PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR MANUFACTURING (ORAL DOSAGE)

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Manufacturing (OSD)	**Date Of Quality Risk Assessment:**

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.	**Material Staging after dispensing**	Cross Contamination	Product Failure	➢ During the transfer sugar bag opens and sugar transfer activity is performing. ➢ There is no physical segregation available ➢ No over gowning procedure is available for sugar transferring area as the person is directly come in contact with material.	➢ Dispensed material is kept in tightly closed double polybags. ➢ Segregation and Controlled area provided for storage of material. Only authorized persons allowed in the area. ➢ Secondary gowns and Gowning procedure is available for all person		4	3	1	12	NA	NA	NA	NA	NA
2.		Probability of mix up of material after dispensing	Mix up changes of different dispensed materials. 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	➢ 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		4	4	1	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				storage is not available. ➢ Procedure is not available for material movement.	storage of material. Only authorized persons allowed in the area and procedure is available for Material movement										
	Batch Manufacturing	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 are not provided for Storage of Garments	➢ 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 for entry and exit procedure available.		4	2	1	8	NA	NA	NA	NA	NA
		Foreign particles may enter during batch manufacturing area.	Product failure.	➢ Procedure is not available for Entry and Exit Procedure for Production Area (Tablet & Capsule & TDP) ➢ If pressure differential is not maintained.	➢ Procedure is available for Entry and Exit Procedure for manufacturing Area (Tablet & Capsule & TDP) ➢ Pressure differential is maintained properly & monitoring properly & monitoring at		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	
	Batch Manufacturing			➢ Area is not provided with air locks. ➢ Area & HVAC is not qualified. ➢ Activity is performed in Uncontrolled/Unclassified Area. ➢ Untrained / Unqualified personnel are allowed in the area.	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.										
		Probability of missing of one or two material during transfer of material from warehouse	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 in the presence of QA & Production personnel.	BMR of Product	2	1	4	8	NA	NA	NA	NA	NA
		Probability of microbial contamination during manufacturing activity	Product Failure.	➢ If Manufacturing equipments (FBD Blender, Compression Machine, Tablet Dedusting Machine,, Sifter, Multi Mill) & Accessories are not cleaned properly ➢ If untrained person performing activity.	➢ Proper Cleaning activity is performed before manufacturing of batch. ➢ Only trained person performed all the activities.		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	
	Batch Manufacturing			➢ 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.	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.										
		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. ➢ 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	➢ Cleaning performed as per SOP. ➢ Gowning procedure followed as per SOP. ➢ Manufacturing process performed under controlled condition and record maintained. ➢ 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.		4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				send to QC for analysis.											
		Variation in particle size distribution during granulation	Poor compaction properties ,poor flow of granules , Poor homogeneity.	➢ Variable granulation end point ➢ Incorrect equipment ➢ Wrong screen sizes used ➢ Person not trained to performed the activity	➢ Proper screen size taken during milling and sifting process as per BMR ➢ Granulation done as per BMR instruction and as per SOP of equipment and area. ➢ Only trained persons performed all the activity.	Batch manufacturing Record	4	1	3	16	NA	NA	NA	NA	NA
3.	**Blending**	Probability of improper cleaning	Contamination & product failure	➢ Blender is not qualified. ➢ Blender 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.	➢ Blender is qualified. ➢ Blender is working properly & preventive maintenance schedule available & followed. ➢ Blender checked daily as per provided check list. ➢ Activity is performed by the trained personnel. ➢ All washing process done on controlled area.	Qualification Protocol	4	1	2	8	NA	NA	NA	NA	NA
		Probability of improper working of blender	False result	➢ Blender is not qualified. ➢ Blender is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel.	➢ Blender is qualified. ➢ Blender is working properly & preventive maintenance schedule available & followed. ➢ Blender checked daily as per provided check list. ➢ Activity is performed by the		4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					trained personnel.										
