PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR EXTERNAL PREPARATION IN MANUFACTURING FACILITY

Reference Document No.:	**Risk Assessment No.:** …….

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Production (External Preparation)	**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.	**Sampling**	Probability of use of Un-cleaned garments	Product Failure & mix-up chances	➢ Procedure is not available for Garments cleaning ➢ Garments cleaning are performed by untrained personnel. ➢ In-adequate cleaning ➢ Garments Storage Cabinets are not provided for Storage of Garments ➢ Garments cabinet is not Qualified	➢ Cleaning is performed by trained personnel. ➢ Cleaning Procedure is available. ➢ Storage Cabinets are provided for storage of garments. ➢ HEPA filter is provided in garments storage cabinets. ➢ Garments cabinet is previously qualified	**Qualification protocol**	4	1	4	16	NA	NA	NA	NA	NA
		Probability of mix up of material after Sampling	Contamination and Product failure	➢ Proper Status of Labeling is not done in each container of material. ➢ Material transfer procedure is not available. ➢ Container of Raw material are not segregated ➢ Proper storage condition not followed. ➢ Unskilled/Untrained person performing Sampling. ➢ Material transfer in unsafe manner.	➢ All containers of materials properly identified by status label. ➢ Staging room is provided for storage of sampled material and kept in Container with proper status label. ➢ SOP is available for Raw material sampling. ➢ Demarcation already done for placing more than one batch in staging area for segregation of batches. ➢ Provision for controlled storage	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				➢ Unclean Tools used for Sampling. ➢ RLAF not clean properly and Pressure Differential not in Limit. ➢ Weighing Balances are not clean.	condition is available. ➢ Line clearance procedure followed before start the Sampling										
		Personnel Safety during Sampling	Contamination of raw material and Effect on Human Health	➢ Proper gowning procedure is not followed. ➢ Safety devices are not available. ➢ Unskilled/untrained person performing Sampling. ➢ Activity is performed by without supervision of senior person.	➢ Provision of Secondary Change Room before entry in dispensing Area. Gowning procedure are provided and followed. ➢ Safety devices are available i.e. PPE (personnel protective equipments), Gloves, mask, goggles, etc required safety devices are provided. First aid facility is provided in case of any miss happening. ➢ Untrained person is not allowed to work in sampling area. ➢ List of Authorized personnel is displayed in all area. ➢ All activity is performed in presence of senior/experienced chemist.	**Safety manual**	1	1	4	4	NA	NA	NA	NA	NA
		Contamination & Cross Contamination	Product Failure	➢ In adequate cleaning ➢ Area not qualified. ➢ HVAC is not qualified.	➢ Proper cleaning & sanitization procedure are followed. ➢ HVAC & area are previously	SOP		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 for area cleaning is not available & followed. ➢ Procedure is not available for cleaning schedule of area. ➢ Validated Cleaning Procedure is not available. ➢ Pressure differential of area is not maintained & monitored in regular intervals. ➢ Untrained / Unqualified personnel are allowed in the area. ➢ Cleaning is performed by untrained personnel. ➢ Dedicated area is not provided for Storage of Cleaned sampling tools. ➢ Separate Washing Area is not provided. ➢ Dedicated AHUs is not provided for all the area. ➢ Procedure is not available for AHU cleaning & filter cleaning ➢ Gowning procedure is not available & not followed. ➢ Unidirectional men material	qualified. ➢ Validation cleaning procedure is available, followed & documented. ➢ Procedure is available & followed for cleaning schedule of area ➢ Pressure differential of the area is maintained, monitored at defined frequency. ➢ Untrained/Unqualified personnel is not allowed in the area. ➢ All activity is performed by trained personnel. ➢ Dedicated area is provided for Storage of Cleaned dispensing tools. ➢ Separate Washing Area is provided. ➢ Dedicated AHUs is provided for all the store area. ➢ Procedure is available for AHU cleaning & filter cleaning ➢ Gowning procedure is available & followed. ➢ Unidirectional Men Material Movement / Flow are provided. ➢ Pictorial for gowning procedure are displayed in respective area.										

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				movement / Flow are not provided. ➢ Pictorial for gowning procedure are not displayed in respective area. ➢ Procedure is not available for Line clearance of sampling area. ➢ Procedure is not available for cleaning of AHU & equipment filter ➢ Two different products sampled at a time.	➢ Procedure is available for Line clearance of sampling area. ➢ Procedure is available for cleaning of AHU & equipment filter ➢ Only single product sampled at a time.										

