Risk Analysis Study Protocol cum Report for Process Mapping from Dispensing to Dispatch

1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk during process from Dispensing to Dispatch.

2. **SCOPE:** The scope of this document is limited to Risk Assessment of Process Mapping from Dispensing to Dispatch in Oral Dosage section of …… facility.

3. **RESPONSIBILITY:**

Department	Responsibility
Quality Assurance	• Preparation, Review, and Compilation of FMEA. • Post Approval of FMEA.
Warehouse	• Review of FMEA.
Production (Manufacturing)	• Review of FMEA.
Production (Packing)	• Review of FMEA.

4. **REASON FOR RISK ANALYSIS:**
To mitigate & monitor the risk associated with the Process Mapping from Dispensing to Dispatch.

5. **SITE OF STUDY:**

6. **RISK COMMUNICATION & TRAINING:**
   - The Risk analysis team shall be authorized by the Head-QA or his/her designee.
   - Quality Risk Management Team shall be cross functional team comprised of expert from different areas.
   - Training shall be imparted to the concerned team.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT
FOR
PROCESS MAPPING FROM DISPENSING TO DISPATCH

Procedure: Process Mapping from Dispensing to Dispatch | **Quality Risk Assessment No.: .....**

S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
WAREHOUSE															
1.	Receipt of materials	• Receipt of raw material and packing material from the unapproved source. • Receipt of material not as per required grade/specifications	• Material not purchased as per approved vendor list • GRN prepare without material verification. • Material verification procedure not followed.	• Impact on process validation study. • Impact on the product stability study. • Impact on the quality of the product. • Market Complaint • Fail in QC specification.	• Procedure for "Receipt of Raw Materials in Warehouse" (SOP No.-.....) is in place. • Procedure for "Receipt of Packing Materials in Warehouse" (SOP No.-.....) is in place. • Procedure is available for verification of raw material and packing material like batch information, vendor name, material grade etc.	• SOP No.-..... • SOP No.:.....	3	1	1	3 **Severity:** Product failure may lead to health issues **Occurrence:** Material receiving procedure is in place **Detectability:** Awaiting GRN procedure is in place. Materials with any type of deficiency are kept in awaiting GRN.	NA	NA	NA	NA	NA
		Receipt of material without label/damage label, uncleaned container/damage container,damage material	• Incomplete information of material. • Use of uncleaned vehicle for the material transportation. • Cleaning and de-dusting procedure not	• Contamination of area • Contamination of material. • Mix up	• Procedure for "Receipt of Raw Materials in Warehouse" (SOP No.-.....) is in place. • Procedure for "Receipt of Packing Materials in Warehouse" (SOP No.-.....) is in place. • There is well defined	• SOP No.-..... • SOP No.-..... • SOP No.	3	1	1	3 **Severity:** Contamination or mix up of material can lead to product failure **Occurrence:** Material receiving	NA	NA	NA	NA	NA

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			followed. • Material verification procedure not followed. • Mishandling of containers.		procedure to receipt of materials, all material should received after checking of cleaning, weight verification, batch information and physical condition as per checklist (raw & packing material receipt checklist, SOP annexure). • Containers shall be cleaned by moping with dry clean cloth. • Procedure is available for de-dusting of received material through De-dusting tunnel (SOP No. .....) in place before entry of material inside the area.					procedure is in place **Detectability:** Awaiting GRN procedure is in place. Materials with any type of deficiency are kept in awaiting GRN.					
2.	Storage of Materials	• Storage of material in inappropriate area. • Material may got degraded • Improper segregation	• Due to space constraint, material not stored as per their dedicated place. • Low RH, light sensitive or temperature sensitive material not stored as per recommendation	• Material got fail in specification • Mix-up	• Procedure for "Handling and Storage of Raw and Packing Materials in Warehouse" (SOP No.- .....) is in place. • Storage of materials to separate area through line marking system for different stages shall be done. (Blue colour for	• SOP No.-	3	2	1	6 **Severity:** Severity is high as the product may got degraded or got mix up due to improper storage. **Occurrence:**	NA	NA	NA	NA	NA

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					Quarantine Area, Yellow colour for Under Test Area, Red colour for Rejected Area and Green colour for Approved Area). • Temperature Mapping • Cold Storage available for temperature sensitive material. • Material list available for special storage conditions. • Rack wise distribution is there. • Bin location is provided through SAP.					Chance of Occurrence of improper segregation is possible due to space constraint. **Detectability:** Can be easily Detected as Bin Locations are Provided through SAP.					
3.	Labelling of materials (Quarantine, Under Test, Approved, Reject)	Wrong labelling on material.	Wrong label prepares.	Impact on the identity of the product.	• Procedure for "Labelling of Receipt Raw Material Containers" (SOP No. .....) is in place. There is well defined procedure for preparation of label, label checking and label verification. • Procedure for "Handling and Storage of Raw and Packing Materials in Warehouse"	• SOP No. ..... • SOP No.	3	1	1	3 **Severity:** Severity is high as the material identity is lost in case of improper labelling **Occurrence:** Chance of	NA	NA	NA	NA	NA

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					(SOP No. .....) is in place. There is well defined procedure to storage of materials to separate area through Line marking system for different stages and storage of material according to their manufacturer name, Batch No. / Lot No., Mfg. date. retest/expiry date, Grade etc.					Occurrence of improper segregation is possible due to space constraint. **Detectability:** Can be easily Detected as, if Containers are not labelled.					
4.	Improper Gowning	• Secondary gowning not done • Dirty Gowning	Untrained & Unaware	Contamination & Cross - Contamination	• Gowning & De-gowning procedure in place.	SOP No.: ..... "Entry & Exit Procedure for Oral Solid Dosage Facility"	3	2	1	3 **Severity:** Improper gowning can lead to contamination **Occurrence:** Chance of occurrence is possible. **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
5.	Dispensing of Raw material	Dispensing done usingdirty tools.	Dispensing tools not cleaned.	Contamination & Cross - Contamination	• Procedure for "Handling and Cleaning of Dispensing Tools in Warehouse" (SOP No.- .....) is in place. There is well defined procedure for cleaning of dispensing tools.	• SOP No.- ..... • SOP No.-	3	1	1	3 **Severity:** Severity is High, as dirty tools can lead to contamination	NA	NA	NA	NA	NA

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					Procedure for "Line-Clearance of Raw Material Sampling & Dispensing Area In Warehouse" (SOP No.- .....) is in place. There is well defined procedure for line-clearance for material dispensing.					**Occurrence:** Chance of occurrence is not possible, as line clearance procedure is at place. **Detectability:** Can be easily detected visually					
		Dispensing done through un-calibrated balance.	Balance calibration not done as per schedule.	Wrong quantity dispensed	• Procedure for "Operation, Cleaning, Verification and Calibration of Electronic Weighing Balances" (SOP No. .....). • Procedure for "Operation, Cleaning, Verification and Calibration of Weighing Balance" (SOP No.: .....) is in place. There is well defined procedure to verification and calibration of weighing Balance.	• SOP No.- ..... • SOP No.-	3	1	1	3 **Severity:** Severity is high, as wrong quantity may dispensed **Occurrence:** Chance of occurrence is low, as daily verification & monthly calibration is in place **Detectability:** Can be easily detected	NA	NA	NA	NA	NA

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		Wrong material dispensed	• GWP not followed • Dispensing not done as per procedure • Improper segregation	Material mix ups Product failure Market Complaint	• Procedure for "Dispensing of Raw Materials to Production" (SOP No. .....) is in place. • There is well defined procedure for dispensing of material, Batch dispensing slip and identification slip generated through SAP system.	SOP No.:	3	2	2	6 **Severity:** Severity is high, can lead to product failure **Occurrence:** Chance of Occurrence is Possible, as Look alike materials are not properly segregated. **Detectability:** As material containers are look alike hence difficult to identify.	NA	NA	NA	NA	NA
6.	Qualification	Differential Pressure across filters not maintained	• Planner not in place • RLAF not working	• Contamination & cross contamination	• Qualification planner in place	SOP No.: ..... "Qualification Planner" SOP No.: ..... "Calibration Policy"	3	1	1	3 **Severity:** Severity is high, as contamination can take place **Occurrence:** Chance of occurrence is low. As	NA	NA	NA	NA	NA