		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 handling of Machine Parts. ➢ Cleaning of change parts not done properly	➢ Verification of cleaning of machine parts by QA. ➢ Only trained persons performed all the activity. ➢ Procedure of handling of change parts is available. ➢ Cleaning of change parts done properly		4	1	4	16	NA	NA	NA	NA	NA
		Variation in particle size distribution	Poor compaction properties ,poor flow of granules , Poor homogeneity.	➢ Variable granulation end point ➢ Incorrect equipment ➢ Wrong screen sizes used ➢ Person not trained to performed the activity	➢ Proper screen size taken during milling and sifting process as per BMR ➢ Granulation done as per BMR instruction and as per SOP of equipment and area. ➢ Only trained persons performed all the activity.	All SOP of Manufacturing Area	4	1	2	8	NA	NA	NA	NA	NA
4.	**Compression**	Probability of improper working of machine	Contamination & product failure	➢ Compression machine is not qualified. ➢ Compression machine is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel. ➢ Defects not checked for	➢ Compression machine is qualified. Calibration done of all gauzes and other on routine basis ➢ Compression machine is working properly & preventive maintenance schedule available & followed. ➢ Compression machine	Qualification Protocol	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	
				its appearance or shape/size ➢ Change parts like hopper, chute are not cleaned. ➢ Procedure is not available for Inspection, Handling, Polishing and Destruction of Punches and Dies	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 hopper, chute are cleaned after completion of batch manufacturing activity. And rinse water sample send to QC department for analysis. ➢ Procedure is available for Inspection, Handling, Polishing and Destruction of Punches and Dies									
		Probability of defects in compressed tablets	Market Complaint	➢ Proper setting of machine is not done. ➢ If compression machine not checked. ➢ Non availability of metal detector. ➢ Punch not cleaned properly by operator ➢ In process or machine run by untrained persons.	➢ Initial setting parameter is checked by the Operator and Production Personnel for proper setting of the machine before starting batch. ➢ Initial parameter also verified by QA Personnel. ➢ SOP for operation of metal detector is available. ➢ Proper cleaning of machine	Qualification Protocol	4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				➢ If In-process not done at regular interval by trained person. ➢ Compression machine is not qualified	parts before every batch. ➢ Only trained person performed the in- process. ➢ Regular in-process checks are performed by the production and QA. ➢ Compression machine is qualified										
5.	**Coating**	Probability of improper working of machine	Contamination & product failure	➢ Coating machine is not qualified. ➢ Coating machine 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 or area not specified for washing of equipments. ➢ Procedure for cleaning is not available and followed	➢ Coating machine is qualified. ➢ Coating machine is working properly & preventive maintenance schedule available & followed. ➢ Activity is performed by the trained personnel. ➢ Calibration done of all gauzes and other on routine basis ➢ All washing process done in controlled area. ➢ Dedicated area provided for washing of equipments. ➢ Procedure for cleaning is available and followed	**Qualification Protocol**	2	1	4	8	NA	NA	NA	NA	NA
		Probability of microbial contaminatio	Product failure	➢ If machine parts are not cleaned ➢ If untrained persons	➢ Machine parts are cleaned before using in process. Procedure of handling of		4	1	2	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		n in product through machine parts		performing activity. ➢ Procedure in not available for handling of Machine Parts. ➢ Storage of machine parts	change parts is available. ➢ Only trained persons performed all the activity. ➢ Verification of cleaning of machine parts by QA. ➢ SOP for cleaning & storage of machine change parts accessories.										
