

Mastering AVI

Module 3: Considerations on primary containers and product properties

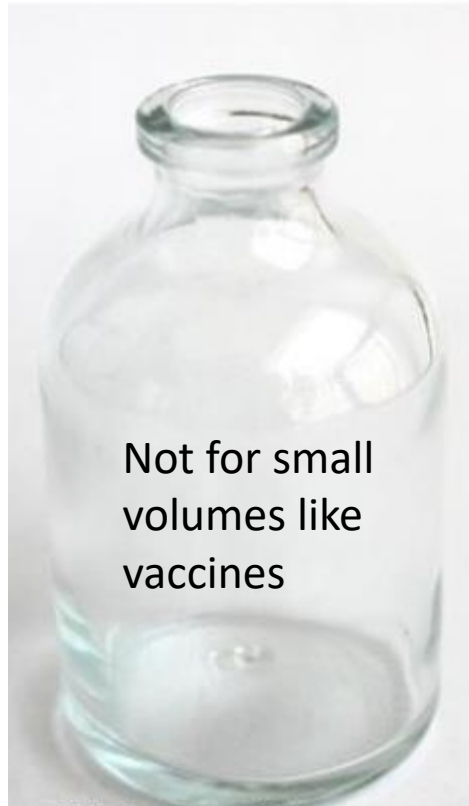


- Vials, Ampoules, Syringes, Blow – Fill - Seal,
- Closure systems
- Viscous liquids, Air bubbles / scratches,
- Refrigerated product containers

- Molded vs tubular glass
- Glass defect
 - Ref PDA TR 43
 - Crack
- Closure defect
 - vial crimping
 - syringe closure
- Size Tolerance impact on AVI
- Multiple supplier
- workshop with practical glass defect reviewing:
 - Forming defect / Airline / inclusion /scratches / size
 - Product fill level / Opacity / color / Viscosity
 - Lyo product aspect



