QUALITY RISK ASSESSMENT & MITIGATION PLAN	
FAILURE MODE EFFECT ANALYSIS FOR COATED TABLET DEFECTS	
Reference Document No.:	**Risk Assessment No.:**

RISK ANALYSIS STUDY PROTOCOL CUM REPORT

FOR EVALUATION OF COATED TABLET DEFECTS

DATE OF RISK ANALYSIS	
SUPERSEDE PROTOCOL CUM REPORT No.	**NIL**

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PROTOCOL CUM REPORT CONTENTS

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1.0 PROTOCOL CUM REPORT APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- The objective of this Protocol Cum Report is to evaluate the impact of coated tablet defects.

3.0 SCOPE:

- Risk analysis study Protocol cum Report is applicable for ……

4.0 RESPONSIBILITY:

Department	Responsibility
Production Team	• Review & Pre Approval of Risk Assessment Protocol cum Report. • Post Approval of Risk Assessment Protocol Cum Report.
Quality Assurance Team	• Preparation, Review, and Compilation of Risk Assessment Protocol cum Report. • Post Approval of Risk Assessment Protocol Cum Report.
Quality Control	• Review & Pre Approval of Risk Assessment Protocol cum Report • Post Approval of Risk Assessment Protocol Cum Report.

5.0 REASON FOR RISK ANALYSIS:

- To mitigate & monitor the risk of defects of coated tablets.

6.0 SITE OF STUDY:

7.0 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.

8.0 RISK IDENTIFICATION, EVALUATION& MITIGATION:

Introduction: Film coating is a process of polymeric solution to bring a uniform film.

Following are the advantages of the film coated tablets.

- Mask the odor of the tablet.
- Provides physical & chemical protection of the drug.
- Improves pharmaceutical elegance by using colours& contrasting printing.

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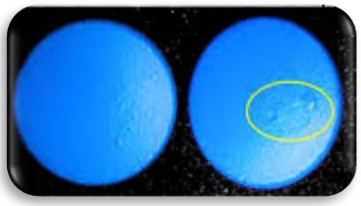
Following are the film defects related to surface of the film coated tablets:

- **Blistering:** Blistering of a surface film occurs when its elasticity or adhesive properties are compromised. The result is that the film becomes detached from the tablet's substrate.
  Cause: Blistering is usually a result of high temperatures that may occur during the drying process, during the spraying stage or at the end of the coating process



- **Chipping:** Chipping occurs when the film becomes dented and chipped and this is most notably visible on the edges of the tablet.
  Cause: Deformity in the tablet cam occur when there is a decrease in the rotation speed in the machinery during the coating process. Another cause would be a poor polymer or coating solution – e.g., an incorrect amount of plasticizer is used in the coating solution.

- **Cratering:** Cratering happens when a defect on the film's coating results in craters appearing on the tablet which in turn results in the exposure of the tablet's surface.
  Cause: Cratering can occur in certain instances where there is insufficient drying time to seal the film or a high volume of coating solution is applied. In these cases excess polymer solution can penetrate to the surface of the tablet, especially in the crown area, causing the disruption of the coating and degeneration of the tablet's core.

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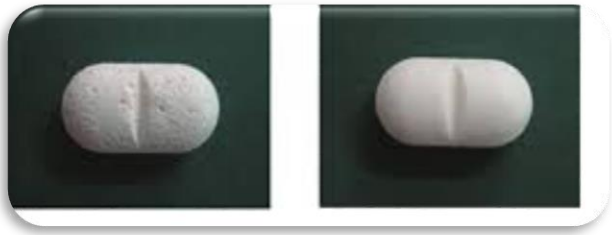

- **Picking/Sticking:** Picking/Sticking happens when part of the film sticks to the pan resulting to some of the tablet pieces being detached from the core.
  Causes: Picking/Sticking occurs when there is over wetting of tablets by the polymer solution, making the film become tacky which results to the tablets sticking to one another.

- **Pitting:** Pitting is the deformation of the core of the tablet without any visible signs of disruption of the film coating .
  Causes: Pitting can occur when the tablet core becomes hotter than the melting point of the materials used in its preparation.

- **Blooming:** Blooming is the fading or dulling of a tablet colour after a prolonged period of storage at a high temperature.
  Causes: The tablet colour can become dull as a result of changes in the composition of the surface film. It is usually the result of using too much plasticizer or of using a plasticizer with a low molecular weight.

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- **Blushing:** Blushing is a haziness or appearance of white specks in the film.
  Causes: Haziness or white specks are particles of polymer that has precipitated in the film. It usually forms as a result of an excessively high coating temperature. Alternatively it may be formed by gelation of the polymer when used in certain combinations with other materials.