	Coating	Probability of microbial contamination in product though coating solution	Product failure	➢ If equipment used for preparing coating solution not cleaned. ➢ If untrained person performing activity. ➢ Solution not filter before using in coating ➢ Persons doing work in coating area are not qualified ➢ Door interlocking is not present to prevent cross contamination ➢ Unidirectional Men Material Movement / Flow are not maintained.	➢ Equipment are cleaned Verification of cleaning is bone by QA. ➢ Only trained person performed all the activity. ➢ Solution filtered through muslin cloth or as define in the BMR of respective procedure. ➢ All persons doing work in coating area are trained. ➢ Door interlocking is present to prevent cross contamination ➢ Unidirectional Men Material Movement / Flow are provided.	Personal Training Record	4	1	3	12	NA	NA	NA	NA	NA
		Probability of defects in coated tablets	Market Complaint & defects into the	➢ Proper setting of machine is not done. ➢ If spray gun and coating pan not	➢ Initial setting parameter is checked by the Operator and Production Personnel for proper setting of the	Visual Inspector	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	
			product	checked. ➢ If In-process not done at regular interval by trained person. ➢ Procedure is not available for controlling visual defects.	machine. Proper cleaning of machine parts before every batch. ➢ Initial parameter also verified by QA Personnel. ➢ Only trained person performed the in- process. ➢ Regular in-process checks are performed by the production and QA. ➢ Visual checks performed in different time intervals.	Qualification									
	Coating	Probability of weight variation	Weight variation and product failure during QC testing	➢ Tablets not checked for tablet weight. ➢ In-process checks not performed. ➢ Weight variation not performed. ➢ Activity is performed by untrained personnel. ➢ Balance is not calibrated ➢ Proper setting of machine is not done by operator initially.	➢ Weight Variation of all the parameters at initially and defined frequency is performed for tablets by trained personnel as it is part of BMR. ➢ In-process checks performed at frequency defined in BMR. ➢ Weight variation performed at regular frequency. ➢ Activity is performed by trained personnel. ➢ Daily verification and monthly calibration is in practice. ➢ Calibrated weighing balance	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	
					is used for weighing, ➢ Machine setting parameters checked by operator & production personnel before starting the Coating activity.										
	Coating	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.	➢ Pallets 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. ➢ Quarantine room shall be lock & key arrangement & Access of authorized persons only is there in quarantine area	Authorized Persons List	4	1	2	8	NA	NA	NA	NA	NA
6.	**Visual Inspection**	Probability of mix-up of Rejected tablets in Good tablets Container	Product Failure / Market complaint	➢ Tablet/capsule Inspection machine is not qualified. ➢ Visual Inspectors are not trained for sorting of tablets/Capsule.	➢ Tablet/capsule Inspection machine is qualified. ➢ Visual Inspectors are trained for sorting of tablets/Capsule. ➢ Medical Examination also	Qualification Protocol	4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				➢ Status label put on each container "Ready for packing". ➢ Unauthorized entry in quarantine area. ➢ Light intensity is not suitable for the activity. ➢ Inspection activity is performed by untrained personnel. ➢ Procedure not available for process of inspection checks during tablet packing	performed for inspectors. ➢ Status label put on each container "Ready for packing". Lid of container closed and properly tight with cable tie ➢ All drums are placed pallets wise affix status label "Ready for packing" ➢ Only of authorized persons access is there in inspection area ➢ Light intensity is suitable for the activity. ➢ Inspection activity is performed by trained personnel. ➢ Procedure available for process of inspection checks during tablet packing									
		Probability of storage of sorted tablets in unclean container	Chance of Contamination	➢ If Clean Container not available for storage of inspected tablets. ➢ Procedure not available for Cleaning of Container.	➢ Dedicated Container provided for storage of inspected tablets. ➢ Cleaning procedure is available & cleaning log also available for Cleaning of Container.		4	1	3	12	NA	NA	NA	NA	NA
7.	**Labeling**	Mixing of packing	Products mix up.	➢ Two different product of packing material	➢ Only one product packing material kept in Day Store at		4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		material in secondary packing area		placed in same area /Line. ➢ Procedure is not available for verification of packing material after dispensing or packing material keeping in Staging area. ➢ Status labeling not in practice. ➢ Separate area not provided. ➢ Material not stored properly. ➢ Activity is performed by untrained personnel.	a time. ➢ One product & one batch taken at a time in packing area ➢ Procedure is available for verification of packing material after dispensing or packing material keeping in Staging area. ➢ Status labeling is in place. ➢ Dedicated Day store is provided for storage of Material line wise. ➢ Unidirectional flow is provided for the material movement. ➢ In case of use of extra material, Packaging Material taken in cubical only after verification from QA. ➢ All packing activity is performed by trained personnel.									
