Standard Operating Procedure

Title: Classification of defects in manufacturing Operations

Department	Quality Management		Document no	QMS-145	
Title: Classification of Defects in Manufacturing Operations					
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1.0 DOCUMENT OWNER

Technical/Quality Manager

2.0 PURPOSE

To provide a guide for the actions required to investigate and document the occurrence of an event or an observation suggesting the existence of a potential quality related problem.

3.0 SCOPE

This SOP applies to all semi-finished goods, manufactured finished goods and fully imported products within disposition management.

This procedure defines the requirements for the following:

- Identification of defects and their respective AQLs (Acceptable Quality Limits)
- Actions that must be taken when critical, major or minor defects are encountered during the Production/ Packaging Process.

Note: SOP **QMS-150** covers the *Classification of Defects for Incoming Packaging Components*.

4.0 RESPONSIBILITY \ BUSINESS RULES

4.1 Responsibility of Production and Packaging Operators / Managers

4.1.1 It is the responsibility of the Production/ Packaging Operators and Manager to ensure this SOP is adhered to.

4.1.2 It is the responsibility of the Production/ Packaging Operators to immediately inform Production/ Packaging Manager and Quality Assurance if a deviation from control methods specified in Production/ Packaging documents or from standard operating procedures is detected.

4.1.3 It is the responsibility of the Production/ Packaging Manager to train Production/ Packaging Operators.

4.1.4 It is the responsibility of the Production/ Packaging Manager to ensure that the product that has been involved in an unusual event is segregated from the rest of the lot or batch.

4.2 Responsibility of Quality Assurance Manager / Manager or Delegate

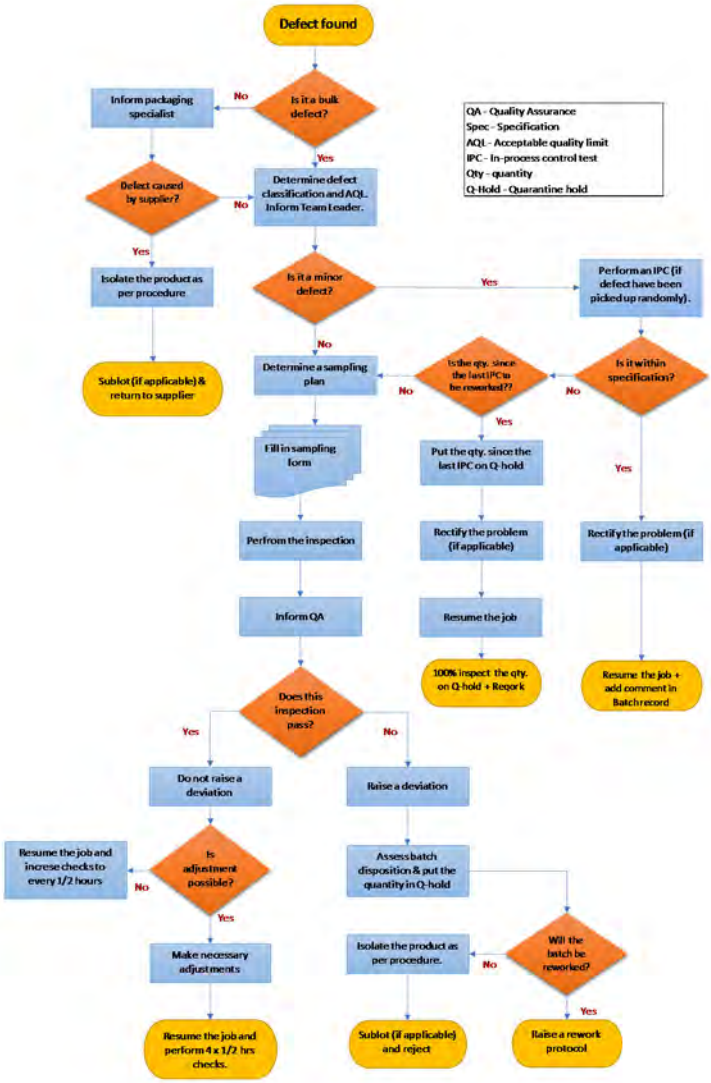
4.2.1 It is the responsibility of the Quality Assurance Manager or Delegate to ensure this SOP is adhered to.