- Molded Glass



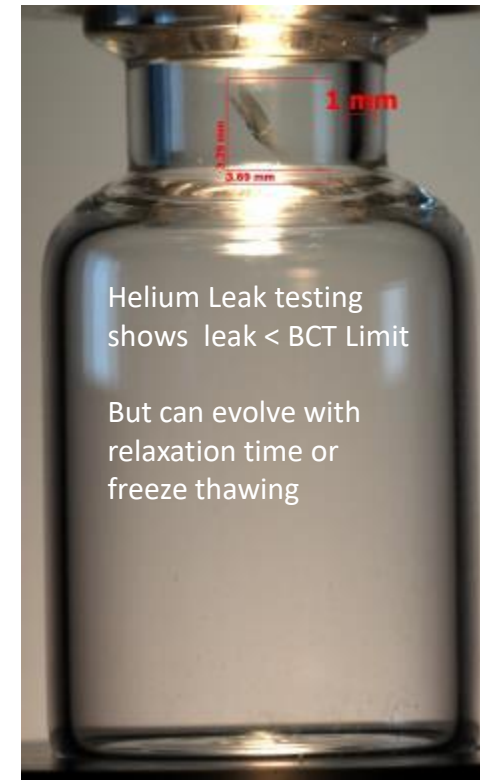
- Tubular glass



- Crossing crack

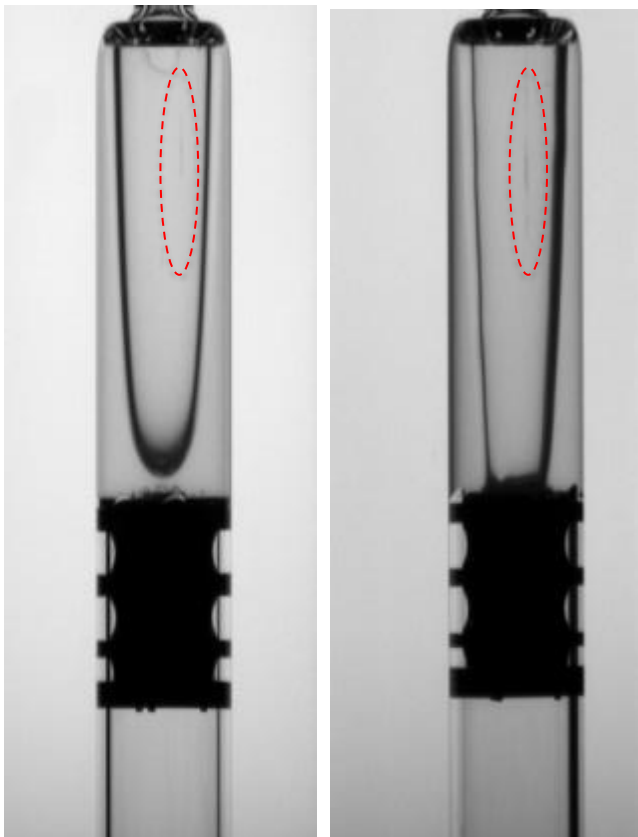


- Non Crossing crack



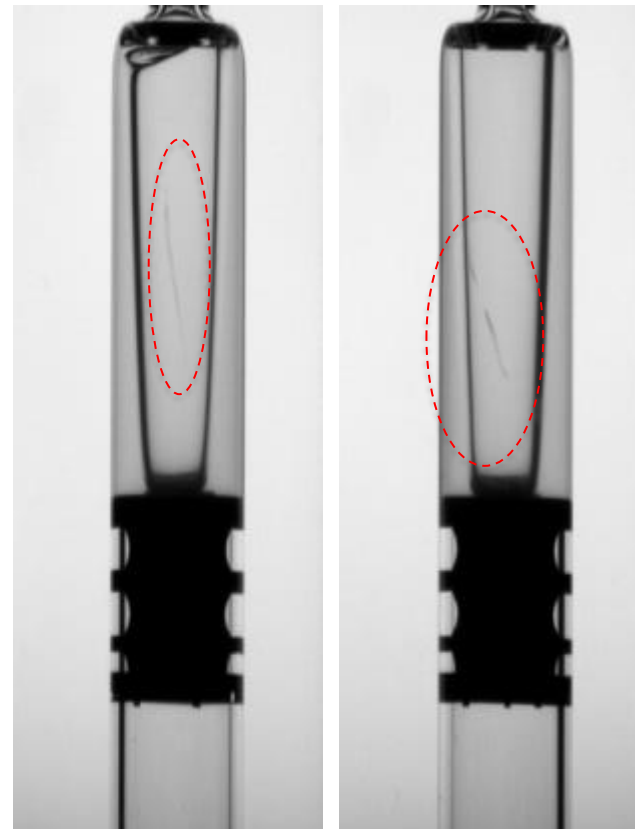
- Scratch : **minor**

