1 Generic Filled Product Defect Classification

1.1 Vial Product Defect Classification

1.1.1 Critical Vial Defects

Vial Defect Classification = Critical	
Defect Type	**Example of Defect**
Filled Container	Broken – Fragmented into separate parts and causes
	Cracked – Fissured without separation of parts. (Any surface flaw that compromises sealing and overall product integrity.) (NOTE: During AQL, questionable surface flaws may be submitted to QA for CCIT)
	Incorrect Container
Closures	Crimp area - Malformed, incomplete to a point where the integrity is lost (NOTE: During AQL, questionable crimps may be submitted to QA for CCIT)
	Metal seal - Torn or badly damaged (NOTE: During AQL, questionable damage may be submitted to QA for CCIT)
	Missing stoppers
	Incorrect Stopper or Flip-Cap Type
Volume	Low Volume – for single-dose vial, 50% or less of required dose. (Note: Questionable low volume found during AQL will be submitted to QA for volume check per SOP)
Product Appearance	Discrepancy in product appearance or color. See SOP

1.1.2 Major Vial Defects

1.1.2.1 Major Non-Particulate Defects

Vial Defect Classification = Major (Non-Particulate)	
Defect Type	**Example of Defect**
Closures	Damaged or Missing Flip-Off Seal
Volume	Low Volume - for multi-dose vial, missing 25% or more of the required listed volume.
	Empty Vial

1.1.2.2 Major Particulate Defects

Vial Defect Classification = Major (Particulate)	
Defect Type	**Example of Defect**
Product Appearance	All particulates observed in the product contact area of the finished unit. Only QA further defines particulates into the following sub-categories: Fibers, Rubber, Plastic, Lubricant, Glass, Stainless Steel, Endogenous, Other - All particles located anywhere in the product contact area of the vial, including clear (potentially glass) or opaque rapidly sinking (potentially stainless steel) particles, are submitted for ID. Confirmed glass or stainless steel will initiate a deviation per SOP.

1.1.3 Minor Vial Defects

Vial Defect Classification = minor	
Defect Type	**Example of Defect**
Filled Container	Glass Imperfections - Heavy scoring or large glass chips on outer container surface
Closures	Fully formed but irregular Crimp or dented Metal Seal that does not affect the integrity of the seal or functionality of the product.
Volume	High Volume – over filled container, 150% or greater of required dose.

1.2 Syringe Product Defect Classification

1.2.1 Critical Syringe Defects

Syringe Defect Classification = Critical	
Defect Type	**Example of Defect**
Filled Container	Broken – Fragmented into separate parts and causes leakage
	Cracked – Fissured without separation of parts located in the product contact area. (Any surface flaw that compromises sealing and overall product integrity.) Cracks in the flange area are not considered critical defects. (NOTE: During AQL, questionable surface flaws may be submitted to QC for CCIT)
	Incorrect Container
	Missing or damaged stopper that would affect the sealing (NOTE: During AQL, questionable damage may be submitted to QC for CCIT)
	Missing rubber tip cap or Raised to a point that compromises sealing and overall product integrity. (NOTE: During AQL, questionable tip cap positions may be submitted to QC for CCIT)
	Leaking container- Liquid leaking past rib 4 of syringe stopper. See Figure 1. (NOTE: During AQL, questionable flaws may be submitted to QC for CCIT)
	Incorrect Stopper
Volume	Low Volume – for single-dose syringe, 50% or less of required dose. (Note: Questionable low volume found during AQL will be submitted to QC for volume check)
Product Appearance	Discrepancy in product appearance or color.

