Risk Analysis Study Protocol cum Report for Mix-ups Dispensing to Dispatch (D_2D)

"the undesired introduction of impurities of a Chemical or Microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport"

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

2. **SCOPE:** The scope of this document is limited to Risk Assessment of Mix ups 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 mix up from Dispensing to Dispatch.

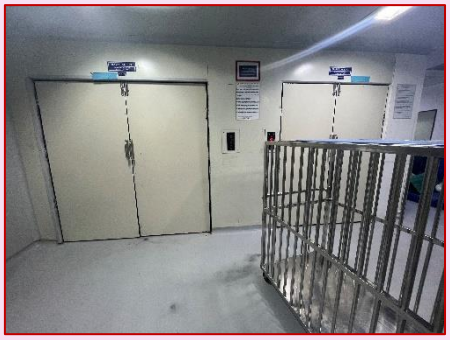
5. **SITE OF STUDY:**
M/s ……

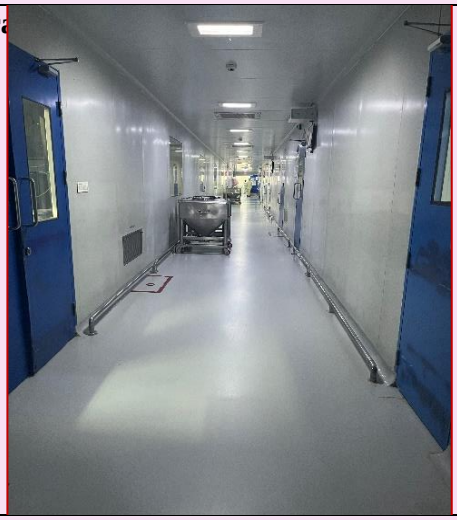
6. **RISK COMMUNICATION & TRAINING:**
- The Risk analysis team shall be authorized by the Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of expert from different areas.
- Training shall be imparted to the concerned team.

7. RISK IDENTIFICATION, EVALUATION & MITIGATION:

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Warehouse		
Rece  exter	All materials are received at receiving bay, from there the material containers are verified and forwarded to waiting for GRN area. In case receiving materials are not verified properly (Physical appearance of containers & labelling) and remain kept at the receiving bay, it can be contaminated or mix up with the next upcoming material.	SOP for "Receipt of Raw materials in Warehouse" is in place (…….).All containers are checked for integrity of package & seal. All API containers are weighed 100% while excipients are weight √n+1.
De-dusting tunnel(De-dusting tunnel not working or not qualified)	De-dusting tunnel is used for cleaning the outer side of receiving containers. Failure of the de-dusting tunnel can lead to contamination & cross contamination.	SOP for Operation & Cleaning of De-Dusting Conveyor tunnel (……..) is in place. Preventive maintenance of the same is done on Quarterly basis. While qualification is already performed.
GRN Waiting(Material kept in GRN waiting area may got inter mixed with othe 	Material kept for long waiting in GRN area can result into mixing with other awaiting materials.	Materials are kept segregated with status labelling as per SOP No. ……..“Status Labelling”
Rejected Material(Rejected material is not in lock & key) 	Rejected materials are inter mixed with good material.	Separate area with lock & key is in place, rejected materials are labelled as per SOP of Status Labelling “……..” & kept for 90 days only.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Quarantine(Containers not segregated & neither properly labelled) 	After receiving all the related documents, the material from GRN is transferred to the Quarantine area. To avoid inter mixing, materials in Quarantine area must be segregated by rope. Status labelling shall be done accordingly.	All containers are kept segregated as per SOP of Receipt of Raw Material (……. & Status labelling shall be done as per SOP No. …….
Sampling (Complete sampling not done & material kept in Approved area without final approval) 	In case material received from other plants & kept in Approved area without any proper labelling may lead to intermixing.	SOP No.: ……for Sampling is in place (Sampling of Non Sterile Raw Materials). All materials are sampled as per SOP along with status labelling.
Under Test(Containers not segregated & neither properly labelled) 	After sampling, the materials are kept in under test area, separate rack system is in place and containers are segregated by using ropes. Improper segregation can lead to mix ups of similar look alike material containers.	All containers are kept segregated as per SOP of Receipt of Raw Material (…….) & Status labelling shall be done as per SOP No. .....
Approved(Containers not segregated & neither properly labelled) 	After analysis, the material containers are kept in Quarantine area. All racks in quarantine area are segregated and identified rack wise. Materials in same racks are segregated by partitions. Improper segregation can lead to mix ups of similar look alike material containers.	As per SOP ..... “Handling & Storage of Raw Materials”. SAP BIN allocation for materials index is maintained by ware house personnel& rack ID allocated accordingly.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Dispensing(Number of materials dispensed at a time without proper labelling) 	There are separate dispensing areas for API & excipients, at one time only 10 same materials can be dispensed. As all materials dispensed are of same appearance and kept in one pallet, so in case of any mix ups, traceability is difficult.	Dispensing is performed by trained personals, partition is given between each material with labelling.
Da 	After Dispensing, materials are kept batch wise, if not properly segregated, mix up chances may take place.	Proper segregation is done along with proper labelling.
Staging Area 01 	There are 02 staging areas, one near day store & the next one in manufacturing area. Proper segregation & labelling plays important role. If not properly segregated& labelled, mix up may take place.	Proper segregation is done along with proper labelling.
Lift 	By lift, the dispensed material is transferred to the Staging area 02 (Manufacturing area). Again segregation plays important role. One batch at a time is transferred by lift.	Single batch is transferred at a time. Before transfer, the batch is verified by the chemist.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Granulation		
Staging Area 02 	After dispensing, the materials are transferred to the staging area. Materials kept in containers & separate pallets.	Batch receiving process is in place.
Gra 	As per the requirement, the containers are kept in corridor for granulation. All Granulation areas are adjacent to each other. In case, if look alike products runs parallel in adjacent areas, there may be the chance of mix ups.	Containers are segregated & properly labelled. Batch is completely verified for its content & identity. Weight of each content is verified for its quantity. Reviewed by QA personnel.
	During granulation, material verification plays important role, if not verified, the wrong material may be used for further processing activity.	
	Labelling plays important role, if not verified before granulation, then chance of mix up increases.	
Granules Quarantine 	Granules kept in quarantine must be segregated rack wise and should be traceable.	After completion of the granulation, the containers are labelled & stored in granules quarantine with proper segregation & identification.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Compression		
Compression Area 	As per the requirement, the containers are kept in corridor for Compression. All Compression areas are adjacent to each other. In case, if look alike products runs parallel in adjacent areas, there may be the chance of mix ups.	After granulation, the granules are kept inside the containers with proper labelling & segregation. Further transferred to Compression to compression area through Static pass box.
	During Compression, material verification plays important role, if not verified, the wrong material may get Compressed.	Material verification is done before going for Compression.
	Labelling plays important role, if not verified before Compression, then chance of mix up increases.	Labelling verification is done before going for Compression.
Die & Punch Storage Area 	Care must be taken before punch issuance, in case of punch with almost same type of description may result into wrong punch issuance.	Punches and Dies are kept rack wise with separate identification. Punches are issued as per the BMR. Further each tablet is being verified during inching to avoid any mix up.
Compressed Tablet Quarantine 	Compressed Tablets kept in quarantine must be segregated rack wise and should be traceable.	Segregation and proper identification is in place and tablet containers are kept batch wise.
Coating		

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Coating Area 	Improper coating material verification can lead to wrong coating or mix ups.	Coating materials are issued as per BMR, the same is re-verified by QA Chemist.
Coating Quarantine 	Segregation & Labelling plays important role in coated tablet quarantine.	Segregation and proper identification is in place and tablet containers are kept batch wise.
Primary Packing Storage Area		
Artwork Verification	Artwork not verified properly for its label claim& name may result into mix ups. The issues are with same look alike foils & cartons.	Separate art work development team available, all artworks are being verified and handled through software. Further reviewed by QC and finally approved by QA.
Packing material Dispensing	At one time, dispensing of one packing material shall be done to avoid mix up.	QA check the A.R.No./Material Batch no. of the material to be dispensed against the packing material issue slip.
		FIFO system is in place.
		Loose packing materials are identified for their integrity, appearance & numbers.
		Operating Person Warehouse issue Cartons/Catch Covers by counting, in a polythene bag, tie it with cable tie & transfer to over printing area with the details in BPR.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
		• The dispensed packing material shall be stored in crates/polybags/cage in closed/sealed conditions at various stages of packing.
Primary Packing Storage 	To avoid mix ups, all packing materials are being kept segregated and with identification labels.	All Secondary and Tertiary packing materials are checked as per mother label/approved label and loose packing materials are counted or weighed manually.
Batch Coding: Although Batch detail missing or miss printing does not have any risk related to health, but it is important for product identification in the market. During any complaint (counterfeit prod… 	There may be a chance that Cartons got stick with each other from vendor side, as the equipment used for batch coding is semi-automatic and manual interference is there, so there may be the possibility that the overlapped Cartons may be missed and passed forwarded for further packing which again missed during secondary packing by the visual inspectors.	One person is deputed for verification of the carton for stickiness.
		SOP No.: ……"Batch Coding/Printing System" has been revised to incorporate the procedure of 200% verification after dispensing of carton for sticking and after over coding to avoid such type of issues.
		The misprinted or rejected packing material generated during coding is placed in another dedicated crate which is placed between the operator and inspector.
		After coding of foil/label, write the roll no. on the foil/label, check and sign. the coding details on the foil/label. After signing from production and QA attach specimen sample in the BPCR.

		At the end of the coding process for label, cut label, cartons and catch covers, take a specimen sample, write "end sample", get is checked and signed by production and QA personal for its correctness. Attach this specimen sample in the BPCR as a proof of specimen sample of end of the process.
RISK IDENTIFICATION	**RISK EVALUATION**	**RISK MITIGATION**
		After completion of coding process, all the coded packing material are collected in the poly bag/shippers/ plastic crates, seal the plastic crates/poly bag properly. Status label has to be affix on each poly bag/shippers/ plastic crate and numbering has to be done on the status labels.
		Rejection of the over printing process shall be placed in closed condition throughout the over printing operation. Record the rejection generated during over printing operation in the respective BPR.
		The coded cartons shall be sealed properly before shifting to next stage.
		100% inspection shall be done after overprinting of cartons (SOP No.: ..... Batch Coding/ Printing System is in Place). Proposal for online carton coding and Camera detection system for improved controls.

Primary Packing Area 	Containers of different primary packing areas kept adjacent to each other. By mistake containers may got inter mixed. There may be the chance that rejection may got intermixed if not segregated properly	Containers in corridor are kept in segregation with proper labelling. .....Rejection Handling Management during packing in Process.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Primary Packing Quarantine 	Containers kept in Quarantine not segregated & neither identified with proper labelling.	Containers are segregated with partitions & labelled properly.
Change Part Storage Area 	Wrong issuance of change parts may result into wrong packing.	SOP is in place (.....)"Issuance, Cleaning and Retrieval of Change Parts for Blister Alu-Alu and Strip Machine".
Secondary Packing Storage Area		
 **Carton Mixing:** **Carton mixing may be 04 types:** 1. Carton of same products with different batch nos. 2. Carton of different products with same content & claim. 3. Carton of different products with different content & claim. 4. Carton of same product with different label claim.	**Criticality of mixing of cartons depends on type of carton mixing:** 1. Mixing of same Cartons with different batch nos. having same claim & content does not have any impact on product quality. 2. Mixing of cartons of different products with same content & claim have product identity problem. 3. Mixing of different cartons with different content & claim comes under critical observation & may lead to severe impact on health. 4. Mixing of carton of same product with different label claim may or may not have impact, it depends on mixing potency.	• Packing materials are stored in separate racks. • Primary & Secondary material are stored separately. • Line clearance procedure is followed before start the overprinting & packing. • Overprinting on Carton/Catch covers/labels are done batch wise, only one product at a time. • Different product is not packed in close proximity unless there is proper physical segregation. • Outdate, obsolete and rejected packaging materials are destroyed and records are maintained. • Persons doing visual inspection are trained to perform their activities. • Proper design of flow of material.

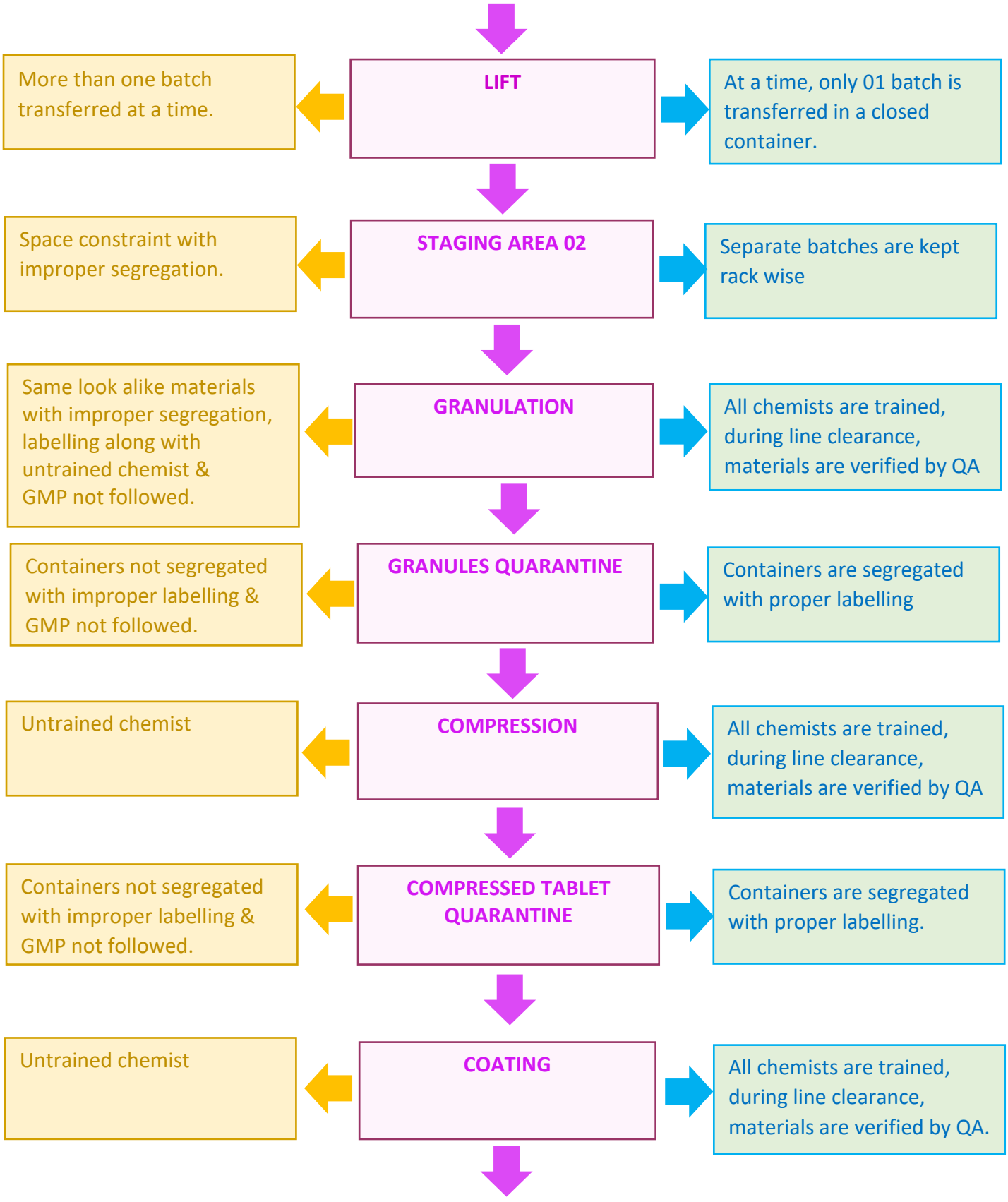
RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
		• Rotation of the visual inspectors for carton overprinting shall be recorded in the respective BPR. • The list of visual inspectors shall be displayed in the respective area. • Rejection box shall be made available with lock and key provision for rejection of primary packing which are generated during initial machine setting, foil change over, intermittent stoppages, camera rejections or breakdown if any. • Revised the SOP No.: ..... (Do's and Don'ts in Packing) and mentioned the clause that the cartons of same colour, size, shape and layout shall be procured from alternate vendor. Freeze the vendor in SAP for similar looking cartons to avoid the mix up and same shall be also mentioned in SOP. • The list of the cartons of same colour, size, shape and layout with different strength shall be prepared for proper identification and to avoid the carton mix-ups.
Tertiary Packing Storage Area		
Shipper Storage Area 	Shippers not segregated properly & without properly labelled.	Shippers are properly labelled & segregated rack wise.

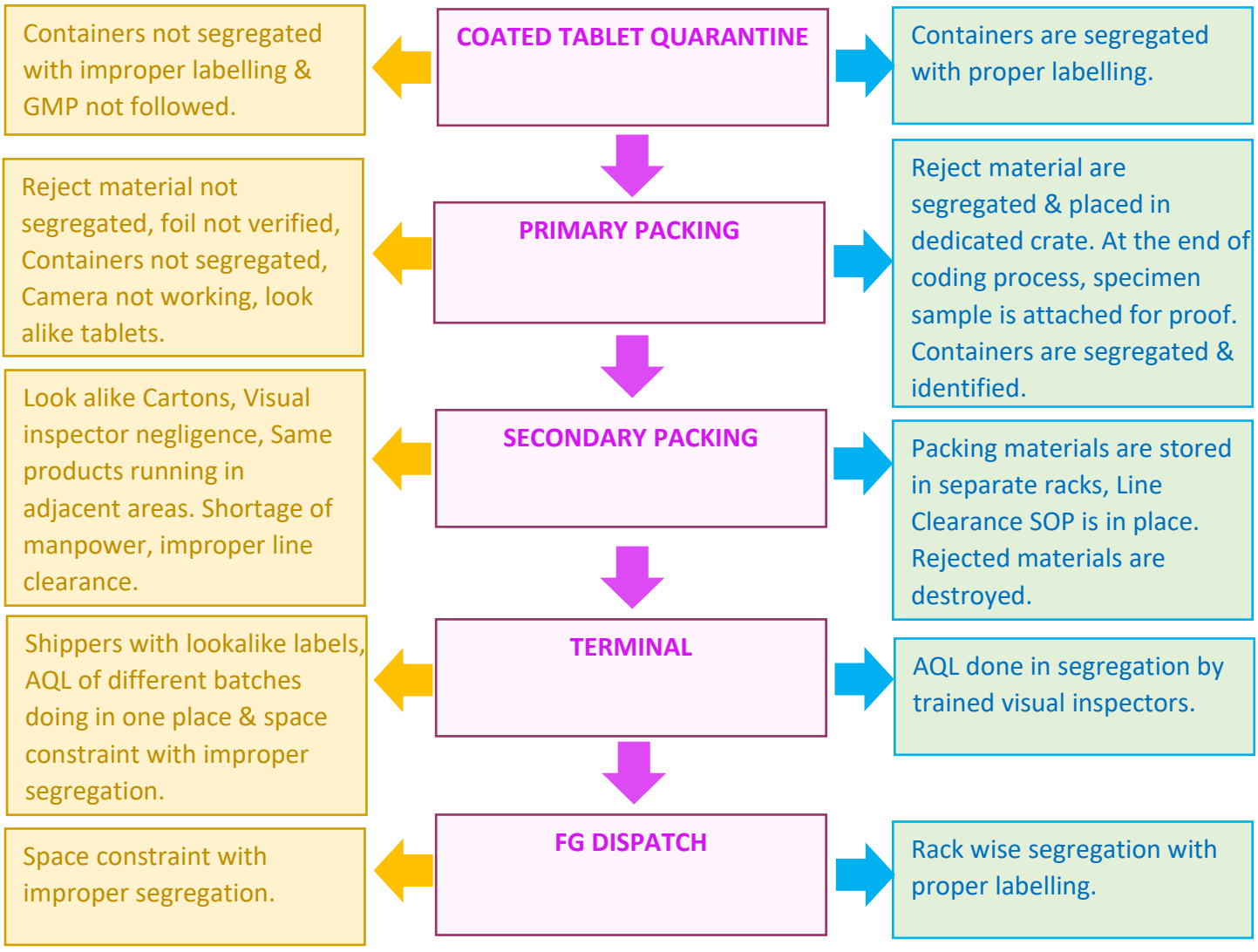
RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Secondary Packing Area 	Products with same carton design or same foil runs in adjacent areas may result into inter mixing.	Instruction given to the production planning, not to run same design products in adjacent areas.
	Rejected material got intermixed with the good material.	SOP for Rejection Handling Management During Packing in Process (.....).
Label Storage 	Labels of different products kept in open condition.	Labels are kept in lock & key.
Secondary Packing Storage 	Secondary packing material not kept in segregation & neither labelled.	Properly segregated & labelled.

RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
Terminal		
Shipper mixing may be 03 types: • Shipper of same products with different batches. • Shipper of different products with same content & claim. • Shipper of different products with different content & claim. 	**Mixing of products comes under critical observations.** Mixing of shipper with different batch nos. having same claim & content does not have any impact on product quality. Mixing of shippers of different products with same content & claim have product identity problem. Mixing of different product with different content & claim comes under critical observation.	After receipt of the batch, all shippers are checked for appropriate labelling. Shippers of different batches are staged in different racks at proper distance to avoid mix ups. Labels are affixed on front side of the shipper. Similar looking products shall not be packed in adjacent packing areas.
FG Dispatch		
	Shippers not properly segregated, labelled & shippers with lookalike labels kept adjacent to each other may result into intermixing.	Shippers are kept in segregation with proper labelling.

PROCESS FLOW CHART (D_2D)

POTENTIAL	PROCESS STEPS	MITIGATION
Intermixing, if not properly labelled from vendor side	MATERIAL RECEIVING	Vendors are qualified& containers are verified as per checklist.
Material with improper documentation transferred to Quarantine	GOODS RECEIVING NOTE	Separate dedicated area available for awaiting GRN.
Container got mix up due to space constraint & Improper labelling	QUARANTINE	Dedicated area available for Quarantine material.
Container got mix up due to space constraint & Improper labelling	UNDER TEST	Dedicated areas with proper segregation.
Container got mix up due to space constraint & Improper labelling	APPROVED	Bin location is provided from SAP for each material.
Too much of materials dispensed at a time	DISPENSING	As per SOP, 10 same materials can be dispensed at a time.
Space constraints with improper segregation.	DAY STORE	Partition is given for each batch.
Space constraint with improper segregation.	STAGING AREA 01	Separate batches are kept rack wise


LIFT
More than one batch transferred at a time.
At a time, only 01 batch is transferred in a closed container.
STAGING AREA 02
Space constraint with improper segregation.
Separate batches are kept rack wise
GRANULATION
Same look alike materials with improper segregation, labelling along with untrained chemist & GMP not followed.
All chemists are trained, during line clearance, materials are verified by QA
GRANULES QUARANTINE
Containers not segregated with improper labelling & GMP not followed.
Containers are segregated with proper labelling
COMPRESSION
Untrained chemist
All chemists are trained, during line clearance, materials are verified by QA
COMPRESSED TABLET QUARANTINE
Containers not segregated with improper labelling & GMP not followed.
Containers are segregated with proper labelling.
COATING
Untrained chemist
All chemists are trained, during line clearance, materials are verified by QA.

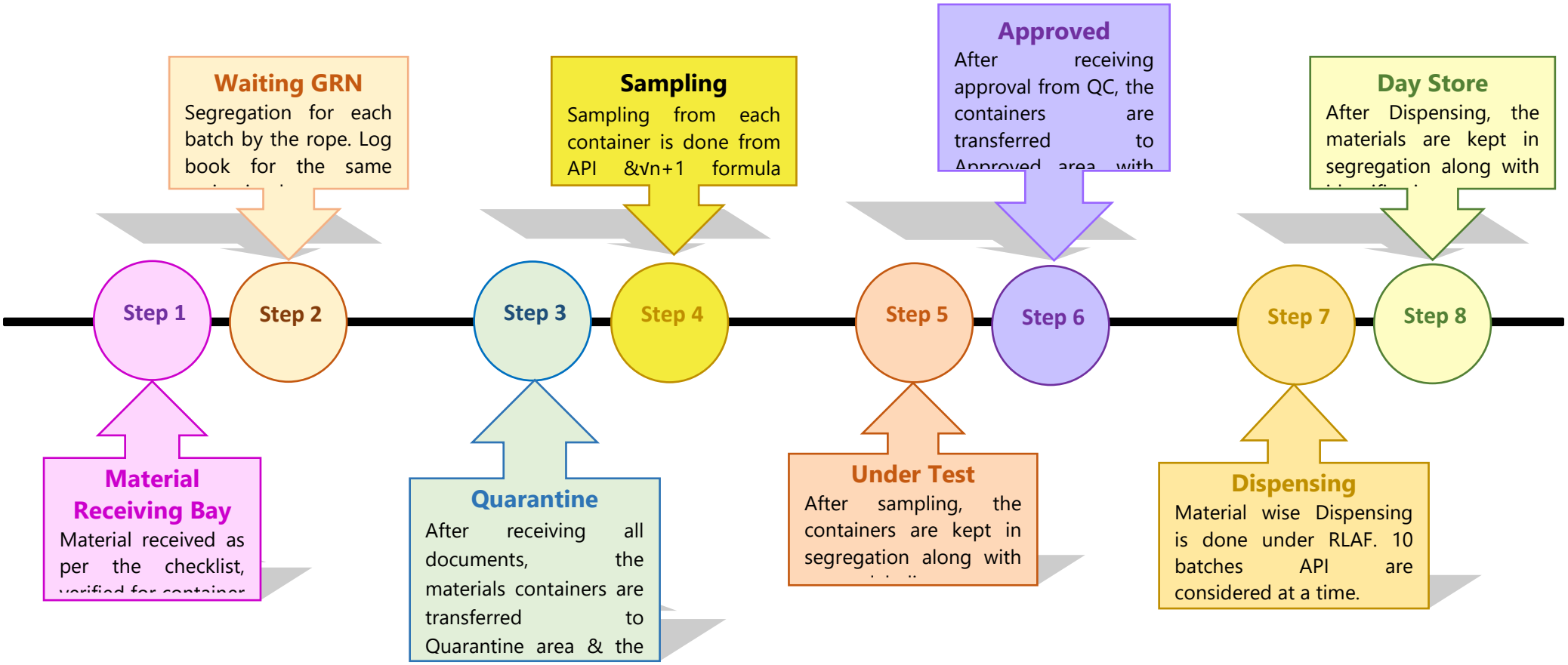

COATED TABLET QUARANTINE
Containers not segregated with improper labelling & GMP not followed.
Containers are segregated with proper labelling.
PRIMARY PACKING
Reject material not segregated, foil not verified, Containers not segregated, Camera not working, look alike tablets.
Reject material are segregated & placed in dedicated crate. At the end of coding process, specimen sample is attached for proof. Containers are segregated & identified.
SECONDARY PACKING
Look alike Cartons, Visual inspector negligence, Same products running in adjacent areas. Shortage of manpower, improper line clearance.
Packing materials are stored in separate racks, Line Clearance SOP is in place. Rejected materials are destroyed.
TERMINAL
Shippers with lookalike labels, AQL of different batches doing in one place & space constraint with improper segregation.
AQL done in segregation by trained visual inspectors.
FG DISPATCH
Space constraint with improper segregation.
Rack wise segregation with proper labelling.

RISK ASSESSMENT TOOLS:

8.1 Process Mapping (Warehouse)

Introduction: The warehouse plays an important role in manufacturing quality products, it is responsible for all incoming goods (including labelling and packaging) and for releasing finished products, there are GMP rules in place to ensure that materials are handled and stored properly, while appropriate documentation is maintained. Several factors which plays important role to avoid mix ups:

- Material Segregation.
- Labelling.
- Verification.



MATERIAL RECEIVING BAY

- During the audit time, several materials are kept near the receiving bay for 2-3 days until the audit completed. This is in regular practice. Code to code transferred materials are kept outside. **Encircled here, bird excretion can be observed.** The same material transferred to the Quarantine area without proper cleaning which can lead to contamination.

- API & Excipients received from …… are kept directly inside the awaiting GRN area, the same containers are labeled as Approved at …….. site.

WAITING GRN

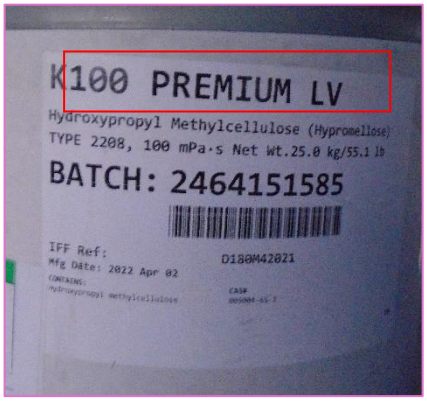
- All the damaged or exposed containers/bags shall be stored in Quarantine area having the status "Materials awaiting for GRN".

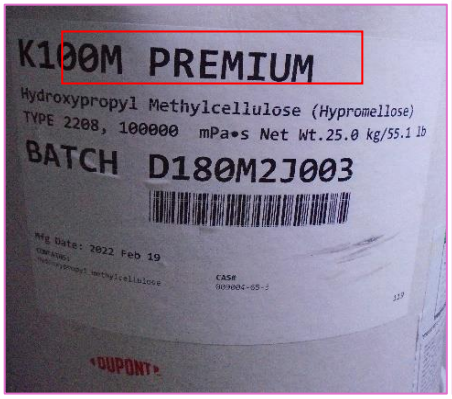
- In case Certificate of Analysis is not available at the time of receipt, information shall be given to purchase to provide the COA within six working days. GRN shall be prepared on receipt of COA from purchase department after getting from vendor.

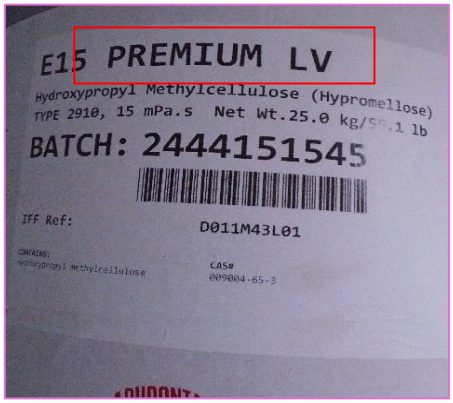
- There may be chance of mix ups of material kept in Awaiting GRN area. So to avoid mix ups, the material kept in awaiting GRN are surrounded by Blue colored rope.

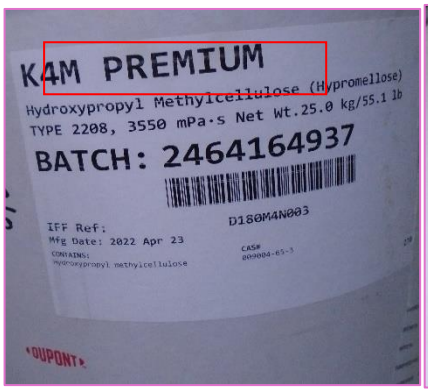
QUARANTINE

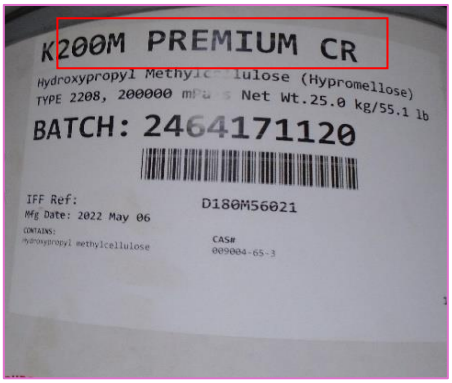
In Quarantine, all materials are kept rack wise with proper labelling. There are some materials which are packed in same type of containers and are difficult to identify. In case of improper segregation & labelling, there may be the chance of inter mixing of containers with same type of appearance resulting into product failure or market complaint.

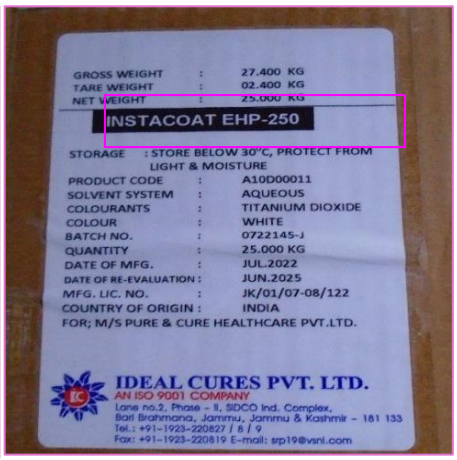


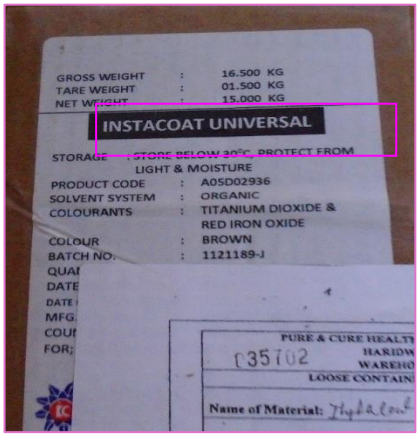












- **Same Alike Look Alike Containers (SALA), Bags & Drums should be kept in different rack & location to avoid mistakes.**
  - Hydroxypropyl Methylcellulose of different grade (K100 Premium LV, K100 M Premium, E15 Premium LV, K4M Premium, K15M Premium, K200M Premium CR) comes in same containers with same type of labels.
  - Coating material of different grade (Insta moistshield Aqua II, Instacoat EHP 250, Insta Moistshield, Instacoat Universal) comes in same containers with same type of labels.
- **Without segregation, expired material (R & D) kept in**

UNDER TEST

- After Sampling, the materials are kept in under test area, rack wise materials are placed with proper labelling. In case of too much material received from other plants, due to space constraints, there may be the chance of mix ups.

APPROVED

- After getting QC approval, the material is transferred to Approved area. All containers are segregated rack wise & labelled properly. The material location is identified through SAP. Bin location is given to each API.

DISPENSING

- As per SOP of Dispensing of Raw Material, Campaign of maximum 10 same batch/ product or different product/batch of same ingredient of API/Excipient or Product can be dispensed. There may be the chance of mix ups in case of campaign batches dispensing.

DAY STORE

- In Day Store, dispensed RM are kept in segregated manner. Improper partitions may lead to mix ups, as the day store area is in continuous movements, dispensed materials are continuously transferred to the staging area. As most of the dispensed materials are white in color, so their may be the possibility of inter-mixing.

STAGING AREA

- Staging area is the last stage before granulation. From staging area, dispensed materials are directly transferred to the Granulation area for manufacturing, in case of any inter mixing taking place in staging area, there may be the chance that the same will not be identified further also. So segregation & labelling plays important role in staging area.

8.2CAUSE & EFFECT ANALYSIS:

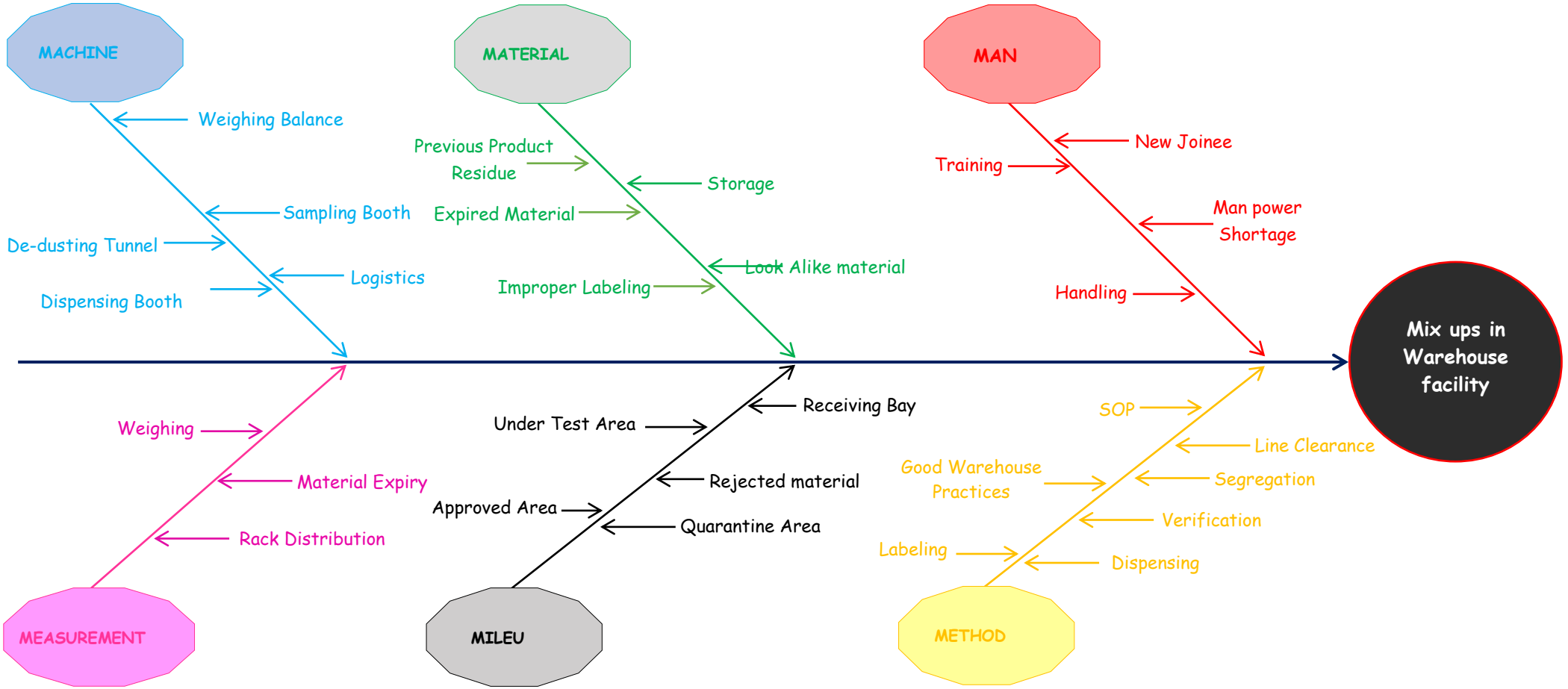


Figure 1: Fish & Bone Diagram

SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: It is used for the evaluation of inadequate warehouse facility on finished products; following are the areas of concern considered for investigation. Man, Material, Measurement, Method, Milieu & Machine. It has been evaluated that all of the 6 M may contribute in failure of new warehouse facility resulting in failure of product.