Metal parts contact

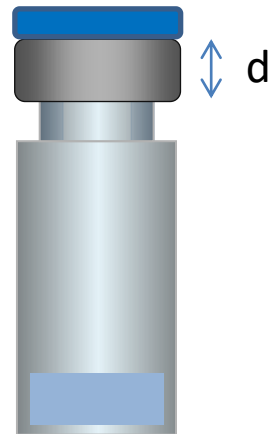


- Crack: **critical**

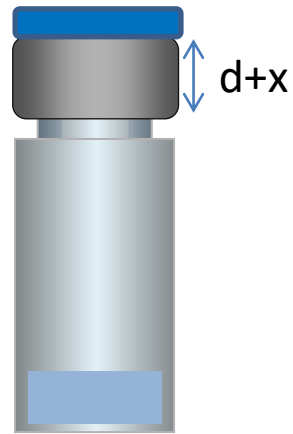
Glass to glass contact or thermal shock



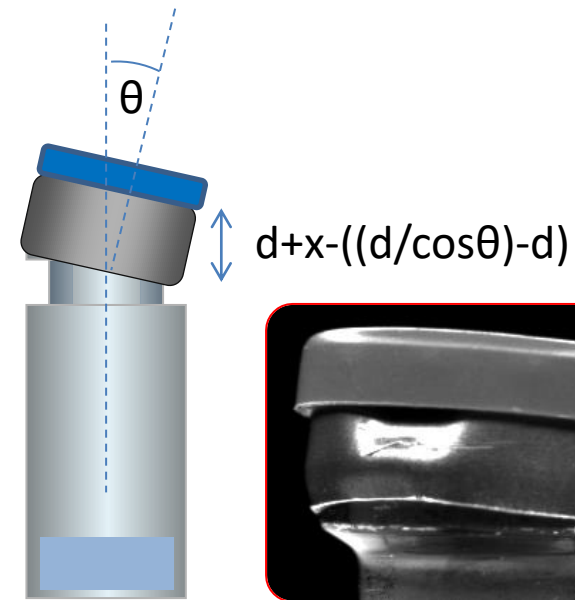
