PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR CLEANING & SANITIZATION OF EQUIPMENT & AREA

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	RM Receipt	De-dusting not done	• Contamination and cross-contamination • Ingress of dust particles	• SOP not followed properly. • Inadequate training. • Un availability of facility in working condition	• De-dusting procedure is available. • Training has been provided of Area cleaning as per SOP. • Training has been provided of incoming material cleaning as per SOP. • Automatic De-Dusting machine for in the material entry and is maintained.	• SOP No. • Training record • Incoming material checklist	4	2	2	16	Risk is low hence no action plan is required	NA	NA	NA	NA
2	Area Cleaning (Warehouse, sampling area, dispensing area, manufacturing area, and packing area)	• Disinfectant wrongly prepared. • No rotation of dis-infectant. • Drains not sanitized. • Inadequate area cleaning. • Return Filters not cleaned. • AHU breakdown • Improper gowning.	• Product failure • Contamination & cross contamination. • Area microbial count may be increase.	• Disinfectant preparation procedure not available. • Disinfectant rotation schedule not available. • Drain point sanitization procedure not available. • Area cleaning procedure not available. • Filter cleaning procedure not available. • Gowning procedure not available. • Inadequate training.	• There is well defined procedure for preparation, filtration, usage and destruction of disinfectant solution. • Disinfectant rotation schedule is in place. • Procedure of drain sanitization is in place. • Training has been provided of all concerned personnel for preparation, filtration, usage and destruction of disinfectant solution. • Procedure of cleaning for area cleaning of sampling dispensing area, manufacturing area, and packing area is in place. • Training has been provided for area cleaning of sampling dispensing area, manufacturing area, and packing area. • Line clearance procedure is in place. • Filter transfer from production area to filter cleaning area is in place. • Training has been provided of Filter transfer from production area to filter cleaning area.	• SOP No. • Preventive maintenance record. • Environmental monitoring record.	4	3	2	24	Risk is low hence no action plan is required	NA	NA	NA	NA

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												S	O	D	RPN SxOxD
					• Environmental monitoring record is in place. • Preventive maintenance procedure is in place. • Gowning procedure is in place.										
3	Sampling and Dispensing Equipment	• Sampling and dispensing accessories not cleaned. • Dynamic Pass box are not cleaned. • RLAF is not cleaned • Vacuum cleaner is not cleaned.	Cross-contamination	• Sampling and dispensing accessories cleaning procedure not available. • Dynamic pass box cleaning procedure not available. • RLAF cleaning procedure not available. • Vacuum cleaner cleaning procedure not available. • Inadequate training.	• Sampling and dispensing accessories cleaning procedure is in place. There is well defining procedure for accessories cleaning is in SOP. • Training has been provided of all concerned personnel for accessories cleaning. • Dynamic pass box cleaning procedure is in place. • Training has been provided of all concerned personnel for dynamic pass box cleaning. • RLAF cleaning procedure is in place. • Training has been provided of all concerned personnel for RLAF cleaning. • Vacuum cleaner cleaning procedure is in place. • Training has been provided of all concerned personnel for vacuum cleaner cleaning.	• SOP No.	4	2	2	16	Risk is low hence no action plan is required	NA	NA	NA	NA
4	Manufacturing equipment cleaning in	• Vibro shifter not cleaned.	• Product failure. • Contaminatio	• Vibro shifter cleaning procedure not available.	• Vibro shifter cleaning procedure is in place. • Training has been provided of all	• SOP No.	4	3	2	24	Risk is low hence no	NA	NA	NA	NA

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												S	O	D	RPN SxOxD
	tablet, hard gelatin capsule and soft gelatin capsule.	• Paste kettle not cleaned. • Mass mixer not clean. • RMG not cleaned. • Multi mill not cleaned. • Comminuting mill not cleaned. • Oscillating granulator not cleaned. • Roll compactor not cleaned. • FBD not cleaned. • FBP not cleaned. • Blender	n & cross-contamination. • Microbial count may be increase.	• Paste kettle cleaning procedure not available. • Mass mixer cleaning procedure not available. • RMG cleaning procedure not available. • Multi mill cleaning procedure not available. • Comminuting mill cleaning procedure not available. • Oscillating granulator cleaning procedure not available. • Roll compactor cleaning procedure not available. • FBD cleaning procedure not available. • FBP cleaning procedure not available.	concerned personnel for vibro shifter cleaning. • Paste kettle cleaning procedure is in place. • Training has been provided of all concerned personnel for paste kettle cleaning. • Mass mixer cleaning procedure is in place. • Training has been provided of all concerned personnel for Mass mixer cleaning. • RMG cleaning procedure is in place. • Training has been provided of all concerned personnel for RMG cleaning. • Multi mill cleaning procedure is in place. • Training has been provided of all concerned personnel for multi mill cleaning. • Comminuting mill cleaning procedure is in place. • Training has been provided of all concerned personnel for Comminuting mill cleaning. • Oscillating granulator cleaning procedure is in place. • Training has been provided of all concerned personnel for Oscillating granulator cleaning.						action plan is required				

