DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Rejection Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. Purpose: The purpose of this SOP is to describe the procedure for rejection analysis of rejection generated during different processing stage of manufacturing & packing.

2. Scope: This SOP is applicable for, the procedure for different type of rejections generated during processing stage of manufacturing & packing at ……..

3. References, Attachments & Annexures:

3.1 **References:**
3.1.1 In-house
3.1.2 SOP: Procedure for Disposal of Waste.

3.2. **Attachments:**
3.2.1 Attachment 1: Flow diagram of Root Cause Analysis (RCA)
3.2.2 Attachment 2: WHY -WHY Analysis methodology
3.2.3 Attachment 3: Investigation Report
3.2.4 Attachment 4: Rejection Analysis format for Packing Section.

3.3. **Annexures:** NA

4. Responsibilities:

4.1 Concerned Department:

4.1.1Rejections generated during processing stage (coated & uncoated) & Finish Goods (printed Al foil, PVC/PVDC), concern department officer inform to QA officer for the same.

4.1.2 Segregated the material with Proper label and transfer the material in respective area to avoid mix up with good quantity material.

4.2.3 Proper investigation shall be done through "6-M Methodology or Ishikawa diagram/Fish Bone Diagram & "WHY -WHY Analysis".

4.2 Quality Assurance:

4.2.1 To verify the rejection generated.
4.2.2 To affix "REJECT" status label on the rejected drum or containers or shippers.
4.2.3 To investigate properly with the concerned department, find exact Root Cause, Impact Analysis, Implementation of CAPA & Closure of CAPA.
4.2.4 QA Head – To impart training & ensure implementation of SOP.

4.3 Regulatory Affairs, Quality Head & Plant Head:

4.3.1 To review and approve the SOP.

5. Distribution:

5.1 Quality Assurance

5.2 Ware House (Both RM & PM)
5.3 Production (Both Manufacturing & Packing)
5.4 Quality Control

6. Abbreviations & Definition of terms:

6.1 **Abbreviations:**

6.1.1 CAPA: Corrective Action Preventive Action.
6.1.2 PM: Packing Material
6.13 QA: Quality Assurance
6.1.4 RM: Raw Material
6.1.5 RCA: Root Cause Analysis
6.1.6 SOP: Standard Operating Procedure

6.2 **Definition of terms:**

6.2.1 **Critical Defects:** A critical defect is on that judgment and experience indicate is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the products.

6.2.2 **Major Defects**: A major defect is one, other than critical, that is likely to result in failure, or to reduce materially the usability of the unit of product for its intended purpose.

6.2.3 **Minor Defects:** A minor defect is one that is not likely to reduce materially the usability of the unit of product for its intended purpose, or is a departure from established standards.

7. Procedure:

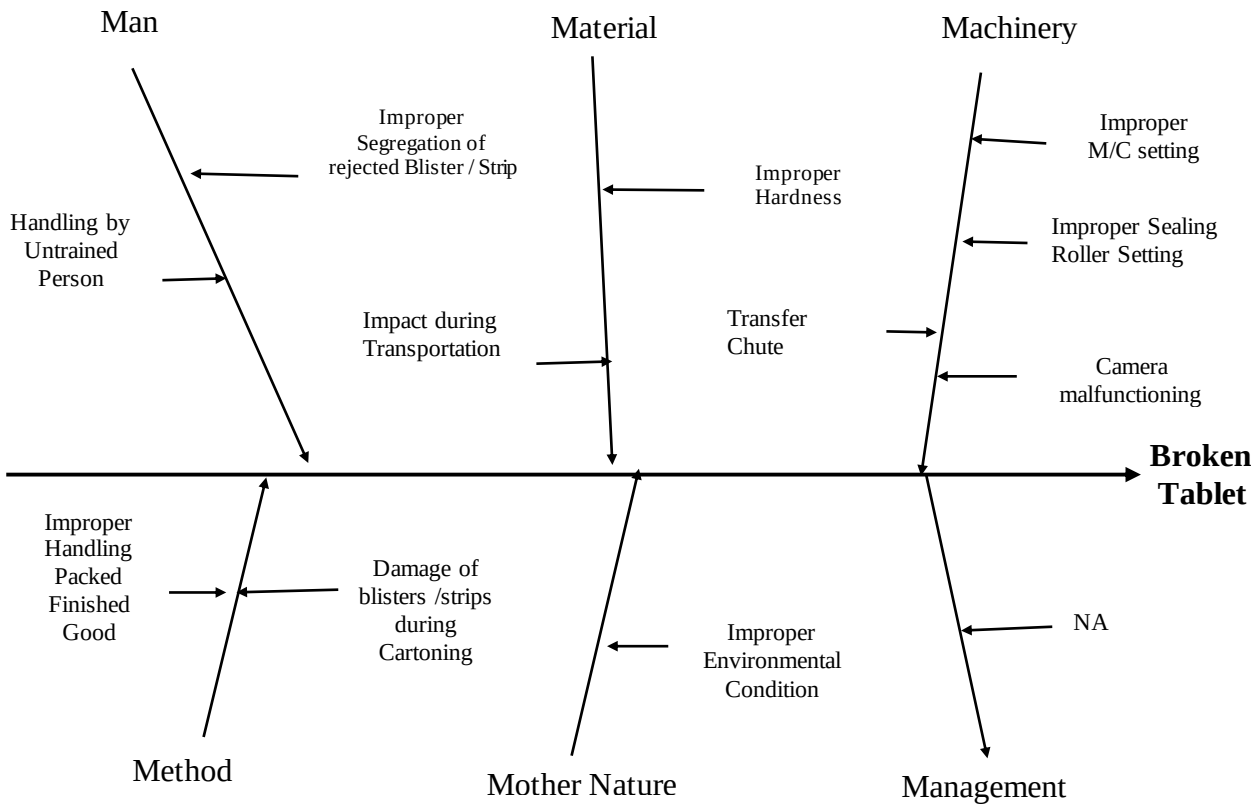
7.1 Based on rejections generated, concerned department first identify why this rejection is generated and shall be inform to QA regarding the same.
7.2 Rejection analysis shall be carried out for those batches which are having high rejection i.e. more than the specified limit.
7.3 Quality Assurance shall check & verify the rejection. After verification, Quality Assurance officer shall affix the status label "REJECT" on the material.
7.4 Proper investigation shall be done by QA officer & respective department through Root Cause Analysis & WHY-WHY Analysis (interrogation done with concerned machine-operator or concerned-officer) & find probable cause.
7.5 If root cause or probable root cause identify, take CAPA, do impact Analysis (If required) & close the CAPA.
7.6 For investigation of "Rejection- Analysis" Follow Attachment -3.
7.7 Attach sample as specimen with investigation report (If possible attach pictorial details).
7.8 Investigation for Critical finding shall be complete within 15 working days & for Non-Critical findings shall be within the 30 working day. If it is not closed within the time period, then proper justification shall be given by concern department.
7.9 Rejection analysis report shall be approved by QA Head.

