Defect Classification Strategies

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PDA Parenteral Drug Association

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Contents

Definition of defects

- Critical
- Major
- Minor

Defect Zones

Tools

Definition of Defects

CRITICAL: Product is not usable. The defect might have an impact on the patient health. E.g. Sterility/ impact on patient health.

MAJOR: Performance of the product might be lowered due to an impact on handling or package functionality

MINOR: Product quality is affected but functionality of the product is not limited

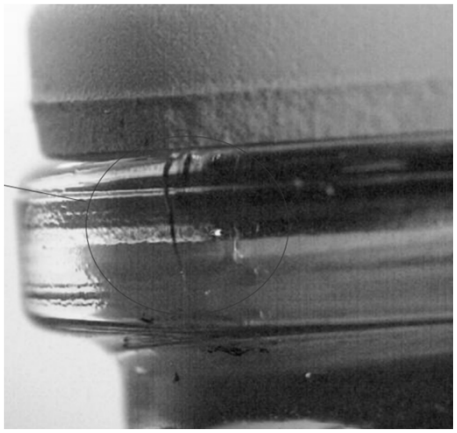
Critical Defects

Patient safety
Vial integrity might be injured (sterility)

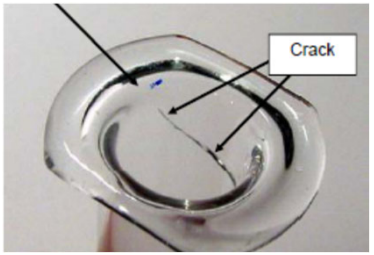
Regulatory
Does not comply with specification

Customer perception
Bad reputation due to recall
Potential loss of market share

Critical Defects



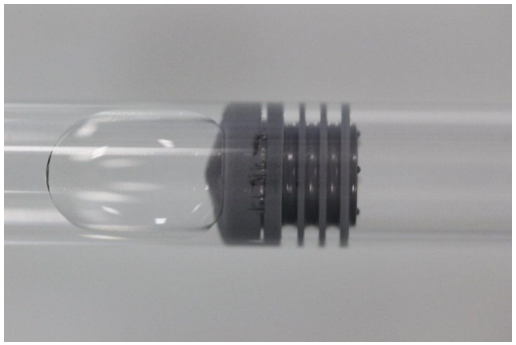
Critical Defects



Cracks going through the glass wall

Critical Defects ?

- Liquid between rips



Dirt or liquid between libs

- Precipitation in solution
- Shrunken collapsed cake
- Leaking container
- Incorrect color point or band at ampoules

Major Defects

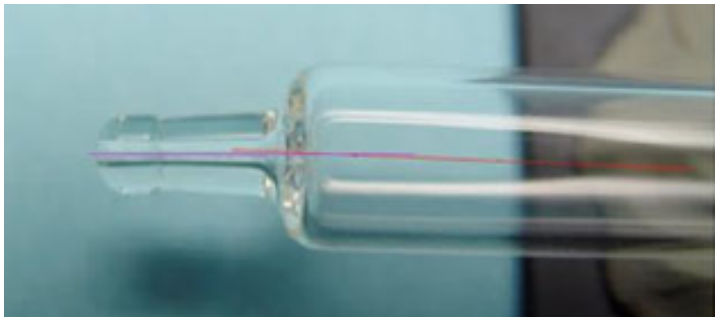
Patient safety
Patient safety is not compromised

Regulatory
Conform with (drug) specifications

Customer Perception
Defect might be observed by the customer.
Consider regional differences in acceptance (Japan)
Potential loss of customers