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										planner is in place **Detectability:** Can be easily detected					
7.	GDP	Entry not properly done	Too many cuttings Not readable	Wrong quantity of material got dispensed	• Training on GDP is in place.	SOP No.: ..... "Good Documentation Practices"	3	2	1	6 **Severity:** Severity is high, as wrong quantity may dispensed, if not readable **Occurrence:** Chance of occurrence is possible **Detectability:** Detection is Possible as reviewed by procedure is in place.	NA	NA	NA	NA	NA
8.	Temperature & RH	Temperature & RH not maintained	Temperature & RH sensitive materials may got degraded.	Product failure Market Complaint	Materials are stored as per storage condition.	Handling & Storage of Raw Materials (SOP No.: .....)	3	1	1	3 **Severity:** Severity is high as material may got degraded.	NA	NA	NA	NA	NA

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										Occurrence: Chance of occurrence not possible **Detectability:** Can be easily detected					
9.	**Look Alike material**	Wrong Dispensing	Materials which are lookalike or having same name or containers may be dispensed unknowingly by the operator or workers.	Batch failure or Market Complaint	Proper segregation	SOP No.: ..... "Handling and Storage of Raw Materials"	3	1	1	6 **Severity:** Severity is high due to intermixing **Occurrence:** Verification procedure is in place **Detectability:** Can be easily detected, as labelling process is there	NA	NA	NA	NA	NA
GRANULATION															
10.	Cleaning	Improper cleaning	SOP of cleaning not followed	Contamination & Cross Contamination	• Line Clearance procedure is in place	SOP No.: ..... "Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid"	3	2	1	3 **Severity:** Cross contamination can lead to product failure **Occurrence:** Chance of	Risk is low hence no action plan is required	NA	NA	NA	NA

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										Occurrence is Possible. **Detectability:** Can be easily Detected visually					
11.	Sifting	Fine Particles Coarse Particles	Wrong sieve used for sifting	Non Uniform Granules	Sieve are issued as per SOP	..... Management of SS Sieves	2	1	1	3 **Severity:** Severity is moderate as IPQA parameters may got disturbed **Occurrence:** Chance of Occurrence is not possible **Detection:** Can be easily detected	NA	NA	NA	NA	NA
		Extraneous material contamination	Due to ruptured sieves, foreign particles may pass & mix with the good material	Product contamination	Sieve Integrity verified before & after use. Shifting of RM procedure is available at granulation stage. Activity is being performed under Production officer	..... Management of SS Sieves ..... "Line Clearance in Oral Solid Dosage, External Preparation and	3	1	1	3 **Severity:** Metal wires of **r**uptured Sieves can Contaminate the product	NA	NA	NA	NA	NA

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					and verified by IPQA. Material sifted as per the BMR in presence of QA person.	Oral Liquid"									
		Loss of sieve Integrity	• Improper handling of sieve. Washing, Storage, Usage. Sieve integrity pre and post verification not performed.	Non Uniform particles Mix-up of un-sifted material in batch	• Identification number is in place for each sieve. • Sieve washing procedure is designed to prevent the damage of the sieve. • The persons are trained for the activity. • Procedure for cleaning of sieve is in place. Cleaning of sieve carried out as per SOP. • The integrity verification is carried out before and after uses.	SOP No.:	1	1	1	1 **Severity:** Does not have any impact on health **Occurrence:** Low chance of occurrence **Detectability:** Can be easily detected.	NA	NA	NA	NA	NA
		Improper sizing	Required sieve not used Improper labelling on sieve. Improper labelling on sieve by the manufacturer.	Non Uniform particles Mix-up of un-sifted material in batch	• Sieve codification and labelling procedure in place i.e. as per SOP (.....). • Certification of the mesh size by using Densometer. • Certification of the screen size, Receipt checklist as per SOP. 'Disposal of rejected	..... Management of SS Sieves	1	1	1	1 **Severity:** Does not have any impact on health **Occurrence:** Low chance	NA	NA	NA	NA	NA

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			Wrong sieve identification. Human error.		accessories 'as per SOP (.....). • Sieve verification checks are introduced in the BMR. • Sieve verification checks procedure is in place • Experienced trained personals are allowed to work.					of occurrence **Detectability:** Can be easily detected.					
12.	Binder preparation	Improper binder solution	High or low consistency Human error. Inadequate heating of the steam kettle Inadequate paddling during preparation Quantity of HPMC & IPA deviated	Lumps formation	• Adequate procedure of binder preparation is introduced in the BMR and only trained personals are allowed to prepare it. • The water heating steps are introduced in the BMR • Trained personals are allowed to prepare it. • Qualified steam kettle is used for binder solution preparation. • Only trained personals are allowed to prepare it. • Validated during process designing. • No lump formation takes place.	Dedicated BMR	1	1	1	1 **Severity:** Does not have any impact on health **Occurrence:** Low chance of occurrence **Detectability:** Can be easily detected.	NA	NA	NA	NA	NA

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			Inadequate paddling during preparation Due to improper sequence binding agents addition in the steam kettle	Lumps formation	• Only trained personals are allowed to prepare it. • Only trained personals are allowed to prepare it. Sequence of addition mentioned in the BMR										
			Due to improper flow of binding agents addition in the steam kettle	No consistency	Before adding each material in the batch for each step, production supervisor verifies the material.	Dedicated BMR									
13.	Appearance of Paste	Particles in paste preparation Improper paste.	Starch used for paste not sieved Proper temperature not maintained Foreign particles contaminate the paste. Temperature sensor not working	Lumps formation IPQA parameters not achieved	Raw materials used are sieved through 100# sieve. Paste kettle is qualified	Dedicated BMR	1	1	1	1 **Severity:** Does not have any impact on health **Occurrence:** Low chance of occurrence **Detectability:** Can be easily detected.	NA	NA	NA	NA	NA
14.	Mixing Time in RMG	Deviation in critical control parameters	• Wrong interpretation of Ampere load • Bulk Density not	• Binder addition time not as per BMR	• Tablet hardness during online IPQA verification observed within limit	• BMR • APQR	3	2	1	6 **Severity:** Severity of failure of	Risk probable number calculated is	NA	NA	NA	NA
15.	Chopper speed of RMG														

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16.	Impeller speed of RMG		achieved • Improper size distribution • Flow property of granules will be affected • End point not achieved • Reproducible results not achieved • Roping flow motion of granules not achieved • Bumping motion of granules observed • Critical Quality parameters not achieved • RPM of impeller not achieved • RPM of chopper not achieved	• Manual binder addition • Raw material supplier not qualified • Formulation not validated • Equipment not qualified • Improper wet mixing time not achieved • Possibility of passing the wet granules between the mixing chamber base and impeller resulting into wrong ampere load interpretation • Traditional method (Banana breaking method of verification by taking wet granules in fist) used for verifying	• Tablet hardness verified online by Tantra software • Checked by process is in place • Ampere load verified & noted in BMR during binder addition • Ampere load verified noted in BMR after binder addition • All the critical process variables (speed of impeller, speed of chopper, Ampere load of impeller, Ampere load of chopper, time of wet mixing at each stage) are controlled by PLC i.e. recipe entered during the processing • Raw material used from approved vendor • Process validation already done for 03 batches • No any variation in critical quality attributes observed in Annual product quality review • Equipment qualified as per	• Qualification planner • Approved vendor list • Process validation report				ampere load is high, as it may affect the product quality **Occurrence:** Possibility of occurrence of wrong interpretation of ampere load is there. **Detectability:** Detection of Ampere load is done by verifying from PLC	low hence no recommended action required				
17.	Binder Addition time in RMG														
18.	Granulation time in RMG														

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				granules properties • PLC showing ampere load not qualified • Breakdown during processing • Chance of fluctuation in electric current may result into fluctuation in ampere load. • IPQA parameters got disturbed.	schedule • PLC validation already done										
19.	Mixing in RMG	Improper mixing of binder	Human error	Quality Issues during compression	• Binder quantity is weighed and recorded in BMR. • Binder Preparation is carried out as per instruction given in BMR • Activity carried out by trained Staff under supervision of production officer.	As per dedicated BMR	3	1	1	3 **Severity:** Severity is moderate, IPQA parameters got affected **Occurrence:** Chance of Occurrence is there **Detectability:** Can be detected	NA	NA	NA	NA	NA
		Improper granules	Improper poring of binder solution in the batch	Lump formation	• Binder addition in the batch carried out with mixing and is mentioned in BMR. Carried out under supervision.										

