PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation/Product:	**Production (OSD)**

S. No.	Description of Activity	Potential Failure Mode	Failure Causes	Failure Impact	Current Control	Reference Doc. No.	Risk with Current control Measure				Proposed Control Measures (if any)	Risk after control measure			Risk Priority Number (RPN)
							Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	Risk Priority Number (RPN)		Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	
1.	**Dispensing**	Probability of use of Un-cleaned garments	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	Product Failure & mix-up chances	➢ 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	1	4	4	16	NA	NA	NA	NA	NA
		Probability of wrong weight of raw material	➢ If weighing balance is not calibrated. ➢ Proper Weighing is not performed. ➢ Verification activity is not performed	Product Failure	➢ 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	4	1	4	NA	NA	NA	NA	NA
		Probability of mix up of material after Dispensing	➢ Proper Status of Labeling is not done in each container of material. ➢ Material transfer procedure is not available. ➢ Batches are not segregated in staging area ➢ Provision for controlled substances storage is not available. ➢ Unauthorized person entry not restricted in production area. ➢ Material transfer by untrained personnel.	Product Failure	➢ All containers of materials properly identified by status label. ➢ Staging room is provided for storage of dispensed material and 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 substances storage is available. ➢ Authorized person entry allowed on staging area and proper lock & key to be done for entry in staging area	SOP		4	1	16	NA	NA	NA	NA	NA

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		Personnel Safety during dispensing	➢ 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. ➢ Emergency switch are not provided in machine.	Effect on Human Health	➢ 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 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.	SOP Safety manual	1	4	1	4	NA	NA	NA	NA	NA
		Contamination & Cross Contamination	➢ 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. ➢ Cleaning is performed by untrained personnel. ➢ Dedicated area is not provided for Storage of Cleaned	Product Failure	➢ 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. ➢ Dedicated area is provided for Storage of Cleaned dispensing tools.	SOP Qualification Protocol Cleaning validation	1	4	4	16	NA	NA	NA	NA	NA

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			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.		➢ 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.	SOP Layout SOP								
2.	**Material Staging after dispensing**	Cross Contamination	➢ Material staging room is available at Production tablet area where dispensed material of tablet is lying. There is a vacuum transfer system for sugar transfer system for liquid orals are also available in this area through which sugar is transfer to liquid area. ➢ During the transfer sugar bag opens and sugar transfer activity is performing. ➢ There is no physical segregation available between the staging and transferring area. ➢ Entry for Sugar transferring area and staging area is same. ➢ No over gowning procedure is available for sugar transferring area as the person is directly	Product Failure	➢ 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.		10	4	10	400	Separate area is to be provided for sugar transferring activity along with separate change room for over gowning.	1	1	1	1

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			come in contact with material.												
3.	**Batch Manufacturing**	Probability of mix up of material after dispensing	➢ 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 oral liquid production area.	Mix up changes of different dispensed materials. Product failure.	➢ 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.	SOP	4	1	4	16	NA	NA	NA	NA	NA
		Probability of use of Un- clean dress in manufacturing Area	➢ 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 ➢ No labeling practice is available.	Increase in microbial load in manufacturing and product failure	➢ 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.	SOP Training record of Personnel.	4	1	4	16	NA	NA	NA	NA	NA

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		Foreign particles may enter during batch manufacturing area.	➢ Procedure is not available for Entry and Exit Procedure for Production Area (Tablet & Capsule & TDP) ➢ 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.	Product failure.	➢ Procedure is available for Entry and Exit Procedure for manufacturing Area (Tablet & Capsule & TDP) ➢ 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 / Unqualified personnel are not allowed in the area.	SOP HVAC qualification	1	4	4	16	NA	NA	NA	NA	NA
		Probability of missing of one or two material during transfer of material from warehouse.	➢ If material not verified before processing the batch	Product failure.	➢ 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.	SOP BMR	1	4	1	4	NA	NA	NA	NA	NA
		Probability of microbial contamination during manufacturing activity	➢ If Manufacturing equipments (RMG,FBD Conta Bin Blender, Compression Machine 29 Station, Tablet Dedusting Machine,, Sifter,Multi Mill,Paste Kettle) & Accessories are not cleaned properly ➢ If untrained person performing activity. ➢ Cleaning procedure not available	Product Failure.	➢ 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 avaibale. ➢ Segregated Cleaned Equipment Storage area is provided. ➢ Proper Status of Labeling is done in each cleaned & container after	SOP	1	4	4	16	NA	NA	NA	NA	NA