MAN: Personnel supervising or performing warehouse activities are not aware of GMP & are untrained which may result into:

- Manpower Shortage
- Persons not trained
- Improper handling

MATERIAL: Handling & Storage of raw materials plays an important role in Warehouse management. Miss Management may lead to:

- Improper storage without proper segregation.
- Improper labelling
- Intermixing of Look Alike material.
- FIFO not followed resulting into usage of expired materials.
- Improper Cleaning may lead to mixing of previous product residues.

MILIEU: The facility of the warehouse plays major role in maintaining proper storage conditions, Inadequate surrounding environment may lead to:

- Material received at receiving bay are not properly verified.
- Improper handling & segregation in Quarantine Area.
- Improper handling & segregation in Under Test Area.
- Improper handling & segregation in Approved Area.
- Rejected materials not kept in lock & key.

MACHINE: The equipment & instruments used in warehouse plays important role in day to day activities:

- Weight not verified.
- Weighing Balance not calibrated.
- Sampling Booth not qualified or cleaned.
- De-dusting tunnel not qualified.
- Mix ups may take place from containers of different plants provided through same logistics.

METHOD: There are various reasons during warehouse practices which may lead to mix ups:

- Improper segregation.
- SOP not followed.
- Labelling not proper.
- Improper Verification.
- Improper Line Clearance.
- Improper Dispensing.
- Improper training and unaware about the Good Warehouse Practices.

MEASUREMENT: There are many factors which shall be regularly monitored & recorded such as:

- Rack distribution shall be appropriate & traceable.
- Proper weighing.
- FIFO not followed.

8.3BOW TIE ANALYSIS:

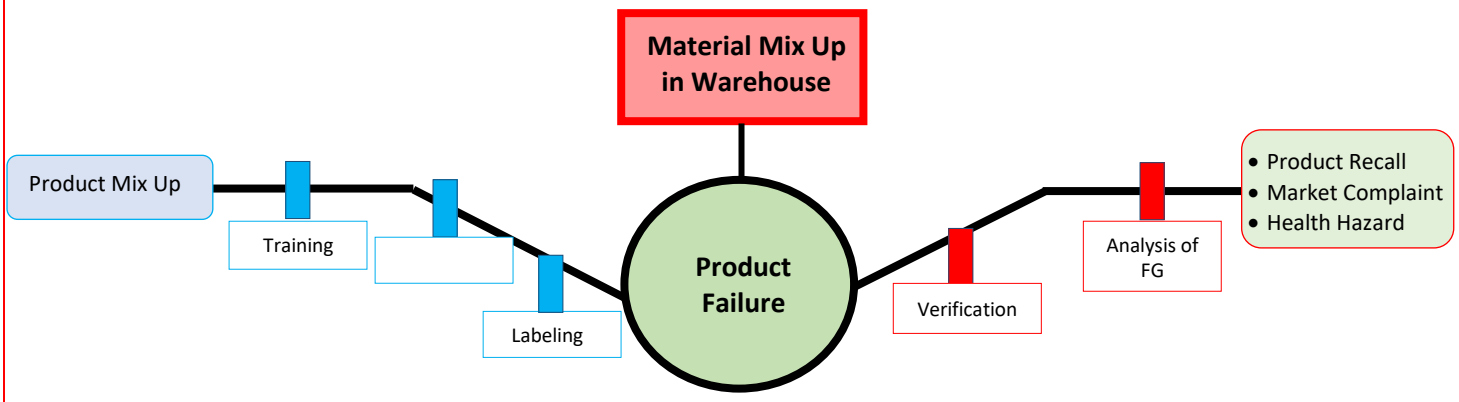


Figure 1: Bow Tie diagram

SUMMARY OF THE BOW TIE ANALYSIS: Bow Tie analysis for Material Mix ups in warehouse facility gives an overview of multiple plausible scenarios in a single picture. It provides a simple, visual explanation of a risk that would be much more difficult to explain.

A hazard is being identified as **"Material Mix up in Warehouse Facility"**, which may result into moment when control is lost over the hazard. There is no damage or negative impact yet, but it is imminent. Threats are considered on the left side and consequences are on the right side. Barriers on the left side interrupt the threats do not occur while barriers on the right side mitigate the impact.

Following are the barriers need to be focused to control the threats and consequences:

- ✓ Training
- ✓ Segregation.
- ✓ Labeling.
- ✓ Verification process in each stage.
- ✓ Analysis at FG Stage.

8.4 FAILURE MODE EFFECT ANALYSIS:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

Column 1:	**Serial number** of Risk Analysis item
Column 2:	**Item/Function:** Identify the process step or component associated with the risk.
Column 3:	**Potential Failure Mode:** Identify the type of risk associated with the process or component.
Column 4:	**Effect of Potential Failure/Cause:** Verify that whether risk have **GMP impact.**
Column 5/6/7/8/9:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 10:	**Risk Mitigation**: Write the risk mitigation strategy as considered in design.
Column 11/12/13/14/15:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated after mitigation by taking Severity, Occurrence & Detection of potential failure into consideration.
Column16:	**Recommended action:** Recommended actions should be given for controlling failure occurrence.

Table 2: Instruction for each column given above

Procedure: Mix up in Warehouse												**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**
MAN																
1.	**Man power shortage**	Manpower shortage plays important role in following GMP, all activities in warehouse are dependent on manpower.	• Improper segregation on racks. Containers not properly placed. • Improper labelling. • Due to manpower shortage, labelling not done by QC for Quarantine, Under Test, Approved area.	• Improper segregation may lead to intermixing. • Improper labelling may lead to inter mixing.	Planning is done as per manpower availability	Dash board provided in area is daily updated as per attendance record.	3	2	1	6	NA	NA	NA	NA	NA
2.	**Handling**	Improper material handling	• Containers not cleaned for extraneous material. • Containers not properly verified at the time of receiving. • Containers not stored in controlled conditions.	• Improper Handling may lead to mix ups.	Trained persons are available for performing any activity.	Training SOP is in place	3	2	1	6	NA	NA	NA	NA	NA
3.	**Training**	• Untrained persons	• GDP, GMP & GWP not followed. • Verification not done by the reviewer.	• Poor documentation. • Process related issues	SOP of training in place	• SOP No.: "Training of Employees" • SOP No.: "Good Documentation Practices" • SOP No.: "Daily Verification of Good Manufacturing and Good Documentation"	3	1	1	3	NA	NA	NA	NA	NA
MATERIAL																
4.	**Storage**	Improper storage	Storage areas not proper, materials kept randomly without proper identification & segregation in uncontrolled areas.	Improper storage may lead to intermixing.	CNC areas are used for material storage.	As per Schedule M	3	2	1	6	NA	NA	NA	NA	NA
5.	**Improper Labeling**	Labelling is used for material identification, improper labelling may	• Labelling not done • Wrong labelling	Materials are difficult to identify.	All incoming materials are identified and	SOP of Status Labelling	3	1	1	3	NA	NA	NA	NA	NA

Procedure: Mix up in Warehouse											**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**
		result into mix ups			labelled as pre SOP of Status labelling.										
6.	**Previous Product Residue**	If area not cleaned properly, previous product residue may leads to cross contamination or mix ups.	Remains of previous product may contaminate the upcoming product resulting into mix up.	Market Complaint & Product recall.	Line Clearance process is in place for every activity.	SOP of Line Clearance is in place	3	1	1	3	NA	NA	NA	NA	NA
7.	**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	2	1	6	NA	NA	NA	NA	NA
METHOD															
8.	**SOP Implementation**	• Warehouse practices not followed	• Improper cleaning • Improper line clearance • Improper verification • Data integrity issues may take place. • Cross Contamination. • Environmental failures. • Improper storage of materials.	• Batch failures • Material deterioration • Safety related incidents may take place.	• SOP's are in place for all warehouse activities..	• Warehouse SOP's	3	1	1	3	NA	NA	NA	NA	NA
9.	**Segregation**	Improper segregation	• Different materials not segregated properly. • Look alike materials not identified separately.	Market Complaint & Product recall.	All materials are segregated batch wise.	SOP No.: "Handling and Storage of Raw Materials"	3	2	1	6	NA	NA	NA	NA	NA
10.	**Good Warehouse Practices**	Good warehouse practices is not followed.	Not following GWP can leads to contamination & mix ups.	Market Complaint & Product recall.	Persons are trained to follow good warehouse activities.	Warehouse SOP's	3	2	1	6	NA	NA	NA	NA	NA
11.	**Rack arrangement**	• Rack distribution improper or not identified.	• Containers kept without segregation. • Containers kept without identification. • Containers kept one above each	• Inter mixing • Market Complaint & Product recall.	• All racks are identified & materials are placed as per bin allocation (SAP).	• SOP No.: "Handling and Storage of Raw Materials"	3	1	1	3	NA	NA	NA	NA	NA

Procedure: Mix up in Warehouse											**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**
			other and difficult to reach.												
12.	**Verification**	Material verification not done	• Wrong material identified. • Weight of material not verified.	• Inter mixing • Market Complaint & Product recall.	Reviewed mechanism is in place & every critical activity is verified by QA.	Warehouse SOP's	3	1	1	3	NA	NA	NA	NA	NA
13.	**Dispensing**	SOP of Dispensing not followed	As per SOP, 10 same materials can be dispensed at a time after that type B cleaning to be done. In case of too many materials, mix up or cross contamination may take place.	• Inter mixing • Market Complaint & Product recall.	SOP of Dispensing is in place.	SOP No.: "Dispensing of Non-Sterile Raw Material"	3	1	1	3	NA	NA	NA	NA	NA
14.	**Double Checks**	Single person can miss the check	• Wrong entry in formats & log books	• Wrong calculations resulting into wrong quantity of material dispensed. • Can lead to Data integrity.	SOP is in place for Good Documentation Practices.	SOP "Good Documentation Practices"	3	1	1	3	NA	NA	NA	NA	NA
15.	**Containers**	• Damaged containers. • Containers without label.	• Material Spillage takes place. • Intermixing of material takes place.	• Contamination & Cross contamination.	Material are verified after receiving.	SOP No.: "Receipt of Raw Materials in Warehouse"	3	1	1	3	NA	NA	NA	NA	NA
16.	**Status Labeling**	• Improper Status labels • Status labels not available	• Label got faded. • Forget to put label.	Difficult to identify material.	SOP is in place.	SOP "Handling and Storage of Raw Materials"	3	1	1	3	NA	NA	NA	NA	NA
17.	**Line Clearance**	Line Clearance not done properly.	• Previous product residues may contaminate the next product.	• Inter mixing • Market Complaint & Product recall.	Sop of Line Clearance is in place.	SOP of Line Clearance	3	1	1	3	NA	NA	NA	NA	NA
MILEU															
18.	**Receiving Bay**	• Material not received through de-dusting tunnel.	• De-dusting tunnel not working. • Procedure of material receiving not in place. • De-dusting Tunnel not available.	• Dust particles over the container surface may contaminate the area.	• De-dusting tunnel is in place & all materials are received through qualified tunnel.	SOP No.: "Operation and Cleaning of De-Dusting Conveyor Tunnel".	3	1	1	3	NA	NA	NA	NA	NA
19.	**Quarantine**	Improper segregation & improper labelling	• Partitions not provided for segregation.	• Inter mixing	All materials are placed in different	SOP "Handling and Storage of Raw Materials"	3	2	1	6	NA	NA	NA	NA	NA

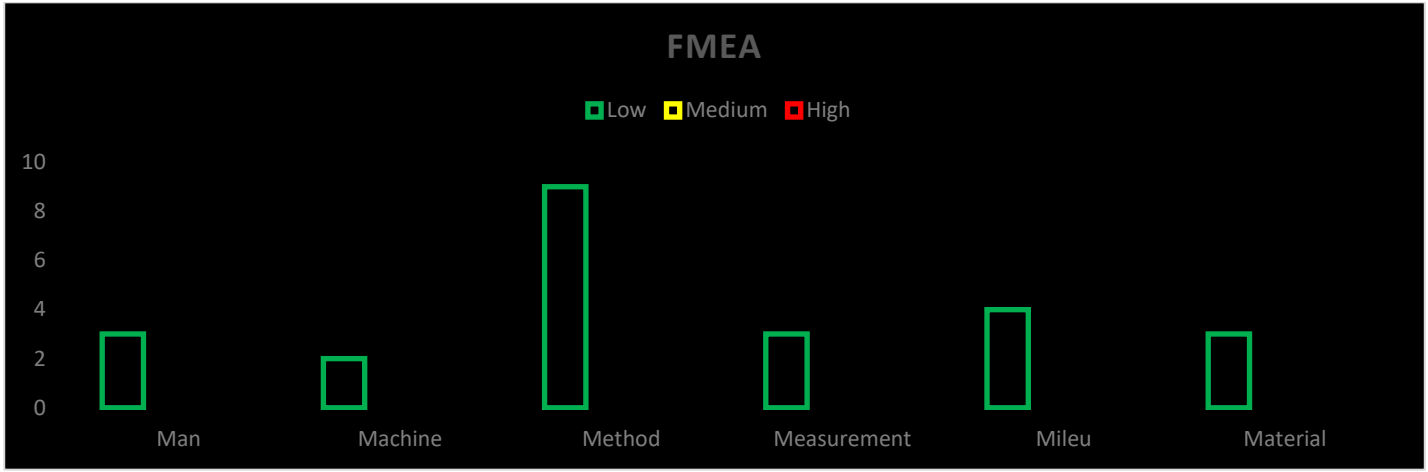
Procedure: Mix up in Warehouse												**Quality Risk Assessment No.:**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference Document No.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
20.	**Under Test Area**		• Different materials of different batches placed on same rack.	• Market Complaint & Product recall.	identified bin locations as per SAP.		3	2	1	6	NA	NA	NA	NA	NA
21.	**Approved Area**						3	2	1	6	NA	NA	NA	NA	NA
					MACHINE										
22.	**De-dusting Tunnel**	Not working	• Dust Contamination • Qualified Tunnel not available	• Cross contamination	• De-dusting tunnel available.	• SOP No.: "Qualification Planner"	3	1	1	3	NA	NA	NA	NA	NA
23.	**Weighing Balances**	• Weighing Balance not verified • Weighing Balance not Calibrated • Calibration Planner not in place. • Preventive maintenance not available.	• Malfunctioned.	• Wrong data interpretation. • Wrong material quantity weighed.	• BMR in place.	• SOP No.: "Calibration Policy"	3	1	1	3	NA	NA	NA	NA	NA
					MEASUREMENT										
24.	**Weighing**	Quantity of weighed material not appropriate	Materials not verified for weight.	• Market Complaint & Product recall.	• All materials are weighed as per the BMR and reviewed by QA.	As per BMR	3	1	1	3	NA	NA	NA	NA	NA
25.	**Rack Distribution**	Numbering not done	• Material kept randomly • All categories of materials kept together.	• Tracking improper • Intermixing	• Bin location is given to each material and all materials are tracked as pre bin location provided through SAP.	SOP "Handling and Storage of Raw Materials"	3	1	1	3	NA	NA	NA	NA	NA
26.	**Balance Verification**	Daily verification not Done.	• Miss to do so.	• Wrong results interpretation	• Calibration & Verification Planner not available	SOP No.: "Operation Cleaning Verification Calibration of Electronic Weighing Balances"	3	1	1	3	NA	NA	NA	NA	NA

Table 3: FMEA tool

High Risk

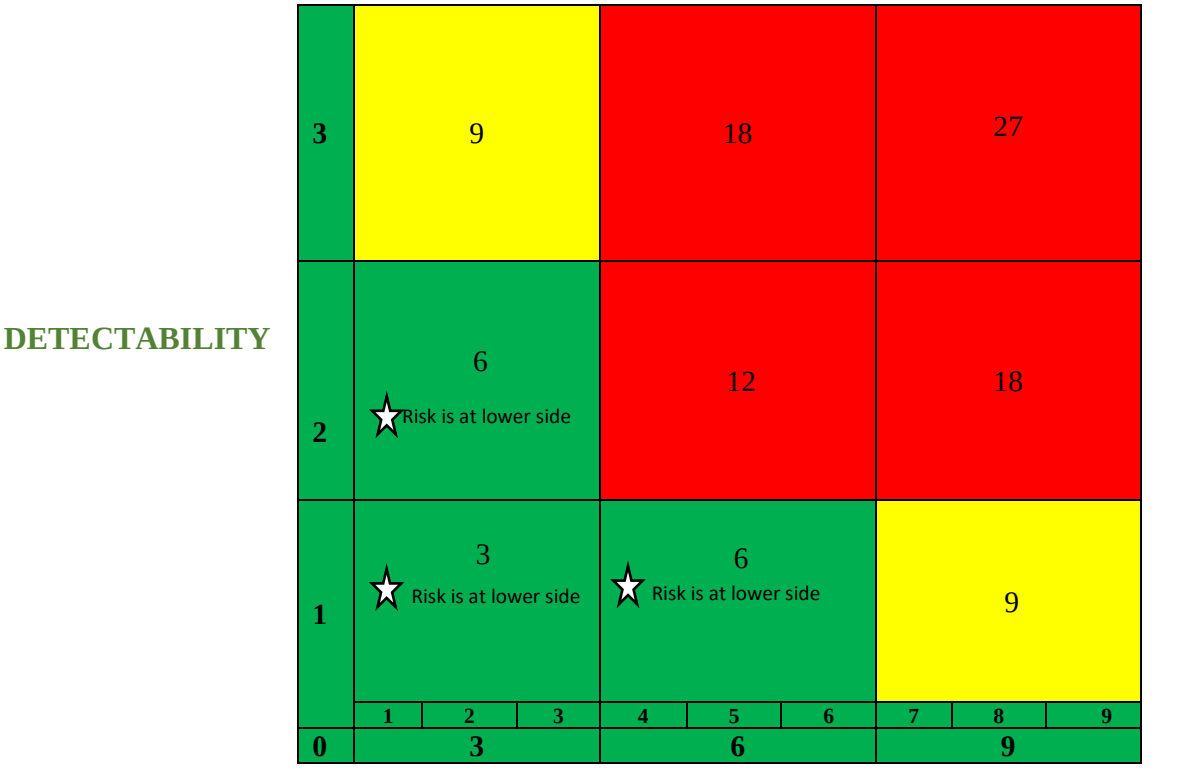
Medium Risk

Low Risk



Graph 1: Graphical presentation shows that environmental factors contribute the most to the severity of the risk.