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												S	O	D	RPN
										visually					
		Batch / Lot mix up	Impact on batch yield.	• Wrong labelling • Product failure	• Lot wise transfer of material into sifting area. Instruction given in BMR • Label is counter checked by production officer prior to sifting and dry mixing. Activity carried out under supervision of production officer.	Dedicated BMR	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of Occurrence is Low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
		Improper Granulation	Variation in agitator speed	Over or under granulation	• Calibration for RPM & Timer is done after every 06 months	Qualification Dedicated BMR	2	1	1	3 **Severity:** Severity can be high in case of assay failure **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages **Detection:** Can be easily detected	NA	NA	NA	NA	NA
			Improper binder addition		• Binder addition and further mixing is done as per instruction given in BMR and same is recorded in BMR by production officer.										
			Very slow or fast binder addition		• Binder addition and further mixing is done as per instruction given in BMR and same is recorded in BMR by production officer.										
		Hard granules	Slow binder addition	High disintegration time	• Binder addition and further mixing is done as per instruction given in BMR and same is recorded in										

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					BMR by production officer.										
		Soft granules	Fast binder addition	Low hardness	• Binder addition and further mixing is done as per instruction given in BMR and same is recorded in BMR by production officer.										
		More Granules	Slow chopper speed	Weight variation at lower side, lower thickness	• Binder addition and further mixing is done as per instruction given in BMR and same is recorded in BMR by production officer.										
		More lumps	Slow speed of co-mill	Weight variation in compression	• Operation and cleaning of Co-mill SOP is in place and only trained personnel are allowed to operate and maintained.	Dedicated BMR	3	1	1	3 **Severity:** Severity can be high in case of assay failure **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages **Detection:** Can be easily detected	NA	NA	NA	NA	NA
			Slow speed of co-mill	Inadequate drying	• Operation and cleaning of Co-mill SOP is in place and only trained personnel are allowed to operate and maintained.										
			Fast speed of co-mill	High weight tablets	• Operation and cleaning of Co-mill SOP is in place and only trained personnel are allowed to operate and maintained.										
			Fast speed of co-mill	Less compressibility	• Operation and cleaning of Co-mill SOP is in place and only trained personnel are allowed to operate and maintained.										

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20.	Wet Milling	• Improper Sizing of granules • Different screen size used • Different RPM used	• Quality Issues during compression • Bioavailability of the drug decreases	• Improper particle size distribution • Lump formation • Moisture content increases	• Bulk & Finished analysis done by trained QC personnel & complies report available. • Trained operator performs the milling activity. • Parameters are approved as per validation recommendation.	Dedicated BMR	3	1	1	3 **Severity:** Severity can be high in case of assay failure **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages **Detection:** Can be easily detected	NA	NA	NA	NA	NA
21.	Drying	Loss of granules	Low yield	• Integrity of FBD bag failed. • Failure of SFM test	• FBD bag integrity checks introduced in BMR, shall be done before use and recorded in BMR • Procedure for SFM test in FBD is in place. SOP (.....) having well define procedure for Daily Operational check log for SFM Sensor and SFM Challenge Test fortnightly.	Dedicated BMR	3	1	1	3 **Severity:** Severity can be high in case of assay failure **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages	NA	NA	NA	NA	NA
		More fines	Over shaking of the FBD bag	High weight tablets	• Operation and cleaning of FBD SOP is in place and only trained personnel are allowed to operate and										

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												S	O	D	RPN
					maintained.					**Detection:** Can be easily detected					
		Over Drying	• Drying for longer time or low outlet temperature • To achieve proper granules	Low compressibility	• Drying time and outlet temperature validated during process designing. • Process Validation done to determine the end point. • LOD within the acceptance criteria.										
		Under drying	Drying for less time or high out let temperature	Sticking during compression	• Drying time and or outlet temperature validated during process validation. • LOD within the acceptance criteria.	Dedicated BMR	3	1	1	3 **Severity:** Severity can be high in case of assay failure **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages **Detection:** Can be easily detected	NA	NA	NA	NA	NA
		Out of limit LOD	Error in detection of LOD due to faulty moisture analyser	Compression issues	• SOP in place for operation, cleaning and calibration of Halogen moisture analyser.										
22.	Sizing	Screen size	• Wrong Screen size selected	Any variation in size may affect the particle size of the material	• Identification number mentioned on each Screen. • Operator is trained to perform sizing activity.	Dedicated BMR	2	1	1	2 **Severity:** Severity can be moderate a process	NA	NA	NA	NA	NA

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												S	O	D	RPN
				leading to variation in the process parameters.	• Process Validation batch. • Finished results are within the acceptance criteria.					parameters are verified during IPQA **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages **Detection:** Can be easily detected					
			The size of sieves to be used is mentioned in the batch manufacturing record.	Improper size could lead to non-removal of foreign particles that may be present in the material.	• The procedure mentioned in the BMR must be followed.										
		• Torn Sieve Different speed used	Process should be monitored manually. Visual checking should be done before and after use, and the information recorded in the BMR. Every unit is passed through the metal detector before final batch release.	Particle size distribution not as desired. Metal contamination. Mass variation problem during compression	• Procedural controls are in place. • Operator performing the sizing activity is well experienced & trained. • Parameters of Compressed tablets within the acceptance criteria. • Finished product result observed within the acceptance criteria.										
23.	Lubrication	Over lubrication	Over mixing	Capping of tablets	• Lubrication time shall be validated during process optimization. • Operator performing the	Dedicated BMR	3	1	1	3 **Severity:** Severity will be high due to variation in	NA	NA	NA	NA	NA
		Non-uniformity of blend	Over Mixing	The content may vary and dose variation											

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												S	O	D	RPN
		Flow of granules	Under Mixing	• Poor flow of granules • Sticking of granules	blending activity is well experienced & trained. • Lubrication time validated during Process Validation. • Parameters of Compressed tablets within the acceptance criteria. • In-process verification is in place • Bulk &FG COA meeting with specification.					assay **Occurrence:** Chance of Occurrence is low, can be easily detected in next stages **Detection:** Can be easily detected					
24.	Segregation	Containers not properly segregated Small quantity materials shall be kept in single polybag	• Too much of polybags or Containers. • Space shortage	• Product mix up • Product failure • Market Complaint	Each granulation area is having static pass box, materials are kept inside the pass box	SOP of Production Process and Control (.....)	3	1	1	3 **Severity:** Severity is high, can lead to mix ups **Occurrence:** Chance of Occurrence is low, can be easily traceable **Detectability :** Can be easily detected	NA	NA	NA	NA	NA
25.	Steam	Steam fluctuations	• Improper drying in FBD	• Drying time delay • Too much moisture	PLC based system installed in FBD		1	3	1	3 **Severity:** Does not have severe effect on health **Occurrence:**	Steam fluctuations shall be controlled				

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										Chance of Occurrence is there **Detection:** Can be easily detected					
COMPRESSION															
26.	Compression	High speed	Manual error during setting	Weight variation	Trained operators are allowed to operate the machine	Dedicated BMR	3	1	1	3 **Severity:** Low Assay can lead to severity **Occurrence:** Chance of Occurrence is low **Detection:** Can be easily detected during IPQA	NA	NA	NA	NA	NA
		Improper / inadequate feeding of dies	High speed	Weight variation	High speed challenged during process validation to determine the maximum speed.										
		Change in Machine setting	Due to continuous mechanical moment of machine	Variation in the batch	Initial middle and end, in-process sample tested during process validation to determine access the impact of continuous machine run on the product										
		Low hardness	Low compression force	Breaking and lamination	Compression force monitoring during process validation.		3	1	1	3 **Severity:** Tablet got break during transportation **Occurrence:** Chance of Occurrence is low **Detection:**	NA	NA	NA	NA	NA

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												S	O	D	RPN
										Can be easily detected during IPQA					
		High hardness	High compression force	Prolonged Disintegration time	Compression force monitoring during process validation.		3	1	1	3 **Severity:** Severity is High, can lead to low therapeutic effect **Occurrence:** Chance of Occurrence is low **Detection:** Can be easily detected during IPQA & QC analysis	NA	NA	NA	NA	NA
		Low thickness High thickness	Improper setting of the parameters. Wrong specifications in BMR. Human error	High hardness	Initials checks done and certified by production officer, same as recorded in BMR. Manufacturing done as per approved master BMR. • Procedure for personals training is in place. • Trained personnel to perform the job.		1	1	1	1 **Severity:** Thickness does not impact on health of user **Occurrence:** Chance of Occurrence is	NA	NA	NA	NA	NA

