



Defect Classification Strategies

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September 2019



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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

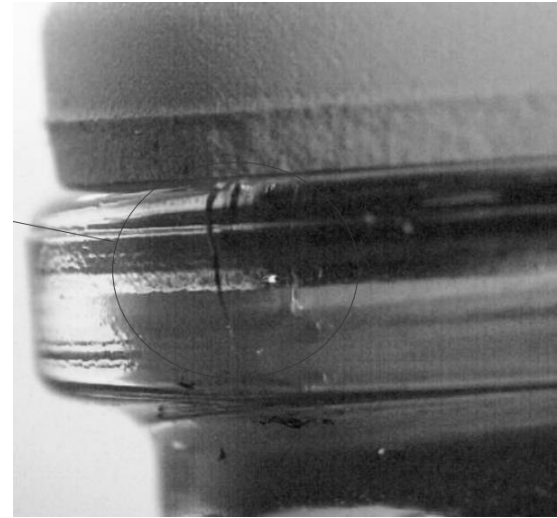
Customer perception

Bad reputation due to recall

Potential loss of market share

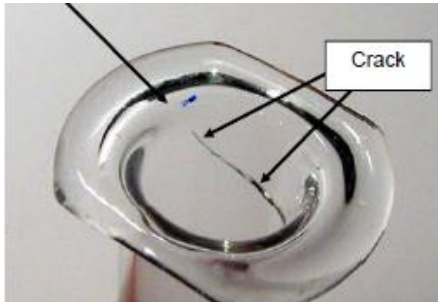


Critical Defects





Critical Defects



Cracks going through the glass wall

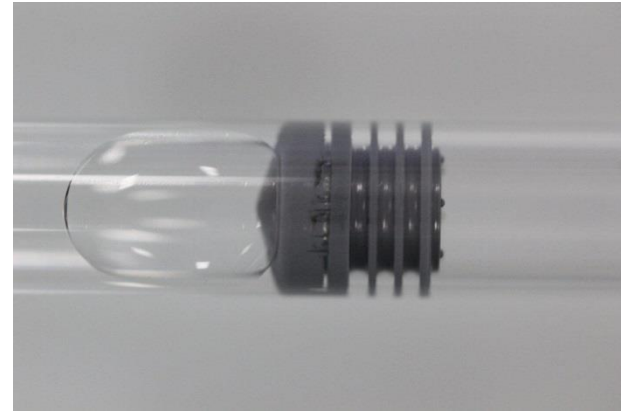




Critical Defects ?



- Liquid between ribs



Dirt or liquid between ribs

- 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)

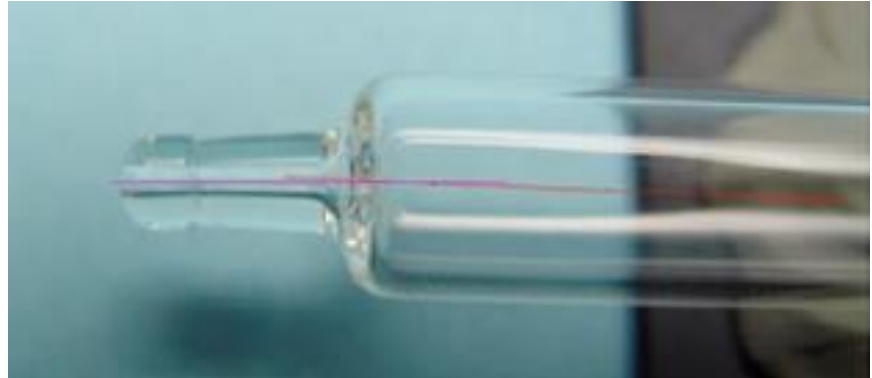
Potential loss of customers



Major Defects



Stone



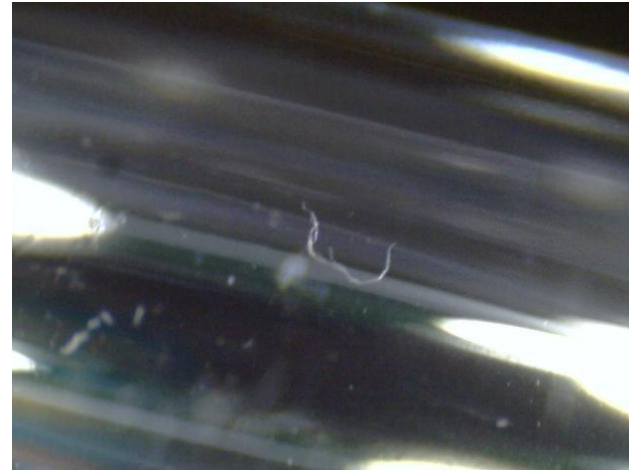
Bent tip



Major defects



Fingertip not properly tooled



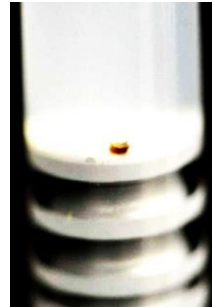
Fibre in syringe



Major Defects ?



