PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR MANUFACTURING OF EXTERNAL PREPARATIONS

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure				Recommended Actions (if any)	Risk after control measure			RPN (S*O*D)
							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
1.	**Batch Manufacturing**	Probability of mix up of material after dispensing	Mix up and Product failure.	➢ Proper labeling is not done in each container of materials. ➢ Material transfer procedures are not available. ➢ Material is transferred by untrained personnel. ➢ Provision of controlled storage is not available. ➢ Procedure is not available for material movement in External Preparation production area.	➢ All bags/containers of materials properly identify by status label. ➢ Material is transferred to production area via staging room. ➢ Material is transferred by trained personnel. ➢ Controlled area provided for storage of material. Only authorized persons allowed in the area. ➢ Procedure is available for material movement in External Preparation production area	**SOP**	4	4	1	16	NA	NA	NA	NA	NA
		Probability of use of Un-clean dress in manufacturing Area	Increase in microbial load in manufacturing and product failure	➢ Procedure is not available for Cleaning of manufacturing & filling Area Garments. ➢ Garments cleaning are performed by untrained personnel. ➢ In-adequate cleaning of Dress. ➢ Garments Storage Cabinets	➢ Cleaning Procedure is available. ➢ Cleaning is performed by trained personnel. ➢ Storage Cabinets are provided for storage of garments. ➢ Garment cabinet for cleaned garments and Bin for used garments provided in change rooms.	**SOP**	4	4	1	16	NA	NA	NA	NA	NA

