocol issuance. • Wrong Report issuance.	• Training given to qualification/validation team before start activity as SOP.	SOP	4	2	3	24	Low Risk category	4	1	3	12
		• Wrong method selected for testing.	• Batch failure. • OOS.	• Wrong AMV issuance.	• SPC/STP prepared through electronic application (LIMS).	SOP	4	2	3	24	Low Risk category	4	1	3	12

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR DOCUMENT ISSUANCE CONTROL

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	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
		• Wrong specification selected.	• OOT. • Cleaning validation failure.												
		• Cleaning status of equipment/instrument/ area cannot be traceable. • Usages detail of equipment/instrument cannot be traceable. • Wrong entry in BMR/BPR.	• Data integrity. • No traceability of Instrument/area / equipment.	• Wrong Log book issuance. • Wrong Formats issuance.	• All controlled copy of Documents / Log books / Registers etc. of all the departments shall be issued by QA after receiving the request Form for Issuance of Documents as per format shown in Annexure-II. • QA shall affix issuance slip as per format shown in Annexure-III on the back side of front cover page of Bound Book (Registers, Ledgers, Duplicate / Triplicate Book / Log Books and Pre Printed forms) and Controlled Copy stamp shall be on the right corner of the slip. • In case controlled copy of documents are to be carried out for external / internal purpose, shall be authorized by Head QA as per Annexure-II. • QA shall maintain the Issuance, Retrieval and Destruction Record of all Documents / Formats as per format shown in Annexure-V.	SOP	4	2	3	24	Low Risk category	4	1	3	12
		• Incomplete supporting document for QMS document.	• QMS document cannot be closed.	• Wrong QMS document issuance.	• All QMS maintain through electronic application (Ample logic). • Activity performed as per change control SOP.	• SOP	4	2	3	24	Low Risk category	4	1	3	12

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR DOCUMENT ISSUANCE CONTROL

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	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
					• Activity performed as per deviation SOP. • Activity performed as per CAPA SOP. • Activity performed as per incident SOP.										

Where: S=Severity; O=Occurrence Probability; D=Detection:, Risk category up to 25 is low risk, 26-50 is medium risk, 51 -125 high risk.

Remarks (if any): The entire above failure mode and their severity, Occurrence, Detectability rating done & found risk is Low.

Conclusion:- On the basis of above risk assessment the document issuance control leads to low risk, all evaluated risk during assessment of all concern department like warehouse, manufacturing area, packing area, quality assurance, quality control department which can be lower down after follow above mentioned controls.

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 PLAN FOR DOCUMENT ISSUANCE CONTROL

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Document Issuance Control

Verification of Recommended Action: NIL

Remarks (if any): **NA**

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)