- **Color variation:** Variation in the colour of tablets within a batch.
  Causes: Colour variations may occur by a number of different faults in the preparation e.g., poor mixing, uneven spray patterns of the machinery, insufficient coating, migration of soluble dyes-plasticizers and other additives during drying.

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- **Orange peel:** The tablet has the appearance of an "Orange Peel" on account of having a rough surface, which may also have a matt rather than glossy texture.
  Causes: Orange peel can be the result of poor tablet composition causing it to become soft. It can also be caused by too high a spray pressure combined with a fast spray rate, leading to uneven coating of the tablet.

- **Cracking:** Cracking occurs when the film coating the tablet cracks in the crown area or splits around the edges.
  Causes: Cracking occurs when the film's internal stress exceeds the tensile strength of the film. This is common with higher molecular weight polymers or polymeric blends.

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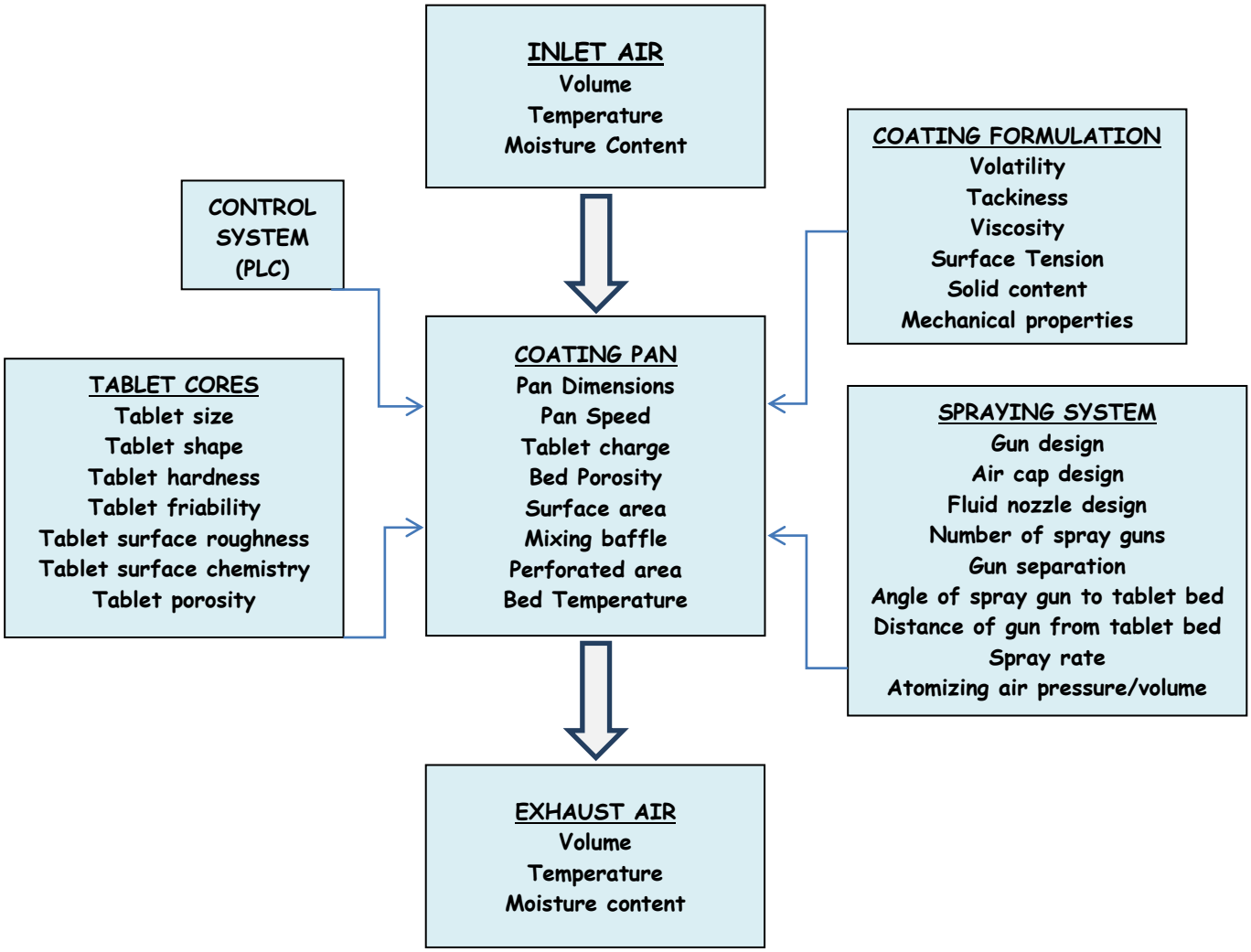
FACTORS AFFECTING COATED TABLETS