4.2.2 Quality Assurance Manager is responsible for deciding on the disposition of the batch after the inspection. If the batch exceeds the acceptance criteria it is the responsibility of the Quality Assurance Manager or delegate to notify the Production Manager to establish the corrective action to be carried out.

4.2.3 It is the responsibility of the Quality Assurance Delegate to ensure that all batches under investigation are to remain in Quarantine Hold status until the inspection is complete and all relevant data / signatories from Quality Assurance and Production/ Packaging have given approval of the deviation report or rework procedure.

4.2.4 It is the responsibility of the Quality Assurance and Compliance Manager or Delegate to determine the need for a Cross Functional Investigation (CFI).

5.0 **PROCEDURE – DEFECT DECISION TREE**



5.7 **Review Results of the Inspection**

5.7.1 If the number of nonconforming items is equal to or less than the Acceptance number (Ac), the lot is being considered **ACCEPTABLE** and therefore passes the inspection. In this case, no deviation will be raised.

5.7.2 If the number of nonconforming items is greater than the Acceptance number (Ac) the lot is being considered **UNACCEPTABLE** therefore fails the inspection. In this case, the Production/ Packaging Manager will raise a **deviation**.

5.7.3 Sign and date the Form **870** and ensure it is attached to the Batch Record.

5.8 **Make Adjustment**

5.8.1 If the inspection passes, the defect has been identified and the problem can be adjusted, then:

Resume the packaging / Production operation.

Write a comment to state the time and a description of the problem in the Batch Record.

Perform **4 x ½ hour** checks. If those checks successfully pass, Operators can perform the IPC normally as requested by the Packaging Shop Order.

5.8.2 If the inspection passes but the problem can't be adjusted, then:

Resume the packaging / Production operation.

Write a comment to state the time and a description of the problem in the Batch Record.

Increase the checks to **every ½ hour** until the end of the batch.

5.9 **Assess the Batch Disposition**

If the inspection fails**,** the Quality Assurance Manager and Packaging / Production Manager must be notified in order to investigate and decide on the disposition of the lot in question.

5.10 **Rework the Batch**

If the decision is made to rework the batch in question, then:

5.10.1 Production will raise a Rework Protocol.

5.10.2 The Rework Protocol must be authorized by either the Packaging / Production Manager and must be approved by Quality Assurance Manager or delegate prior to the Rework operation to begin as per QMS-200-Repackaging Procedure.

5.11 **Reject the Batch as per SOP WAR-015-Reject Procedure**

If the decision is made to reject the batch in question, then:

5.11.1 The Quality Assurance delegate must document the Reject status on the relevant Batch Record.

5.11.2 The Quality Assurance Delegate applies a Red Rejected label to each drum / container of material or at least 2 sides of unitized pallet (if labelling each drum / container is not practical).

(Follow the procedure QMS-190-Reject Procedure for a sample of Reject label to be used.)

5.11.3 The material status must be immediately updated to "R" in ERP system as per

QMS-090 Evaluation of Batch Documentation and Release for Sale.

5.11.4 The Quality Assurance delegate arranges for material to be rejected as per QMS-190-Reject Procedure.

Appendix 3 - Classification of Defects – Packaging of Blisters

BLISTER PACKAGING OF TABLETS AND CAPSULES			
	Critical (<0.01%)	**Major (<1%)**	**Minor (<4%)**
Product Appearance	▪ Gross foreign material that can cause personal injury (e.g. glass, metal or wood). ▪ Incorrect product strength. ▪ Appearance or color of the tablet NOT matching product description.	▪ Foreign matter that may not cause personal injury (e.g. hair or fingernails). ▪ Missing or partially debossed monograms ▪ Telescoping ▪ Broken / cracked / brittle.	▪ Malformed ▪ Capped ▪ Crushed ▪ Chipped ▪ Dusty ▪ Embedded surface spots (e.g. dark specks, oil or grease).
Vacuum Test		▪ Failing leak test: holes in blister or split or broken foil (due to mechanical damage from equipment or packaging material defective).	
Blister Appearance	▪ Missing, incomplete or incorrect batch information (batch number / expiration date). ▪ Presence of foreign matter (in pocket).	▪ Incorrect foil identification number. (PM) ▪ Illegible batch information (batch number / expiration date). ▪ Illegible print on foil. ▪ Missing perforations. ▪ Malformed or cracked blister pocket. ▪ Empty or under-fill blister pockets. ▪ Heat marked or burned blister. ▪ Presence of holes / tears in forming material or foil. ▪ Excessive powder in cavity. ▪ Die cut off-centre.	▪ Presence of channel in forming material or foil. ▪ Minor perforation imperfections. ▪ Surface blemishes / scratches. ▪ Print / coding off-registration. ▪ Twinning: Extra tablet / capsule in blister. ▪ Presence of foreign matter