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				are not provided for Storage of Garments ➢ No labeling practice is available.	➢ SOP for entry and exit procedure available.										
		Foreign particles may enter during batch manufacturing area.	Product failure.	➢ Procedure is not available for Entry and Exit Procedure for External Preparation Area. ➢ If pressure differential is not maintained. ➢ Area is provided with air locks. ➢ Area & HVAC is not qualified. ➢ Activity is performed in Uncontrolled/Unclassified Area. ➢ Untrained / Unqualified personnel are allowed in the area.	➢ Procedure is available for Entry and Exit Procedure for External Preparation Area. ➢ Pressure differential is maintained properly & monitoring properly & monitoring at required/predefine intervals. ➢ Area is provided with air locks. ➢ Area & HVAC is qualified. ➢ Activity is performed in controlled/classified area. ➢ Untrained personnel are not allowed in the area.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Probability of missing of one or two material during	Product failure.	➢ If material not verified before processing the batch	➢ Verification of material by store and QA in dispensing & production and QA in manufacturing area is in practice. ➢ Batch manufacturing is performed	**BMR of Product**	1	1	4	4	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		transfer of material from warehouse.			in the presence of QA & Production personnel.										
		Probability of microbial contamination during manufacturing activity	Product Failure.	➢ If Manufacturing equipments (Mfg .tank, Filling machine Stirrer, transfer Pipe, Storage Tank) & Accessories are not cleaned properly ➢ If untrained person performing activity. ➢ Cleaning procedure not available ➢ Separate Cleaned Equipment Storage area is not provided. ➢ Proper Status of Labeling is not done in each cleaned & container after washing.	➢ Proper Cleaning activity is performed before manufacturing of batch. ➢ Only trained person performed all the activities. Only authorized person allow in manufacturing area. ➢ SOP for cleaning is available. ➢ Segregated Cleaned Equipment Storage area is provided. ➢ Proper Status of Labeling is done in each cleaned & container after washing.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Probability of increase in bio burden in the area	Product Failure	➢ If cleaning is not performed as per recommended SOP. ➢ If gowning procedure is not followed. ➢ If environment condition not as per requirement.	➢ Cleaning performed as per SOP. ➢ Gowning procedure followed as per SOP. ➢ Manufacturing process performed under controlled condition and record maintained.	**SOP** **BMR**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				➢ If batch change over process not followed as per SOP. ➢ Procedure is not available for sanitization of drain. ➢ Procedure is not available for cleaning of floors & wall. ➢ Wash/Rinse sample not send to QC for analysis.	➢ Wash water analysis performed as per SOP during product change over. ➢ Procedure is available for sanitization of drain. ➢ Procedure is available for cleaning of floors & wall. ➢ Wash/Rinse sample send to QC for analysis.									
		Poor Mixing of Bulk	Poor compaction properties, poor Mixing of Bulk .	➢ Variable sped of Stirrer ➢ Incorrect equipment ➢ Person not trained to performed the activity	➢ Stirrer Speed verified. ➢ Bulk Solution Prepared as per BMR instruction and as per SOP of equipment and area. ➢ Only trained persons performed all the activity.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
2.	**Mixing**	Probability of improper cleaning	Contaminatio n & product failure	➢ Manufacturing Tank r is not qualified. ➢ Stirrer is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by	➢ Manufacturing Tank is qualified. ➢ Stirrer is working properly & preventive maintenance schedule available & followed. ➢ Manufacturing Tank checked daily as per provided check list. ➢ Activity is performed by the trained personnel.	**Qualification Protocol** **SOP**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				untrained personnel. ➢ All washing process not done on controlled area.	➢ All washing process done on controlled area.										
		Probability of improper working of Manufacturing Tank	False result	➢ Manufacturing Tank r is not qualified. ➢ Stirrer is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel. ➢ All washing process not done on controlled area.	➢ Manufacturing Tank is qualified. ➢ Stirrer is working properly & preventive maintenance schedule available & followed. ➢ Manufacturing Tank checked daily as per provided check list. ➢ Activity is performed by the trained personnel. ➢ All washing process done on controlled area.	**Qualification Protocol** **SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Probability of microbial contamination in product through machine parts	Product failure	➢ If machine parts are not cleaned properly. ➢ If untrained persons performing activity. ➢ Procedure in not available for Cleaning of transfer Pipes. ➢ Cleaning of transfer Pipes not done properly	➢ Verification of cleaning of machine parts by QA. ➢ Only trained persons performed all the activity. ➢ Procedure is not available for Cleaning of transfer Pipes. ➢ Cleaning of transfer Pipes done properly as per the cleaning procedure.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
3.	**Filling & Sealing**	Probability of improper working of machine	Contamination & product failure	➢ Filling & Sealing machine is not qualified. ➢ Filling & Sealing machine is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel. ➢ Defects not checked for its appearance or shape/size ➢ Change parts like Die, Filling Nozzle, and Hopper are not cleaned. ➢ Procedure is not available for cleaning of Filling & sealing Machine.	➢ Filling & Sealing is qualified. Calibration done of all gauzes and other on routine basis ➢ Compression machine is working properly ➢ Preventive maintenance schedule available & followed. ➢ Filling & Sealing machine checked before taking product as per provided check list. ➢ Activity is performed by the trained personnel. ➢ Visual checks in different time interval for visual defects. ➢ Change parts like Die, Filling Nozzle, and Hopper are cleaned after completion of batch filling activity. And rinse water sample send to QC department for analysis. ➢ Procedure is not available for cleaning of Filling & sealing Machine.	**Qualification Protocol** **SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Probability	Market	➢ Proper setting of machine is	➢ Initial setting parameter is checked	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		of defects in Filled &Sealed tubes.	Complaint	not done. ➢ If Filling & sealing machine not checked. ➢ If the sealing Temperature not checked ➢ If Machine not cleaned properly by operator ➢ In process or machine run by untrained persons. ➢ If In-process not done at regular interval by trained person. ➢ Filling machine is not qualified. ➢ If Batch coding not embossing properly.	by the Operator and Production Personnel for proper setting of the machine before starting batch. ➢ Initial parameter also verified by QA Personnel. ➢ Proper cleaning of machine parts before every batch. ➢ Only trained person performed the in- process. ➢ Regular in-process checks are performed by the production and QA. ➢ Filling machine is qualified ➢ Proper batch coding Verifying by Production chemist as well as IPQA.	**Qualification Protocol**									
		Probability of weight variation	Weight variation and product failure during QC testing	➢ In-process checks not performed. ➢ Weight variation not performed. ➢ Activity is performed by untrained personnel.	➢ Weight Variation of all the parameters at initially and defined frequency is performed for Filled Tube by trained personnel as it is part of BMR. ➢ In-process checks performed at frequency defined in BMR.	**BMR**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				➢ Balance is not calibrated ➢ Proper setting of machine is not done by operator initially.	➢ Weight variation performed at regular frequency. ➢ Activity is performed by trained personnel. ➢ Daily verification and monthly calibration is in practice. ➢ Calibrated weighing balance is used for weighing,	**SOP**									
		Probability of Product Mix up (Quarantine Area)	Product mix up	➢ Batches are not segregated with proper status labeling. ➢ Labeling not done in the container in which product is placed. ➢ Unauthorized/untrained entry in quarantine area. ➢ Lock and key arrangement not available for access of unauthorized person entry.	➢ Batches are provided for segregation of different batches and different products. And also status label put on all carats ➢ Access of authorized persons only is there in quarantine area. ➢ Logbooks are maintained for filled product/Good products inwards and outwards of different products.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Probability of storage of Filled Tubes in unclean container	Chance of Contamination	➢ If Clean Carats not available for storage of filled tubes. ➢ Procedure not available for Cleaning of Carats.	➢ Dedicated Carats provided for storage of filled tubes. ➢ Procedure is available for Cleaning of Carats.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

Note: Action shall be taken if Risk Priority Number is more than 64.

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Where: S=Severity; O=Occurrence Probability; D=Detection

Remarks (if any):

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 Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	Manufacturing of External Preparations

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

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):

_____

_____

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date