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
2.	**Dispensing**	Probability of use of Un-cleaned garments	Product Failure & mix-up chances	Procedure is not available for Garments cleaning Garments cleaning are performed by untrained personnel. ➢ In-adequate cleaning ➢ Garments Storage Cabinets are not provided for Storage of Garments ➢ Garments cabinet is not Qualified	➢ Cleaning is performed by trained personnel. ➢ Cleaning Procedure is available. ➢ Storage Cabinets are provided for storage of garments. ➢ HEPA filter is provided in garments storage cabinets. ➢ Garments cabinet is previously qualified	**SOP** **Qualification protocol**	4	1	4	16	NA	NA	NA	NA	NA
		Probability of wrong weight of raw material	Product does not complies with specification	➢ If weighing balance is not calibrated. ➢ Proper Weighing is not performed. ➢ Verification activity is not performed	➢ Daily verification and monthly calibration is in practice. ➢ Calibrated weighing balance is used for weighing, verification of raw materials verification of status label is displayed on every weighing balance. ➢ Proper line clearance is followed & calibration of weighing balance is also part of line clearance. ➢ Weighing activity is performed in the presence of QA &Production Personnel.	**SOP**	1	1	4	4	NA	NA	NA	NA	NA
		Probability of mix up of material after	Contaminatio n and Product failure	➢ Proper Status of Labeling is not done in each container of material. ➢ Material transfer procedure	➢ All containers of materials properly identified by status label. ➢ Staging room is provided for storage of dispensed material and	**SOP**	1	4	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		Dispensing		is not available. ➢ Container of Raw material are not segregated in staging area ➢ Proper storage condition not followed. ➢ Unskilled/Untrained person performing Dispensing. ➢ Material transfer in Unsafe manner. ➢ Unclean Tools used for Dispensing. ➢ RLAF not clean properly and Pressure Differential not in Limit. ➢ Weighing Balances are not clean.	kept in Separate Pallets with proper status label. ➢ SOP is available for transfer of dispensed material. ➢ Demarcation already done for placing more than one batch in staging area for segregation of batches. ➢ Provision for controlled storage condition is available. ➢ Authorized person entry allowed on staging area and proper lock & key to be done for entry in staging area ➢ Line clearance procedure followed before start the Dispensing	**SOP**									
		Personnel Safety during dispensing	Effect on Human Health	➢ Proper gowning procedure is not followed. ➢ Safety devices are not available. ➢ Trained personnel are not available in the area. ➢ Activity is performed by without supervision of senior person. ➢ Machine is not covered by safe guard.	➢ Provision of Secondary Change Room before entry in dispensing Area. Gowning procedure are provided and followed. ➢ Safety devices are available i.e. PPE (personnel protective equipments), Gloves, mask, goggles, etc required safety devices are provided. First aid facility is provided in case of any miss happening.	**SOP** **Safety manual**	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	
				➢ Emergency switch are not provided in machine.	➢ Untrained person is not allowed to work in dispensing area. ➢ List of Authorized personnel is displayed in all area. ➢ All activity is performed in presence of senior/experienced chemist. Personal involved in manufacturing are qualified ➢ All machine and utility are covered & safe guards are provided for all machine & emergency switch also provided.										
		Contamination & Cross Contamination	Product Failure	➢ In adequate cleaning ➢ Area not qualified. ➢ HVAC is not qualified. ➢ Procedure for area cleaning is not available & followed. ➢ Procedure is not available for cleaning schedule of area. ➢ Validated Cleaning Procedure is not available. ➢ Pressure differential of area is not maintained & monitored in regular intervals. ➢ Untrained / Unqualified personnel are allowed in the area.	➢ Proper cleaning & sanitization procedure are followed. ➢ HVAC & area are previously qualified. ➢ Validation cleaning procedure is available, followed & documented. ➢ Procedure is available & followed for cleaning schedule of area ➢ Pressure differential of the area is maintained, monitored at defined frequency. ➢ Untrained / Unqualified personnel is not allowed in the area. ➢ All activity is performed by trained personnel.	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	
				➢ Cleaning is performed by untrained personnel. ➢ Dedicated area is not provided for Storage of Cleaned dispensing tools. ➢ Separate Washing Area is not provided. ➢ Dedicated AHUs is not provided for all the area. ➢ Procedure is not available for AHU cleaning & filter cleaning ➢ Gowning procedure is not available & not followed. ➢ Unidirectional men material movement / Flow are not provided. ➢ Pictorial for gowning procedure are not displayed in respective area. ➢ Procedure is not available for Line clearance of dispensing area. ➢ Procedure is not available for cleaning of AHU & equipment filter ➢ Two different products dispensed at a time.	➢ Dedicated area is provided for Storage of Cleaned dispensing tools. ➢ Separate Washing Area is provided. ➢ Dedicated AHUs is provided for all the store area. ➢ Procedure is available for AHU cleaning & filter cleaning ➢ Gowning procedure is available & followed. ➢ Unidirectional Men Material Movement / Flow are provided. ➢ Pictorial for gowning procedure are displayed in respective area. ➢ Procedure is available for Line clearance of dispensing area. ➢ Procedure is available for cleaning of AHU & equipment filter ➢ Only single product dispensed at a time.									