Appendix 4 - Classification of Defects – Packaging of Tubes / Syringes / Suppositories

TUBES / SYRINGES / SUPPOSITORIES FILLING OF SEMI-SOLIDS AND LIQUIDS			
	Critical (<0.01%)	**Major (<1%)**	**Minor (<4%)**
Product Appearance (Tube / Syringe / Suppositories Filling)	▪ Gross foreign material that can cause personal injury (e.g. glass, metal or wood). ▪ Appearance or color of the product NOT matching product description. ▪ Non-characteristic odour of the product.	▪ Foreign matter that may not cause personal injury (e.g. hair or fingernails). ▪ Underfill. ▪ Empty tube / syringe. ▪ Undissolved or particulate matter. ▪ Product not uniform.	▪ Overfill.
Tube / Syringe / Suppositories Appearance and Labelling	▪ Missing, incomplete or incorrect batch information (batch number, expiry date and manufacturing date if applicable).	▪ Incorrect tube identification number. ▪ Label not fully adhering. ▪ Defaced surface / print. ▪ Damaged / bent tubes / syringes (leaking). ▪ Poorly formed and leaking. ▪ Missing Cannula (if applicable).	▪ Smeared but legible print, labelling or coding. ▪ Poorly formed but not leaking. ▪ Damaged / bent tubes (not leaking). ▪ Soiled package.
Capping			▪ Damaged ▪ Soiled ▪ Defaced, Scratched ▪ Loose.
Carton Appearance	▪ Missing, incomplete or incorrect batch information (batch number, expiry date and manufacturing date, if applicable).	▪ Underfill pack. ▪ Defaced surface / print. ▪ Incorrect number of tubes / syringes per carton. ▪ Incorrect carton identification number. (PM)	▪ Overfill pack. ▪ Tuck cartons – tears tucked incorrectly. ▪ Torn, soiled or defaced.
Leaflet appearance (if applicable)		▪ Missing leaflet. ▪ Incorrect leaflet identification number. (PM) ▪ Illegible print on leaflets (either side). ▪ Wrong cutting	▪ Faint printing but legible
Bundling and Shipper Labels		▪ Missing, incomplete or incorrect batch information (batch number, item code or expiry date). ▪ Illegible labelling.	▪ Incorrect number of bundles per shipper. ▪ Incorrect number of cartons per bundle. ▪ Incorrect shipper identification number. ▪ Damaged / smeared labelling but still legible. ▪ Malformed / Loose bundles. ▪ Incorrect pallet pattern (if specified).

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Form 865: Packaging Reconciliation form

This form is to be attached to return pallets. Each return and transfer quantity should be written separately. A copy of this form is to be returned with the packaging shop order record for reconciliation.

Product Description:			
Shop order:		Lot number:	

RETURN & REJECTS:

PACKAGING				WAREHOUSE	
ITEM NUMBER		DELIVERY NUMBER	QUANTITY		
			RETURNED	REJECTED	LOCATION	PALLET NUMBER
Bulk						
Lid Foil						
Cold Form Film						
Cartons						
Leaflets						
Stretch Wrap						
Shippers						
Shipper Labels						
Caps						
Bottles						
Other						

DEFECTIVE COMPOENTS:

PACKAGING USE ONLY				
PM/ITEM NUMBER	DELIVERY NUMBER	QUANTITY	REJECT LABEL APPLIED BY	DATE

Return completed, ERP note added (warehouse)	SIGN		DATE	

COMPONENT TRANSFER:

ITEM NUMBER	DELIVERY NUMBER	QUANTITY

From S/O:			To S/O		
Completed by:		Date:		Time:	