FMEA MATRIX(Warehouse)



☆ Risk observed at lower side in all factors (Man, Machine, Method, Material, Mileu & Measurement)

Figure 2: FMEA Matrix

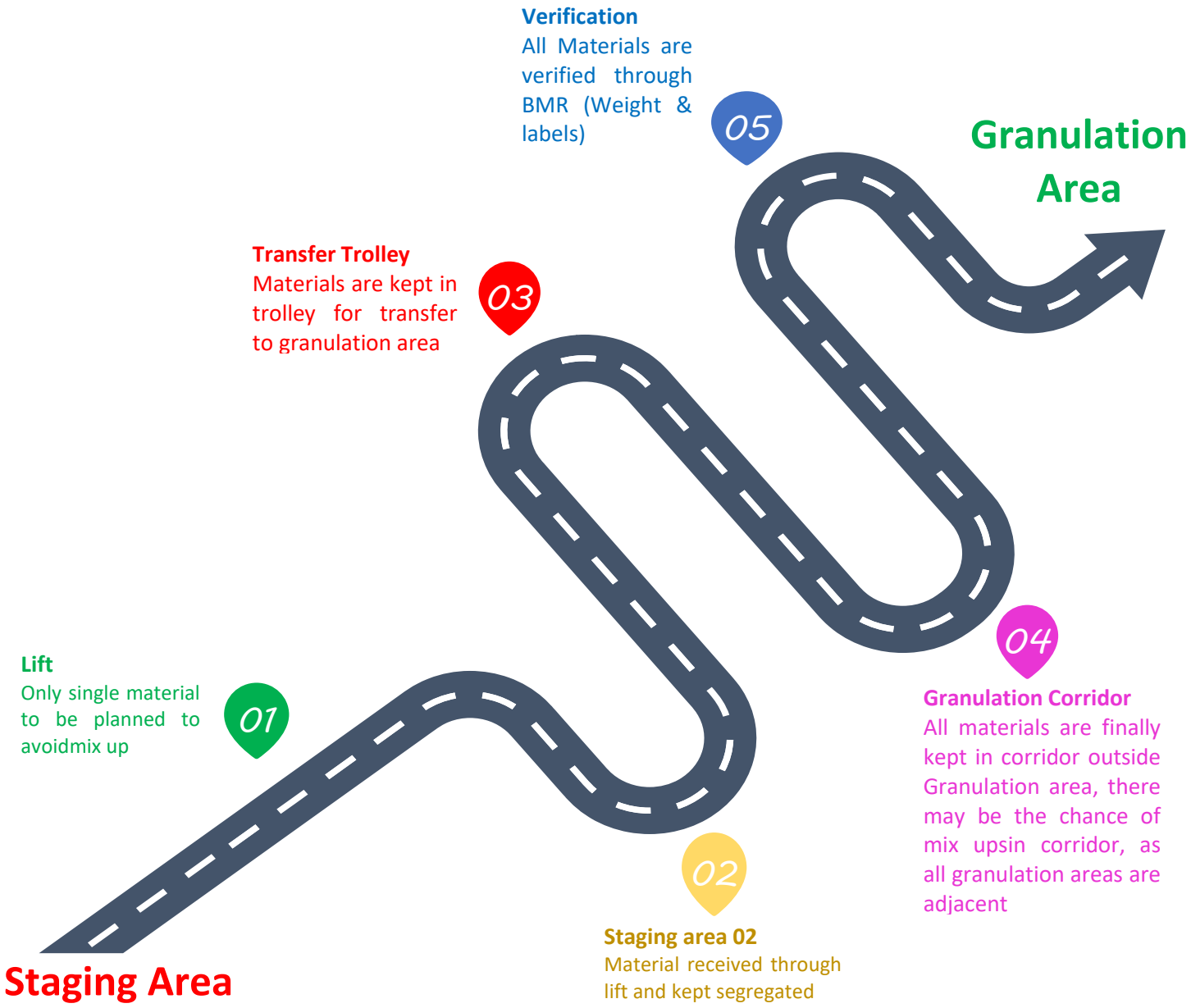
Low Risk	Medium Risk	High Risk
• Manpower shortage • Material Handling • Untrained persons • Storage • Improper Labelling • SOP Implementation • Warehouse practices not followed • Rack arrangement • Verification • Dispensing • Physical Segregation • Double Checks • Damaged Containers • Containers without label • GMP not followed during Sampling & Dispensing • Improper Status labels • Material not received through de-dusting tunnel • Look alike material	No Medium Risk	No High Risk

Table 4: Summary of FMEA

GRANULATION

Introduction: Granulation area is used for manufacturing of different products. Raw materials are collected in staging area, from there as per the batch requirement, the materials are transferred to the dedicated area, before the granulation, all dispensed materials are kept in corridor. There may be the chance of mix ups in corridor, as all granulation areas are adjacent to each other, Verification & Labelling plays critical role to avoid mix ups.

8.5 Process Mapping (Granulation):



8.2 CAUSE & EFFECT ANALYSIS:

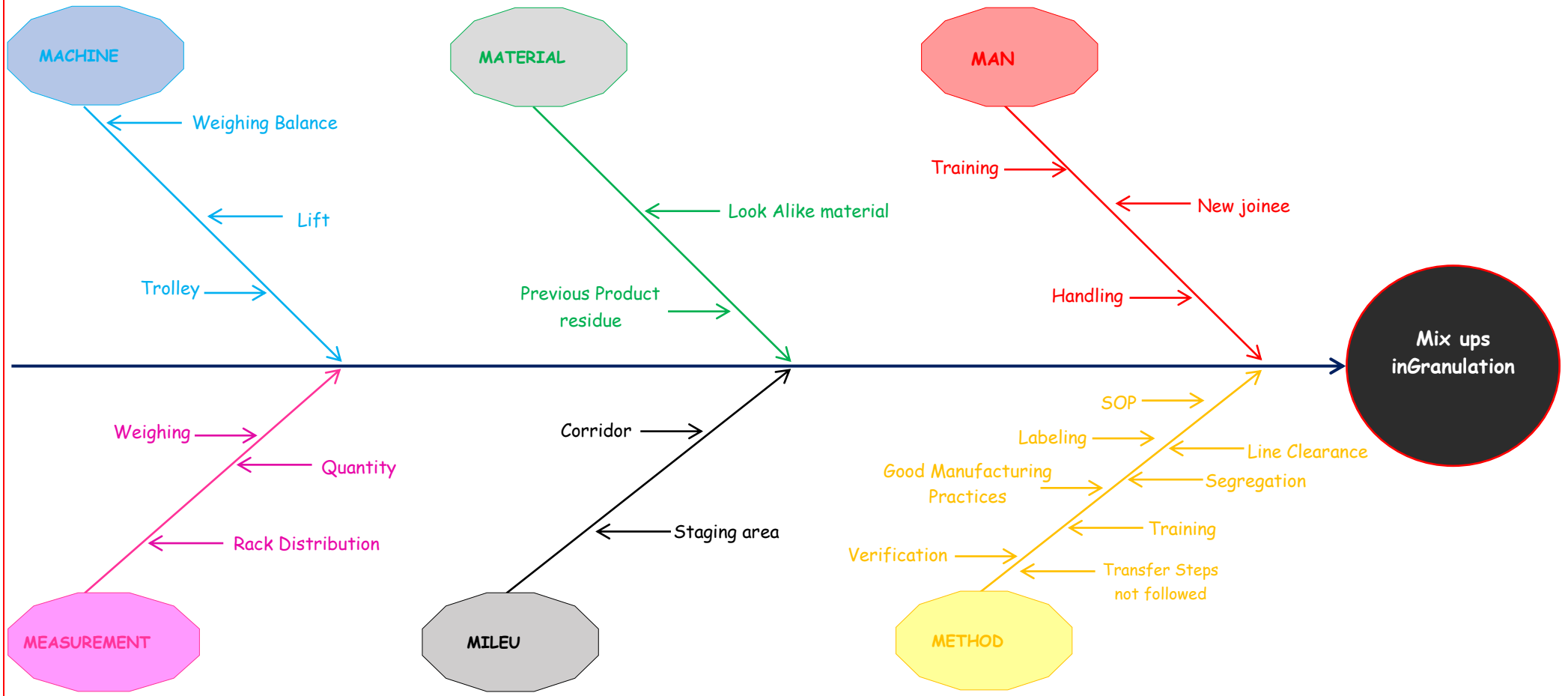


Figure 1: Fish & Bone Diagram

SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: It is used for the evaluation of Mix ups in Granulation areas; following are the areas of concern considered for investigation.
Man, Material, Measurement, Method, Milieu & Machine. It has been evaluated that all of the 6 M may contribute in Mix ups in granulation area finally resulting in failure of product& Market Complaints.

MAN: Personnel supervising or performing Granulation activities are not sufficient or untrained: which may result into:

- Manpower Shortage
- Persons not trained
- Improper handling

MATERIAL: Inter mixing of Lookalike materials plays an important role in Granulation management. Miss Management may lead to:

- Improper storage without proper segregation.
- Improper labelling.
- Look Alike materials.
- Previous Product Residues.

MILIEU: The storage of Granules plays major role to avoid any mix ups:

- Improper segregation in staging area.
- Material bags or containers kept randomly in corridor.

MACHINE: The equipment & instruments used in Granulation plays important role in day to day activities:

- Weight not verified.
- Weighing Balance not calibrated.
- Materials not verified during line clearance.
- More than one batch materials kept in lift may result into intermixing.
- Trolley used for transfer of granules is not under lock & key.

METHOD: There are various reasons during warehouse practices which may lead to mix ups:

- Improper segregation.
- SOP not followed.
- Labelling not proper.
- Improper Verification.
- Improper Dispensing.
- Improper training and unaware about the Good Warehouse Practices.

MEASUREMENT: There are many factors which shall be regularly monitored & recorded such as:

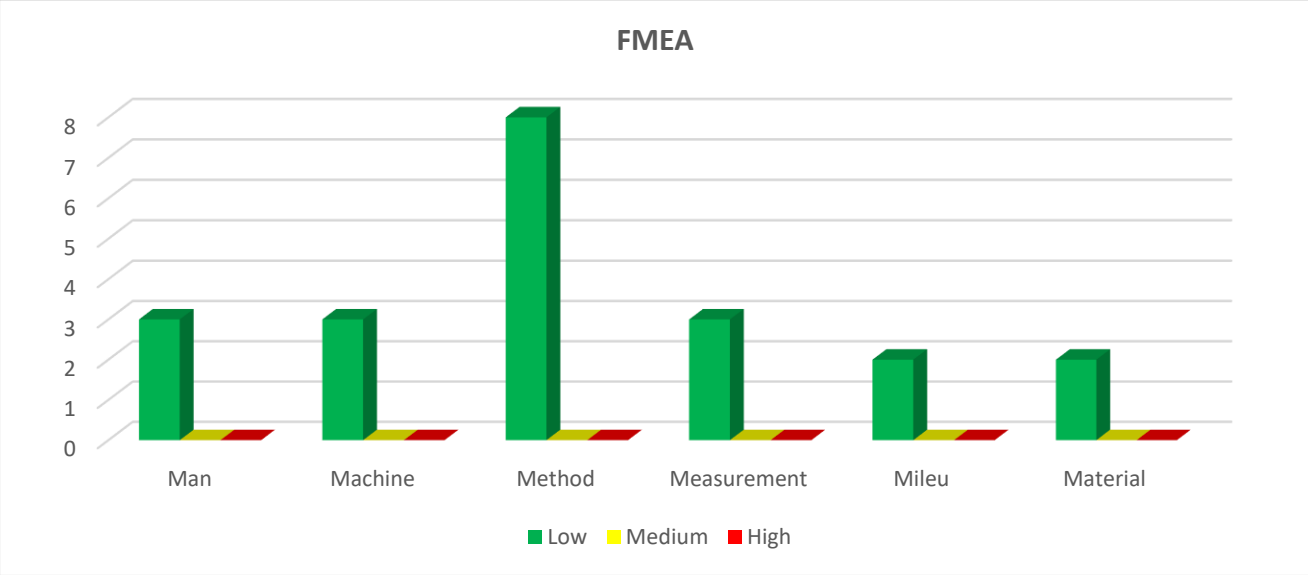
- Rack distribution shall be appropriate & traceable.
- Weighing Balances shall be Calibrated & Verified on daily basis.
- Material verification as per BMR.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR MIXUPS FROM DISPENSING TO DISPATCH (D_2D)

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
MAN															
1.	Training	Untrained Operators	• Product mix up • Product failure • Market Complaint	• Untrained person will not be able to segregate look alike material or containers. • Untrained person may put wrong labels.	Persons are trained enough for material handling & labelling.	Training SOP is in place " Training of Employees"	3	2	1	6	NA	NA	NA	NA	NA
2.	New Joinee	Untrained Chemist or Operator or Worker									NA	NA	NA	NA	NA
3.	Material Handling	Improper handling									NA	NA	NA	NA	NA
MATERIAL															
4.	Look Alike Material	Containers of same shape & same type along with material of same color	• Product mix up • Product failure • Market Complaint	• Improper segregation. • Improper labelling	• Dispensed materials are kept inside the static pass box. • Verification is done before granulation activity.	-	3	2	1	6	NA	NA	NA	NA	NA
5.	Previous Product residue	Remaining of previous product	Contamination & Cross Contamination	Improper line clearance	QA chemist are trained for the Line Clearance	Dedicated BMR	3	1	1	3	NA	NA	NA	NA	NA
METHOD															
6.	SOP	SOP of GDP & Material Handling not followed	• Product mix up • Product failure • Market Complaint	SOP of Good Manufacturing Practices not followed.	GMP training is given to all the new joinee at the time of induction.	GMP SOP is in place " Daily Verification of Good Manufacturing and Good Documentation Practices on Shop Floor"	3	1	1	3	NA	NA	NA	NA	NA
7.	Labelling	Improper labelling	• Product mix up • Product failure • Market Complaint	• Untrained persons mishandled the containers • Too much of containers with improper segregation	• SOP of labelling is in place. • All dispensed materials are kept in double polybags.	SOP of Status Labelling is in place	3	1	1	3	NA	NA	NA	NA	NA
8.	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	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
9.	Good Manufacturing Practices	GMP not followed	Contamination & Cross Contamination	Improper line clearance	Training SOP is in place. Line Clearance is a part of BMR.	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
10.	Training	Persons involved in manufacturing activities not trained	• Product mix up • Product failure • Market Complaint	• Untrained person will not be able to segregate look alike material or containers. • Untrained person may put wrong labels.	Training SOP is in place.	Training SOP is in place " Training of Employees"	3	2	1	6	NA	NA	NA	NA	NA
11.	Verification	Verification of material not done	• Improper labelling • Wrong quantity of batch dispensed • Contamination & Cross Contamination	Untrained persons	Reviewed by mechanism is in place	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
12.	Transfer Steps not followed	Step wise activities not followed	• Improper labelling	Containers not transferred batch wise.	BMR is the guidance documents	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
13.	Line Clearance	Improper line clearance	Contamination & Cross Contamination	• Person not trained for Line Clearance. • Line Clearance not performed.	Line Clearance is the part of BMR. QA Chemist is trained for the Line Clearance.	SOP of Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid	3	2	1	6	NA	NA	NA	NA	NA
MACHINE															
14.	Weighing Balance	Wrong weight showed in display	Wrong weight calculated	Balanced not Calibrated	Weighing Balance are daily verified & monthly calibrated. Tare weight is done before weighing.	SOP of Operation Cleaning Verification Calibration of Electronic Weighing Balances is in place	3	1	1	3	NA	NA	NA	NA	NA
15.	Lift	Materials transferred through lift not segregated	Intermixing	• More than 01 batch transferred at a time • Material transferred is in open condition not in containers.	Only 01 batch is transferred at a time.	SOP of Receipt, Storage & Issuance of Materials in Staging Area & Quarantine Area	3	2	1	6	NA	NA	NA	NA	NA
16.	Trolley	Trolley used for transfer are not with lock & key	Intermixing	More than 01 batch kept in trolley for the transfer.	Lock & key is in place for each trolley.	-	3	2	1	3	NA	NA	NA	NA	NA
MEASUREMENT															

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
17.	Weighing	Materials not weighed as per weighment sheet of BMR	• Product Failure • Product not complies	Untrained Chemist not verified material	BMR is in place Verification is done as per weighment sheet.	Dedicated BMR	3	1	1	3	NA	NA	NA	NA	NA
18.	Quantity	Quantity of material not appropriate	• Product Failure • Product not Complies	Balance not found calibrated	Balance are verified daily & calibrated on monthly basis as per the planner.	SOP of Operation Cleaning Verification Calibration of Electronic Weighing Balances is in place	3	1	1	3	NA	NA	NA	NA	NA
19.	Rack Distribution	Racks distribution in Granules Quarantine area not segregated	• Material Intermixing • Product failure • Market Complaint	• FIFO system not followed in Granules Quarantine. • Containers not segregated. • Containers not properly labelled.	FIFO system is followed. Containers are properly segregated & labelled.	SOP for Receipt Storage Issuance of Materials in Staging Area Quarantine Area	3	2	1	6	NA	NA	NA	NA	NA
MILEU															
20.	Corridor	Material kept randomly in Corridor	• Material Intermixing • Product failure • Market Complaint	• Containers not segregated. • Containers not properly labelled. • Different batches of same appearance running in adjacent areas. • Space constraint	Proper planning is in place.	SOP for Receipt Storage Issuance of Materials in Staging Area Quarantine Area	3	2	1	6	NA	NA	NA	NA	NA
21.	Staging Area	Materials kept randomly in staging area without proper segregation	• Material Intermixing • Product failure • Market Complaint	Batches kept randomly in staging area	Dedicated persons are available for staging area.	SOP for Receipt Storage Issuance of Materials in Staging Area Quarantine Area	3	2	1	6	NA	NA	NA	NA	NA



Graph 1: Graphical presentation shows that environmental factors contribute the most to the severity of the risk.