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3.	**Material Staging after dispensing**	Cross Contamination	Product Failure	➢ Material staging room is available at Production External Preparation area where dispensed material is lying. ➢ There is no physical segregation available between the staging and transferring area. ➢ No over gowning procedure is available for Manufacturing area as the person is directly come in contact with material.	➢ Area cleaning procedure is available. ➢ Dispensed material is kept in tightly closed double polybags. ➢ There is no product cross contamination observed in previously manufactured batches. ➢ Quality control analysis is performing at different stages.	SOP	4	4	1	16	NA	NA	NA	NA	NA
4.	**Batch Manufacturing**	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 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	Increase in	➢ Procedure is not available for	➢ Cleaning Procedure is available.	SOP	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	
		of use of Un- clean dress in manufacturing Area	microbial load in manufacturing and product failure	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 ➢ No labeling practice 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.										
		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

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		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	1	1	4	4	NA	NA	NA	NA	NA
		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	➢ Cleaning performed as per SOP. ➢ Gowning procedure followed as per SOP. ➢ Manufacturing process performed	**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	
				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 send to QC for analysis.	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.										
		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
5.	**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 untrained personnel.	➢ 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	**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	
				➢ All washing process not done on controlled area.	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**	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 in not available for Cleaning of transfer Pipes. ➢ Cleaning of transfer Pipes.done properly	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
6.	**Filling & Sealing**	Probability of improper working of	Contamination & product failure	➢ Filling & Sealing machine is not qualified. ➢ Filling & Sealing machine is	➢ Filling & Sealing is qualified. Calibration done of all gauzes and other on routine basis	Qualification Protocol	4	1	4	16	NA	NA	NA	NA	NA

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		machine		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, Hopper are not cleaned. ➢ Procedure is not available for Cleaning of Filling & sealing Machine.	➢ 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, 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.	**SOP**									
		Probability of defects in Filled &Sealed tubes.	Market Complaint	➢ Proper setting of machine is not done. ➢ If Filling & sealing machine not checked. ➢ If the sealing Temperature not checked ➢ If Machine not cleaned	➢ 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. ➢ Proper cleaning of machine parts		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	
				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.	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.	**SOP** **Qualification Protocol**									
		Probability of weight variation	Weight variation and product failure during QC testing	➢ Tube 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 Filled Tube 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 is used for weighing,	**BMR** **SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Probability	Product mix	➢ Batches are not segregated	➢ Batches are provided for		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 Product Mix up (Quarantine Area)	up	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.	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									
		Probability of storage of Filled Tubes in unclean container	Chance of Contaminatio n	➢ 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
9.	**Packing**	Mixing of packing material in secondary packing area	Products mix up.	➢ Two different product of packing material 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	➢ Only one product packing material kept in Day Store at 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.	SOP	4	1	4	16	NA	NA	NA	NA	NA

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QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR EXTERNAL PREPARATION IN MANUFACTURING FACILITY

Reference Document No.: | **Risk Assessment No.:** …….

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	
				untrained personnel.	➢ 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 health	➢ If handling of stereos not proper. ➢ Written Procedure not available. ➢ Personnel handling stereo not trained. ➢ Lock & key system not available for keeping stereos. ➢ Procedure of Destruction of stereos not available.	➢ SOP for handling of Stereo is available & followed. ➢ One product issuance procedure is in practice. ➢ All stereo is handled by trained personnel. ➢ 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.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		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	➢ 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.	**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	
				prices list is not available& followed. ➢ Line clearance procedure not followed.	➢ 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. ➢ Procedure is available for Line clearance & followed properly.										
		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.	➢ 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. .	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Variation in Quantity during Packing Operation	Market Complaint	➢ Inspection is not performed. ➢ Activity is performed by untrained personnel. ➢ 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. ➢ All packed shipper are checked for weight in BPR ➢ Balance Verification / Calibration activity is performed on defined frequency. ➢ Procedure is available for Weighing of Shipper	**BPR** **SOP** **BPR**	4	1	4	16	NA	NA	NA	NA	NA

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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	
10.		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	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
11.	**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	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
12.	**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	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

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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		

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

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QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR EXTERNAL PREPARATION IN MANUFACTURING FACILITY

Reference Document No.:	**Risk Assessment No.:** …….

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