Conform crimp



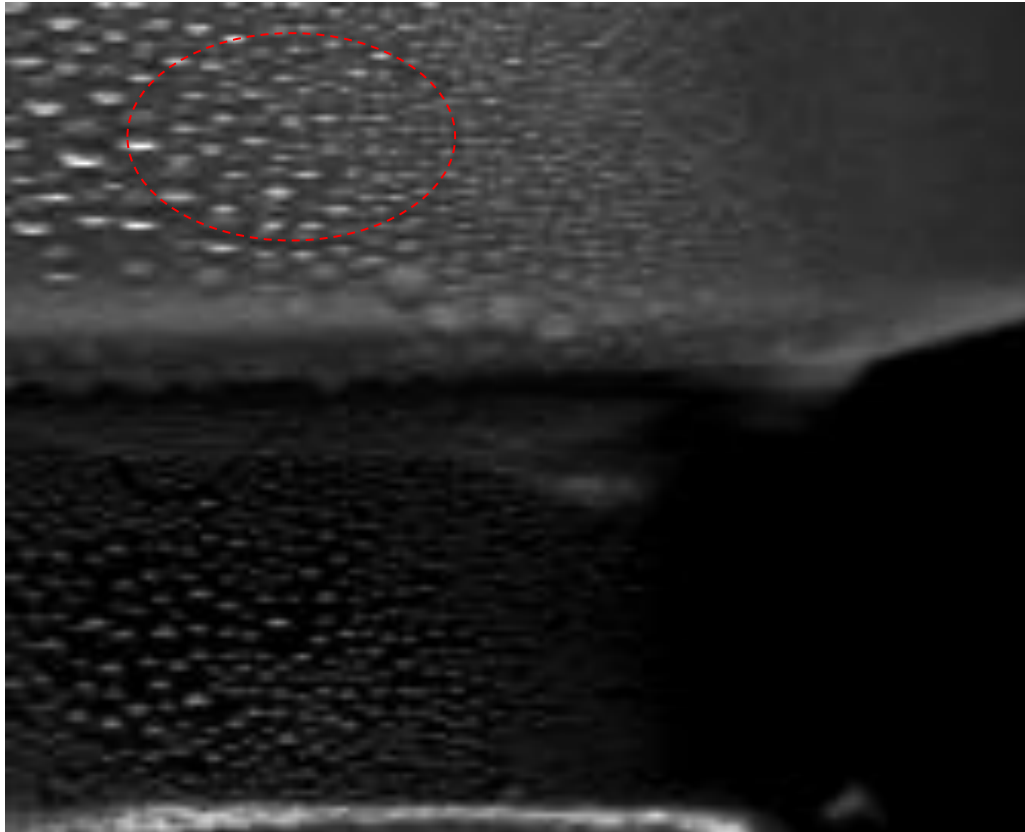
Not crimped



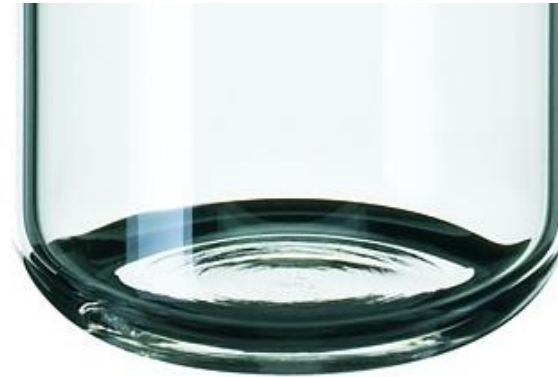
Partially crimped

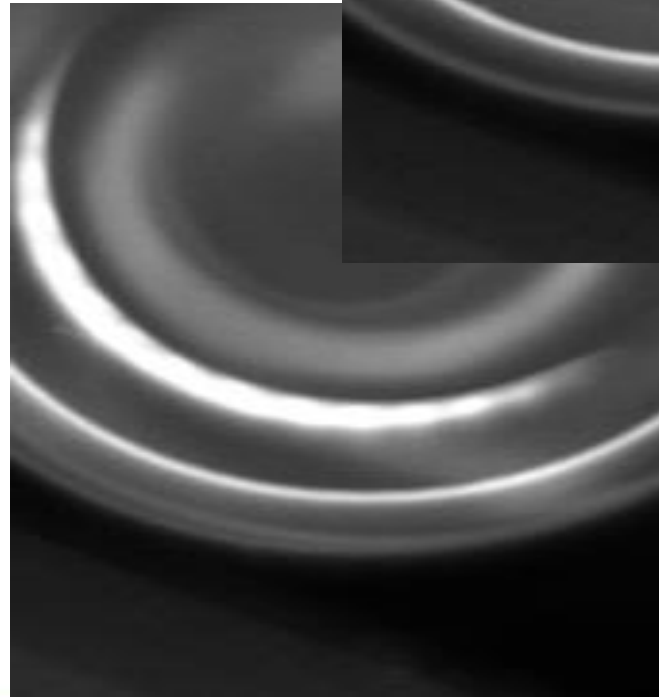
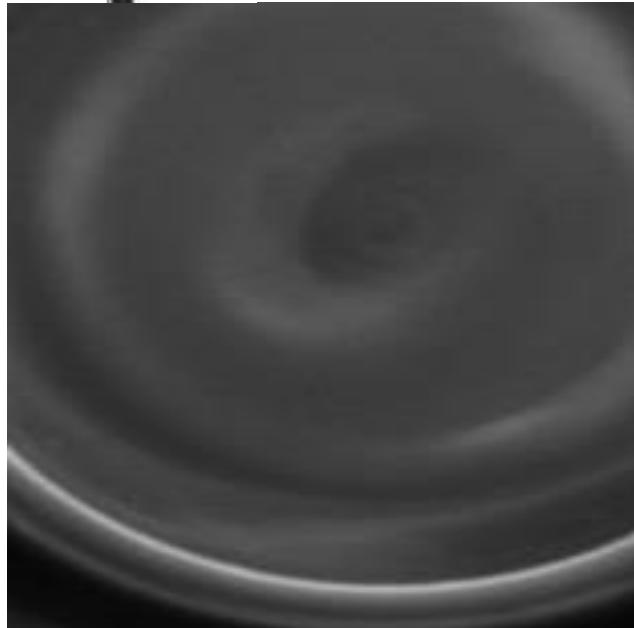