7.10 Decision for destruction of rejects generated, Reprocessing & Reworking shall be given by concerned department and QA head.

7.11 De-foiling goods is manually checked & ensured by QA and packed in last Shipper, record should be maintained for de-foiled goods & also training maintained for the checkers.

7.12 Destroy the rejected materials as per SOP.

Attachment -1
Flow diagram of Root Cause Analysis
Cause and Effect diagram for Potential cause of Broken Tablet
(Ishikawa/Fish Bone Diagram)



Prepared By/Date:----------
(Concerned Dept.)

Checked By/Date:----------
(Quality Assurance)

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Attachment – 2

WHY-WHY Analysis (Minimum 5 Questions Exercise)

(Interrogation done by investigation team to concerned machine Operator or with concern officer in following sequence)

What is the problem (Identify the Problem)?

↓

Where did the Problem occur?

↓

When did the Problem occur?

↓

Why the Problem occur?

↓

By Whom/How the Problem occur?

Prepared By/Date:----------
(Concerned Dept)

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Attachment -3

Investigation Report

1.	**Product/Material Name:**	
2.	**Batch No/A.R No:**	
3.	**Batch Size in Kgs/Nos:**	
4.	**Mfg. date**	
5.	**Exp Date:**	
6.	**Nature of Rejects/Problem:**	
7.	**Stage at which Problem occur:**	
8.	**Pack style/ Material (if any)**	
9.	**Product History :**	
10.	**Batch record (BMR/BPR/SOPs/System) Review:**	
11.	**Investigation Details:**	
12.	**Investigation findings:**	
13.	**Interrogation done with person:**	
14.	**Probable Cause & Root cause:**	
15.	**Impact analysis:**	
16.	**CAPA:**	
17.	**Conclusion:**	
18.	**Attachment:**	

Prepared by:---------- **Checked By:**---------- **Approved by** :----------

(Concerned Department) (Quality Assurance) (QA/Quality Head)

Attachment- 4

Rejection Analysis format for Packing

Product Name	
Batch No.	
Mfg Date	
Exp Date	
Line No	
Line Officer Name	
Line QA officer	
Line Operator Name	
Total Qty/Nos. of Rejections in whole Batch	

Type of Rejections

S.No.	Type of Rejection	Nos. of Rejection	Remark
1.	Damage strip/Blister		
2.	Empty Pocket		
3.	Empty show box		
4.	Sealing/Knurling		
5.	Broken Tab/Black spot		
6.	Cut Pocket		
7.	Miss-Print		

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Root Cause for generation of Rejection:

_____

_____

_____

_____

Corrective Action & Preventive Action:

_____

_____

_____

_____

Conclusion:

_____

_____

_____

_____

Prepared By Sign/Date	Checked by IPQA Packing Sign/Date	Checked by Packing Head Sign/Date	Checked by QA Sign/Date

8.0 History

Version No.		Effective Date	
Implementations:			