

# Defect Classification Strategies

Markus Lankers, PhD  
November 2021



Connecting People, Science and Regulation®



Connecting People, Science and Regulation®

CONNECTING  
PEOPLE  
SCIENCE AND  
REGULATION®



Connecting People, Science and Regulation®

## Definition of defects

- Critical
- Major
- Minor

## Defect Zones

## Tools



**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



Parenteral Drug Association



Connecting People, Science and Regulation®

## **Patient safety**

Vial integrity might be injured (sterility)

## **Regulatory**

Does not comply with specification

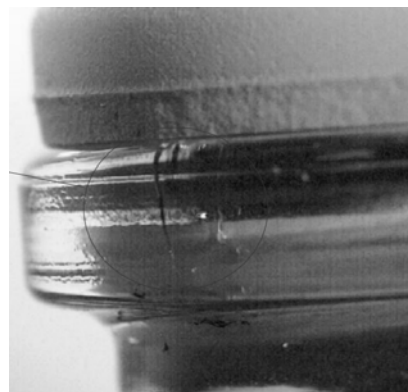
## **Customer perception**

Bad reputation due to recall

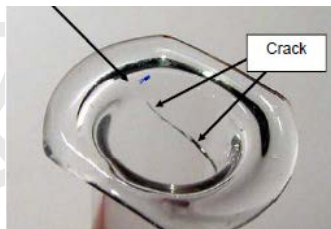
Potential loss of market share



Connecting People, Science and Regulation®



# Critical Defects



Cracks going through the glass wall





Connecting People, Science and Regulation®



- Liquid between ribs



Dirt or liquid between ribs

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



Connecting People, Science and Regulation®

## 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





Connecting People, Science and Regulation®



Stone



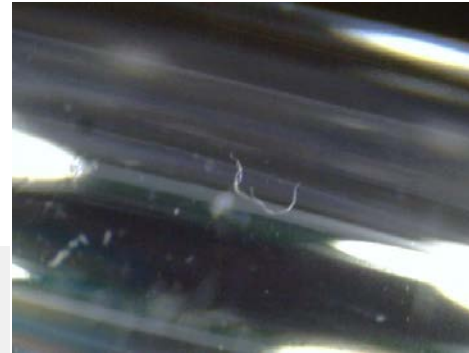
Bent tip



Connecting People, Science and Regulation®



Fingertip not properly tooled



Fibre in syringe

# Major Defects ?



particles



Crack not touching the drug

## Patient safety

Patient safety is not compromised

## Regulatory

Conform with specifications

## Customer perception

Defect might be observed by the customer.

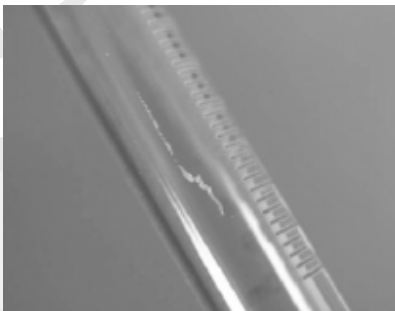
Consider regional differences in acceptance

(Japan)

Potential loss of customers



Connecting People, Science and Regulation®



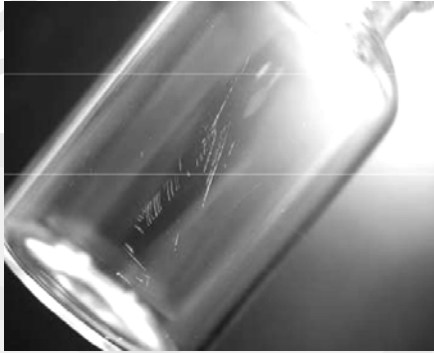
Scratch outside



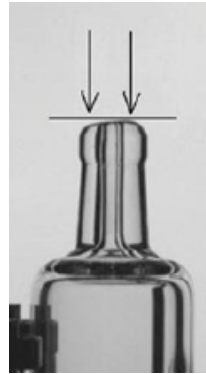
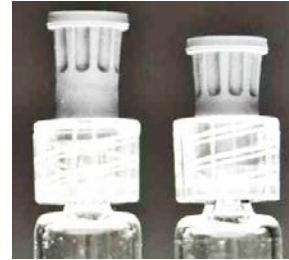
Dirt outside



Connecting People, Science and Regulation®

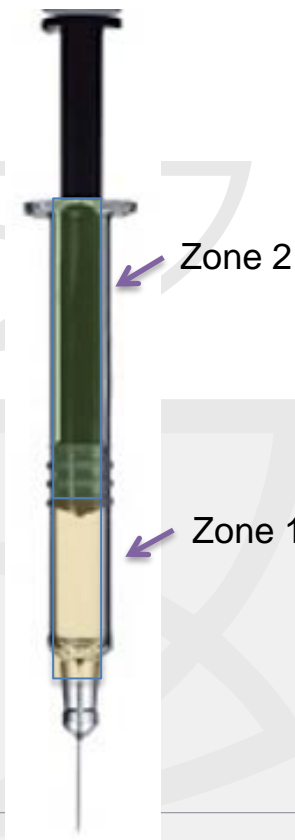


Surface scratches

Cone not properly  
tooled



Connecting People, Science and Regulation®



Zone concept:

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

Defect classification:

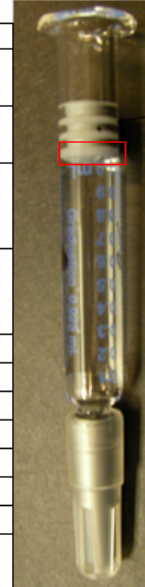
Zone + Defect

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



Connecting People, Science and Regulation®

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	



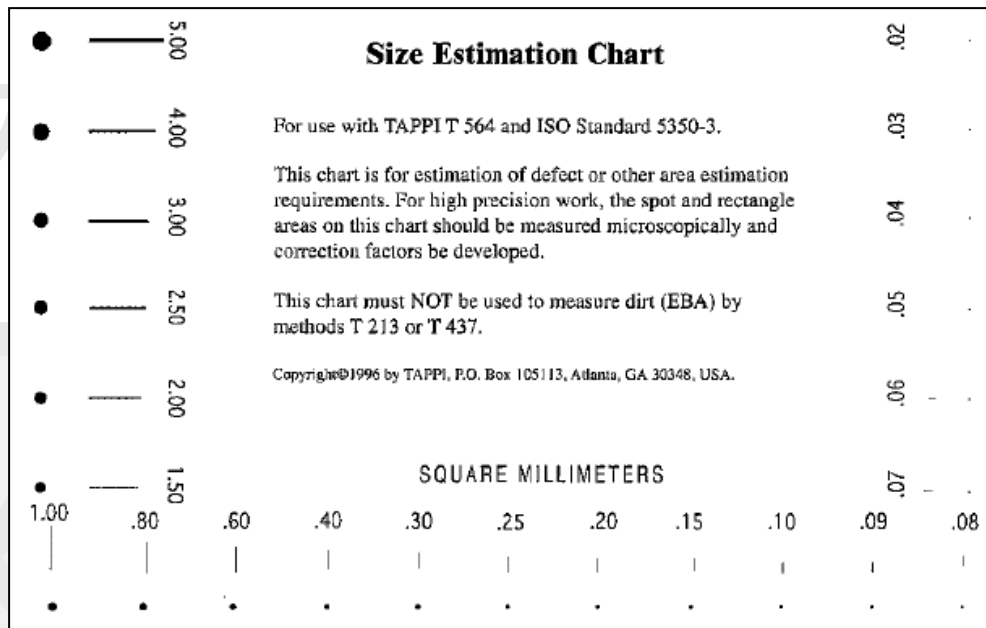
Zone 2

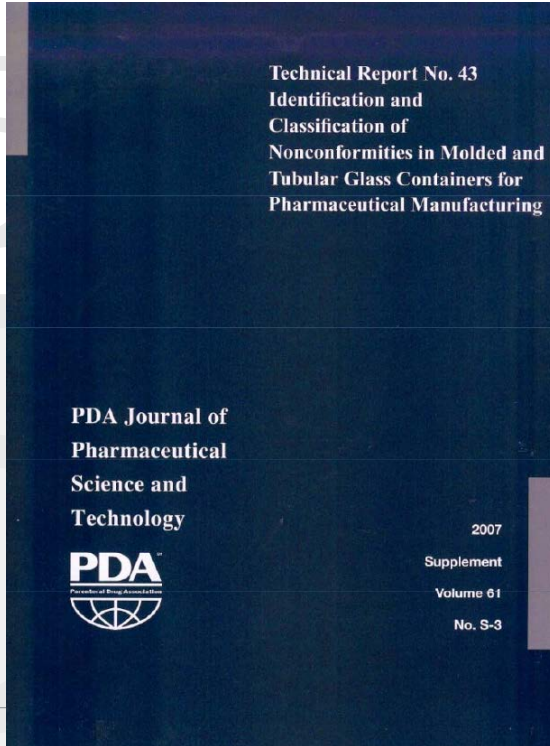
Zone 1

Zone 1 inside of the barrel  
Zone 2 outside



Technical  
association of  
the Pulp and  
Paper  
Industry  
(TAPPI)





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)

Location: Any



Class: Critical



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



Connecting People, Science and Regulation®



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

- 
- A large, light gray, stylized globe graphic is positioned on the left side of the slide, partially overlapping the text. It consists of a semi-circle at the top with several curved lines radiating from the center to the edge, creating a grid-like pattern.
- Georg Roessling
  - John Shabushnig