FMEA MATRIX (Granulation)

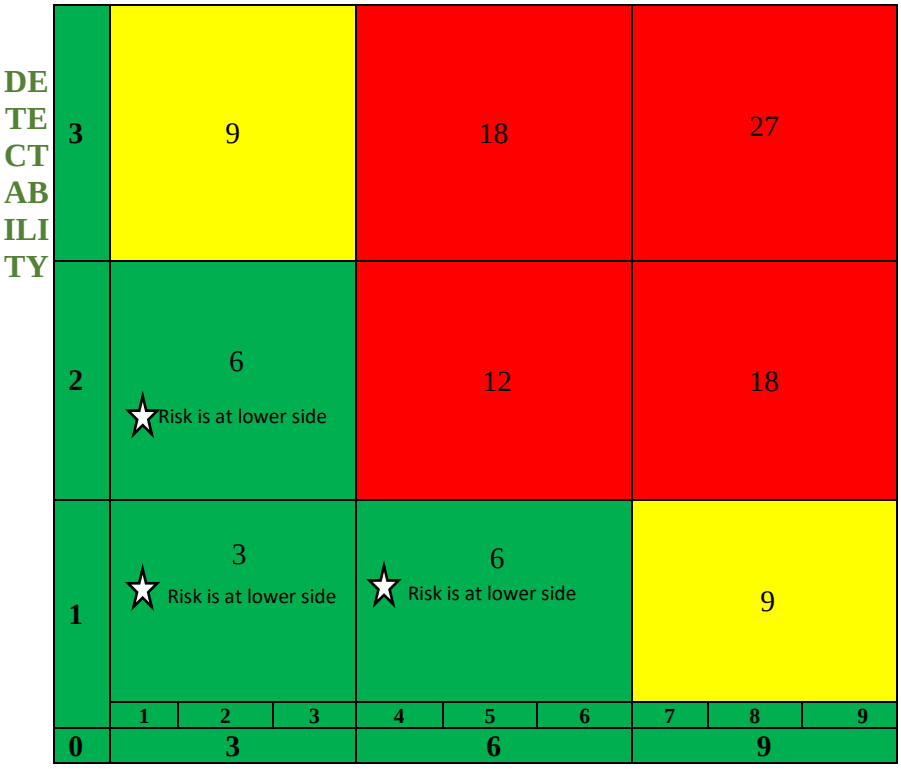


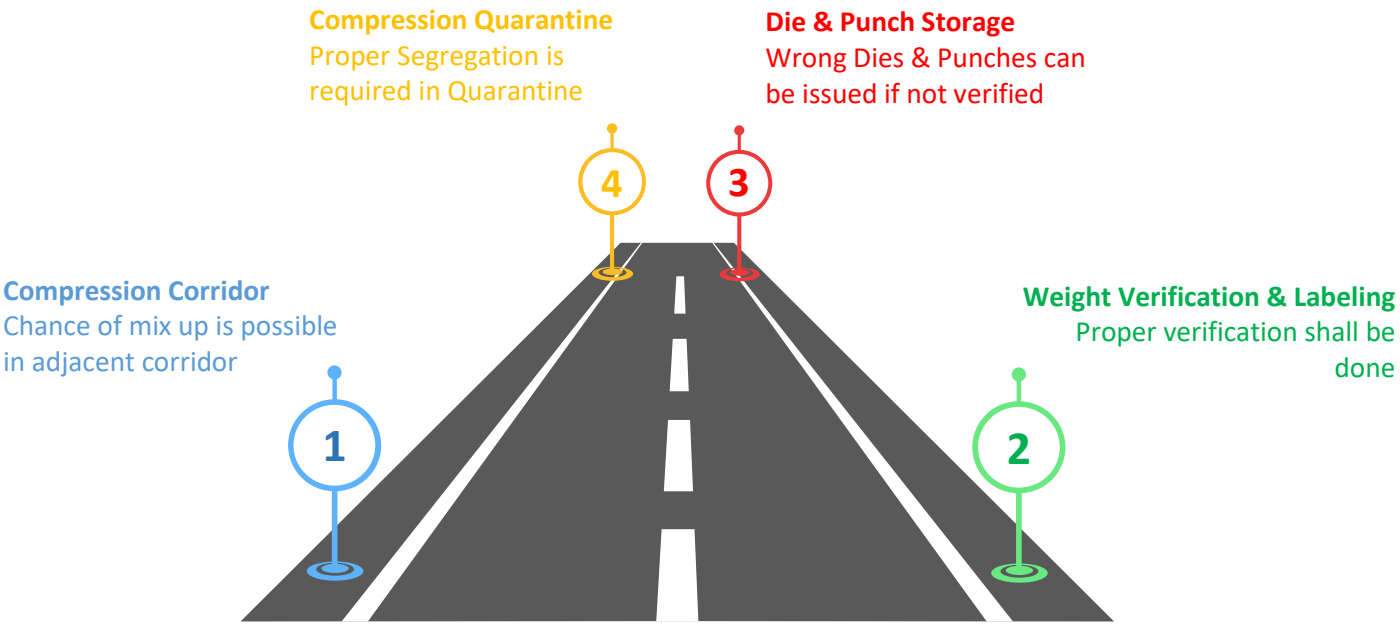
Figure 2: FMEA Matrix

Low Risk	Medium Risk	High Risk
• Manpower shortage • Material Handling • Untrained persons • Storage • Improper Labelling • SOP Implementation • Look Alike Products • Previous product Residue • Segregation • Rack arrangement • Verification • Physical Segregation • Double Checks • GMP not followed during transfer & manufacturing • Material Containers kept randomly in Corridor	No Medium Risk	No High Risk

Table 4: Summary of FMEA

COMPRESSION

Introduction: There may be the chance of mix up in Compression also, if not properly verified & labeled, mix up can take place in Compression corridor, as all Compressions are adjacent to each other. Weight verification & label verification are important to avoid mix ups. During Dies & Punches issuance, verification shall be done to avoid any wrong punch issuance. Further after Compression, tablet containers shall be kept segregated to avoid any mix ups.



8.3 CAUSE & EFFECT ANALYSIS:

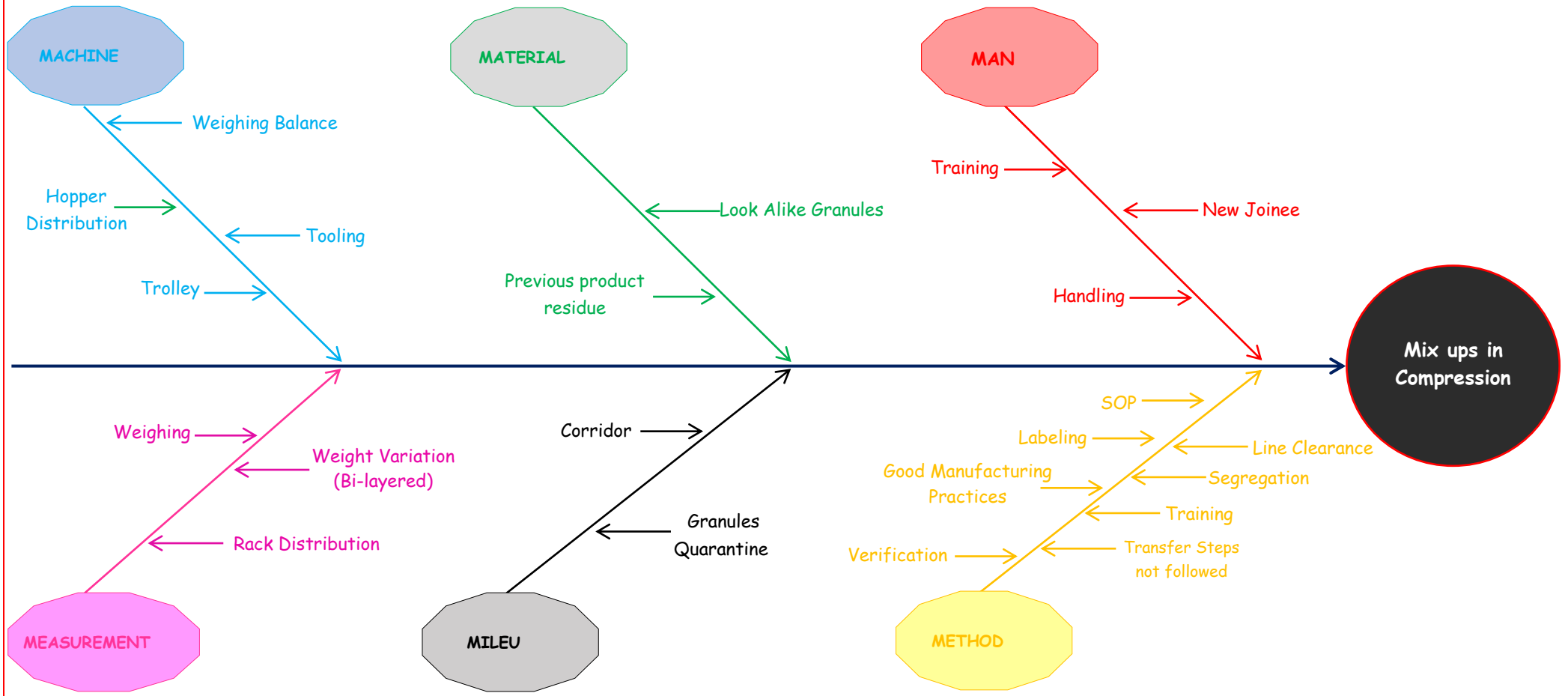


Figure 1: Fish & Bone Diagram

SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: 6 M is used for the evaluation of reasons of Mix Ups in Compression area; following are the areas of concern considered for the investigation, Man, Material, Measurement, Method, Milieu & Machine. It has been evaluated that all of the 6 M may contribute in Mix ups of Compression area.

MAN: Personnel supervising or performing the Compression activities are not aware of GMP practices & are Untrained which may result into:

- May take material into Compression without verifying resulting into mix ups.
- Market Complaints
- Product failure

MATERIAL: Handling & Storage of Compressed tablets plays an important role in mix ups during Compression stage. Miss management during Compression may lead to:

- Inter mixing of Lookalike tablets.
- Previous product residue may contaminate the next upcoming product.

MILIEU: The facility of the Compression plays major role in maintaining proper storage conditions, inadequate surrounding environment may lead to mix ups:

- Improper segregation in Corridor.
- Improper segregation in Granules Quarantine.
- Improper labelling in Containers.

MACHINE: The equipment & instruments used during Compression plays important role in day to day activities:

- Weight not verified.
- Improper tooling.
- Hopper not filled with proper layer content (in case of bi-layered tablets).
- Trolley not having lock & key

METHOD: There are various reasons during Compression practices which may lead to mix ups:

- Improper segregation.
- SOP not followed.
- Labelling not proper.
- Improper Verification.
- Line Clearance not done.
- Good Manufacturing Practices not followed.
- Transfer steps not followed.

MEASUREMENT: There are many factors which shall be regularly monitored during Compression& recorded such as:

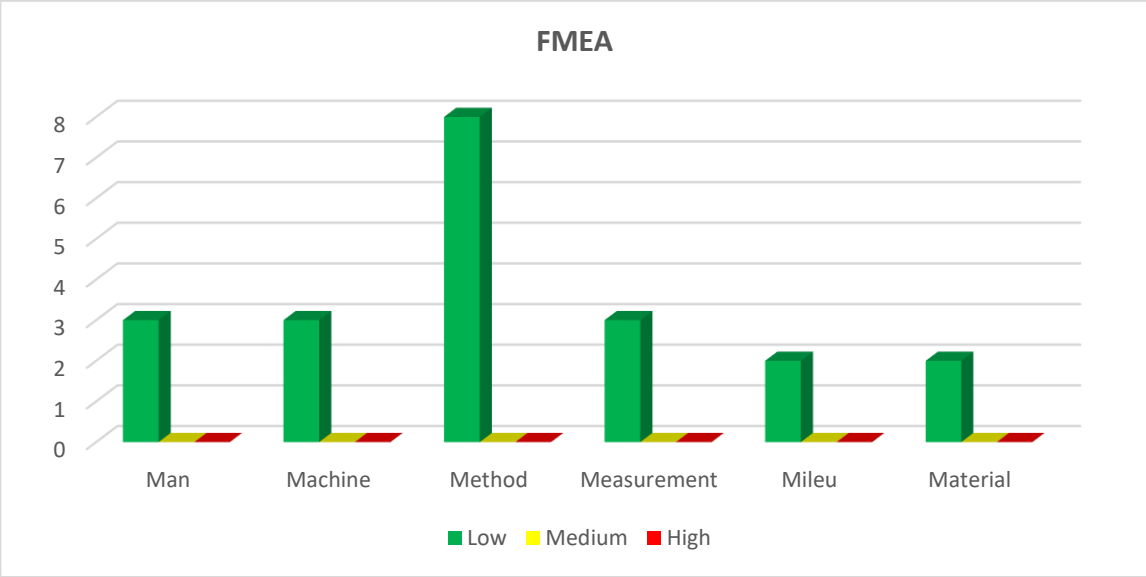
- Rack distribution shall be appropriate & traceable in Granules quarantine.
- Weighing Balances shall be Calibrated & Verified on daily basis.
- Weight variation during compression of bi-layered tablets.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR MIXUPS FROM DISPENSING TO DISPATCH (D_2D)

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
MAN															
1.	Training	Untrained Operators	• Product mix up • Product failure • Market Complaint	• Untrained person will not be able to segregate look alike material or containers. • Untrained person may put wrong labels.	Persons are trained enough for material handling & labelling.	Training SOP is in place "Training of Employees"	3	2	1	6	NA	NA	NA	NA	NA
2.	New Joinee	Untrained Chemist									NA	NA	NA	NA	NA
3.	Material Handling	Improper handling									NA	NA	NA	NA	NA
MATERIAL															
4.	Look Alike Granules	Containers of same shape & same type along with material of same color	• Product mix up • Product failure • Market Complaint	• Improper segregation. • Improper labelling	• Dispensed materials are kept inside the static pass box. • Verification is done before granulation activity.	-	3	2	1	6	NA	NA	NA	NA	NA
5.	Previous Product residue	Remaining of previous product	Contamination & Cross Contamination	Improper line clearance	QA chemist are trained for the Line Clearance	Dedicated BMR	3	1	1	3	NA	NA	NA	NA	NA
METHOD															
6.	SOP	SOP of GDP & Material Handling not followed	• Product mix up • Product failure • Market Complaint	SOP of Good Manufacturing Practices not followed.	GMP training is given to all the new joinee at the time of induction.	GMP SOP is in place " Daily Verification of Good Manufacturing and Good Documentation Practices on Shop Floor"	3	1	1	3	NA	NA	NA	NA	NA
7.	Labelling	Improper labelling	• Product mix up • Product failure • Market Complaint	• Untrained persons mishandled the containers • Too much of containers with improper segregation	• SOP of labelling is in place. • All dispensed materials are kept in double polybags.	SOP of Status Labelling is in place	3	1	1	3	NA	NA	NA	NA	NA
8.	Segregation	Containers not properly segregated	• Product mix up • Product failure • Market	• 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	NA	NA	NA	NA	NA

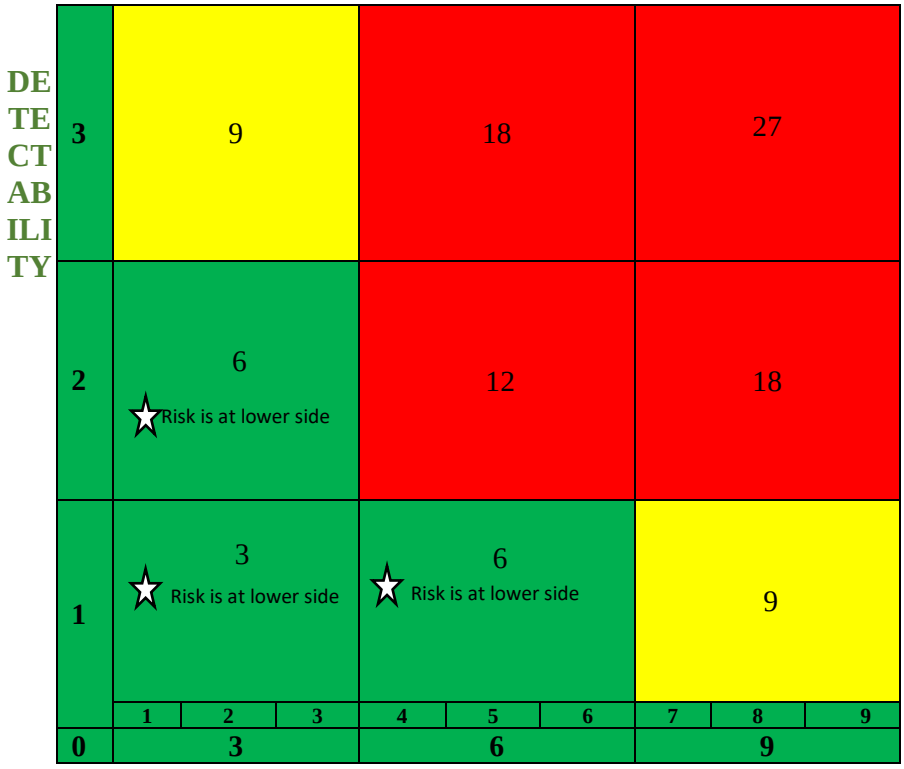
S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
			Complaint												
9.	Good Manufacturing Practices	GMP not followed	Contamination & Cross Contamination	Improper line clearance	Training SOP is in place. Line Clearance is a part of BMR.	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
10.	Training	Persons involved in manufacturing activities not trained	• Product mix up • Product failure • Market Complaint	• Untrained person will not be able to segregate look alike material or containers. • Untrained person may put wrong labels.	Training SOP is in place.	Training SOP is in place "Training of Employees"	3	2	1	6	NA	NA	NA	NA	NA
11.	Verification	Verification of material not done	• Improper labelling • Wrong quantity of batch dispensed • Contamination & Cross Contamination	Untrained persons	Reviewed by mechanism is in place	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
12.	Transfer Steps not followed	Step wise activities not followed	• Improper labelling	Containers not transferred batch wise.	BMR is the guidance documents	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
13.	Line Clearance	Improper line clearance	Contamination & Cross Contamination	• Person not trained for Line Clearance. • Line Clearance not performed.	Line Clearance is the part of BMR. QA Chemist is trained for the Line Clearance.	SOP of Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid	3	2	1	6	NA	NA	NA	NA	NA
MACHINE															
14.	Weighing Balance	Weighing Balance not calibrated	Wrong weight calculated	Balanced not Calibrated	Weighing Balance are daily verified & monthly calibrated. Tare weight is done before weighing.	SOP of Operation Cleaning Verification Calibration of Electronic Weighing Balances is in place	3	1	1	3	NA	NA	NA	NA	NA
15.	Trolley	Trolley used for transfer are not with lock & key	Intermixing	More than 01 batch kept in trolley for the transfer.	Only 01 batch is being transferred in one trolley	-	3	1	1	3	NA	NA	NA	NA	NA
16.	Tooling	Wrong issuance of Dies & Punch	Wrong tablet compressed	Verification of the issued punches not done.	Reviewed by QA is in place for issuance of Dies & Punches	SOP for Handling of Dies and Punches	3	1	1	3	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
17.	Hopper Distribution	Wrong layer filled in hopper	Intermixing of bi-layered tablets	Upper layer hopper filled by lower layer & vice versa	BMR is in place, weight variation is done as per BMR	Dedicated BMR	3	1	1	3	NA	NA	NA	NA	NA
MEASUREMENT															
18.	Weighing	Materials not weighed as per weighment sheet of BMR	• Product Failure • Product not complies	Untrained Chemist not verified material	• BMR is in place • Verification is done as per weighment sheet.	SOP of Operation Cleaning Verification Calibration of Electronic Weighing Balances is in place	3	1	1	3	NA	NA	NA	NA	NA
19.	Weight Variation	Layer not properly distributed	• Weight variation • Assay failure	• Improper layer setting • Operator not trained • Weight variation not verified	• BMR is in place • Weight variation is performed	Dedicated BMR	3	1	1	3	NA	NA	NA	NA	NA
20.	Rack Distribution	Racks distribution in Quarantine area not segregated	• Material Intermixing • Product failure • Market Complaint	• FIFO system not followed in Granules Quarantine. • Containers not segregated. • Containers not properly labelled.	• FIFO system is followed. • Containers are properly segregated & labelled.	SOP for Receipt Storage Issuance of Materials in Staging Area Quarantine Area	3	2	1	6	NA	NA	NA	NA	NA
MILEU															
21.	Corridor	Material kept randomly in Corridor	• 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	NA	NA	NA	NA	NA
22.	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	NA	NA	NA	NA	NA



Graph 1: Graphical presentation shows that environmental factors contribute the most to the severity of the risk.