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												S	O	D	RPN
										low **Detection:** Can be easily detected during IPQA					
			Improper setting of the parameters. Wrong Specifications in BMR. Human error	Low Hardness	Initials checks done and certified by production officer, same as recorded in BMR.	Dedicated BMR	2	1	1	2 **Severity:** Severity is moderate **Occurrence:** Chance of Occurrence is low **Detection:** Can be easily detected during IPQA	NA	NA	NA	NA	NA
					Manufacturing done as per approved master BMR.		3	1	1	3 **Severity:** Severity is high in case of specification failure **Occurrence:** Chance of Occurrence is low **Detection:**	NA	NA	NA	NA	NA

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												S	O	D	RPN
										Can be easily detected during verification					
					• Procedure for personals training is in place. • Trained personnel to perform the job.		3	1	1	3 **Severity:** Severity is high in case of specification failure **Occurrence:** Chance of Occurrence is low **Detection:** Can be easily detected during verification	NA	NA	NA	NA	NA
		Poor flow	Low hopper level	Weight Variation	Hopper level challenges included in process validation to identify the impact on the compression of the product		3	1	1	3 **Severity:** Severity is high in case of weight variation **Occurrence:** Chance of Occurrence is Low as weight is verified	NA	NA	NA	NA	NA
		Excessive feeding	High hopper level		Hopper level challenges included in process validation to identify the impact on the compression of the product										
		Chocking of the hopper chute	High hopper level		Hopper level challenges included in process validation to identify the impact on the compression										

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												S	O	D	RPN
					of the product					during IPQA. **Detection:** Can be easily detected during verification					
		Wrong tooling fixed	• Wrong dose. • Incorrect identification.	Improper verification.	• Tooling certification by Production officer prior to machine setting as per BMR . • The upper and lower punch check is included in the BMR as initial setting	Dedicated BMR	3	1	1	3 **Severity:** Severity is high due to improper tooling **Occurrence:** Chance of Occurrence is low as verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA
				Mix-Up of tooling.	• Segregation of punch set during storage and punch set number recorded in BMR. • SOP for usage of punches and dies. • Visual check & certification for correct tooling during issue										
				Human error	• Procedure for personals training is in place. • Trained personnel to perform the job.										
		Wrong product taken for compression	Improper labelling. Wrong IPC delivered in cubicle	System failure. Product cross contamination. Poor	Label affixed to the container. Bin ID reflects in the BMR and is engraved on the bin.	Dedicated BMR & Labelling	3	1	1	3 **Severity:** Severity is	NA	NA	NA	NA	NA

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												S	O	D	RPN
			Human error	identification.	• Container is certified by production officer prior to compression. • Check against the granulation part of the BMR for number of containers. • Trained personnel to perform the job. • Labels counter checked by production officer					high in case of mix ups **Occurrence:** Chance of Occurrence is low as verification process is in place **Detection:** Can be easily detected					
		Wrong certification of initial checks	Improper setting of the parameters. Wrong specifications in BMR. Wrong reading from the IPQA instrument.	Product will not match with the standard specification.	Initials checks done and certified by production officer, same as recorded in BMR. • Manufacturing done as per approved master BMR. • Master BMR is prepared and cross checked by Q.A. Calibration of instrument as per schedule specified in respective SOP.	STS & STP	3	1	1	3 **Severity:** Severity is High in case of wrong specification **Occurrence:** Chance of Occurrence is low as verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA

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												S	O	D	RPN
		Parameters below or above the limit	Improper machine setting. Wrong reading from the IPQA instrument Human Error	• Out of specification (OOS) results. • Can affect the drug dosing.	• Initial and in process checks recorded in BMR. • Parameters certified by production officer and intermediate checks by QA officer. • Calibration of instrument as per scheduled specified in respective SOP. • Procedure for personals training is in place. • Trained personnel to perform the job.	STS & STP	3	1	1	3 **Severity:** Severity is high in case of deviation in parameters **Occurrence:** Chance of Occurrence is low as verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA
		Weight variation.	Uneven dose. Balance not calibrated Granules not fine. Equipment not qualified Human error Machine speed variation. Improper granulation.	Product Failure	• Trained personnel to perform the job. • Limit of weight specified in BMR. • Machine limit specified in BMR and recorded in BMR. • Trained personnel to perform the job. • In process tests (percentage fines, LOD) carried out and recorded in BMR. • Limit for in process tests specified in BMR.	Dedicated BMR	3	1	1	3 **Severity:** Severity is high in case of product failure **Occurrence:** Chance of Occurrence is low as verification process is in place **Detection:**	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
										Can be easily detected					
27.	Metal Detector	Generation of metal pieces during process due to defective sieves/screens, improper fitment of Multi mill screen into screen housing, improper setting of dies/punches to compression machine which that dies/punches can be damaged.	• Metal detector not works properly. • Magnetic grill to arrest metal pieces is not installed in octagonal blender • There is no procedure for empty run of compression machine to ensure unwanted abnormality. • AQL inspection is not performed. • There is no Standby and good condition of metal detector available in case of running metal detector goes out of work. • Challenge test for metal detector were not performed. • Sieve and Screen not verified for usage.	• Metal contamination in product. • Market compliant • Customer dissatisfaction. • Health impact.	• Metal detector to ensure metal contamination in product is used during compression process of every product, moreover, standby, clean and good condition of metal detector is used in case of any abnormality observes during operation by addressing the same through quality notification and by performing impact assessment. • Metal detector Challenge test is performed as per frequencies specified in SOP No. ..... of Metal Detector. • Magnetic grill to arrest metal pieces installed in octagonal blender, there is no chance of metal pieces exceptionally/ rarely if are carrying through excipients. • Sieve/screen integrity is checked during issuance and retrieval, written procedure is in place. • Integrity of sieves/screens is checked efficiently through	SOP No. ..... 'Operation and Cleaning of Metal Detector' SOP No. ..... 'Acceptable Quality Level for Oral Solid Dosage' SOP No. ..... 'Handling of Sieve and Screen' SOP No. ..... 'Cleaning, Lubrication, Tightening and Inspection of Machine'	3	1	1	3 **Severity:** Severity is high in case of metal contamination **Occurrence:** Chance of Occurrence is low as challenge test is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA

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												S	O	D	RPN
					illuminated light board. • The empty trial/run of compression machine before start the operation is done to ensure unwanted abnormality. • AQL inspection is performed for every batch of product after compression and coating process.										
28.	Granules Quarantine	Materials kept randomly in Granules Quarantine area without proper segregation & labelling.	• Material Intermixing • Product failure • Market Complaint	• Containers not segregated. • Containers not properly labelled. • Different batches of same appearance running in adjacent areas.	Proper planning is in place.	SOP for Receipt Storage Issuance of Materials in Staging Area Quarantine Area (.....)	3	2	1	6 **Severity:** Severity is high, can lead to mix ups **Occurrence:** Chance of Occurrence is possible **Detectability :** Can be easily detected	NA	NA	NA	NA	NA
29.	Physical Parameters	Tolerance limit mismatched with BMR & FG Specification	Typographical error	Product compressed with wrong parameters	IPQA parameters verified as per BMR	BMR	3	2	1	6	BMR & FG Specification to be aligned				
COATING															
30.	Gun to Gun distance	• Rough tablets • Twins • Higher thickness	• Improper Gun to Gun distance • Gun distance not measured	• Market complaint • Tablet fail in finished product specification.	• Always validate the gun to gun distance before the start of the coating. • Measuring scale available.	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
			• No measuring scale available • Untrained persons		• All operators are well trained & experienced.					impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected					
	Gun to Bed distance	• Twins • Higher thickness • Lower thickness • Shade variation	• Improper gun to bed distance • Gun distance not measured • No measuring scale available • Untrained persons	• Market complaint • Tablet fail in finished product specification.	• Always validate the gun to bed distance before the start of the coating. • Measuring scale available. • All operators are well trained & experienced.										
	Atomization air pressure	• Lumps formation over tablet surface	• Untrained person. • Improper flow of Compressed air. • Improper setting of air pipe. • Untrained persons	• Market complaint • Tablet fail in finished product specification. • Nozzle jam	• All controls are through PLC. • Pressure Gauge is installed for measuring atomization pressure. • Atomization pressure is recorded at regular interval in BMR. • All operators are well trained & experienced	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA

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												S	O	D	RPN
	Spray Rate	• Twins • Higher thickness • Lower thickness • Shade variation • Sticking of tablets	• Spray rate increases. • Spray rate decreases. • Fault in peristaltic pump. • Untrained operator. • Compressed air pressure fluctuation. • Wrong gun nozzle (size) selection.	• Market complaint • Tablet fail in finished product specification.	• All controls are through PLC. • Gun validation done before start of the coating process. • In-process checks verified regularly at fix interval for peristaltic pump & recorded in BMR. • All operators are well trained & experienced • Gun nozzle size identified before start.	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA
	Inlet air temperature	• Shade variation • Blistering • Orange peel • Lamination • Capping • Twins • Sticking	• Less drying. • Over drying. • Air processing unit not working properly. • Filter choked. • Scrubber tank malfunctioned. • Untrained operator.	• Market complaint • Tablet fail in finished product specification.	• All activities are PLC based. If any error occurred Equipment will be stopped automatically. • Inlet temperature is monitored at regular intervals. • Indicator towers are installed in all equipment. • Preventive maintenance done quarterly. • Water level in scrubber tank is monitored on daily basis. • All operators are well	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in	NA	NA	NA	NA	NA

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												S	O	D	RPN
					trained & experienced.					place **Detection:** Can be easily detected					
	Coating solution	• Tablet lumps • Shade variation • Twins tablets	• Improper milling • Improper filtration • Nozzle jam • Untrained operator • Material received from unapproved vendor.	• Market complaint • Tablet fail in finished product specification.	• Well defined procedure (BMR) for coating solution preparation. During preparation of coating solution, different process like milling of material is in place, so there is no change for nozzle jam. • All operators are well trained & experienced. • All materials are used from the approved vendor & vendor qualification procedure is in place.	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA
	Pan Speed	• Rough surface. • Edge broken • Scratch marks • Twins	• High pan RPM • Low pan RPM • Untrained operator	• Market complaint • Tablet fail in finished product specification.	• Separate recipe for every batch & product specific coating is done. • All operators are well trained & experienced. • All products are validated for Pan RPM & verified after regular frequency & recorded in BMR accordingly.	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:**	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
										Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected					
	Peristaltic pump	• Shade variation • Thickness variation	• Non-uniform flow of coating solution • Untrained operator	• Market complaint • Tablet fail in finished product specification	• It is a process parameter & verified during coating in-process. • All operators are well trained & experienced.	Dedicated BMR	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected	NA	NA	NA	NA	NA
	Utility (Compressed Air)	• Twins • Higher thickness • Lower thickness • Shade variation	• Spray rate increases. • Spray rate decreases. • Untrained operator. • Compressed air	• Market complaint • Tablet fail in finished product specification.	• All controls are through PLC. • In-process checks verified regularly at fix interval for	Compressed Air Qualification	2	1	1	2 **Severity:** Severity is low as it does not	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
		• Lumps formation	pressure fluctuation. • Malfunctioning of compressed air system		air pressure & recorded in BMR. • All operators are well trained & experienced • Yearly qualification done for pressure checks at all points. • Preventive maintenance on quarterly basis.					have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily detected					
	Mixing Baffle	• Shade variation	• Inappropriate (baffle selection) coating pan	• Market complaint • Tablet fail in finished product specification.	• All products are validated	Process Validation & Equipment Qualification	2	1	1	2 **Severity:** Severity is low as it does not have any impact on health **Occurrence:** Chance of Occurrence is low as BMR verification process is in place **Detection:** Can be easily	NA	NA	NA	NA	NA

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										detected					
31.	Gaskets of inlet & outlet duct	• Gasket got contaminated over a period of time	• Solution fumes got stuck on the surface of gasket over a period of time	• Contamination & Cross-contamination • Market Complaint	• Verification of gasket during line clearance	Reference BMR	3	2	1	6 **Severity:** Severity is High, as it can result into market complaint **Occurrence:** Chance of Occurrence is possible **Detection:** Can be easily detected	Gaskets shall be changed routinely				
32.	Segregation	Containers not properly segregated	• Product mix up • Product failure • Market Complaint	• Too much of Containers. • Space shortage	Each granulation area is having static pass box, materials are kept inside the pass box	SOP of Production Process and Control (.....)	3	1	1	3 **Severity:** Improper segregation can lead to inter mixing **Occurrence:** Chance of occurrence is not possible can be easily identified visually **Detectability :** Can be	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
										easily detected					
PACKING															
33.	Untrained Operator	Hands after sanitization not properly dried	Wet hands result into smudging of batch coding detail	Smudging & Miss- printing of details over Blister foil	Trained Operators	• SOP No.: ..... "Rejection Handling Management during Packing In-Process" • SOP No.: ..... "Training of Employees" • SOP No.: ..... "Qualification Challenge Test of Visual Inspector"	3	1	1	3 **Severity:** Severity is high, untrained operators can lead to serious issues **Occurrence:** Chance of Occurrence is not possible **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
		Spillage of thinner by mistake	Smudging of batch coding details												
		Rubber Stereo not adequately set	May be displaced												
		Batch code missed during initial setting	Possibility of less no. of rubber stereos set over printed foil												
		Specimen sample not collected	Miss printing missed out												
		Rejected strips not removed after break	Mixed with normal strips												
		Hopper loaded before verifying printing	Miss printed blister strips packed												
		Wrong change part issued or installed	Product wrongly packed	Change parts of different product not verified as per BMR	All change parts are issued as per the BMR.	SOP for Issuance, Cleaning and Retrieval of Change Parts for Blister/Alu-Alu and Strip Machine (.....)	3	1	1	3 **Severity:** Severity is high, can lead to wrong packing **Occurrence:** Chance of Occurrence is not possible **Detectability:**	NA	NA	NA	NA	NA

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												S	O	D	RPN
										Can be easily detected					
34.	Untrained Visual Inspectors	Missed out defective or look alikeBlister Strips& Cartons	Weak eye sight Un-attentiveness Untrained	Look alike foils & cartons not identified during secondary packing.	Trained Operators Visual Inspector Qualification	SOP for Do's and Don'ts in packing (.....)	3	1	1	3 **Severity:** Severity is high, can lead to wrong packing **Occurrence:** Chance of Occurrence is not possible **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
35.	Material Handling	Improper handling during different packing activities	Product mix up	• Availability of stereo of previous batch. • Additional issuance of stereo. • Usage of stereo without impression verification. • Usage of stereo having legibility problem. • Kept in open. • Stereo collected and sorted in between packing. • Decision taken by operator. • Stereo used without	SOP of Do's and Don'ts in Packing	Do's and Don'ts in Packing (.....)	3	2	2	12 **Severity:** Improper handling can lead to serious issues **Occurrence:** Chance of occurrence is possible, as the activities are person dependent **Detectability:**	Continuous training program is required				

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
				verification from production and QA. • Usage of similar type of change parts in parallel packing lines. • Usage of similar type of cartons in parallel packing lines.						Detectability is less					
36.	Material Receipt Note	Remaining foils may got mix up	Tracking of remaining foil is difficult	Mix ups	Foils are stored with identification	-	3	2	2	12	MRN of printed foil shall be stored with mother consignment				
37.	Art work	Wrong art work verified	Product Mix ups	Look alike carton verification not properly done Look alike foil with different label claim.	Art works are verified as per standard Art works are verified as per Product Information Sheet Reviewed by procedure is in place.	SOP No.: ..... "Artwork, Preparation and Approval" SOP No.: ..... "Handling of Artwork Through Management software"	3	2	1	6 **Severity:** Severity is high, product can packed into wrong carton or foil **Occurrence:** Chance of occurrence is possible **Detectability:** Can be easily detected visually	NA	NA	NA	NA	NA
38.	Rubber Stereo	Improper size of rubber stereo	Improper impression on blister foil	Smudging & Miss-printing of details over Blister foil	Proper records of Stereo are maintained	SOP No.: ..... "Manufacturing of Rubber	3	1	1	3 **Severity:** Severity is high	NA	NA	NA	NA	NA
		Improper dilution	Solution A & B not		Hold time established for										