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S.No.	RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
1.	**Operating parameters:** There are different coating parameters which plays important role during the coating process like, gun to gun distance, gun to bed distance, atomization air pressure, spray rate, inlet air temperature, coating solution, pan speed, peristaltic pump, utility (compressed air) and mixing baffles. Any deviation or malfunctioning in these parameters may lead to coating defects.	Any deviation in Operating parameters may leads to several type of defects in coated tablets; Blistering, chipping, sticking , lamination, capping, orange peel, bridging, lump formation, twins & shade variation etc. Further coated tablet defects can lead to market complaint & fail in finished product specification.	• All the coating formulations are recipe based & saved in PLC system. • Batches are manufactured in coating stage as per batch manufacturing record & all operating parameters are monitored & recorded as per the BMR at fixed intervals. • In coating process all used equipment& instruments are qualified & calibrated, having well defined standard procedure for operation & cleaning. Well-defined preventive maintenance schedule for all equipments is in place. • Persons involved in coating process are well trained, & on job training is given to each operator & staff as per training planner.
2.	**Product specification:** As per the product specification, all coated tablets shall be free from any defects, several type of defects are observed in coated tablets; Blistering, chipping, sticking , lamination, capping, orange peel, bridging, lump formation, twins & shade variation etc. Coated tablet defects can lead to market complaint & fail in finished product specification.	Film coating is done to mask the odor of the tablet, provides physical & chemical protection of the drug& Improves pharmaceutical elegance by using colors & contrasting printing. It does not have any direct impact on the health & safety of the person.	• For manufacturing of each product there are standard operating procedures, Batch manufacturing records & validation protocols. • Persons involved in coating process are well trained, & on job training is given to each operator & staff as per training planner.

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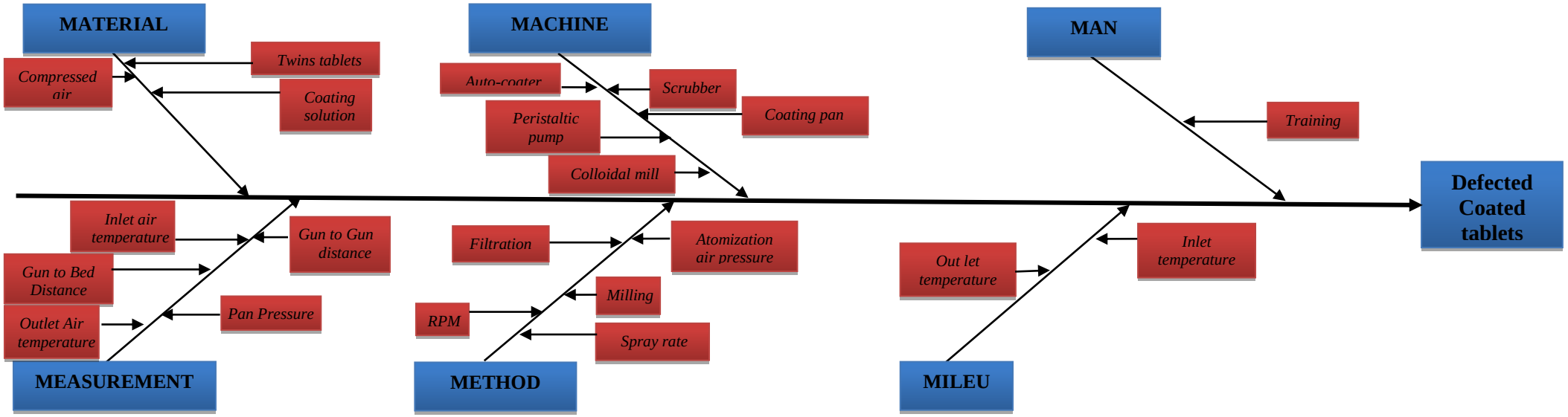
9.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSISCRITERIA:

9.1 Fish bone/6M/Ishikawa diagram:



Fish bone tool used for risk assessment, area of concern along with their sub-categories:

1. **Method**
2. **Machine**
3. **Material**
4. **Man**
5. **Measurement**
6. **Milieu**

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SUMMARY OF THE 6 M/FISH BONE DIAGRAM/ISHIKAWA DIAGRAM: It is used for the evaluation of defects in coated tablets; 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 coated tablet defects.