FMEA MATRIX (Compression)



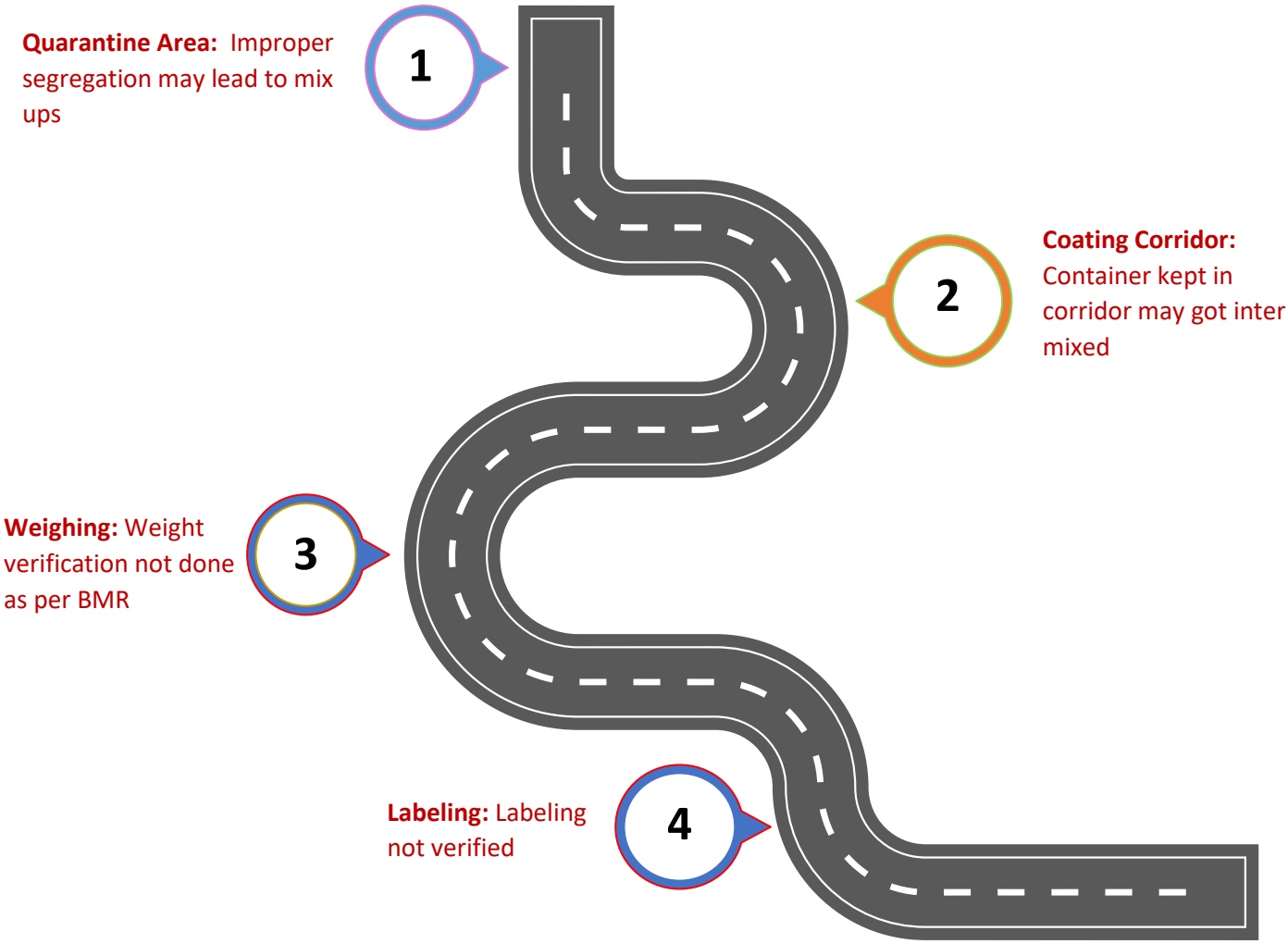
Risk observed at lower side in all factors (Man, Machine, Method, Material, Mileu & Measurement)

Figure 2: FMEA Matrix

COATING

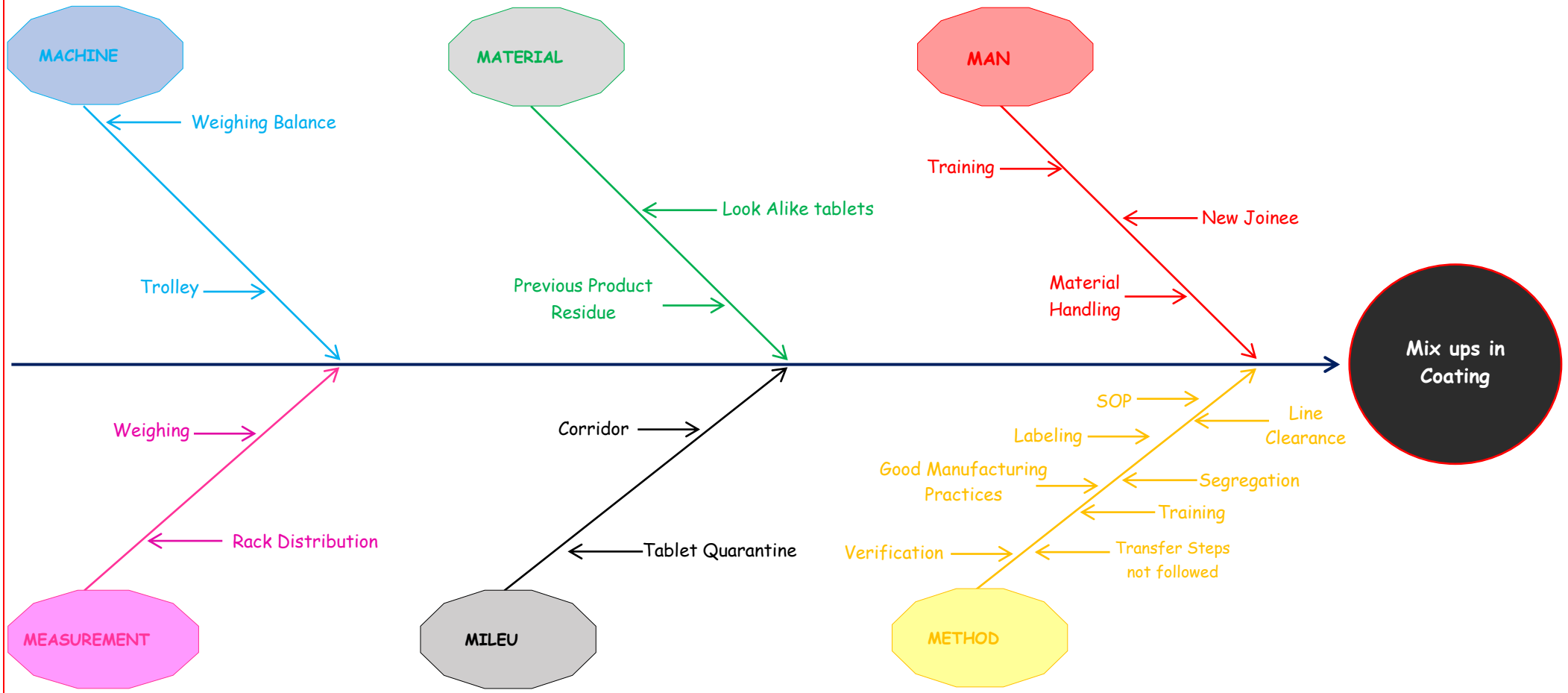
Introduction: After Compression, tablets are forwarded for Coating. At the initial stage, compressed tablet containers are kept in corridor and after line clearance, the product is transferred to the coating area for coating. There may be the chance that the product got intermixed in the corridor area, as like all other areas, all coatings are adjacent to each other. Further segregation shall be done in Compressed tablet quarantine.

COMPRESSED TABLET QUARANTINE



COATING

CAUSE & EFFECT ANALYSIS:



SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: It is used for the evaluation of Mix ups during Coating activity; following are the areas of concern considered for investigation. Man, Material, Measurement, Method, Milieu & Machine. It has been evaluated that all of the 6 M may contribute in failure of new warehouse facility resulting in failure of product.

MAN: Personnel supervising or performing the Coating related activities are not aware of GMP & are untrained which may result into:

- Wrong coating material for Coating.
- Wrong weighment of Coating.

MATERIAL: Handling & Storage of Coating material plays an important role in Coating. Miss management may lead to:

- Improper storage without proper segregation.
- Improper labelling.
- Improper Cleaning of Coating pan.
- Improper issuance of coating material.

MILIEU: The facility of the Coating plays major role in maintaining proper storage conditions, Inadequate surrounding environment may lead to:

- Inter Mixing.
- Wrong Coating.
- Fail in Description.

MACHINE: The Equipment &Instruments used in Coating plays important role in day to day activities:

- Balance not Calibrated.

METHOD: There are various reasons during Coating activities which may lead to mix ups:

- Improper segregation.
- SOP not followed.
- Labelling not proper.
- Improper Verification.
- Improper Line Clearance.
- Transfer steps not followed.

MEASUREMENT: There are many factors which shall be regularly monitored & recorded such as:

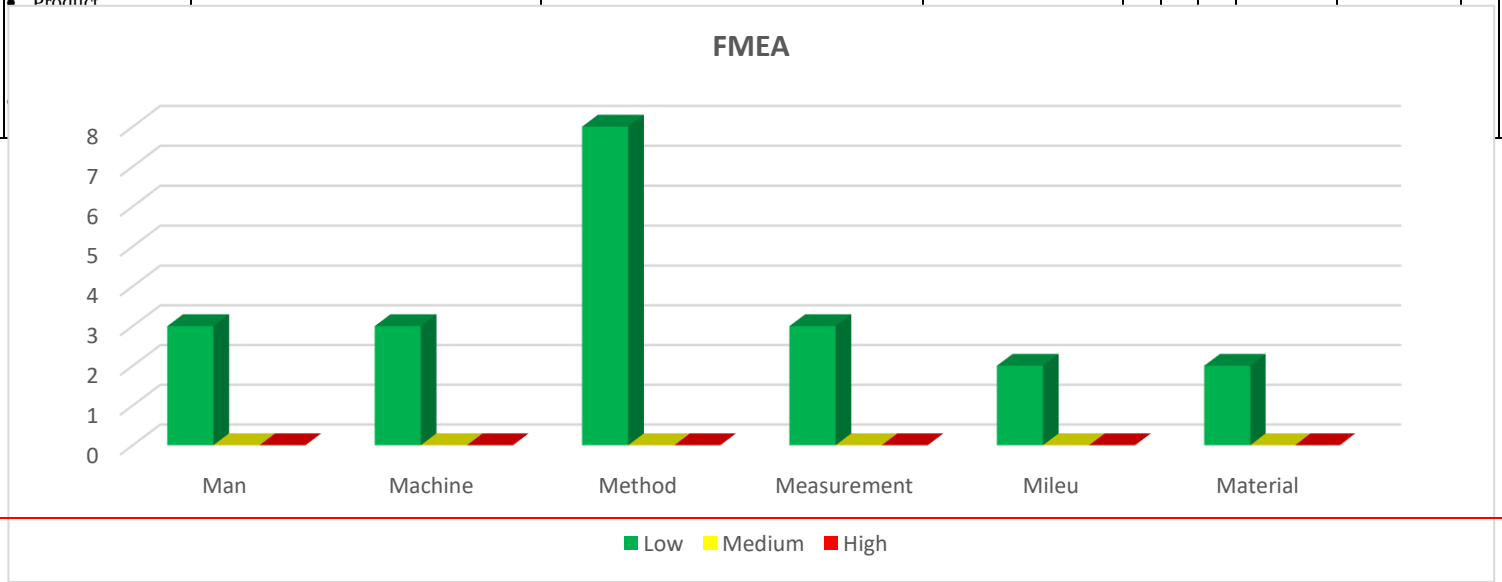
- Rack distribution shall be appropriate & traceable.
- Weighing Balances shall be Calibrated & Verified on daily basis.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR MIXUPS FROM DISPENSING TO DISPATCH (D_2D)

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
MAN															
1.	Training	Untrained Operators	• Product mix up • Product failure • Market Complaint	• Untrained person will not be able to segregate look alike material or containers. • Untrained person may put wrong labels.	Persons are trained enough for material handling & labelling.	Training SOP is in place "Training of Employees"	3	2	1	6	NA	NA	NA	NA	NA
2.	New Joinee	Untrained Chemist									NA	NA	NA	NA	NA
3.	Material Handling	Improper handling									NA	NA	NA	NA	NA
MATERIAL															
4.	Look Alike Tablets	Containers of same shape & same type along with material of same color	• Product mix up • Product failure • Market Complaint	• Improper segregation. • Improper labelling	• Dispensed materials are kept inside the static pass box. • Verification is done before granulation activity.	-	3	2	1	6	NA	NA	NA	NA	NA
5.	Previous Product residue	Remaining of previous product	Contamination & Cross Contamination	Improper line clearance	QA chemist are trained for the Line Clearance	Dedicated BMR	3	1	1	3	NA	NA	NA	NA	NA
METHOD															
6.	SOP	SOP of GDP & Material Handling not followed	• Product mix up • Product failure • Market Complaint	SOP of Good Manufacturing Practices not followed.	GMP training is given to all the new joinee at the time of induction.	GMP SOP is in place " Daily Verification of Good Manufacturing and Good Documentation Practices on Shop Floor"	3	1	1	3	NA	NA	NA	NA	NA
7.	Labelling	Improper labelling	• Product mix up • Product failure • Market Complaint	• Untrained persons mishandled the containers • Too much of containers with improper segregation	• SOP of labelling is in place. • All dispensed materials are kept in double polybags.	SOP of Status Labelling is in place	3	1	1	3	NA	NA	NA	NA	NA
8.	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	NA	NA	NA	NA	NA

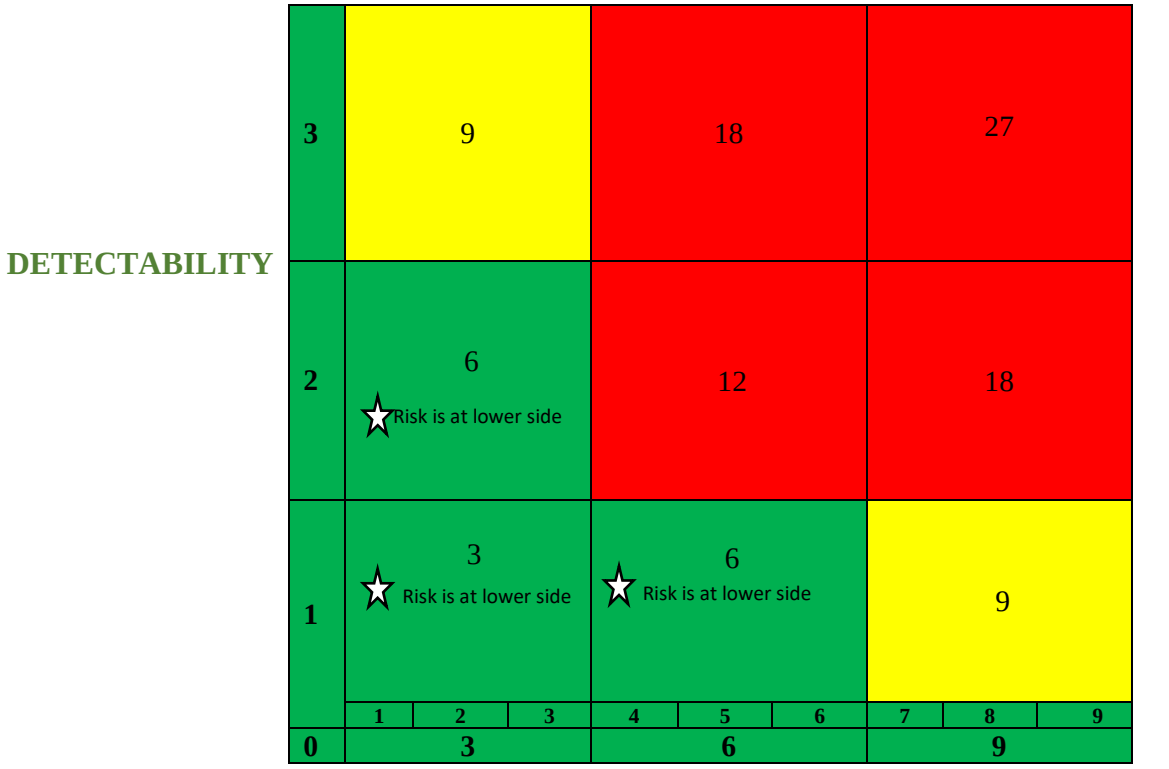
S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
9.	Good Manufacturing Practices	GMP not followed	Contamination & Cross Contamination	Improper line clearance	Training SOP is in place. Line Clearance is a part of BMR.	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
10.	Training	Persons involved in manufacturing activities not trained	• Product mix up • Product failure • Market Complaint	• Untrained person will not be able to segregate look alike material or containers. • Untrained person may put wrong labels.	Training SOP is in place.	Training SOP is in place "Training of Employees"	3	2	1	6	NA	NA	NA	NA	NA
11.	Verification	Verification of material not done	• Improper labelling • Wrong quantity of batch dispensed • Contamination & Cross Contamination	Untrained persons	Reviewed by mechanism is in place	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
12.	Transfer Steps not followed	Step wise activities not followed	• Improper labelling	Containers not transferred batch wise.	BMR is the guidance documents	SOP in place Daily verification of Good Manufacturing and Good Documentation	3	2	1	6	NA	NA	NA	NA	NA
13.	Line Clearance	Improper line clearance	Contamination & Cross Contamination	• Person not trained for Line Clearance. • Line Clearance not performed.	Line Clearance is the part of BMR. QA Chemist is trained for the Line Clearance.	SOP of Line Clearance in Oral Solid Dosage, External Preparation and Oral Liquid	3	2	1	6	NA	NA	NA	NA	NA
MACHINE															
14.	Weighing Balance	Weighing Balance not calibrated	Wrong weight calculated	Balanced not Calibrated	Weighing Balance are daily verified & monthly calibrated. Tare weight is done before weighing.	SOP of Operation Cleaning Verification Calibration of Electronic Weighing Balances is in place	3	1	1	3	NA	NA	NA	NA	NA
MEASUREMENT															
15.	Weighing	Materials not weighed as per weighment sheet of BMR	• Product Failure • Product not complies	Untrained Chemist not verified material	• BMR is in place • Verification is done as per weighment sheet.	SOP of Operation Cleaning Verification Calibration of Electronic Weighing Balances is in place	3	1	1	3	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
16.	Rack Distribution	Racks distribution in Quarantine area not segregated	• Material Intermixing • Product failure • Market Complaint	• FIFO system not followed in Granules Quarantine. • Containers not segregated. • Containers not properly labelled.	• FIFO system is followed. • Containers are properly segregated & labelled.	SOP for Receipt Storage Issuance of Materials in Staging Area Quarantine Area	3	2	1	6	NA	NA	NA	NA	NA
MILEU															
17.	Corridor	Material kept randomly in Corridor	• 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	NA	NA	NA	NA	NA
18.	Tablet Quarantine	Materials kept randomly in Tablet Quarantine area without proper segregation & labelling.	• Wrong batch issued for coating • Product failure • Product	• Log book of issuance not maintained & product will be not tracked. • Containers not verified before issuance	Log book of issuance is in place.	SOP for Receipt, Storage & Issuance of Materials in Staging Area & Quarantine Area	3	1	1	3	NA	NA	NA	NA	NA



Graph 1: Graphical presentation shows that environmental factors contribute the most to the severity of the risk.