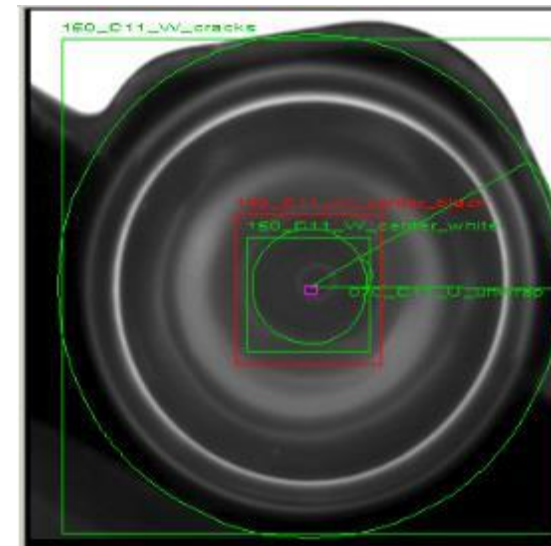
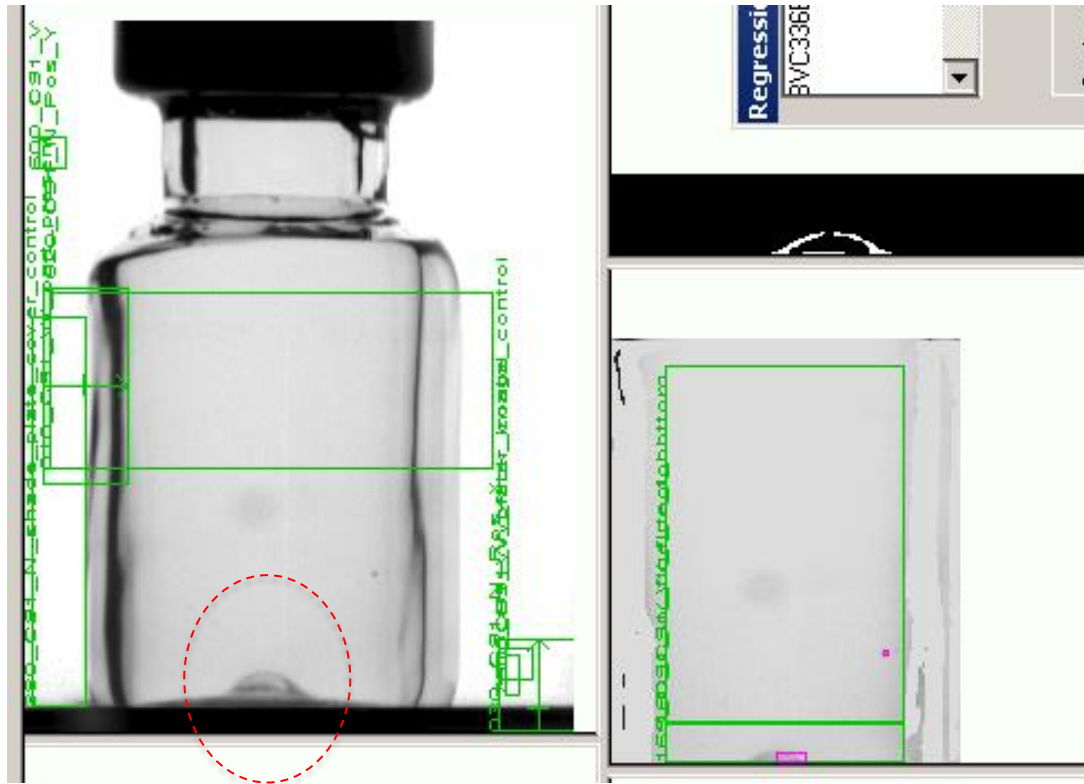
Defective crimping can be defined regarding cap height or angle