- **MAN:** Untrained manpower can leads to machine operation failure (equipments runs in manual mode) which further result into defected tablets. Hence trainings are conducted on regular basis.

- **MATERIAL:** Defected coating material may lead to defected coated tablets. Hence all coating materials are purchased from qualified approved vendors.

- **MILIEU:** Inlet & outlet bed temperature have important role in coated tablet finishing. Hence temperature are monitored and noted down on regular basis.

- **MACHINE:** Malfunctioned equipment can lead to defective tablets. Hence equipments are qualified as per schedule & preventive maintenance is done quarterly.

- **METHOD:** There are different parameters which are critical and affects the product quality if not controlled like, filtration, atomization, milling, spray rate, pan RPM etc. Hence all critical parameters are monitored & recorded regularly.

- **MEASUREMENT:** Gun to bed distance, bed to bed distance, inlet temperature, outlet temperature, pan pressure and other operating parameters which can lead to product defects if not controlled. Hence all critical parameters are monitored & recorded regularly.

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9.2 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 1: Instruction for each column given above

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Procedure: Risk analysis for Evaluation of defected coated tablet	**Quality Risk Assessment Date:** ……. **QRA No.:** ……..

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
1.	**Gun to Gun distance**	• Rough tablets • Twins • Higher thickness	• Improper Gun to Gun distance • Gun distance not measured • No measuring scale available • Untrained persons	• Market complaint • Tablet fail in finished product specification.	• Always validate the gun to gun distance before the start of the coating. • Measuring scale available. • All operators are well trained & experienced.	• Related BMR. • Training of Employees . • Operation of Coating pan/Auto-coater	4	3	1	12	Risk is low hence no action plan is required	NA	NA	NA	NA
2.	**Gun to Bed distance**	• Twins • Higher thickness • Lower thickness • Shade variation	• Improper gun to bed distance • Gun distance not measured • No measuring scale available • Untrained persons	• Market complaint • Tablet fail in finished product specification.	• Always validate the gun to bed distance before the start of the coating. • Measuring scale available. • All operators are well trained & experienced.	• Related BMR. • Training of Employees. • Operation of Coating pan/Auto-coater	4	3	1	12	Risk is low hence no action plan is required	NA	NA	NA	NA
3.	**Atomization air pressure**	• Lumps formation over tablet surface	• Untrained person. • Improper flow of Compressed air. • Improper setting of air pipe. • Untrained persons	• Market complaint • Tablet fail in finished product specification. • Nozzle jam	• All controls are through PLC. • Pressure Gauge is installed for measuring atomization pressure. • Atomization pressure is recorded at regular interval in BMR. • All operators are well trained & experienced	• Related BMR. • Training of Employees. • Operation of Coating pan/Auto-coater	4	3	1	12	Risk is low hence no action plan is required	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
4.	**Spray Rate**	• Twins • Higher thickness • Lower thickness • Shade variation • Sticking of tablets	• Spray rate increases. • Spray rate decreases. • Fault in peristaltic pump. • Untrained operator. • Compressed air pressure fluctuation. • Wrong gun nozzle (size) selection.	• Market complaint • Tablet fail in finished product specification.	• All controls are through PLC. • Gun validation done before start of the coating process. • In-process checks verified regularly at fix interval for peristaltic pump & recorded in BMR. • All operators are well trained & experienced • Gun nozzle size identified before start.	• Related BMR. • Training of Employees. • Operation of Coating pan/Auto-coater	4	3	1	12	• Risk is low hence no action plan is required	NA	NA	NA	NA
5.	**Inlet air temperature**	• Shade variation • Blistering • Orange peel • Lamination • Capping • Twins • Sticking	• Less drying. • Over drying. • Air processing unit not working properly. • Filter choked. • Scrubber tank malfunctioned. • Untrained operator.	• Market complaint • Tablet fail in finished product specification.	• All activities are PLC based. If any error occurred Equipment will be stopped automatically. • Inlet temperature is monitored at regular intervals. • Indicator towers are installed in all equipment. • Preventive maintenance done quarterly. • Water level in scrubber tank is monitored on daily basis. • All operators are well trained & experienced.	• Related BMR. • Cleaning of Coating Scrubber Machine • Qualification documents. • Training of Employees.	4	3	1	12	Risk is low hence no action plan is required	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
6.	**Coating solution**	• Tablet lumps • Shade variation • Twins tablets	• Improper milling • Improper filtration • Nozzle jam • Untrained operator • Material received from unapproved vendor.	• Market complaint • Tablet fail in finished product specification.	• Well defined procedure (BMR) for coating solution preparation. During preparation of coating solution, different process like milling of material is in place, so there is no change for nozzle jam. • All operators are well trained & experienced. • All materials are used from the approved vendor & vendor qualification procedure is in place.	• Related BMR. • Training of Employees • Vendor Qualification through QMS	4	3	1	12	Risk is low hence no action plan is required	NA	NA	NA	NA
7.	**Pan Speed**	• Rough surface. • Edge broken • Scratch marks • Twins	• High pan RPM • Low pan RPM • Untrained operator	• Market complaint • Tablet fail in finished product specification.	• Separate recipe for every batch & product specific coating is done. • All operators are well trained & experienced. • All products are validated for Pan RPM & verified after regular frequency & recorded in BMR accordingly.	• Related BMR. • Training of Employees	4	3	1	12	• Risk is low hence no action plan is required	NA	NA	NA	NA
8.	**Peristaltic pump**	• Shade variation • Thickness variation	• Non-uniform flow of coating solution • Untrained operator	• Market complaint • Tablet fail in finished product specification	• It is a process parameter & verified during coating in-process. • All operators are well trained & experienced.	• Related BMR. • Training of Employees	4	3	2	24	• Risk is low hence no action plan is required	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
9.	**Utility (Compressed Air)**	• Twins • Higher thickness • Lower thickness • Shade variation • Lumps formation	• Spray rate increases. • Spray rate decreases. • Untrained operator. • Compressed air pressure fluctuation. • Malfunctioning of compressed air system	• Market complaint • Tablet fail in finished product specification.	• All controls are through PLC. • In-process checks verified regularly at fix interval for air pressure & recorded in BMR. • All operators are well trained & experienced • Yearly qualification done for pressure checks at all points. • Preventive maintenance on quarterly basis.	• Related BMR. • Training of Employees. • Operation of Coating pan/Auto-coater • Preventive maintenance	4	3	2	24	• Risk is low hence no action plan is required	NA	NA	NA	NA
10.	**Mixing Baffle**	• Shade variation	• Inappropriate (baffle selection) coating pan	• Market complaint • Tablet fail in finished product specification.	• All products are validated	• Validation documents	4	3	1	12	• Risk is low hence no action plan is required	NA	NA	NA	NA