FMEA MATRIX (Coating)



☆Risk observed at lower side in all factors (Man, Machine, Method, Material, Mileu & Measurement)

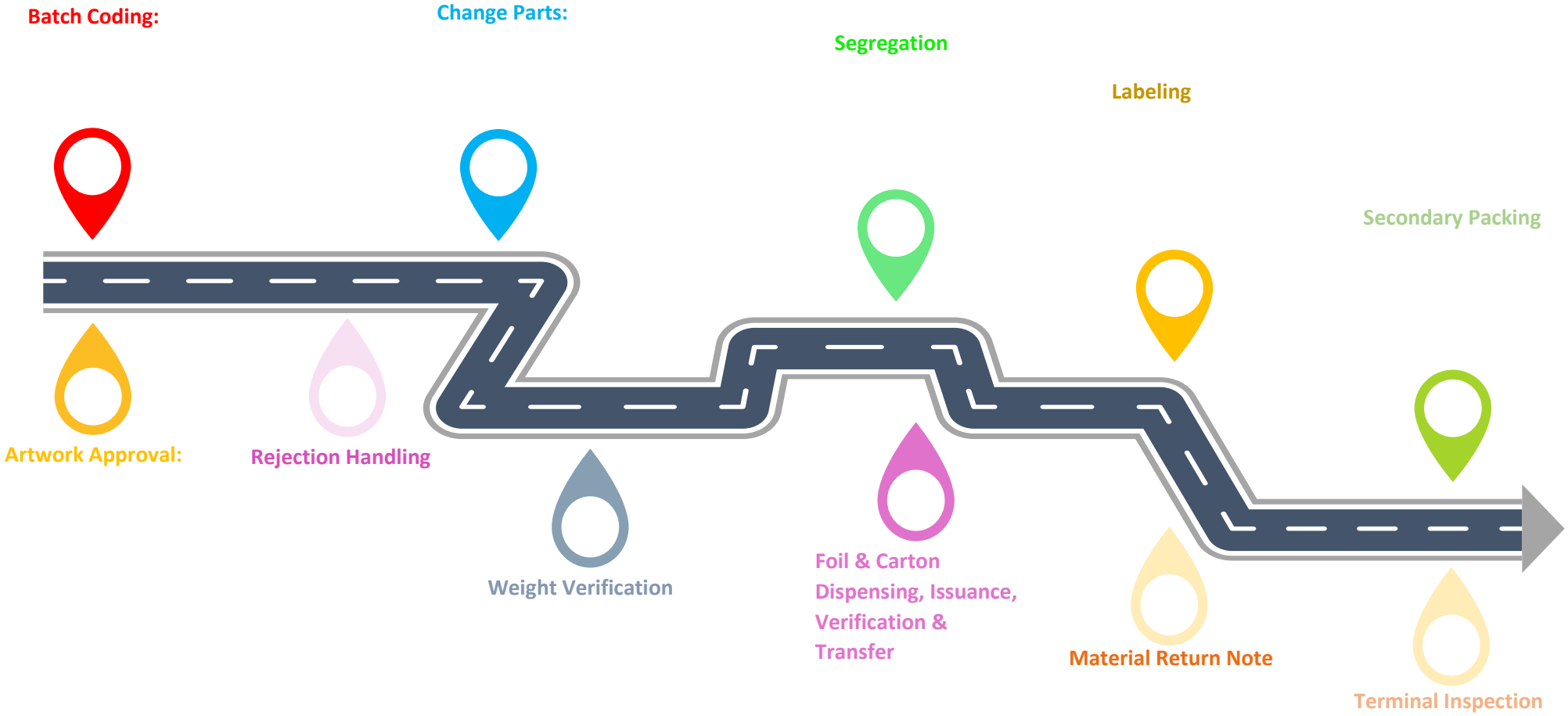
Figure 2: FMEA Matrix

Low Risk	Medium Risk	High Risk
• Manpower shortage • Material Handling • Untrained persons • Storage • Improper Labelling • SOP Implementation • Look Alike Products • Previous product Residue • Segregation • Rack arrangement • Verification • Physical Segregation • Double Checks • GMP not followed during transfer & manufacturing • Material Containers kept randomly in Corridor	No Medium Risk	No High Risk

Table 4: Summary of FMEA

PACKING

Introduction: Coated tablets kept in tablet Quarantine are forwarded for packing. Before packing, the change parts are issued for the next product. Change Parts are verified as per the request; wrong request generation may result into wrong change part issuance. Further there is a chance of mix ups in quarantine area, if not segregated properly. Weight verification & label verification also done before the packing starts. Apart from packing, several other activities which plays important role in packing like; Artwork verification, Batch Coding/Printing, Change part verification& Rejection handling.



CAUSE & EFFECT ANALYSIS:

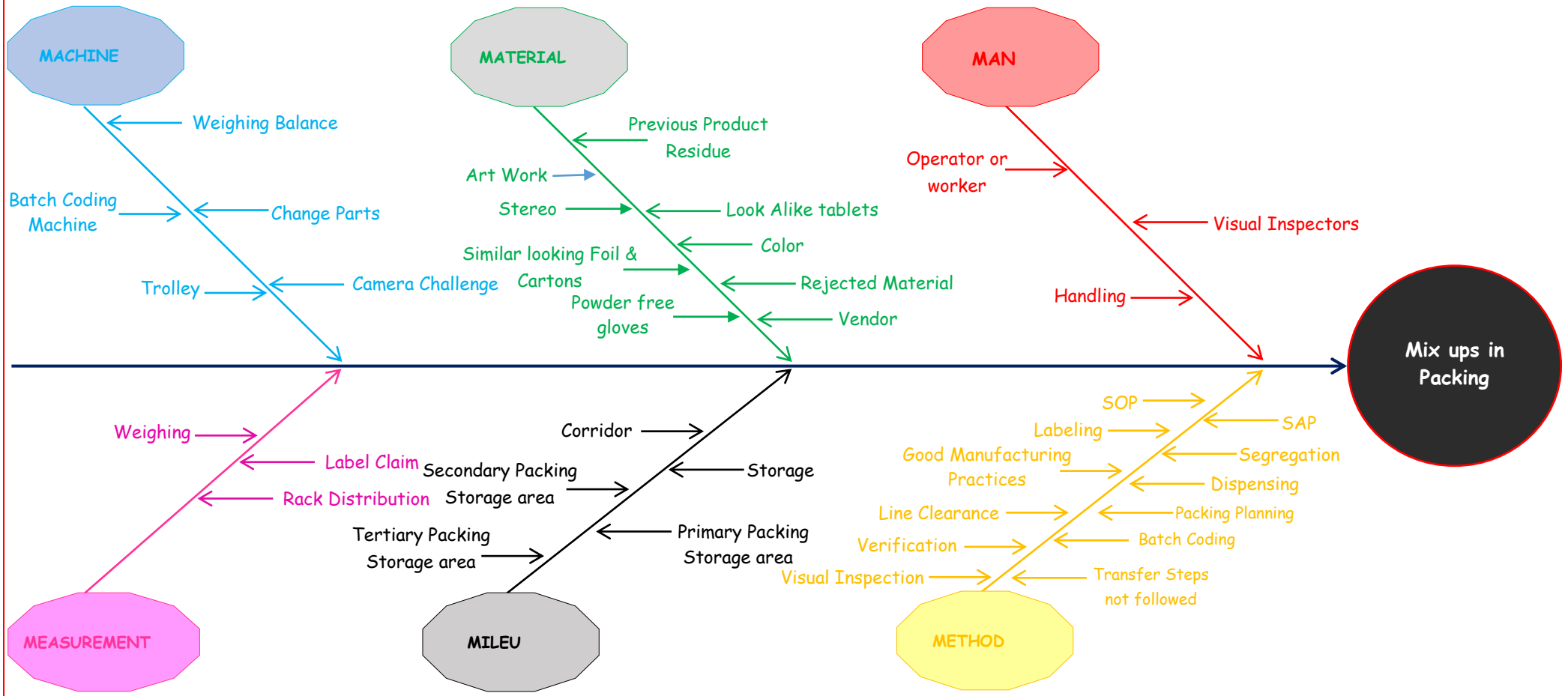


Figure 1: Fish & Bone Diagram

SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: It is used for the evaluation of inadequate activities performed in Packing facility; following are the areas of concern considered for investigation, Man, Material, Measurement, Method, Milieu & Machine. It has been evaluated that all of the 6 M may contribute in failure of Packing facility resulting in failure of product.

MAN: Personnel supervising or performing in packing area activities are not aware of GMP & are untrained Which may result into:

- Visual inspectors are not trained enough to perform inspection.
- Improper handling of products.
- Improper planning, same product of different batches runs in adjacent packing lines.
- Products having cartons of same appearance runs parallel.
- Products of same name & different label claim runs parallel.

MATERIAL: Handling & Storage of foils & cartons plays an important role in packing material management. Miss management may lead to:

- Improper storage without proper segregation.
- Improper labelling.
- Foils of same name & different label claims kept adjacent to each other.

MILIEU: The facility of the primary packing & secondary packing plays major role in maintaining proper storage conditions, Inadequate surrounding environment may lead to:

- Material received at receiving bay are not properly verified.
- Improper handling & segregation in Primary Packing Storage area.
- Improper handling & segregation in Secondary Packing Storage area.
- Improper handling & segregation in Tertiary Packing Storage area.
- Improper handling & segregation in Change parts storage area.

MACHINE: The equipment & instruments used in Packing areas plays important role in day to day activities:

- Weight of foil roll not verified.

METHOD: There are various reasons during Packing area practices which may lead to mix ups:

- Improper segregation.
- SOP not followed.
- Labelling not proper.
- Improper Verification.
- Improper Dispensing of Packing materials.
- Improper training and unaware about the Good Warehouse Practices.
- Improper Line Clearance.
- Improper Batch Coding.
- Good Manufacturing Practices.

MEASUREMENT: There are many factors which shall be regularly monitored & recorded such as:

- Rack distribution shall be appropriate & traceable.
- Weighing Balances shall be Calibrated & Verified on daily basis.
- Product having cartons of same appearance & different label claim.
- Foil of same name & different label claim.

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
MAN															
1.	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	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	NA	NA	NA	NA	NA
2.	Untrained Visual Inspectors	Missed out defective or look alikeBlister Strips& Cartons	Weak eye sight	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	NA	NA	NA	NA	NA
			Un-attentiveness												
			Untrained												

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
3.	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 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.	SOP of Do's and Don'ts in Packing	Do's and Don'ts in Packing	3	1	1	3	NA	NA	NA	NA	NA
4.	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	SOP No.: "Artwork, Preparation and Approval" SOP No.: "Handling of Artwork Through Management software"	3	2	1	6	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					in place.										
MATERIAL															
5.	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 Stereo "SOP No.: "Batch Coding/ Printing System	3	1	1	3	NA	NA	NA	NA	NA
		Improper dilution	Solution A & B not equally prepared		Hold time established for Ink (7 days)										
		Improper setting of stereo over drum	Untrained operator		All Operators & their subordinates are qualified & trained										
6.	Ink	Expired ink used	Impression not rinted on Blister foil		Ink purchased from approved vendor										
7.	Thinner	Spillage of thinner over printed strips	Inks used for printing are organic in nature & easily diluted by thinner or IPA (Solvent)	Smudging & Miss-printing of details over Blister foil	Dedicated box available for thinner										
8.	Hand Sanitizer	Hands of operator remain wet after sanitization		Smudging & Miss-printing of details over Blister foil	Trained Operator										
9.	Specimen Sample	Not verified	Miss printing missed during verification	Smudging & Miss-printing of details over Blister foil	Printing detail available in BPR & Stereo log book Specimen sample jointly verified by QA	BPR	3	1	1	3	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					& production										
10.	Printed Foil	Vendor not approved	Foil is of bad quality	Smudging & Miss-printing of details over Blister foil	Approved Vendor	Approved Vendor	3	1	1	3	NA	NA	NA	NA	NA
11.	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	NA	NA	NA	NA	NA
12.	Similar looking product	Mix ups	Market Complaint	Mix-ups of tablets/capsules/ bottles/ sachets/ strips/blister /Alu-Alu pack/cartons /labels & overprinting during adjacent to each other.	• 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.: "Line Clearance"	3	1	1	3	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					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/carto ns/ 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										

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												S	O	D	RPN SxO xD
					defining procedure for line clearance for avoid miss-up.										
	METHOD														
	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 after dispensing and 100% inspection done after overprinting of cartons.	SOP No.: "Receipt Handling and Storage of Packing 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" SOP No. "Qualification Challenge Test of Visual Inspector" SOP No.: "Production Process Control"	1	2	2	4	Proposal for online carton coding and Camera detection system for improved controls.	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					• Rejection album has been revised accordingly										
	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. • Material receipt checklist not available.	• SOP for Receipt, Handling and Storage of Packing Materials (SOP No.) is in place. • Material receipt procedure done through SAP. • Material receipt checklist is in place, during material receipt following check point verified. ➢ E-way bill of the consignment. ➢ Appropriateness of	SOP No.: "Receipt Handling and Storage of Packing 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" SOP No.: "Qualification Challenge Test of Visual Inspector" SOP No.: "Production Process Control"	1	2	2	4 **Severity:** Severity of carton mix up during packing material receipt is of low category as checks are 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	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					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										

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					purchase order tallies with consignment delivery document etc.										
	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. HWH-010) is in place. • Warehouse officer/Executive shall take the daily incoming from SAP and shall entered rack No. in work sheet. • Warehouse person shall enter all noted inventory in SAP bin location.	SOP No.: "Receipt Handling and Storage of Packing 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" SOP No.: Qualification Challenge Test of Visual Inspector" SOP No.: "Production Process Control"	1	2	2	4 **Severity:** Severity of carton mix up during packing material storage is of 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.	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					• After release in SAP all type approved packaging material transfer to dedicated location and enters details in SAP for Bin Location updating.					**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 packing Material procedure not available. • Dispensing done without "Packing Material Issue Slip". • Procedure for printing of material identification slip not available. • Issuance of	• SOP for Dispensing of Packing Materials SOP No. is in place. • All dispensing activity of packing material done through SAP generated packing material issue slip. There is well defining procedure for generation of	SOP No.: "Receipt Handling and Storage of Packing 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" SOP No.: Qualification Challenge Test of Visual Inspector" SOP No.: "Production Process Control"	1	2	2	4 **Severity:** Severity of carton mix up during 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	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
				additional packing materials through Manual procedure.	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					dispensing. **Detection:** 100% verification is not done					

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					packing material issue slip in SOP										
	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 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	• SOP for Batch Coding /Printing System (SOP No. .....) is in place. • SOP having well defined procedure for line clearance of Coding/Printing area. • 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	SOP No.: "Receipt Handling and Storage of Packing 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" SOP No.: "Qualification Challenge Test of Visual Inspector" SOP No.: "Production Process Control"	1	2	2	4 **Severity:** Severity of carton mix up during batch coding is of low category as checks are 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	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
				name as it is a continuous online process and there may be possibility that one such carton could missed.	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										

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												S	O	D	RPN SxO xD
					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.										
18.	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 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	NA	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					• 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 for Qualification					further only terminal inspection is done which does not cover 100% carton inspection. **Occurrence:** Chance of missing the carton mixing during online monitoring rare only incase 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.					