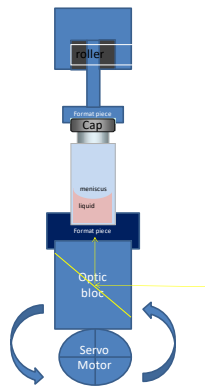
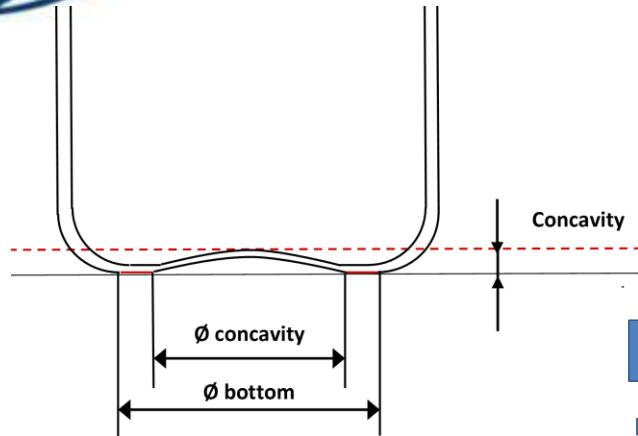


Micro droplet due to condensation will generate false rejects









Best case →



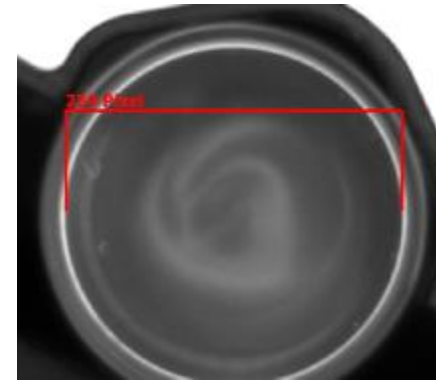
Worst case →



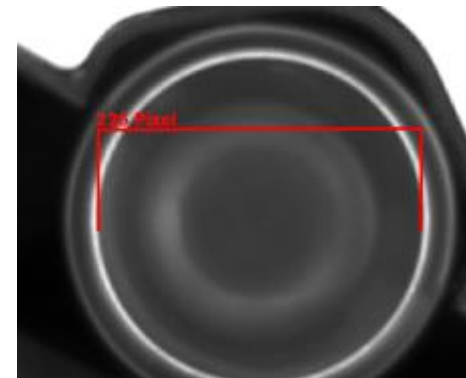
Vials are being rotated fast (3600t/min) from bottom, in order to obtain thin layer suspensions. And 'transparent' window for small particle inspection

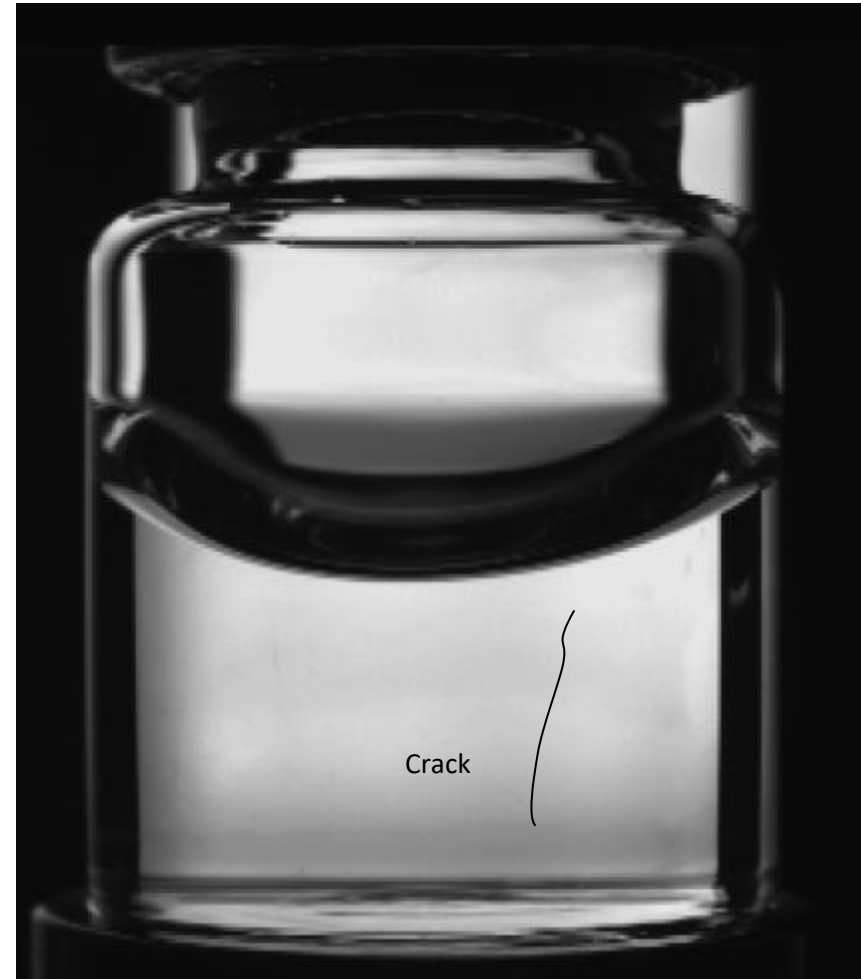
=> Cavitation and wave creation in liquid = seen as defect