particles



Crack not touching the drug



Minor Defects

Patient safety

Patient safety is not compromised

Regulatory

Conform with specifications

Customer perception

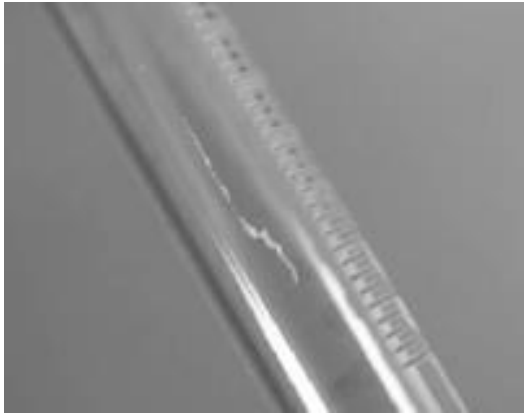
Defect might be observed by the customer.

Consider regional differences in acceptance
(Japan)

Potential loss of customers



Minor Defects



Scratch outside



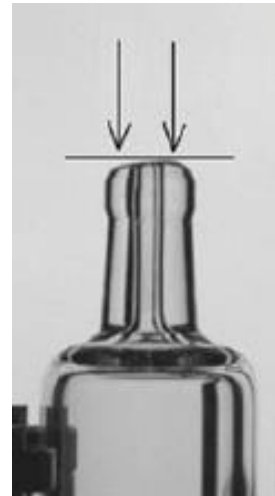
Dirt outside



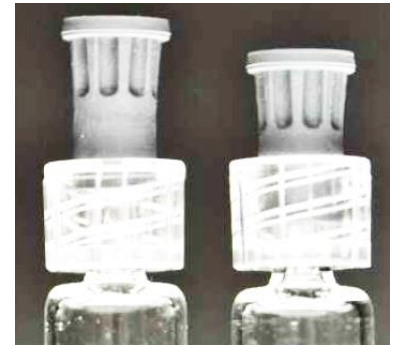
Minor Defects



Surface scratches

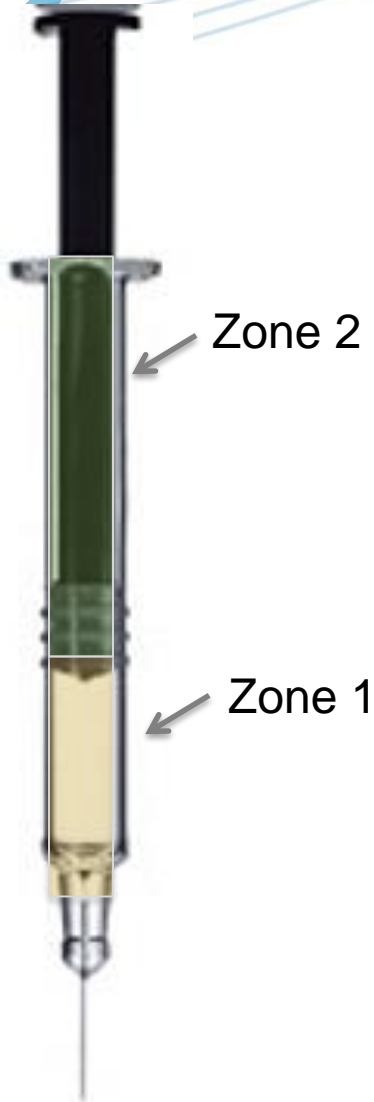


Cone not properly
tooled





Defect specification



Zone concept:

- Zone 1: part or surface has contact to drug
- Zone 2: no contact to product

Defect classification:

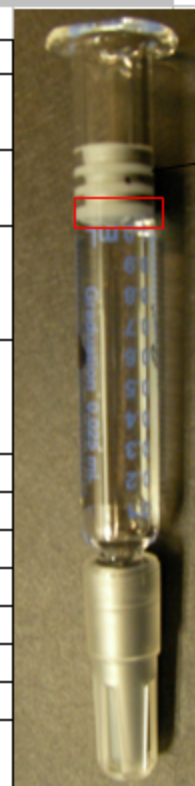
Zone + Defect

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



Defect evaluation form

Specific Defect Evaluationsheet						
m= minor M = Major C=Critical						
Position	No	Defect description	Requirement	Zone1	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	
Container	G1	scratches	no scratches	M	m	
	G2	overfilled		M		
	G3	underfilling		M		
	G4	particles	essentially free	M	M	
	G5	Broken	container intact	C	M	
	G6	Cracked	glass barrel intact	C	M	
	G7	Scratches	no scratches	M	m	
	G8	damaged finger rest	intact finger rest		m	
Needle	N1	hook on canula			C	
	N2	needle sticking through needle shield	needle inside needle sheet		C	



Zone 2

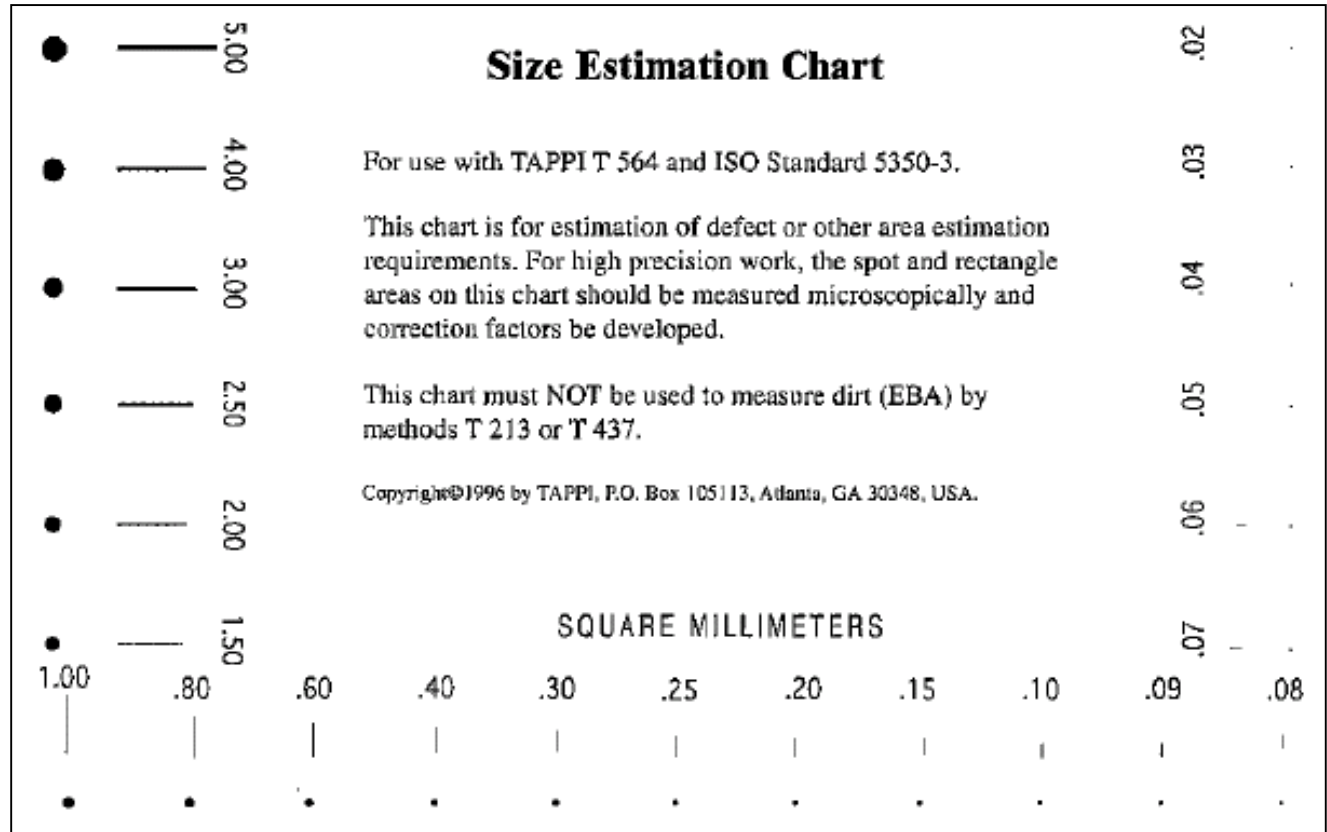
Zone 1

Zone 1 inside of the barrel
Zone 2 outside



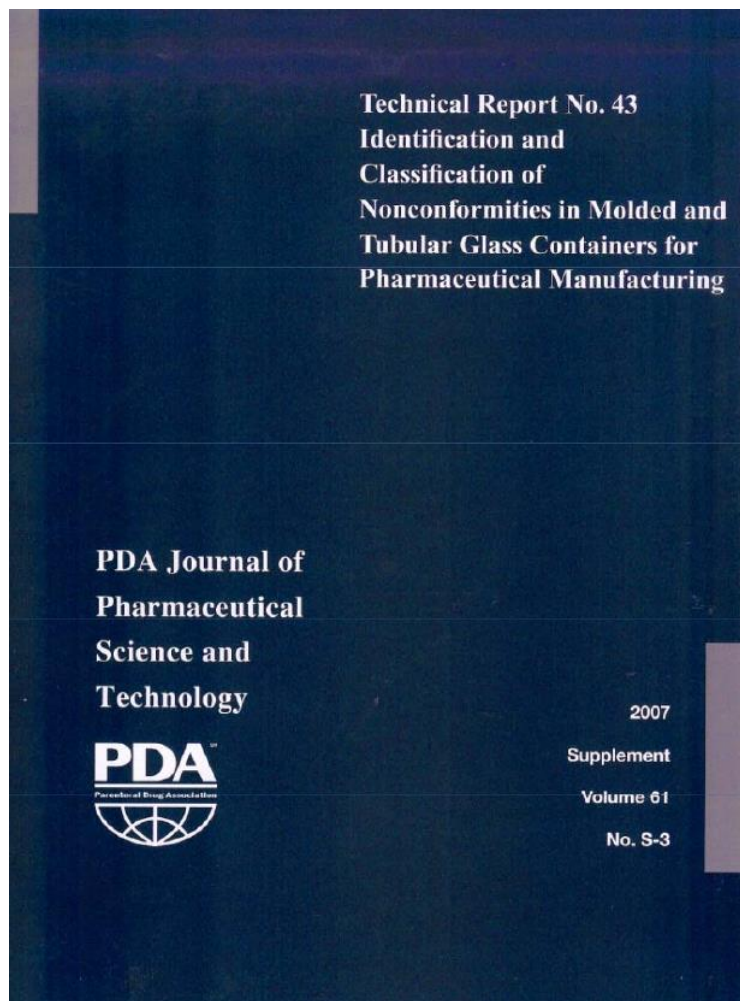
Tools: TAPPI Dirt estimation chart

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

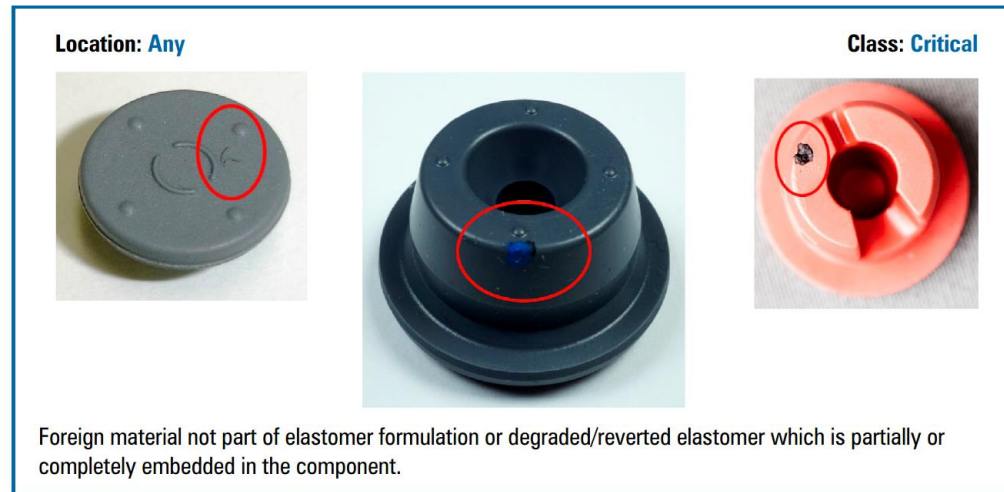


Small particles or fragments of glass adhered to the interior or exterior surface of the vial.

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)





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



Acknowledgments

- Georg Roessling
- John Shabushnig