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												S	O	D	RPN
			equally prepared		Ink (7 days)	Stereo" SOP No.: ..... "Batch Coding/ Printing System									
		Improper setting of stereo over drum	Untrained operator		All Operators & their subordinates are qualified & trained					**Occurrence:** Chance of Occurrence is less, as different verification stages are there. **Detectability:** Can be easily detected					
39.	Ink	Expired ink used	Impression not rinted on Blister foil		Ink purchased from approved vendor										
40.	Thinner	Spillage of thinner over printed strips	Inks used for printing are organic in nature & easily diluted by thinner or IPA (Solvent)		Dedicated box available for thinner										
41.	Hand Sanitizer	Hands of operator remain wet after sanitization			Trained Operator										
42.	Specimen Sample	Not verified	Miss printing missed during verification		Printing detail available in BPR & Stereo log book Specimen sample jointly verified by QA & production	BPR	3	1	1	3 **Severity:** Severity is high, can result into mix ups **Occurrence:** Chance of Occurrence is not possible; as sufficient check points are there. **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
43.	Printed Foil	Vendor not approved	Foil is of bad quality		Approved Vendor	Approved Vendor	3	1	1	3 **Severity:** Severity of bad quality foil is high	NA	NA	NA	NA	NA

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										Occurrence: Vendors are approved, hence chance is less **Detectability:** Can be easily detected					
44.	Rejection	Rejection box not available	Rejected strips mixed	Smudging & Miss- printing of details over Blister foil.	Rejection box with lock & key available. During the initial machine setting and foil change over, the window between the primary and secondary area shall be kept close so as to avoid such observation.	SOP No.: ..... "Packing Material Rejection Stage Wise During Packing" SOP No.: ..... "On line rejection" SOP No.: ..... "Rejection Handling Management During Packing in Process"	3	1	1	3 **Severity:** Severity is high, can leads to mix ups **Occurrence:** Chance of occurrence is not possible **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
45.	Similar looking product	Mix ups	Market Complaint	Mix-ups of tablets/capsules/ bottles/ sachets/ strips/blister /Alu-Alu pack/cartons /labels & overprinting	• Similarly look alike/ similar name product shall not be inspected/ primary packed on adjacent lines. • Similar look alike labels/ cartons/ foils/ leaflets	SOP No.: ..... (Production Process and Control) SOP No.:	3	1	1	3 **Severity:** Severity of mix ups is high **Occurrence:**	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch												**Quality Risk Assessment No.: .....**			
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
				during adjacent to each other.	having similar name shall not be stored adjacent to each other, belt empty or filled with product. • Similar look alike labels/cartons shall not be over coded on adjacent over coding lines. • Similar looking product's strips/ blisters/cartons/ labels/ shippers shall not be packed on adjacent secondary packing lines. • Two different batches of same product shall also not be packed on adjacent lines. • There is well defining procedure for line clearance for avoid miss-up.	"Line Clearance"				Chance of Occurrence is possible **Detectability:** Can be easily detected					
46.	Carton mix-up	Carton mixing at vendor end	Mixed Carton dispensed for packing	Mixed cartons not verified during receiving	• Dispensed material are kept in lock and key. • The list of the cartons of same color, size, shape and layout with different strength have been prepared for proper identification and to avoid the carton mix-ups. • 100% inspection is done	SOP No.: ..... "Receipt Handling and Storage of Packing Materials" SOP No.: ....1 "Dispensing of Packing Materials"	1	2	2	4 **Severity:** Severity of mix ups is high **Occurrence:** Chance of Occurrence is possible	Proposal for online carton coding and Camera detection system for improved controls.	NA	NA	NA	N A

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												S	O	D	RPN
					after dispensing and 100% inspection done after overprinting of cartons. • Rejection album has been revised accordingly	SOP No.: ..... 'Line Clearance" SOP No.: ..... "Operation and Cleaning of Auto-cartonator" SOP No.: ..... "Operation and Cleaning of Packing Conveyor" SOP No.: ....."Qualification Challenge Test of Visual Inspector" SOP No.: ....."Production Process Control"				**Detectability :** Can be easily detected					
	Carton mix-up	Carton mix-up during packing material receipt	Missed cartons may reach to packing storage area.	• Material receipt procedure not available. • Material receipt through manual procedure.	• SOP for Receipt, Handling and Storage of Packing Materials (SOP No. .....) is in place. • Material receipt procedure done through SAP.	SOP No.: ..... "Receipt Handling and Storage of Packing Materials" SOP No.: ..... "Dispensing	1	2	2	4 **Severity:** Severity of carton mix up during packing material receipt is of low category as checks are	NA	NA	NA	NA	NA

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												S	O	D	RPN
				• Material receipt checklist not available.	• Material receipt checklist is in place, during material receipt following check point verified. ➢ E-way bill of the consignment. ➢ Appropriateness of company address on the delivery documents. ➢ Approved Manufacturer / Supplier address with AVL (Approved Vendor List). ➢ Availability of Vendor Certificate of Analysis copy. ➢ Reference of Purchase Order number on the documents. ➢ Description of the material in purchase order tallies with consignment delivery document etc.	of Packing Materials" SOP No.: ..... 'Line Clearance" SOP No.: ....."Operation and Cleaning of Auto-cartonator" SOP No.: ..... "Operation and Cleaning of Packing Conveyor" SOP No.: ..... "Qualification Challenge Test of Visual Inspector" SOP No.:....."Production Process Control"				sufficient in further stages to control the carton mixing. **Occurrence:** Mix up of cartons during receipt is possible as 100% cartons are not verified. **Detection:** 100% verification is not possible					
	Carton mix-up	Carton mix-up during packing material storage	Carton will be forwarded for Dispensing	• Material storage procedure not available.	• SOP for Receipt, Handling and Storage of Packing Materials (SOP No. .....is in place. • Warehouse officer/Executive shall take the daily incoming from SAP and shall entered	SOP No.: ..... "Receipt Handling and Storage of Packing Materials"	1	2	2	4 **Severity:** Severity of carton mix up during packing material storage is of	NA	NA	NA	NA	NA

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
					rack No.in work sheet. ● Warehouse person shall enter all noted inventory in SAP bin location. ● After release in SAP all type approved packaging material transfer to dedicated location and enters details in SAP for Bin Location updating.	SOP No.: ..... "Dispensing of Packing Materials" SOP No.: ..... 'Line Clearance" SOP No.: ....."Operation and Cleaning of Auto-cartonator" SOP No.: ..... "Operation and Cleaning of Packing Conveyor" SOP No.: ..... "Qualification Challenge Test of Visual Inspector" SOP No.: ....."Production Process Control"				low category as checks are sufficient in further stages to control the carton mixing. **Occurrence:** Mix up of cartons during storage is possible in case separator is not available or not properly arranged. **Detection:** 100% verification is not done during storage				
	Carton mix-up	Carton mix-up during dispensing packing material.	Mixed Carton will reach to coding area	● Line Clearance procedure not available. ● Dispensing of	● SOP for Dispensing of Packing Materials (SOP No. .....) is in place. ● All dispensing activity of	SOP No.: ..... "Receipt Handling and Storage of Packing	1	2	2	4 **Severity:** Severity of carton mix up during	NA	NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
				packing Material procedure not available. • Dispensing done without "Packing Material Issue Slip". • Procedure for printing of material identification slip not available. • Issuance of additional packing materials through Manual procedure.	packing material done through SAP generated packing material issue slip. There is well defining procedure for generation of packing material issue slip in SOP. • Material identification slip generated through SAP with pre-printed quantity as per batch packing material issue slip. There is well defining procedure for printing of material identification slip in SOP. • Issuance of additional packing materials activity done through SAP generated packing material issue slip. There is well defining procedure for generation of packing material issue slip in SOP	Materials" SOP No.: ..... "Dispensing of Packing Materials" SOP No.: ....."Line Clearance" SOP No.: ..... "Operation and Cleaning of Auto-cartonator" SOP No.: ..... "Operation and Cleaning of Packing Conveyor"....."Qualification Challenge Test of Visual Inspector" SOP No.: ....."Production Process Control"				dispensing of packing material storage is of low category as checks are sufficient in further stages to control the carton mixing. **Occurrence:** 100% cartons are not verified during dispensing. **Detection:** 100% verification is not done					
	Carton mix-up	Carton mix-up during Batch coding.	Mixed carton will reach to Secondary packing area	• Line clearance procedure not available. • Batch Coding done without verification of	• SOP for Batch Coding /Printing System ..... is in place. • SOP having well defined procedure for line clearance of Coding/Printing area.	SOP No.: ..... "Receipt Handling and Storage of Packing Materials" SOP No.:	1	2	2	4 **Severity:** Severity of carton mix up during batch coding is of low category as checks are	NA	NA	NA	NA	NA