		Probability of mix up of stereos during product change over	Process failure and market complaint and direct impact on patient	➢ If handling of stereos not proper. ➢ Written Procedure not available. ➢ Personnel handling stereo not trained.	➢ SOP for handling of Stereo is available & followed. ➢ One product issuance procedure is in practice. ➢ All stereo is handled by trained personnel.		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	
	Labeling		health	➢ Lock & key system not available for keeping stereos. ➢ Procedure of Destruction of stereos not available.	➢ Destruction activity is performed by trained personnel in presence of QA Person. ➢ Lock & Key arrangement is available for storage of Stereo. ➢ Destruction of stereos after completion of batch done by QA persons only.										
		Probability of Wrong Proof Sign	Market Complaint & Product identification failure	➢ Coding style and price not as per provided list. ➢ Price list updated version not present in packing hall area or its designated place. ➢ Finished product price list not available in packing hall. ➢ SOP for finished product prices list is not available& followed. ➢ Line clearance procedure not followed.	➢ Pre-Printed matter / specimen verified as per maintained coding style and price list as provided. ➢ Verification of specimen from QA after product check. ➢ Proof of coding matter is signed after complete verification from BMR & price List. ➢ Update price list is issued by QA after retrieval of supersede version ➢ In process checks also performed initially & at defined interval. ➢ Line clearance is followed before start of the activity.		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	
					➢ Procedure is available for Line clearance & followed properly.										
	Labeling	Probability of Packing of unprinted strips/carton with un-Coded strips / Carton	Market Complaint & improper identification	➢ If inspection is not performed. ➢ Activity is performed by untrained personnel. ➢ In-process checks not performed at defined intervals. ➢ Challenge test in case of blister machine is not performed at defined frequency.	➢ 100% inspection of printed packing strips/carton is performed. ➢ All packing activity is performed by trained personnel. ➢ In-process checks performed at defined intervals by Production & Quality Assurance Personnel. ➢ Challenge test of blister machine is part of SOP.	Batch Manufacturing Record	4	1	4	16	NA	NA	NA	NA	NA
	Labeling	Variation in Quantity during Packing Operation	Market Complaint	➢ Inspection is not performed. ➢ Activity is performed by untrained personnel. ➢ Camera Challenge test is not performed ➢ Weighing Process is not performed. ➢ Balance Verification / Calibration is not performed ➢ Procedure is not available for Weighing of Shipper	➢ 100% Visual inspection is performed. ➢ Packing activity is performed by trained personnel. ➢ Camera Challenge test is performed. ➢ All packed shipper are checked for weight in BPR ➢ Balance Verification / Calibration activity is performed on defined frequency. ➢ Procedure is available for	**BPR**	4	1	2	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					Weighing of Shipper										
8.	**Batch release**	In-complete analytical records and QA release documentation	System failure/ Market Complaint	➢ No SOP for review of analytical records ➢ No SOP for batch release	➢ SOP for review of analytical records ➢ SOP for review batch release		4	1	4	16	NA	NA	NA	NA	NA
9.	**Storage& dispatch of Finished Goods**	Probability of improper Storage of Finished Goods	Product Failure	➢ Space is not provided for storage of Finished Goods. ➢ Temperature Monitoring is not performed. ➢ Racking System is not provided for proper storage of material with proper status labeling. ➢ Procedure is not available of transfer of Finished Goods to FG Store	➢ Dedicated Finished Goods Storage Area is provided. ➢ Temperature Monitoring is performed on regular basis. ➢ Racking System is provided for proper storage of material with proper status labeling. ➢ Procedure is available & followed of transfer of Finished Goods to Finished Goods Store.		4	1	3	12	NA	NA	NA	NA	NA
10.	**Transfer of scrap**	Probability of contamination	Contamination & cross contamination	➢ Procedure is not available of handling and transfers of scrap ➢ Procedure is not available for Operation and Cleaning of scrap transfer Pass Box	➢ Procedure is available & followed for handling and transfers of scrap ➢ Procedure is available & followed for Operation and Cleaning of scrap transfer Pass Box		4	1	4	16	NA	NA	NA	NA	NA

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

Remarks (if any):

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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:	

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