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			➢ Separate Cleaned Equipment Storage area is not provided. ➢ Proper Status of Labeling is not done in each cleaned & container after washing.		washing.										
		Probability of increase in bio burden in the area	➢ 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 send to QC for analysis.	Product Failure	➢ 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.	SOP BMR	1	4	4	16	NA	NA	NA	NA	NA
		Variation in particle size distribution during granulation	➢ Variable granulation end point ➢ Incorrect equipment ➢ Wrong screen sizes used ➢ Person not trained to performed the activity	Poor compaction properties ,poor flow of granules , Poor homogeneity.	➢ 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.	BMR SOP	1	4	4	16	NA	NA	NA	NA	NA
4.	**Blending**	Probability of improper cleaning	➢ 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.	Contamination & product failure	➢ 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.	**Protocol** SOP	1	4	4	16	NA	NA	NA	NA	NA

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		Probability of improper working of blender	➢ Blender is not qualified. ➢ Blender is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel.	False result	➢ 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.	**Protocol** SOP	1	4	4	16	NA	NA	NA	NA	NA
		Probability of microbial contamination in product through machine parts	➢ 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	Product failure	➢ 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	SOP	1	4	4	16	NA	NA	NA	NA	NA
		Variation in particle size distribution	➢ Variable granulation end point ➢ Incorrect equipment ➢ Wrong screen sizes used ➢ Person not trained to performed the activity	Poor compaction properties ,poor flow of granules , Poor homogeneity.	➢ 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.	BMR SOP	1	4	4	16	NA	NA	NA	NA	NA
5.	**Compression**	Probability of improper working of machine	➢ 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 its appearance or shape/size ➢ Change parts like hopper, chute are not cleaned.	Contamination & product failure	➢ 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 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.	Qualification protocol Calibration certificates SOP	1	4	4	16	NA	NA	NA	NA	NA

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			➢ Procedure is not available for Inspection, Handling, Polishing and Destruction of Punches and Dies		➢ Procedure is not available for Inspection, Handling, Polishing and Destruction of Punches and Dies										
		Probability of defects in compressed tablets	➢ 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. ➢ If In-process not done at regular interval by trained person. ➢ Compression machine is not qualified	Market Complaint	➢ 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 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	BMR SOP Qualification protocol	1	4	4	16	NA	NA	NA	NA	NA
6.	**Coating**	Probability of improper working of machine	➢ 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	Contamination & product failure	➢ Coating washing 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 SOP Calibration certificates	1	4	1	4	NA	NA	NA	NA	NA
		Probability of microbial contamination in product through machine parts	➢ If machine parts are not cleaned ➢ If untrained persons performing activity.	Product failure	➢ Machine parts are cleaned before using in process. Procedure of handling of change parts is available. ➢ Only trained persons performed all the activity. ➢ Verification of cleaning of	SOP	1	4	4	16	NA	NA	NA	NA	NA

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			➢ Procedure in not available for handling of Machine Parts. ➢ Storage of machine parts		machine parts by QA. ➢ SOP for cleaning & storage of machine change parts accessories.										
		Probability of microbial contamination in product though coating solution	➢ 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.	Product failure	➢ 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 qualified. ➢ Door interlocking is present to prevent cross contamination ➢ Unidirectional Men Material Movement / Flow are provided.	SOP	1	4	4	16	NA	NA	NA	NA	NA
		Probability of defects in coated tablets	➢ Proper setting of machine is not done. ➢ If spray gun and coating pan not checked. ➢ If In-process not done at regular interval by trained person. ➢ Procedure is not available for controlling visual defects.	Market Complaint & defects into the product	➢ Initial setting parameter is checked by the Operator and Production Personnel for proper setting of the 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.	**BMR** SOP	1	4	4	16	NA	NA	NA	NA	NA

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		Probability of weight variation	➢ 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 and product failure during QC testing	➢ 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 is used for weighing, ➢ Machine setting parameters checked by operator & production personnel before starting the Coating activity.	**BMR** SOP	1	4	4	16	NA	NA	NA	NA	NA
		Probability of Product Mix up (Quarantine Area)	➢ 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.	Product mix up	➢ 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	SOP Logbook	1	4	4	16	NA	NA	NA	NA	NA
7.	**Visual Inspection**	Probability of mix-up of Rejected tablets in Good tablets Container	➢ Tablet/capsule Inspection machine is not qualified. ➢ Visual Inspectors are not trained for sorting of tablets/Capsule. ➢ Status label put on each container “Ready for packing”.	Product Failure / Market complaint	➢ Tablet/capsule Inspection machine is qualified. ➢ Visual Inspectors are trained for sorting of tablets/Capsule. ➢ Medical Examination also performed for inspectors. ➢ Status label put on each container “Ready for packing”. Lid of	Qualification protocol SOP	1	4	4	16	NA	NA	NA	NA	NA

