PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR MANUFACTURING & PACKING OF PRODUCTS

S.No.	Perceived Failure Mode	Potential Effect (Process/ End users or consequences)	S	Potential causes	P	Current control measures	D	RPN (SXPXD)	RPN category
1.	Improper cleaning of equipment and area	Cross contamination of the product	5	Improper labeling, cleaning procedure is not followed strictly, No trained personnel	3	Status labeling procedure, Line clearance and persons are trained	1	15	Minor
2.	Temperature, RH and pressure differential	The material quality may affect	5	Failure of HVAC System.	3	HVAC validation is completed and before start of batch temperature, RH and pressure differential to be checked at each process.	1	15	Minor
3.	Storage of dispensed raw material, intermediate and finished product	Mix up	5	Improper labeling	3	Dispensed raw material to be kept in day material store with properly labeled and in proper storage condition. Finished product is being stored in the appropriate storage condition.	1	15	Minor
4	Operator does not follow approved procedures	Cross contamination	5	Improper training	3	Trained operator is available.	1	15	Minor
PROCESSING STEP: xxx POWDER									
5	Before dispensing started previous batch material not removed.	Mix up	5	Line clearance not taken properly. Improper training.	3	Training given to respective person.	1	15	Minor
6.	Raw material verification	Batch fail	5	Improper raw material verification, no trained person	3	Prior to start the Manufacturing activity all dispensed material to be verified by production with BMR.	1	15	Minor

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7.	Balance Calibration	Dispense of wrong quantity of material	5	Malfunctioning of weighing balance. Untrained and unskilled persons responsible for dispensing.	3	Different capacity calibrated weighing balances are in place Approved procedures are in place for calibration and verification of weighing balance.	1	15	Minor
8.	Required mesh size not used during mixing & Sifting	Improper Size Reduction	5	Poor flow of material in the filling.	3	Instruction has been specified for the usage of respective sieve in the BMR.	1	15	Minor
9	Failed in assay and other parameter	Batch Failure.	5	Machine has not been set as per the instruction mentioned in the BMR. Machine is not qualified. Untrained Personnel.	3	Machine is qualified, Blending to be done as per BMR. Trained personnel are available for handling of materials during manufacturing. Provision of testing of blend available applicable for filling of powder in bottles.	1	15	Minor
9.	Bulk material containers not covered properly.	Cross contamination	5	Negligence of operator and supervisor.	3	Trained Personnel are available.	1	15	Minor
10.	Air jets not working properly	Cross contamination	5	Dust particles remains in the bottle	3	Procedure of Operation of Air Jet cleaning is available	1	15	Minor
11.	Improper Packing	Market complaint, Market Rejection	5	Instruction not specified in the batch packing record. Procedure of verification of the batches during packing is not available.	3	Instruction specified in the batch packing record. Procedure of verification of the batches during packing is available. Weight verification procedure is	1	15	Minor

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				Weight verification procedure is not available.		available.			
12.	Shipper Packing	Market Complaint	5	Shipper packing done manually	3	Shipper packing to be done by trained staff manually and checked by production and QA as per BPR.	1	15	Minor
13.	Left over packaging material	Mix-up	5	Left over material not returned to store. Untrained Person	3	After completion of batch all left over unprinted packaging material to be return to stores with proper labeling and reconciliation, persons are trained	1	15	Minor
14.	Left over excess or rejected tablets	Mix-up	5	Excess or rejected tablet not destroyed. Untrained person.	3	Excess or rejected tablets to destroy as per SOP after completion of batch. After completion of batch cleaning to be done as per SOP and during line clearance cleaning checked by production and QA. All person	1	15	Minor

QRM Team:

S – Severity rating, P – Probability rating, D – Detection rating, RPN – Risk Priority Number

Conclusion: It can be concluded from the above existing failure mode, overall RPN is below 25 (minor category), Hence no action plan is required.

	Prepared By	Reviewed By	Approved By
Sign/ Date			