Major Defects

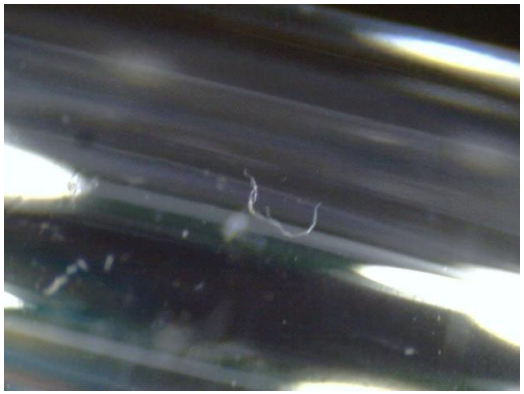
Stone



Bent tip

Major defects

Fingertip not properly tooled



Fibre in syringe

Major Defects ?

particles

Crack not touching the drug

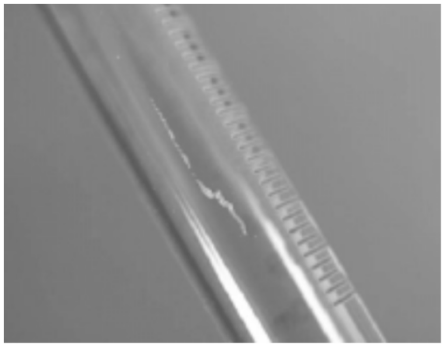
Minor Defects

Patient safety
Patient safety is not compromised

Regulatory
Conform with specifications

Customer perception
Defect might be observed by the customer.
Consider regional differences in acceptance (Japan)
Potential loss of customers

Minor Defects

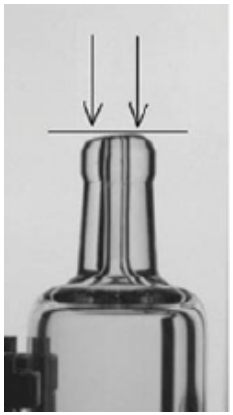


Scratch outside

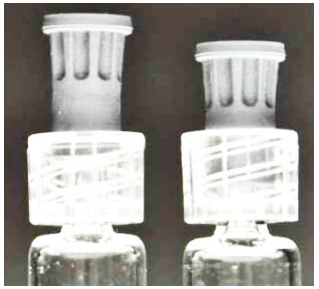
Dirt outside

Minor Defects

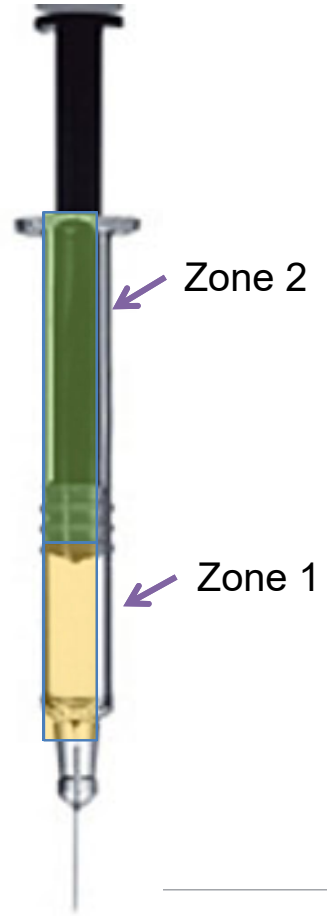
Surface scratches



Cone not properly tooled



Defect specification



Zone concept:

•Zone 1: part or surface has contact to drug

•Zone 2: no contact to product

Defect classification:

Zone + Defect

- Critical: Sterility/ impact on patient health
- Major: impact on functionality
- Minor: cosmetic defect