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					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.										
19.	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	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	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					CB shall be given to production for re-checking.						occurrence as SOP is in place. **Detectability:** Can be easily detected				
20.	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		NA	NA	NA	NA
21.	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		3	1	1	3		NA	NA	NA	NA
22.	Previous complaint	Same complaint accelerated previously also	Improper CAPA of previous complaints		Till now 23 batches manufactured and no any such complaint received		3	1	1	3		NA	NA	NA	NA
23.	Current Practices	Hand Sanitization	Frequently hands are sanitized due to covid-19 pandemic		As per instructions, hands are sanitized before going for machine operation activities		3	1	1	3		NA	NA	NA	NA
24.		Initial machine setting	Stereo drum or		Verification of		3	1	1	3		NA	NA	NA	NA

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												S	O	D	RPN SxO xD
			stereo not properly set initially		strips detail done after initial setting										
25.		Lunch Break	Defective strips remains in web during lunch break & used in packing		Instructions are given to reject those strips which remains in web after a break		3	1	1	3		NA	NA	NA	NA
26.		Stage wise verification	Stage wise verification not done		Verification part is documented after every stage		3	1	1	3		NA	NA	NA	NA
27.		Specimen sample collection	Specimen sample not collected or 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.		3	1	1	3		NA	NA	NA	NA
28.	Terminal Inspection	Terminal Inspection not done	Random terminal inspection not done	Smudging & Miss-printing of details over Blister foil	Terminal inspection is done for each product and documented		3	1	1	3		NA	NA	NA	NA
29.	Training	Persons not trained	Operators, their subordinates and visual inspectors	Smudging & Miss-printing of details over Blister foil	Training given to all related persons		3	1	1	3		NA	NA	NA	NA

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												S	O	D	RPN SxO xD
			not properly trained												
30.	Practices	Current practices not followed	Current verification practices not followed during different stages		Verification practices are a part of documentation		3	1	1	3		NA	NA	NA	NA
31.	Customer	Customer sanitize the strip	Customer used wet hand during receiving strip from pharmacist resulting into smudging of printed details		No control		3	1	1	3		NA	NA	NA	NA
32.	Packing Verification	Strips not verified during packing	Strips missed for detail verification during primary & secondary packing		Verification is a part of documentation							NA	NA	NA	NA
33.		Too hectic schedule	Tired of being continuous working resulting into missing of rejected strips				3	1	1	3		NA	NA	NA	NA
34.	Vendor	Ink & foil quality improper	Ink & foil is of low quality resulting into temporary impression		Approved Vendor		3	1	1	3		NA	NA	NA	NA
35.	Break	Strip kept in web & forwarded for secondary packing	Rejected strips mixed with proper strips	Smudging & Miss-printing of details over Blister foil	As per the practices, Strips are rejected and	• SOP No.: "Rejection Handling Management During Packing in Process"	3	1	1	3		NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					kept in rejection box after any break	SOP No.: "Batch Coding Printing System"									
36.	In-Process checks	Strips not verified during in-process	Rejected strips missed by the checkers		In-process checks are part of documentation and are done after every 1 hour.		3	1	1	3		NA	NA	NA	NA
37.	Camera System	Camera not verify the printing defects	Camera not verified the printing details		Camera system required for verification of any printing defect		3	1	1	3		NA	NA	NA	NA
38.	Initial Challenge	Challenge test not performed for printing detail	Initial challenge test not performed				3	1	1	3		NA	NA	NA	NA
39.	Breakdown	Machine run after breakdown	Rejected strips remained in web after a break & mixed with good strips		Separate rejection box is available for strips generated after a break		3	1	1	3		NA	NA	NA	NA
40.	Window/Hatch	Window/Hatch opened during break	Rejected strips mixed with good strips when hatch remain opened during break		Window/Hatch are always closed as per practice in case of any break		3	1	1	3		NA	NA	NA	NA
41.	Material Storage	Foil, Ink or thinner not properly stored	Temperature/RH reaches high in primary packing storage area		Proper area is maintained for storage of foil etc.		3	1	1	3		NA	NA	NA	NA

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												S	O	D	RPN SxO xD
42.	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
43.		•	Shipper quantities not tally with the batch Ticket.		Final quantity of product tally with batch ticket & approved by Quality Assurance.		2	1	1	2	**Severity:** Differencein shipper quantity can leads to severe impact. **Occurrence:** Chance of difference in shipper quantity **is** unlikely as all shippers are being verified at the end of	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
											the batch during terminal inspection. **Detectability:** Can be easily detected.				
46.			Inward details were not maintained by QA		Inward details were maintained by QA.		3	1	1	3	**Severity:** Severity of not maintaining inward detail is high as tracking is not there. **Occurrence:** Occurrence is unlikely; as written procedure is in place. **Detectability:** Can be easily detected as written records are maintained.	NA	NA	NA	NA
47.			Shippers were not stored properly or segregated at proper distance		Final product stored on racks, suitably spaced from other batches of the same or different product.		3	2	1	6	**Severity:** Severity is high; shippers not segregated can inter mix easily. **Occurrence:** Possibility of occurrence is there **Detectability:**	NA	NA	NA	NA

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												S	O	D	RPN SxO xD
											Can be easily detected as verification process is in place.				
48.			Packing slip not Placed on front side of shipper.		Front side of corrugated box shall bear packing slip.		1	2	1	2	**Severity:** Improper packing slip does not have severe impact on product quality. **Occurrence:** Possibility of improper labelling is there **Detectability:** Can be easily detected during verification	NA	NA	NA	NA
49.			Packing slip not clearly visible		Packing slip shall be clearly visible.		1	2	1	2	**Severity:** Illegible packing slip does not have any serious impact. **Occurrence:** There is a possibility of occurrence **Detectability:** Can be easily detected during verification	NA	NA	NA	NA
50.			Final invoice not verified.		Invoice checked before making an invoice for		2	1	1	2	**Severity:** Wrong invoice can result into wrong	NA	NA	NA	NA

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												S	O	D	RPN SxO xD
					customer.						dispatch & moderately effected the process, there may be the chance of quantity difference **Occurrence:** Chance of occurrence is less as there is a verification process **Detectability:** Can be easily detected, as SOP is in place.				
51.			Quantity of material not checked batch wise.		Quantity of material shall be checked batch wise.		3	1	1	3	**Severity:** Difference in quantity is severe whether any extra shipper is there or less shipper is there **Occurrence:** Quantity is always checked as per SOP **Detectability:** Can be easily detected	NA	NA	NA	NA
52.			All information not Recorded		All the information like Product name, batch		2	2	1	4	**Severity:** Severity is low as information is	NA	NA	NA	NA

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference Document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxO xD
					no., pack size, quantity, manufacturing & expiry date shall be recorded						recorded as per annexure **Occurrence:** No chance of occurrence **Detectability:** Can be easily detected				
53.			Material not removed as per invoice		Remove material from warehouse as per invoice for dispatch.		2	1	1	2	**Severity:** Removal of material does not have any impact on product quality of safety **Occurrence:** Chance of Occurrenceis less **Detectability:** Can be easily detected	NA	NA	NA	NA
54.			Material not re-checked		Materials ready for dispatch shall be re-checked.		2	1	1	2	**Severity:** Re-checking will avoid the chance of mixing **Occurrence:** Chance is very less **Detectability:** Can be easily detected	NA	NA	NA	NA
55.			Shipper not verified with corresponding dispatched shippers		Officer shall strike off shipper no. corresponding to dispatch		2	1	1	2	**Severity:** Dispatched shippers without verification may result	NA	NA	NA	NA

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												S	O	D	RPN SxO xD
					shipper.						into inter mixing **Occurrence:** Chance of occurrence is very less as SOP is in place **Detectability:** Can be easily detected				
MILEU															
56.	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	NA	NA	NA	NA	NA
57.		Window/Hatch not closed during break & initial setting	Window/Hatch used for segregation of primary & secondary packing area remains open during lunch break or initial setting resulting into mixing od defected strips with rejected strips		Hatch is closed as a part of practice during any break		3	1	1	3	NA	NA	NA	NA	NA
MEASUREMENT															
58.	Frequency of Qualifying Visual Inspectors	Visual inspectors not qualified as per schedule	Unqualified Visual inspectors missed the	Too much hectic schedule or visual inspectors not qualified or new	Visual inspectors are qualified as per schedule	SOP No.: "Qualification Challenge Test of Visual Inspector"	3	1	1	3	NA	NA	NA	NA	NA

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												S	O	D	RPN SxO xD
			rejected strips	joinee.											
59.	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	NA	NA	NA	NA	NA
60.	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	NA	NA	NA	NA	NA
61.	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	NA	NA	NA	NA	NA
MACHINE															
62.	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	NA	NA	NA	NA	NA
63.	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	NA	NA	NA	NA	NA
64.	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	NA	NA	NA	NA	NA
65.	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	3	1	1	3	NA	NA	NA	NA	NA

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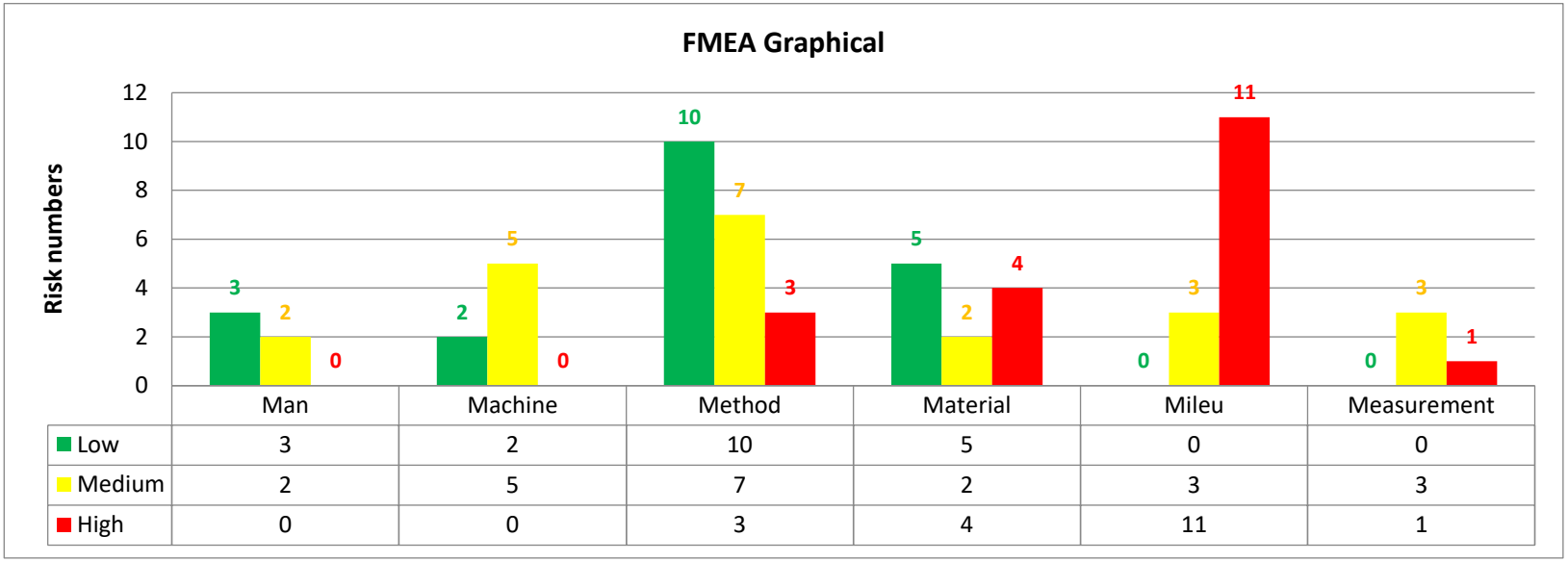
												S	O	D	RPN SxO xD
						Strip Machine									



	Man	Machine	Method	Material	Mileu	Measurement
Low	3	2	10	5	0	0
Medium	2	5	7	2	3	3
High	0	0	3	4	11	1

Graph 1: Graphical presentation shows that environmental factors contribute the most to the severity of the risk.

FMEA MATRIX

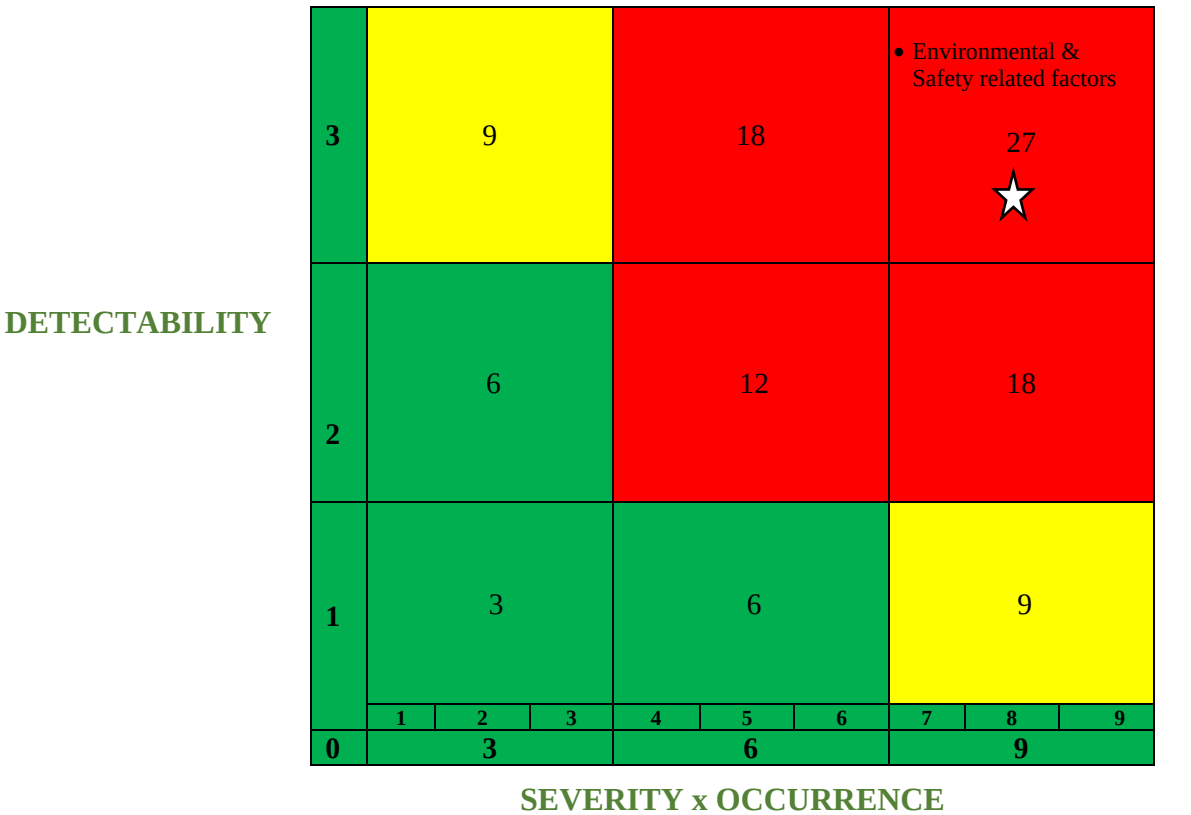


Figure 2: FMEA Matrix

Low Risk	Medium Risk	High Risk

Table 4: Summary of FMEA

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	The Dispensed material shall be kept in lock & key.		
2.	The overprinting of cartons having same size, colour, shape and layout shall be coded in different area, machines and in different period to avoid such type mix-up in future batches. SOP No. (Production process and control) shall be enhanced for better control.		
3.	Revised the SOP (Production process and control) and mentioned the clause that the cartons of same colour, size, shape and layout shall be procured from alternate vendor. Freeze the vendor in SAP for similar looking cartons to avoid the mix up and same shall be also mentioned in SOP**.**		
3.	The list of the cartons of same colour, size, shape and layout with different strength shall be prepared for proper identification and to avoid the carton mix-ups.		
4.	100% inspection shall be done after dispensing and 100% inspection shall be done after overprinting of cartons.		
5.	Proposal for online carton coding and Camera detection system for improved controls.		
6.	During overprinting procedure the initial and end specimen sample of the carton is attached in the BPR. Along with this there is an addition in the procedure that one specimen sample of over coded carton from each carets are checked by QA and Production and recoded in BPR. All the BlueCross BPR shall be revised.		
7.	Request to change the overprinting area one from another so as to identify these cartons and mix-up at any stage remains apparently visible as well as stands out for these same size, shape and layout cartons.		
8.	Revised the SOP (Production process and control) and mentioned the close that the cartons of same color, size, shape and layout shall be procured from alternate vendor.		
9.	The carton Vendor has been already informed about the complaint, site has asked for investigation report about such type of mixing possibility during carton printing/ packing at vendor’s end. The cartons of same size, shape and layout and similar color shall be printed on separate machines on different timings to avoid such type mixing of cartons.		

S.No.	Recommended Action	Responsible Person	Target Date of Completion
10.	The overprinting of cartons having same size, color, shape and layout shall be coded in different area, machines and on different timing to avoid such type mix-up in future batches.		
11.	Proposal for online carton coding and Camera detection system for improved controls.		
12.	After batch coding, BPR shall be revised for the AQL format shall be incorporated in the BPR before reconciliation stage of coded cartons to perform the AQL.		
13.	To incorporate the format of pre-post running products on adjacent lines.		
14.	BPR to be revised to incorporate the rotation of visual inspector in carton overprinting. One inspector deputed before overprinting & one after overprinting.		
15.	During overprinting procedure, the initial and end specimen sample of the carton is attached in the BPR. Along with this there is an addition in the procedure that one specimen sample of over coded carton from each carets are checked by QA and Production and recoded in BPR.		
16.	Qualification of overprinting inspectors shall be done as per the SOP. List of Qualified visual inspectors shall be prepared and same shall be displayed in batch coding area.		
17.	SOP No. (Do's and Don'ts in Packing) has been revised for better control.		
18.	Similar looking product list attached and same shall be displayed in shop floor.		
19.	SOP No. (Sampling Testing Release Approval and Rejection of PM) shall be revised for sampling of similar looking products shall be performed on different date/time & in separate booth.		
20.	Online Re-conciliation to be done.		
	Based on terminal inspection log book review, it has been evidence that both batches were inspected at terminal point and back to back inspection caused mix up.		
	Vendor is same of both cartons might be possibility for such type mixing at vendor end		

S.No.	Recommended Action	Responsible Person	Target Date of Completion
	The batch coding is manual in Carton, after the carton printing carton filled on polybags there is no numbering system found for counting of polybags.		
	Rotation of visual inspectors with packers and counters from 4 hr. to 2 hr.		
	To avoid such type of complaint on similar looking carton and order shall be given to vendor at different time point or alternate vendor shall be developed and finalize.		
	Carton coding SOP shall be revised “To introduce Polybag numbering system” & same shall be implemented in BPR.		
	Catch cover packing shall be packed online in auto-cartonators.		

Quality Risk Management Team			Reviewed By Head Operations (Sign & Date)	Approved By Head QA (Sign & Date)
Name	**Department**	**Sign & Date**		
	Warehouse (RM)			
	Quality Assurance			
	Production (Manufacturing)			
	Production (Packing)			
	Production (Packing)			
	Warehouse (Packing)			

Verification of Recommended Action:

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Remarks (if any):

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Verified By
Operating Person QA

Approved By
Head QA

(Sign & Date) **(Sign & Date)**

8. CONCLUSION:

9. REFERENCES:

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

10. DOCUMENTS TO BE ATTACHED:

- Not Applicable

11. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

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12. CHANGE CONTROL, IF ANY:

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13. 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

14. 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)			