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												S	O	D	RPN
				material. ● Reconciliation procedure of dispensed material procedure not available. ● Procedure for storage of printed carton not available. ● The process of carton over coding is manual process and during the process the person might missed the carton, mistakenly due to same size, shape and layout and similar color except for difference in brand name as it is a continuous online process and there may be possibility that one such carton	● As per SOP two step verification (Doer and checker) procedure by production and QA is in place. ● Production person shall make the request for the overprinted cartons of the required batch as per production plan in in log book. ● After completion of the coding of the cartons, store in separate rack with status label and make entries in log book. ● Reconciliation procedure of dispensed material is a part of BPR and after completion of reconciliation product transfer for further stage. ● Container color code procedure available for handling of different type of material such as good and reject material in SOP. Blue colure container used for storage of good carton and Red color container used for reject carton.	..... "Dispensing of Packing Materials" SOP No.: ..... 'Line Clearance" SOP No.: ..... "Operation and Cleaning of Auto-cartonator" SOP No.: ..... "Operation and Cleaning of Packing Conveyor" SOP No.: ..... "Qualification Challenge Test of Visual Inspector" SOP No.: ....."Production Process Control"				sufficient in further stages to control the carton mixing. **Occurrence:** Mix up can be missed During batch coding, if cartons are of same type or design. **Detection:** 100 % verification is not possible					

Procedure: Process Mapping from Dispensing to Dispatch											**Quality Risk Assessment No.: .....**					
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
				could missed.											
47.	Carton mix-up	Carton mix-up during secondary packing area.	• Market Complaint • If prescribed, may lead to health issue	• Line clearance procedure not available. • After carton packing verification procedure not available. • Handling of similar looking material procedure not available. • Visual Inspectors not trained. • Proper training not available.	• SOP for Line clearance procedure(SOP No. .....) is in place. • SOP for operation & cleaning of auto cartonator (SOP No. .....) is in place. • SOP for operation & cleaning of packing conveyor (SOP No. .....) is in place. • SOP having well defines procedure for line clearance of secondary packing area and equipment's. • As per SOP two step verification (Doer and checker) procedure by production and QA is in place. • Procedure for online inspection after carton packing is in place. • Packed carton verification done by qualified inspector.	SOP No.: ..... "Operation and Cleaning of Packing Conveyor" SOP No.: ..... "Qualification Challenge Test of Visual Inspector" SOP No.: ....."Production Process Control"	3	1	2	6 **Severity:** Severity of carton mix up during secondary packing is of high category as during secondary packing, final check of each carton is done during online visual inspection. In case of online failure (carton mixing not verified) then the severity can be high. Because further only terminal inspection is done which does not cover 100% carton inspection. **Occurrence:**	NA	NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
					• SOP for Qualification and Challenge Test of Visual Inspector (SOP No. .....) is in place. • SOP for Production Process and Control (SOP No. .....) having procedure for Similar looking products shall not be packed on adjacent secondary packing lines. • Remaining pack stocks of Cartons are reviewed. • Control Samples are reviewed.					Chance of missing the carton mixing during online monitoring rare only in case visual inspectors are not properly trained. **Detection:** 100% verification is possible in case of trained visual inspectors but in case of same designed cartons, chance of error is there.					
48.	Action Plan	Mix ups	Action plan not in place in case of mix up	Separate SOP not in place	In case of 1 critical defect observed in FG during terminal inspection, then √N +1 CB shall be given to production for re-checking.	SOP for Do's and Don'ts in packing	2	1	1	2 **Severity:** Severity is moderate in case of no action plan. **Occurrence:** No chance of occurrence as SOP is in place.	NA	NA	NA	NA	NA

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										Detectability: Can be easily detected					
49.	Rejection Box	Unavailability of rejection box	Rejected Strip further forwarded for Secondary packing	Rejected Strips got intermixed with good strips	Separate Rejection boxes are available and as per practice rejected strips are kept in rejected box after any break	SOP for ..... "Rejection Handling Management During Packing in Process"	3	1	1	3 **Severity:** Severity is high can lead to mix ups. **Occurrence:** Occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
50.	Initial Verification	Initial Verification not done	Missed to do initial verification	Wrong strips got packed during secondary packing	Printing detail on plain foils verified before running blister machine	As per BMR	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of Occurrence is not possible **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
51.	Break	Rejected Strips packed	Defective strips remains in web during lunch break	Unintentionally the remains of defective strips got packed during secondary packing	Instructions are given to reject those strips which remains in web after a break. Trained Visual Inspectors available for secondary	SOP No.: …… "Do's and Don'ts in Packing"	3	1	1	3 **Severity:** Severity is high, can lead to mix ups **Occurrence:**	NA	NA	NA	NA	NA

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
					packing.					Chance of occurrence **Detectability:** Can be easily detected					
52.	Verification	Stage wise verification not done	Mix ups Market Complaint	Verification not done at initial, after break, at middle & at the end of primary packing.	Verification part is documented after every stage	Reference BPR	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is high **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
53.	Specimen Sample	Specimen sample not collected & verified	Mix ups Market Complaint	Specimen sample not attached in BPR for reference	Specimen sample is attached with BPR for reference purpose & stereo are returned and their rejection record is maintained for tracking purpose.	Reference BPR	3	1	1	3 **Severity:** Severity is high **Occurrence:** Occurrence is not possible **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
54.	Terminal Inspection	Terminal Inspection not done	Random terminal inspection not done	Label not Verified over Shipper, Cartons not verified	Terminal inspection is done for each product and documented	Reference BPR	3	1	1	3 **Severity:** Severity is high	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
										Occurrence: Chance of occurrence is low **Detectability:** Can be easily detected					
55.	Training	Persons not trained	Operators, their subordinates and visual inspectors not properly trained	Smudging & Miss-printing of details over Blister foil	Training given to all related persons	SOP No: ....."Training of Employees"	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
56.	Practices	Current practices not followed Transfer practices not followed	Current verification& transfer practices not followed during different stages	Specimen sample not verified Rejection not kept separated	Verification practices are a part of documentation	SOP No.: ……"Do's and Don'ts in Packing"	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of Occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
57.	Customer	Customer sanitize the strip	Smudging & misprinting over carton	Customer used wet hand during	No control	-	3	1	1	3 **Severity:**	NA	NA	NA	NA	NA

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												S	O	D	RPN
			or blisters	receiving strip from pharmacist resulting into smudging of printed details						Severity is high **Occurrence:** Occurrence is low **Detectability:** Can be easily detected					
58.	Mixing of Shippers	• Mixing of shipper of different batches of same product. • Mixing of shipper of different batches (similar looking product). • Mixing of shipper of different batches (different looking products)	Appropriate labelling or labelling not done	• Chance of mix up increases as shippers are not identified. • Actual shipper quantity mismatched with the batch ticket. • Tracking not possible • Mixing chance increases.	After receipt of the batch, all shippers are checked for appropriate labelling.	SOP No.: ..... "Preparation, Printing, Checking and application on batch shipper of shipper label" SOP No.: ....."Receipt, Storage & Dispatch of Finished Product" SOP No.: ..... "Terminal Inspection & Transfer of Finished Goods"	3	2	1	6 **Severity:** SeverityofInappropriate labelling is high & may lead to inter mixing of product. **Occurrence:** Chance of occurrence is possible. **Detectability:** Inappropriate labelling can be easily detected during final verification before dispatch.	NA	NA	NA	NA	NA
			Shippers were not stored properly or segregated at	• Chance of mix up increases as	Final product stored on racks, suitably spaced from		3	2	1	6 **Severity:** Severity is	NA	NA	NA	NA	NA

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S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
			proper distance	shippers are not identified. • Actual shipper quantity mismatched with the batch ticket. • Tracking not possible Mixing chance increases.	other batches of the same or different product.					high; shippers not segregated can inter mix easily. **Occurrence:** Possibility of occurrence is there. **Detectability:** Can be easily detected as verification process is in place.					
59.	Illumination	Light intensity low	Missed out look alike foils & cartons	Weak eyesight or low light intensity	Visual Inspector qualification	Monitoring of Light Intensity of Inspection Room/Area	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of Occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
60.	Frequency of Qualifying Visual Inspectors	Visual inspectors not qualified as per schedule	Unqualified Visual inspectors missed the rejected strips	Too much hectic schedule or visual inspectors not qualified or new joinee.	Visual inspectors are qualified as per schedule	SOP No.: .....“Qualification Challenge Test of Visual Inspector”	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of	NA	NA	NA	NA	NA