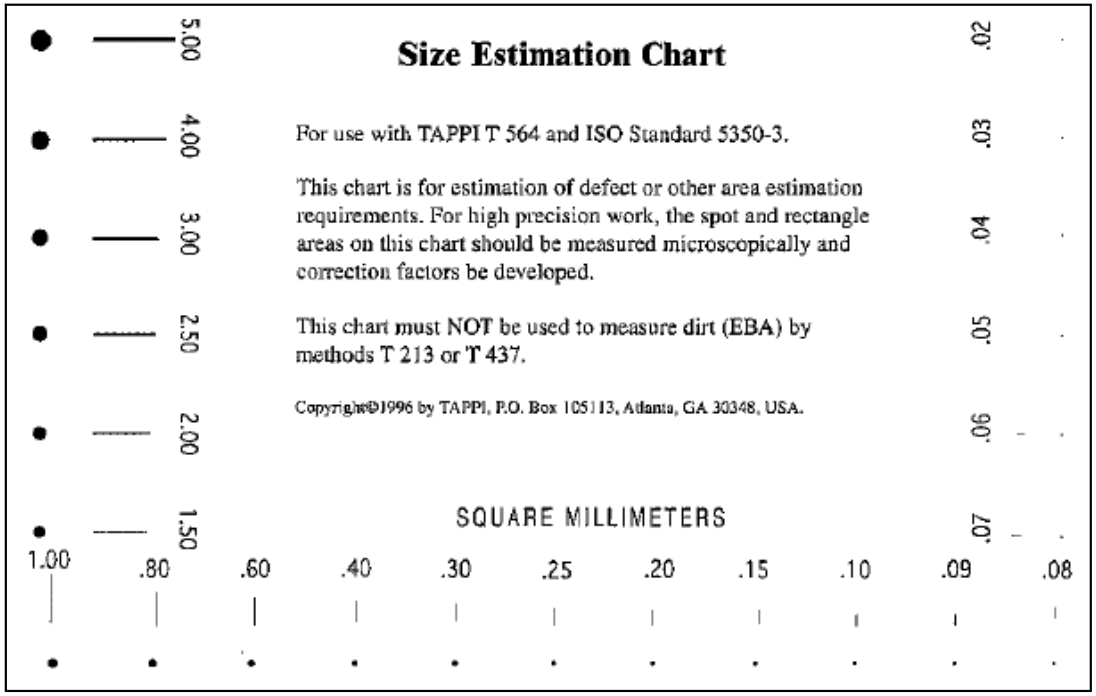
Specific Defect Evaluationsheet m= minor M = Major C=Critical						
Position	No	Defect description	Requirement	Zone 1	Zone 2	Remark
Plunger	P1	spots on plunger		M		
	P2	damaged plunger	intact plunger	C	M	
	P3	wrong orientation of plunger	correct orientation	C	C	
	P4	water in-between lips of plunger		C	c	
Container	GI	scratches	no scratches	m	m	
	G2	overfill		M		
	G3	underfill		M		
	G4	particles	essentiallY free	M	M	
	G5	Broken	Container intact	C	M	
	G6	Cracked	qlass barrel intact	C	M	
	G7	damaged finger rest	intact finqer rest		m	
Needle	N1	hookon canula			C	
	N2	needle sticking through needle shield	needle inside needle sheet		C	

