PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR GOWNING PROCEDURE

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	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Gowning procedure	•Enter in manufacturing area with street cloth. •Wrong gowning procedure followed. •Gowning and De-gowning procedure for primary and secondary not available. •Dirty gowning used. •Dirty shoes and slipper used. •Enter in process area with primary gown.	•Contamination. •Cross-contamination. •Access of dust particles. •Microbial count increase. •Risk to patient safety.	• SOP not available. • Inadequate training. • SOP procedure not followed. • Gowning cleaning procedure not available. • Shoes and slipper cleaning procedure not available.	• Gowning and de-gowning procedure for entry and exit in manufacturing area is in place. • Pictorial procedure displayed for gowning and de-gowning in primary change room for staff & workers. • There is separated secondary change room for every process area. • Pictorial procedure displayed for gowning and de-gowning in secondary change room. • There is well defining procedure for visitor gowning & de-gowning procedure is in place. • Training has been provided to all staff and worker for gowning and de-gowning procedure as per SOP. • There is well defining procedure for gowning cleaning is in place.	• SOP	4	1	4	16	Risk is low hence no action plan is required	NA	NA	NA	NA

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												S	O	D	RPN SxOxD
		• Enter in micro – biology area without gowning procedure			• There is well defining procedure for shoes and slipper cleaning is in place. • There is well define procedure for primary and secondary gowning is in place. • There is well defining procedure for gowning in microbiology section is in place.										

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:- On the basis of above risk assessment the Gowning procedure leads to low risk, all evaluated risk during assessment in all concern department like warehouse ,manufacturing (Tablet, hard gelatin and soft gelatin capsule) area, Microbiology area and packing area, which can be lower down after follow above mentioned controls hence no recommended action required.

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

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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QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Gowning procedure

Verification of Recommended Action: NA

Remarks (if any): NA

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)