QUALITY RISK ASSESSMENT & MITIGATION PLAN	
FAILURE MODE EFFECT ANALYSIS FOR MALFUNCTIONING OR UNAVAILABILITY OF METAL DETECTOR DURING COMPRESSION	
Reference Document No.: ……..	**Risk Assessment No.:**

QUALITY RISK ASSESSMENT & MITIGATION PLAN

(FAILURE MODE EFFECT ANALYSIS FOR MALFUNCTIONING OF METAL DETECTOR OR UNAVAILABILITY DURING COMPRESSION)

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MALFUNCTIONING OR UNAVAILABILITY OF METAL DETECTOR DURING COMPRESSION

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

1. **OBJECTIVE:** To provide the documented evidence that there is low level of risk in case of malfunctioning of metal detector during compression.

2. **SCOPE:** The scope of this document is limited to Metal Detector of all Compression areas at …….facility.

3. **RESPONSIBILITY:**

Department	Responsibility
Quality Assurance	• Preparation, Review, and Compilation of FMEA • Post Approval of FMEA
Production	• Review of FMEA

4. **REASON FOR RISK ANALYSIS:**
   To mitigate & monitor the risk associated with the malfunctioning of Metal Detector during Compression.

5. **SITE OF STUDY**

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

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

7. RISK IDENTIFICATION, EVALUATION & MITIGATION:

Metal detectors are used in pharmaceutical industries to detect metal contamination in products or packets. These are the helping accessories used along with compression and are installed on both the sides of compression machine. In case of any failure, the metal contamination may occur in pharmaceutical products due the presence of metallic pieces or components (viz., fasteners, pins, buds, eroded or corroded metallic parts etc.)

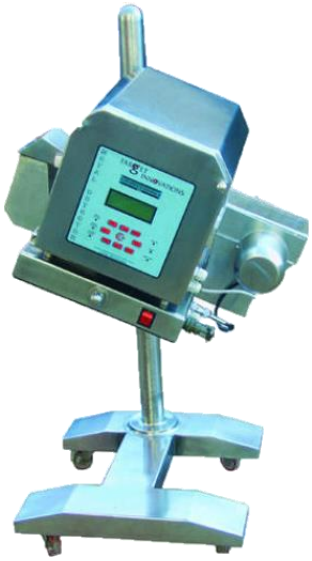

Figure 1: Metal Detector

Working Principle: Metal detectors contain one or more inductor coils that are used to interact with metallic elements on the food or pharmaceutical products. Metallic contaminant in the product creates high frequency magnetic field within the detector coil, which in turn activates a reject flap by means of a solenoid. The detector is designed in such a way that it automatically removes the metal components form tablets without production interruption. The metallic contaminant is reliably rejected with very little loss of material due to the extremely fast and short activation of the reject flap of the detector.

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RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
In case of absence or malfunctioning of Metal Detector, there may be the chance of metal contamination during compression stage. The source of contamination could be distorted sieves, screens, corrosion parts, broken parts of dies & punches.	Risk of metal contamination in product is a serious concern and can have severe impact on health.	Challenge test are performed initially, after 4 hour & at the end of the compression. Further magnetic grill to arrest metal pieces are installed in Octagonal Blender. Sieve screens are also being verified before the start of the activity.

8. RISK ASSESSMENT TOOL:

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	Potential Cause
Column 6	Risk Mitigation as a Current Control: Write the risk mitigation strategy as considered in design.
Column 7	References
Column 8/9/10/11	Severity/Occurrence/Detection/Risk level/Risk Acceptance: Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 12	Recommended action: Recommended actions should be given for controlling failure occurrence.
Column13/14/15/16	Severity/Occurrence/Detection/Risk level/Risk Acceptance: After recommendation implementations, Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.

Table 1: Instruction for each column given above

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

QRA No.: ……..

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Malfunctioning or unavailability of Metal Detector	**Quality Risk Assessment Date: …….**

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure		Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	There might have risk of metal contamination in compressed tablets in case of failure or absence of metal detector during running of product …..	Generation of metal pieces during process due to defective sieves/screens, improper fitment of Multi mill screen into screen housing, improper setting of dies/punches to compression machine which that dies/punches can be damaged.	• Metal contamination in product. • Market compliant • Customer dissatisfaction. • Health impact.	• Metal detector not works properly. • Magnetic grill to arrest metal pieces is not installed in octagonal blender • There is no procedure for empty run of compression machine to ensure unwanted abnormality. • AQL inspection is not performed. • There is no Standby and	• Metal detector to ensure metal contamination in product is used during compression process of every product, moreover, standby, clean and good condition of metal detector is used in case of any abnormality observes during operation by addressing the same through quality notification and by performing impact assessment. • Metal detector Challenge test is performed as per frequencies specified in SOP No:. Operation and cleaning of Metal Detector. • Magnetic grill to arrest	SOP No. ‘Operation and Cleaning of Metal Detector’ SOP No. ‘Acceptable Quality Level for Oral Solid Dosage’ SOP No. ‘Handling of Sieve and Screen’ SOP No. ‘Cleaning, Lubrication, Tightening and	3	2	1	6 **Severity** is high, as metal contamination in product may cause health problems **Occurrence:** chance is possible in case of metal detector failure in between process **Detectabi**	• SOP No. ‘Operation and Cleaning of Metal Detector shall be revised for challenge test at initially, after every four hour and towards end of process. • Training shall be imparted to personnel for revised	1	1	1	1

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

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure		Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
				good condition of metal detector available in case of running metal detector goes out of work. • Challenge test for metal detector were not performed. • Sieve and Screen not verified for usage.	metal pieces installed in octagonal blender, there is no chance of metal pieces exceptionally/ rarely if are carrying through excipients. • Sieve/screen integrity is checked during issuance and retrieval, written procedure is in place. • Integrity of sieves/screens is checked efficiently through illuminated light board. • The empty trial/run of compression machine before start the operation is done to ensure unwanted abnormality. • AQL inspection is performed for every batch of product after compression and coating process.	Inspection of Machine'				**lity** is always as all tablets are passed through metal detector	SOP.				

Where: S=Severity; O=Occurrence Probability; D=Detection

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Assessment of Severity, Occurrence and Detection:

Severity Effect	Likelihood Occurrence	Likelihood of Detection	Rating
No Effect	Unlikely	Always Detected	1
Moderate Effect	Possible	Might Detect Failure	2
Serious Effect	Almost Certain (Every time)	Lack of Detection Control	3

Evaluation of RPN:

RPN Rating	Category
12 to 27	High
7 to 11	Medium
Upto 6	Low

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	SOP 'Operation and Cleaning of Metal Detector shall be revised for challenge test at initial, after every four hour and towards end of process.		
2.	Training shall be provided to all concerned personnel for revised SOP		

CAPA (Required/Not Required): Required
If required, mention CAPA No.: ……..

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

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Reference Document No.:	Risk Assessment No.:

Verification of Recommended Action:

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Remarks (if any):

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Verified By
Operating Person QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)

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

9. CONCLUSION:……
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10. REFERENCES:

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

11. DOCUMENTS TO BE ATTACHED:

- Not Applicable

12. DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

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13. CHANGE CONTROL, IF ANY:

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14. 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
QMS	: Quality Management System
DP	: Differential Pressure
RH	: Relative Humidity
ID	: Identification

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15. 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)			