Zone 2

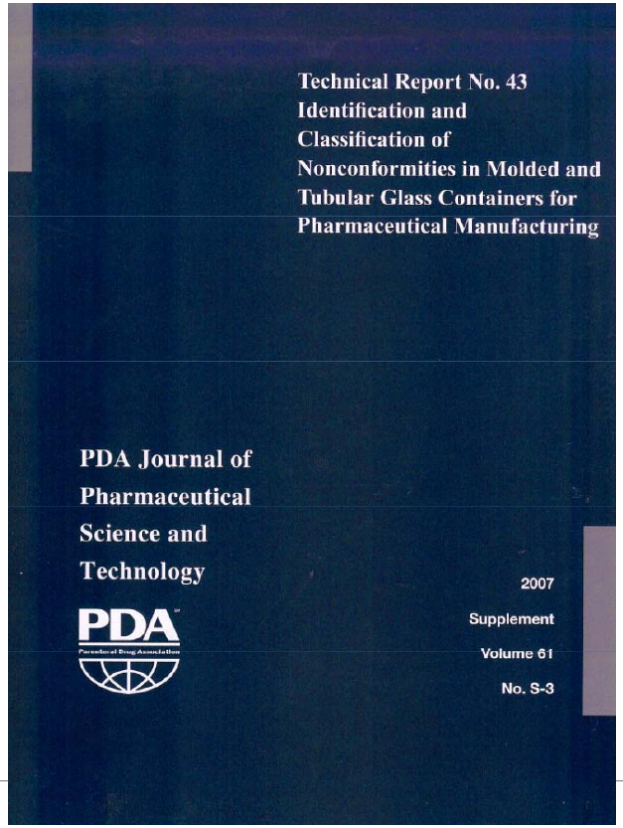
Zone 1

Tools: TAPPI Dirt estimation chart

Technical association of the Pulp and Paper Industry (TAPPI)



TR 43



Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing:
Covering Ampoules, Bottles, Cartridges, Syringes and Vials
Technical Report No. 43 (Revised 2013)

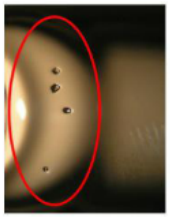
Table 4.2.3-1 Tubular Glass Container Lexicon: Cartridges

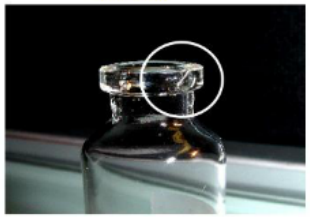
NONCONFORMANCE	DESCRIPTION	LOCATION	CLASSIFICATION
Adhered Glass Particles (a.k.a. Sintered or Fused), Internal or External	Small particles or fragments of glass adhered to the interior or exterior surface of the cartridge	General	Critical if internal or if seal integrity is compromised; Major B if external
Airline, Closed	Elongated gaseous inclusion, parallel to the axis of the body, completely encapsulated	Body	Minor if in the body >0.25 mm wide and full length
Airline, Open	Elongated gaseous inclusion that is not encapsulated and appears as a line parallel to the axis of the body. If open on the interior surface may by-pass the plunger and possibly create a leak path	Body	Critical if on interior surface; Minor if on exterior surface and >0.25mm wide and full length
Bad Cut	Poor cut resulting in an irregular glazed end	Cut End	Major B if it causes processing problems, (Limit Sample); Minor otherwise
Bent	The finish and plane of the seal surface is not perpendicular to the axis of the body	Finish/ Neck	Major B (Limit Sample)

Adhered Glass Particles –
(a.k.a. Sintered or Fused), Internal or External

Location: General

Class: Critical if sharp or seal integrity is compromised; Major B if otherwise





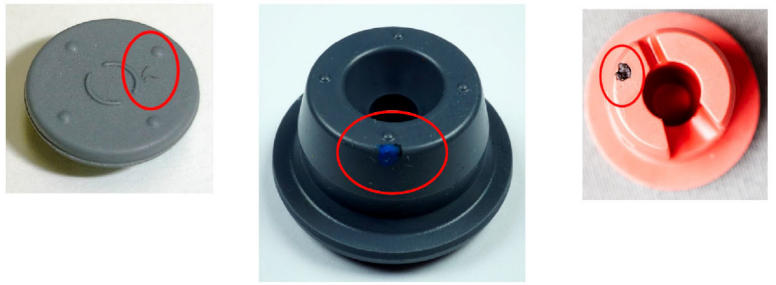
Small particles or fragments of glass adhered to the interior or exterior surface of the vial.

TR 76

PDA Technical Report No. 76 (TR 76) Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging

Figure 8-11 **Embedded Material (Extrinsic)**

Location: Any **Class:** Critical



Foreign material not part of elastomer formulation or degraded/reverted elastomer which is partially or completely embedded in the component.

References

PDA Journal of Pharmaceutical Science and Technology

PDA Technical Report No. 43 (Revised 2013) Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials

PDA Technical Report No. 76 (TR 76) Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging

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