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												S	O	D	RPN SxOxD
		not cleaned. • Roto cube mixer not cleaned. • Compression machine not cleaned. • Metal detector not cleaned. • Dust extractor not cleaned. • Stirrer not cleaned. • Autocoater not cleaned. • Coating Pan not cleaned. • Capsule filling		• Blender cleaning procedure not available. • Roto cube mixer cleaning procedure not available. • Compression machine cleaning procedure not available. • Metal detector cleaning procedure not available. • Dust extractor cleaning procedure not available. • Stirrer cleaning procedure not available. • Coating pan cleaning procedure not available. • Autocoater cleaning procedure not available. • Capsule filling machine cleaning procedure not	• Roll compactor cleaning procedure is in place. • Training has been provided of all concerned personnel for Roll compactor cleaning. • FBD cleaning procedure is in place. • Training has been provided of all concerned personnel for FBD cleaning. • FBP cleaning procedure is in place. • Training has been provided of all concerned personnel for FBP cleaning. • Blender cleaning procedure is in place. • Training has been provided of all concerned personnel for blender cleaning. • Roto cube mixer cleaning procedure is in place. • Training has been provided of all concerned personnel for Roto cube mixer cleaning. • Compression machine cleaning procedure is in place. • Training has been provided of all concerned personnel for compression machine cleaning. • Metal detector cleaning procedure is in place. • Training has been provided of all concerned personnel for metal detector									

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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
		machine not cleaned. • Gelatin melting reactor not cleaned. • Encapsulation machine not cleaned. • Three stage semi drier not cleaned. • Gelatin holding tank not cleaned. • Triple roller mill not cleaned. • Planetary mixer not cleaned. • Medicame		available. • Gelatin melting reactor cleaning procedure not available. • Encapsulation machine cleaning procedure not available. • Three stage semi drier cleaning procedure not available. • Gelatin holding tank cleaning procedure not available. • Triple roller mill cleaning procedure not available. • Planetary mixer cleaning procedure not available. • Medicament vessel cleaning procedure not available. • Inadequate training.	cleaning. • Dust extractor cleaning procedure is in place. • Training has been provided of all concerned personnel for dust extractor cleaning. • Stirrer cleaning procedure is in place. • Training has been provided of all concerned personnel for stirrer cleaning. • Coating Pan cleaning procedure is in place. • Training has been provided of all concerned personnel for coating pan cleaning. • Autocoater cleaning procedure is in place. • Training has been provided of all concerned personnel for autocoater cleaning. • Capsule filling machine cleaning procedure is in place. • Training has been provided of all concerned personnel for capsule filling machine cleaning. • Gelatin melting reactor cleaning procedure is in place. • Training has been provided of all concerned personnel for gelatin melting reactor cleaning.									

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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
		nt vessel not cleaned.			• Encapsulation machine cleaning procedure is in place. • Training has been provided of all concerned personnel for encapsulation machine cleaning. • Three stage semi drier cleaning procedure is in place. • Training has been provided of all concerned personnel for three stage semi drier cleaning. • Gelatin holding tank cleaning procedure is in place. • Training has been provided of all concerned personnel for gelatin holding tank cleaning. • Triple roller mill cleaning procedure is in place. • Training has been provided of all concerned personnel for triple roller mill cleaning. • Planetary mixer cleaning procedure is in place. • Training has been provided of all concerned personnel for planetary mixer cleaning. • Medicament vessel cleaning procedure is in place. • Training has been provided of all									

RISK ANALYSIS STUDY FOR CLEANING & SANITIZATION OF EQUIPMENT & AREA

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
					concerned personnel for medicament vessel cleaning.										
5	Packing equipment cleaning.	• Blister machine not cleaned. • Alu-alu machine not cleaned. • Strip machine not cleaned. • Powder filling machine not cleaned. • Sachet filling machine not cleaned. • Change part not cleaned.	• Product failure. • Contamination & cross-contamination. • Microbial count may be increase.	• Blister machine cleaning procedure not available. • Alu-alu machine cleaning procedure not available. • Strip machine cleaning procedure not available. • Powder filling machine cleaning procedure not available. • Sachet filling machine cleaning procedure not available. • Change part cleaning procedure not available. • Inadequate training.	• Blister machine cleaning procedure is in place. • Training has been provided of all concerned personnel for blister machine cleaning. • Alu-alu machine cleaning procedure is in place. • Training has been provided of all concerned personnel for alu-alu machine cleaning. • Strip machine cleaning procedure is in place. • Training has been provided of all concerned personnel for strip machine cleaning. • Powder filling machine cleaning procedure is in place. • Training has been provided of all concerned personnel for powder filling machine cleaning. • Sachet filling machine cleaning procedure is in place. • Training has been provided of all concerned personnel for sachet filling machine cleaning. • Change part cleaning procedure is in	• SOP No.	4	2	2	16	Risk is low hence no action plan is required	NA	NA	NA	NA

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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
					place. • Training has been provided of all concerned personnel for change part cleaning.										

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.

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 Cleaning and Sanitization of equipment and area leads to low risk, all evaluated risk during assessment in all concern department like warehouse ,manufacturing (Tablet, hard gelatin and soft gelatin) area and packing area, which can be lower down after follow above mentioned controls hence no recommended action required.

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RISK ANALYSIS STUDY FOR CLEANING & SANITIZATION OF EQUIPMENT & AREA

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		

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Cleaning and Sanitization of equipment and area.

Verification of Recommended Action: NA

Remarks (if any): NA

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)