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			➢ 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		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	BPR								
		Probability of storage of sorted tablets in unclean container	➢ If Clean Container not available for storage of inspected tablets. ➢ Procedure not available for Cleaning of Container.	Chance of Contamination	➢ Dedicated Container provided for storage of inspected tablets. ➢ Cleaning procedure is available & cleaning log also available for Cleaning of Container.	SOP	1	4	4	16	NA	NA	NA	NA	NA
8.	**Labeling**	Mixing of packing material in secondary packing area	➢ 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 untrained personnel.	Products mix up.	➢ 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 not 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.	SOP	1	4	4	16	NA	NA	NA	NA	NA
		Probability of mix up of stereos during product change over	➢ If handling of stereos not proper. ➢ Written Procedure not available. ➢ Personnel handling stereo not trained.	Process failure and market complaint and direct impact on patient	➢ SOP for handling of Stereo is available & followed. ➢ One product issuance procedure is in practice. ➢ All stereo is handled by trained personnel.	SOP	1	4	4	16	NA	NA	NA	NA	NA

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							Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	Risk Priority Number (RPN)		Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	
			➢ Lock & key system not available for keeping stereos. ➢ Procedure of Destruction of stereos not available.	health	➢ 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	➢ 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.	Market Complaint & Product identification failure	➢ 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. ➢ Procedure is available for Line clearance & followed properly.	SOP BPR	1	4	4	16	NA	NA	NA	NA	NA
		Probability of Packing of unprinted strips/carton with un-Coded strips / Carton	➢ 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.	Market Complaint & improper identification	➢ 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.	SOP BPR	1	4	4	16	NA	NA	NA	NA	NA

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation/Product:	**Production (OSD)**

S. No.	Description of Activity	Potential Failure Mode	Failure Causes	Failure Impact	Current Control	Reference Doc. No.	Risk with Current control Measure				Proposed Control Measures (if any)	Risk after control measure			Risk Priority Number (RPN)
							Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	Risk Priority Number (RPN)		Likelihood of Occurrence (1-10) (O)	Likelihood of Detection (1-10) (D)	Severity (1-10) (S)	
		Variation in Quantity during Packing Operation	➢ 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	Market Complaint	➢ 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 Weighing of Shipper	BPR SOP	1	4	4	16	NA	NA	NA	NA	NA
9.	**Batch release**	In-complete analytical records and QA release documentation	➢ No SOP for review of analytical records ➢ No SOP for batch release	System failure/ Market Complaint	➢ SOP for review of analytical records ➢ SOP for review batch release	SOP	1	4	4	16	NA	NA	NA	NA	NA
10.	**Storage& dispatch of Finished Goods**	Probability of improper Storage of Finished Goods	➢ 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	Product Failure	➢ 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	1	4	4	16	NA	NA	NA	NA	NA
11.	**Transfer of scrap**	Probability of contamination	➢ Procedure is not available of handling and transfers of scrap ➢ Procedure is not available for Operation and Cleaning of scrap transfer Pass Box	Contamination & cross contamination	➢ Procedure is available & followed for handling and transfers of scrap ➢ Procedure is available & followed for Operation and Cleaning of scrap transfer Pass Box	SOP	1	4	4	16	NA	NA	NA	NA	NA

Potential Failure Mode: What could go wrong?
Failure Causes: Why would the failure happen?
Failure Effects: What would be the consequences of failure?

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation/Product:	Production (OSD)

Likelihood of Occurrence: 1–10, 10 = Very likely to occur
Likelihood of Detection: 1–10, 10 = Very unlikely to detect
Severity: 1–10, 10 = Most Severe Effect
Rating Scales:

- **Occurrence:**
  1 = Not Likely, 10 = Very Likely
- **Detection:**
  1 = Easy to Detect, 10 = Not easy to Detect
- **Severity**
  1 = Not Severe, 10 = Very Severe

Risk Priority Number (RPN): Likelihood of Occurrence × Likelihood of Detection × Severity

Quality Risk Management Team			Approved By Head QA (Sign & Date)
Name	**Department**	**Sign & Date**	

Quality Risk Assessment and Mitigation Summary Report

S. No.	Proposed Control measures	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