PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Equipment handling	❖ **Failure mode at warehouse.** ➢ **Malfunctioning of Dedusting tunnel:-** • Uncleaned/dirty containers stored in quarantine. ➢ **Malfunctioning of RLAF**:- • Cross contamination. • Contamination of material. ➢ **Malfunctioning of Hot Air Oven**:- • Sampling & dispensing accessories will not be dry. ❖ **Failure mode in tablets manufacturing area**: ➢ **Malfunctioning of vibro shifter:-** • Fail in sieve integrity. ➢ **Malfunctioning of Paste Cattle:-** • Paste not prepared as per requirement. • Binder not to be homogenous. ➢ **Malfunctioning of RMG/ Mass mixer:-** • Fail in Uniformity of API at dry mixing. • Binder mixing not homogenous ➢ **Malfunctioning of FBD/**	• Contamination /cross-contamination. • Machine breakdown. • Product failure. • Risk to patient safety. • Market Complaint.	• SOP not available. • Inadequate training. • SOP procedure not followed. • Product manufactured/ packing with un-defined parameters. • Uncalibrated instrument. • Unqualified equipment used. • Inappropriate procedure for initial qualification. • Inappropriate criteria for Re-qualification. • Inappropriate Preventive Maintenance procedures. • Inappropriate handling of maintenance	• Operation and cleaning SOPs for all equipment is in place. • There is well defining procedure for operation of all equipment in standard operating procedure. • Pictorial display available for operation procedure for PLC based equipment. • Training has been provided to all staff and technician/operator for operation and handling of equipment. • There is well define procedure for product manufacturing/packing through product specific BMR/BPR. • Calibration of instrument performed as per their schedule. Calibration planner is in place For instrument calibration. • Equipment qualification activity performed at time of installation. • Re-qualification of equipment shall be performed as per their schedule. Qualification planner is in place For equipment re-qualification.	• SOP No. • Calibration planner. • Qualification planner. • Preventive maintenance planner.	4	1	4	16	Risk is low hence no action plan is required	NA	NA	NA	NA

PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
		FBP: • Fail in LOD. ➢ **Malfunctioning of Multimill /Oscillator granulator/ Communicating mill:-** • Fail in particle size distribution. ➢ **Malfunctioning of Octagonal/Double cone Blander :-** • Fail in uniformity of content. • Fail in lubrication of granules. ➢ **Malfunctioning of Compression machine:-** • Uniformity of weight not achieved. • Average weight not achieved • Length and Width parameter not achieved. • Thickness, Hardness, Friability, DT parameter not achieved. • Defects observed e.g- Rough surface, Picking, Chipping, capping, Brittle tablets. ➢ **Malfunctioning of De-duster:-** • Powder carries with tablets. ➢ **Malfunctioning of Metal detector:-** • Metal in product cannot be		breakdowns. • Product manufacturing/ packing procedure not available. • Product manufacturing/ packing procedure not followed.	• There is procedure for qualification of new equipment / instrument / system SOP in place. There is procedure to prepare URS of new equipment, to evaluate impact of equipment on product quality, to assess level of qualification and to perform qualification w.r.t. ➢ **Design Qualification:** Review of design aspects in accordance with user requirements. ➢ **Installation Qualification:** Verification of installed system & parameters against Approved Design. ➢ **Operational Qualification:** • Ensure and verification of Calibration of Instruments attached to the System. • Verification of Functionality of the System. • Verification of PLC Software. • Verification of Operational Parameters of the System. ➢ **Performance Qualification:** • Verification of equipment in desired range or capacity.									

PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
		identifying. ➢ **Malfunctioning of colloidal mill:-** • Coating solution not be homogenous & smooth. ➢ **Malfunctioning of peristaltic pump:-** • Uneven coating observed. ➢ **Malfunctioning of Coating pan/Autocoater:-** • Various defects observed – Spots on tablet, rough surface, color variation, Blistering, film cracking, broken, twins, chipped & Discoloration. • Uniformity of weight not achieved. • Weight gain not achieved. • Thickness not achieved. DT not achieved. • Thickness problem Tablet. • Layer separation tablets. ❖ **Failure mode in hard gelatin capsule manufacturing area**:- ➢ **Malfunctioning of Capsule filling machine:-** • Weight variation capsule. • Fail in lock length. • Empty capsule.			• There is procedure for attached of References Document with report. • Any Changes made against fixed parameters as identified during qualification, attached with report. • There is procedure for Pre & post approval of protocol and report in place. **Note:-** • At each phase of qualification Training shall be imparted by vendor to all the concerned personals including engineering. ➢ **Qualification/Requalification criteria:** • Periodic Qualification. • Introduction of New System. • Replacement / Modification of Major Component • After Major Breakdown. • Relocation of System. • Requirement revealed through investigations. • Hence the existing re-qualification criteria are adequate as there could not be									

PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
		• Half fill Capsule. • Dented Capsule. • V-notch on capsule. • Telescope on capsule. • Cap on cap. • Pin hole. ❖ **Failure mode in soft gel capsule manufacturing area:-** ➢ **Malfunctioning of Gelatin melting reactor:-** • Gelatin not be homogenous & smooth. ➢ **Malfunctioning of Triple roller mill:-** • In proper milling of material which cause failure of uniformity of content & proper mixing. ➢ **Malfunctioning of Planetary mixer :-** • Fail in uniformity of content. ➢ **Malfunctioning of Encapsulation machine:-** • Empty capsule. • Partial filled capsule. • Air bubble in capsule. • Large dark spot on capsule.			chances that may impact the fitness of equipment during valid period of re-qualification. • There is well defining procedure for preventive maintenance frequency (01 month & 03 months) of equipments/ machines with respect to duty/ criticality of such equipment/machine in place. • There is procedure for preventive maintenance schedule in place. • There is procedure for handling of “Breakdown Maintenance” in place.										

PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
		• Leakage capsule. • Twining capsule. ❖ **Failure mode in Packing area**: ➢ **Malfunctioning of Blister/ Strip/Alu-Alu packing machine:-** • In-proper blister/strip cutting. • In-proper blister/strip sealing. • Pin Pocket. • Empty pocket. • Fail in leak test. • Misprint foil. ➢ **Malfunctioning of Sachet/ bottle filling machine:-** • In-proper sealing. • Fail in weight uniformity. • Half filling. • Empty Sachet/Bottle. ➢ **Malfunctioning of Camera/ NFD:-** • Defect cannot be identifying. ➢ **Malfunctioning of Autocartonator:-** • Carton damage. • Empty carton. • In-proper carton packing. • Missing leaflets.													

PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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	RPN (SxOx D)	Recomm e-nded Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD

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 equipment handling leads to low risk, all evaluated risk during assessment in all concern department like warehouse , manufacturing (Tablet, hard gelatin and soft gelatin capsule) 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

PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR EQUIPMENT HANDLING

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: Equipment handling

Verification of Recommended Action: NA

Remarks (if any): NA

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)