Table 2: The above table shows Potential failure mode, effect of potential failure along with Risk Probable Number, Risk Mitigation & Recommended Actions.

Rating Scale – Severity
1= No Effect
2= Minor Effect
3= Moderate Effect
4= Serious Effect
5= Hazardous Effect

Rating Scale - Occurrence
1= Unlikely
2= Very Rare
3= Possible
4= Likely
5= Almost Certain (every time)

Rating Scale - Detection
1= Always Detected
2= Will Detect Failure
3= Might Detect Failure
4= Almost certain not to Detect Failure
5= Lack of Detection Control

Acceptance Criteria
51 to ≤ 125 = High Categories
26 to 50 = Medium Categories
Upto25 = Low Categories

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***The Risk Priority Number (RPN/Overall Risk) changes based upon the risk. The Risk assessment team shall decide the acceptance criteria. For example the risk priority number is categorized as below:**

Risk Priority Number (RPN)	Risk levels
Upto 25	Low
26-50	Medium
51 to ≤ 125	High

RPN = Severity x Occurrence x Detection

Remark if any:

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility	……..		
S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.			
2.			

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*In-case any recommendations Not completed, to be tracked through CAPA System)

Remark if any:

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Verified By
(QA)
Sign & Date……..

Reviewed By:
(Manager QA)
Sign & Date……..

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10.0 CONCLUSION:

Risk of defected coated tablets on Product Quality & QC Analysis.

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11.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Protocol cum Report for evaluation of Defected coated tablets, clearly stating that there is no impact/adverse impact on the product quality.

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12.0 REFERENCES:

- Reference SOP of Risk Assessment.
- https://www.lfatabletpresses.com/articles/different-tablet-coating-defects-and-remedies

13.0 DOCUMENTS TO BE ATTACHED:

- Related documents.

14.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations from the pre-defined acceptance criteria observed in accordance with QA SOP **"Handling of Deviations"**, **SOP No. ……** shall be documented in the Risk analysis Protocol cum report.

15.0 CHANGE CONTROL, IF ANY:

Change control observed in accordance with QA SOP **"Change Management"**, **SOP No. ……..** shall be documented in the Risk analysis Protocol cum report.

16.0 ABBREVIATIONS:

FMEA	: Failure Mode Effect Analysis
GMP	:Good Manufacturing Practices
RPN	: Risk Priority Number
CAPA	: Corrective action preventive action
WHO	: World health organization

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17.0 PROTOCOL CUM REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			