1.2.2 Major Syringe Defects

1.2.2.1 Major Non-Particulate Defects

Syringe Defect Classification = Major (Non-Particulate)	
Defect Type	**Example of Defect**
Filled Container	Damaged flange, that does not cross into the product contact area, rendering the unit unusable or unsafe to practitioner
	Cracked – Fissured without separation of parts. (A crack that does not compromise sealing or overall product integrity.) (NOTE: During AQL, questionable surface flaws may be submitted to QC for CCIT)
Volume	Missing Stopper and/or Empty container
Closures	Reversed Stopper

1.2.2.2 Major Particulate Defects

Syringe Defect Classification = Major (Particulate)	
Defect Type	**Example of Defect**
Product Appearance	All particulates observed in the product contact area of the finished unit Only QC further defines particulates into the following sub-categories: Fibers, Rubber, Plastic, Lubricant, Glass, Stainless Steel, Endogenous, Other - All particles located anywhere in the product contact area of the vial, including clear colorless (potentially glass) or dark opaque rapidly sinking (potentially stainless steel) particles, are submitted for ID. Confirmed glass or stainless steel will initiate a deviation per SOP.

1.2.3 Minor Syringe Defects

Syringe Defect Classification = minor	
Defect Type	**Example of Defect**
Filled Container	Glass Imperfection - Heavy scoring or large glass chips on outer container surface
	Raised rubber tip cap that does not compromise sealing or overall product integrity.
Closures	Damaged stopper – incomplete molding that would NOT affect the sealing and function of the stopper
Plunger Position	Syringes: Greater than XX mm or less than XX mm as measured from the side of the flange closest to the plunger to the top surface of the plunger.
Volume	High Volume – overfilled container, 150% or greater of required dose.

1.3 Lyophilized Vial Product Defect Classification

1.3.1 Critical Lyophilized Vial Defects

Lyophilized Vial Defect Classification = Critical	
Defect Type	**Example of Defect**
Filled Container	Broken – Fragmented into separate parts and causes leakage
	Cracked – Fissured without separation of parts. (Any surface flaw that compromises sealing and overall product integrity.) (NOTE: During AQL, questionable surface flaws may be submitted to QC for CCIT)
	Incorrect Container
Closures	Crimp area - Malformed, incomplete) (NOTE: During AQL, questionable crimps may be submitted to QC for CCIT - Reconstituted)
	Metal seal - Torn or badly damaged (NOTE: During AQL, questionable damage may be submitted to QC for CCIT - Reconstituted)
	Missing stoppers
	Incorrect Stopper or Flip-Cap Type
Product Appearance	Discrepancy in product appearance or color.

1.3.2 Major Lyophilized Vial Defects

1.3.2.1 Major Non-Particulate Defects

Lyophilized Vial Defect Classification = Major (Non-Particulate)	
Defect Type	**Example of Defect**
Product Appearance	Abnormal Cake - Lyophilized product that is not fully freeze dried or low volume differing by more than 50% of the norm. (Note: could be a Critical in some products)
Closures	Damaged or Missing Flip-Off Seal
Volume	Empty Vial

1.3.2.2 Major Particulate Defects

Lyophilized Vial Defect Classification = Major (Particulate)	
Defect Type	**Example of Defect**
Product Appearance	All particulates observed on or imbedded in the product cake or observed in the product contact area of the container/closure unit including fibers are in the major category. Only QC further defines particulates into the following sub-categories upon Supplemental Reconstitution: Fibers, Rubber, Plastic, Lubricant, Glass, Stainless Steel, Endogenous, Other - All particles located anywhere in the product contact area of the vial, including clear colorless (potentially glass) or dark opaque rapidly sinking (potentially stainless steel) particles, are submitted for ID Confirmed glass or stainless steel will initiate a deviation per SOP.

1.3.3 Minor Lyophilized Vial Defects

Lyophilized Vial Defect Classification = minor	
Defect Type	**Example of Defect**
Filled Container	Glass Imperfection - Heavy scoring or large glass chips on outer container surface
Closures	Fully formed but irregular Crimp or dented Metal Seal that does not affect the integrity of the seal or functionality of the product.
Volume	Dry Product on Stopper (Note: Could be considered Major or Critical in some products) (NOTE: During AQL, questionable vials may be submitted to QC for CCIT)