QMS-145 Classification of Defects in Manufacturing Operation

Appendix 1 - Defect Classification Criteria And Acceptance Quality Limits (AQLs)

Impact of Defect	Critical (C)	Major (MJ/A)	Minor (MN)
AQL Level %	**0.01%**	**0.4%/1%**	**4%**
Effect on Consumer Safety	Will cause personal injury or illness	May cause personal injury	Will not cause personal injury or illness
Effect on Conformance to Regulations	Fails to conform to regulations for safety, purity, efficacy, or identity	Fails to conform to regulations on weight, count or volume	Fully conforms to regulations
Effect on Use	Will render the product unfit for use	May render the product difficult or unfit for use and may cause rejection by the user	Will not affect usability of the product; may affect appearance.
Consumer Relations	Will offend consumers due to odour or appearance. Will very likely result in complaints	May be noticed by consumer, may be an annoyance and reduce product sale ability	May result in complaints
Loss to Company	Will lose consumers and may result in losses greater than value of product. This will include productivity or yield issues related to components	May lose consumers and may result in losses equal to greater than value of product. This will include productivity or yield issues related to components	

Appendix 2 - Classification of Defects – Manufacturing

BULK MANUFACTURED TABLETS		
Critical (<0.01%)	**Major (<1%)**	**Minor (<4%)**
▪ Foreign tablet in bulk container. ▪ Incorrect product strength. ▪ Non-characteristic colour and/or odour of tablet. ▪ Gross foreign material that can cause personal injury (e.g. glass, metal or wood). ▪ Incorrect monogram (either side).	▪ Foreign matter that may not cause personal injury (e.g. hair or fingernails). ▪ Missing and/or illegible monogram (either side). ▪ Splitting or Broken tablets. ▪ Spongy or Soft tablets. ▪ Sticking, Discolored tablets. ▪ Cavitations.	▪ Blemished Surface ▪ Blurred but legible monogram (either side). ▪ Embedded surface spots (e.g. dark specks, oil or grease). ▪ Chipped tablets. ▪ Dusty tablets. ▪ Dye specks. ▪ Burred edge. ▪ Picking.

BULK MANUFACTURED TABLETS (COATED)			
Critical (<0.01%)	**Major A (<0.4%)**	**Major (<1%)**	**Minor (<4%)**
▪ Foreign tablet in bulk container. ▪ Incorrect product strength. ▪ Non-characteristic colour and/or odour of tablet. ▪ Gross foreign material that can cause personal injury (e.g. glass, metal or wood). ▪ Incorrect monogram (either side).	▪ Capped tablets. ▪ Coating non-uniform (e.g. caking). ▪ Missing and/or illegible monogram (either side).	▪ Foreign matter that may not cause personal injury (e.g. hair or fingernails). ▪ Broken tablets. ▪ Embedded surface spots (e.g. dark specks, oil or grease). ▪ Sticking Discolored Tablets. ▪ Cavitations.	▪ Blemished Surface ▪ Blurred but legible monogram. ▪ Chipped tablets. ▪ Dusty tablets. ▪ Dye specks. ▪ Burred edge.

BULK MANUFACTURED CAPSULES		
Critical (<0.01%)	**Major (<1%)**	**Minor (<4%)**
▪ Foreign capsule in bulk container. ▪ Incorrect product strength. ▪ Non-characteristic colour and/or odour of capsules. ▪ Gross foreign matter (e.g. glass, metal or wood).	▪ Foreign matter that may not cause personal injury (e.g. hair or fingernails). ▪ Missing or partially debossed monograms. ▪ Telescoping. ▪ Closure A. ▪ Illegible imprint. ▪ Separated capsules. ▪ Broken / Cracked / Brittle.	▪ Bushing mark. ▪ Dusty. ▪ Dye specks. ▪ Dents. ▪ Double cap / Body. ▪ Closure B.