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												S	**O**	**D**	**RPN**
										Occurrence is high **Detectability:** Can be easily detected					
61.	Product Expiry	Expired product may be used	Expiry cannot be identified	Health issue	Expiry date can be tracked through carton& foils	Reference BPR	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
62.	Sufficient Number of persons	Sufficient persons not available	Insufficient number of visual inspectors	Required persons not available or untrained	Complete strips are verified by sufficient checkers	Planning Dashboard	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
63.	Light Intensity	Light intensity not proper for online verification	Detail not visible	Missed critical details	Light intensity verified during qualification	SOP No.: ..... "Monitoring of Light Intensity of Visual Booth"	3	1	1	3 **Severity:** Severity is high	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch											**Quality Risk Assessment No.: .....**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										Occurrence: Chance of occurrence is low **Detectability:** Can be easily detected					
64.	Initial Machine Setting	Improper initial setting of machine	Stereo not properly in lined with drum	Smudging & Miss- printing of details over Blister foil	Strips are verified and documented during initial machine setting	SOP No.: ..... "Plant Equipment Preventive Maintenance"	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
65.	Preventive Maintenance	Scheduled Preventive maintenance not done	Machine not working properly due to missing of preventive maintenance	Miss printing due to improper setting	Preventive maintenance done as per schedule and records maintained	SOP No.: ....."Preventive Maintenance of Equipment/Machines"	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
66.	Qualification	Blister packing machine not qualified	Unqualified Blister machine not work properly	Camera system not detect the wrong tablets	Camera challenge test is performed as per plan	Qualification of Blister packing machine	3	1	1	3 **Severity:** Severity is	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch											**Quality Risk Assessment No.: .....**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected					
67.	Change Parts	Wrong change part issued or installed	Product wrongly packed	Change parts of different product not verified as per BMR	All change parts are issued as per the BMR.	SOP for Issuance, Cleaning and Retrieval of Change Parts for Blister/Alu-Alu and Strip Machine (.....	3	1	1	3 **Severity:** Severity is high **Occurrence:** Chance of occurrence is low **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
68.	Pressure regulation	Low pressure resulting into small cavities	Pressure fluctuation	Compressed air qualification not in place	Qualification available	-	3	1	1	3 **Severity:** Uncontrolled pressure may result into small cavities resulting into tablet sticking. **Occurrence:** Pressure regulators are in place	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch											**Quality Risk Assessment No.: .....**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										Detectability: Can be easily detected					
				Compressed air regulator not in place	System of automatic cut off n place	NA	3	1	1	3 **Severity:** Uncontrolled pressure may result into small cavities resulting into tablet sticking. **Occurrence:** Pressure regulators are in place **Detectability:** Can be easily detected	NA	NA	NA	NA	NA
69.	Automatic cut off			System of automatic cut off by passed.		NA	3	1	1	3 **Severity:** Uncontrolled pressure may result into small cavities resulting into tablet sticking. **Occurrence:** Pressure regulators are in place	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch											**Quality Risk Assessment No.: .....**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										Detectability: Can be easily detected					
70.	Pressure	Pressure not sufficient	Tablet sticking	Small Cavities	Packing Validation in place	-	3	1	1	3 **Severity:** Low pressure may result into small cavities resulting into tablet sticking. **Occurrence:** Pressure regulators are in place **Detectability:** Can be easily detected through PLC	NA	NA	NA	NA	NA
71.	Placing of tablets	Tablets not placed properly at the center of cavity	During sealing, tablet got stick with base foil.	Brush used for cleaning not properly adjusted	Brushes are properly adjusted	-	3	2	1	6 **Severity:** Misplaced tablets in cavity may got stick with inner side of foil resulting into peel off. **Occurrence:** Chance of misplaced tablets is there, if not	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch											**Quality Risk Assessment No.: .....**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
										monitored properly. **Detectability:** Can be easily detected by operator.					
72.	Sticking tablet verification	Not verified for stickiness	Sticking tablet forwarded for further packing	Tablet verification for stickiness is not a part of SOP	No any control	SOP No.: ....."Operation and Cleaning of Leak Test Apparatus"	3	2	1	6 **Severity:** Defective tablets will not be identified which further result into market complaint. **Occurrence:** Failure may take place, if missed. **Detectability:** Can be easily detected, in case verification procedure is in place.	NA	NA	NA	NA	NA
73.	TB of Cavity	Improper cavity formation	Tablet sticking	Improper pressure	Cavity dimensions are freezed	Change part layout	3	2	1	6 **Severity:** Improper cavity may result into sticking of tablets	NA	NA	NA	NA	NA

Procedure: Process Mapping from Dispensing to Dispatch | **Quality Risk Assessment No.: .....**

S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
										Occurrence: Small cavity may form in case of improper pressure. **Detectability:** Cavity can be measured during the packing.					

S.No.	Recommended Action	Responsible Person	Target Date of Completion
	WAREHOUSE		
1.	Awaiting GRN material shall not be stored in receiving bay area.		
2.	Look Alike raw materials or containers shall be stored with segregation.		
3.	All materials shall be segregated & properly labelled in Day Store & Staging area		
	GRANULATION		
4.	All products shall be evaluated through Quality improvement plan with respect to process, packing & analytical gaps.		
5.	All Containers shall be segregated & properly labelled in Staging area & Quarantine area		
6.	Granules bags shall be properly segregated & shall be kept in closed trolley in corridor.		
7.	Small quantity materials shall be kept wrapped in single polybags		
8.	Steam fluctuations of FBD shall be controlled.		
	COMPRESSION		
9.	Containers shall be kept in segregation along with labels.		
10.	Physical parameters/ acceptance criteria/ Tolerance limit mismatched with respected to the BMR & FG specification (should be aligned).		
11.	Continuous training shall be given.		
	COATING		
12.	Steam fluctuation shall be controlled		

S.No.	Recommended Action	Responsible Person	Target Date of Completion
13.	Gaskets of inlet & outlet ducts shall be changed routinely or whenever required.		
	PRIMARY PACKING		
14.	MRN of Printed foil shall be stored with mother consignment only.		
15.	Batch Inspection System/ Camera/ NFD/ Pin Hole Detector should be operational.		
16.	Defects should be immediately transferred into rejection box.		
17.	Air pressure limit for Look like PVC shall be freezed.		
18.	Window connecting from primary packing to secondary packing should be closed with the acrylic/ SS guard.		
19.	Specimen of foil with batch coding details should be verified by both production and IPQA during initial setting of machine.		
20.	Automatic Batch Coding machine with Camera system to be procured.		
21.	Verify the operating parameters of the machine after any break (Lunch/Tea etc.) and continue the activity, if operating parameters are found satisfactory		
22.	The rotation of the checker has to be done at per the frequency mentioned in the respective procedure and the same shall be recorded in the respective BPCR.		
23.	Base foil should be wrapped in polybag.		
24.	Verify the batch details and no. of rolls from packing material issue slip.		
25.	Discard 01-02 meter of foil before loading on machine.		

S.No.	Recommended Action	Responsible Person	Target Date of Completion
	SECONDARY PACKING		
26.	Empty Carton should be collected from the rejection box at the end of shift, end of batch or any break in presence of production and IPQA line in-charge.		
27.	Rejection album shall be updated and displayed near the leak test apparatus.		
28.	Similar looking carton or similar looking packing components should be procured from different vendors to avoid any mix-up at vendor stage.		
29.	Same product with different strengths or product having similar looking packing component like foil/ cartons/ leaflets or same product with different batches etc. should be planned after completion of one batch or in the areas, where there is sufficient gap to avoid any chances of mix-up.		
30.	Similar looking products, same product different strength or same product different batches should be stored at different location at various stages of packing.		
31.	Used red tape for joint to ease in identification.		

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

Verification of Recommended Action:

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Remarks (if any):

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Verified By
Operating Person QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)

7. CONCLUSION:

8. REFERENCES:

- Reference SOP of Risk Assessment.
- Related SOP's.

9. DOCUMENTS TO BE ATTACHED:

- Not Applicable

10. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

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11. CHANGE CONTROL, IF ANY:

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12. ABBREVIATIONS:

FMEA	: Failure Mode Effect Analysis
RPN	: Risk Priority Number
CAPA	: Corrective action preventive action
SOP	: Standard Operating Procedure
QRM	: Quality Risk Management
QA	: Quality Assurance

13. FMEA APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING PERSON (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			