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

BLISTER PACKAGING OF TABLETS AND CAPSULES			
	Critical (<0.01%)	**Major (<1%)**	**Minor (<4%)**
Carton Appearance	▪ Missing, incomplete or incorrect batch information (batch number, expiry date and manufacturing date if applicable).	▪ Illegible batch information (batch number / expiration date). ▪ Incorrect content as per PSO (number of blisters / leafsert). ▪ Underfill carton ▪ Incorrect glue application / Fibre tear test failure. ▪ Defaced hologram printed (if applicable). ▪ Missing tamper seal (if applicable). ▪ Incorrect carton identification number.	▪ Overfill carton ▪ Tuck cartons – tears tucked incorrectly. ▪ Torn ▪ Distorted ▪ Soiled ▪ Defaced.
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).
Leaflet appearance (if applicable)		▪ Missing leaflet. ▪ Incorrect leaflet identification number. (PM) ▪ Illegible print on leaflets (either side). ▪ Wrong cutting	▪ Faint printing but legible.

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).

Appendix 5 - Classification of Defects – Packaging of Bottles

BOTTLE PACKAGING OF TABLETS AND CAPSULES			
	Critical (<0.01%)	**Major (<1%)**	**Minor (<4%)**
Bottle Appearance (Filling and desiccant)	▪ Gross foreign material that can cause personal injury (e.g. glass, metal or wood). ▪ Incorrect packaging material. ▪ Appearance or color of the tablet NOT matching product description. ▪ Non-characteristic odour of the capsule.	▪ Foreign matter that may not cause personal injury (e.g. hair or fingernails). ▪ Underfill. ▪ Empty bottle. ▪ Missing desiccant. ▪ Telescoping (if applicable). ▪ Broken / cracked / brittle.	▪ Embedded surface spots (e.g. dark specks, oil or grease). ▪ Overfill. ▪ Malformed, crushed, chipped or dusty capsule.
Container Labelling and Coding	▪ Missing, incomplete or incorrect batch information (batch number, expiry date and manufacturing date, if applicable).	▪ Cracked / damaged container. ▪ Illegible Print / coding ▪ Illegible Damaged label ▪ Label not fully adhering.	▪ Print / coding smeared but legible. ▪ Label off-registration. ▪ Damaged label but legible
Capping and Sealing		▪ Missing inner seal material (wad). ▪ Failing torque test (removal torque out of specifications). ▪ Incorrect cap identification number.(PM)	▪ Scratched caps. ▪ Damaged caps / inner seal (charred, etc). ▪ Failing wad seal test (defective application).
Bundling and Shipper Labels		▪ Missing, incomplete or incorrect batch information (batch number, item code or expiry date). ▪ Illegible Damaged / smeared labelling	▪ Incorrect number of bundles per shipper. ▪ Incorrect number of bottles per bundle. ▪ Incorrect shipper identification number. ▪ Damaged / smeared labelling but legible ▪ Malformed / loose bundle. ▪ Incorrect pallet pattern (if specified).

Appendix 6 - Single Sampling Plan for Normal Inspection of Manufacturing and Packaging Materials

Lot Size			Sample Size	AQL							
				Critical* (<0.01%)		Major A* (<0.4%)		Major (<1%)		Minor (<4%)	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re
1	To	8	2	↓	↓	↓	↓	0	1	0	1
9	To	15	3					0	1	0	1
16	To	25	5					0	1	1	2
26	To	50	8					0	1	1	2
51	To	90	13					0	1	1	2
91	To	150	20					0	1	2	3
151	To	280	32			0	1	1	2	3	4
281	To	500	50			0	1	1	2	5	6
501	To	1,200	80			1	2	2	3	7	8
1,201	To	3,200	125			1	2	3	4	10	11
3,201	To	10,000	200			2	3	5	6	14	15
10,001	To	35,000	315			3	4	7	8	21	22
35,001	To	150,000	500			5	6	10	11	21	22
150,001	To	500,000	800			7	8	14	15	21	22
500,001 and over			1250	0	1	10	11	21	22	21	22

Prepared from Australian Standard AS 1199.1-2003: Sampling procedures for inspection by attributes. Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

Ac = Acceptance Number
Re = Rejection Number