Supplier A

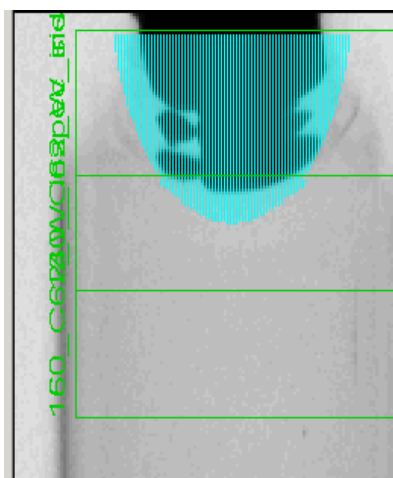


Supplier B

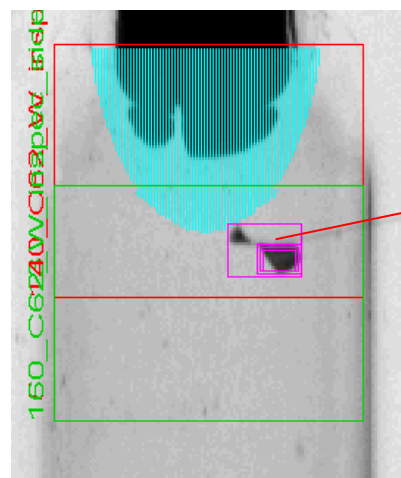




Practical impact of primary packaging impact Shoulder inspection tool and longer stopper impact



Supplier A
Round shoulder
No reflects

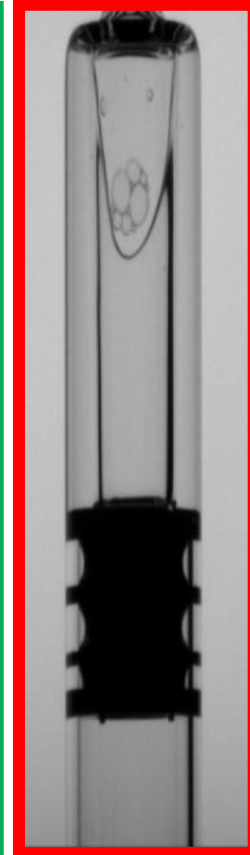


Supplier B
Wave shoulder
many stopper reflects

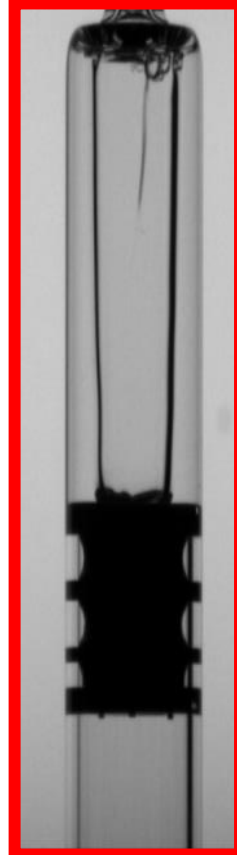
With the mask present for reflects of stopper (blue) the crack control windows is reduced

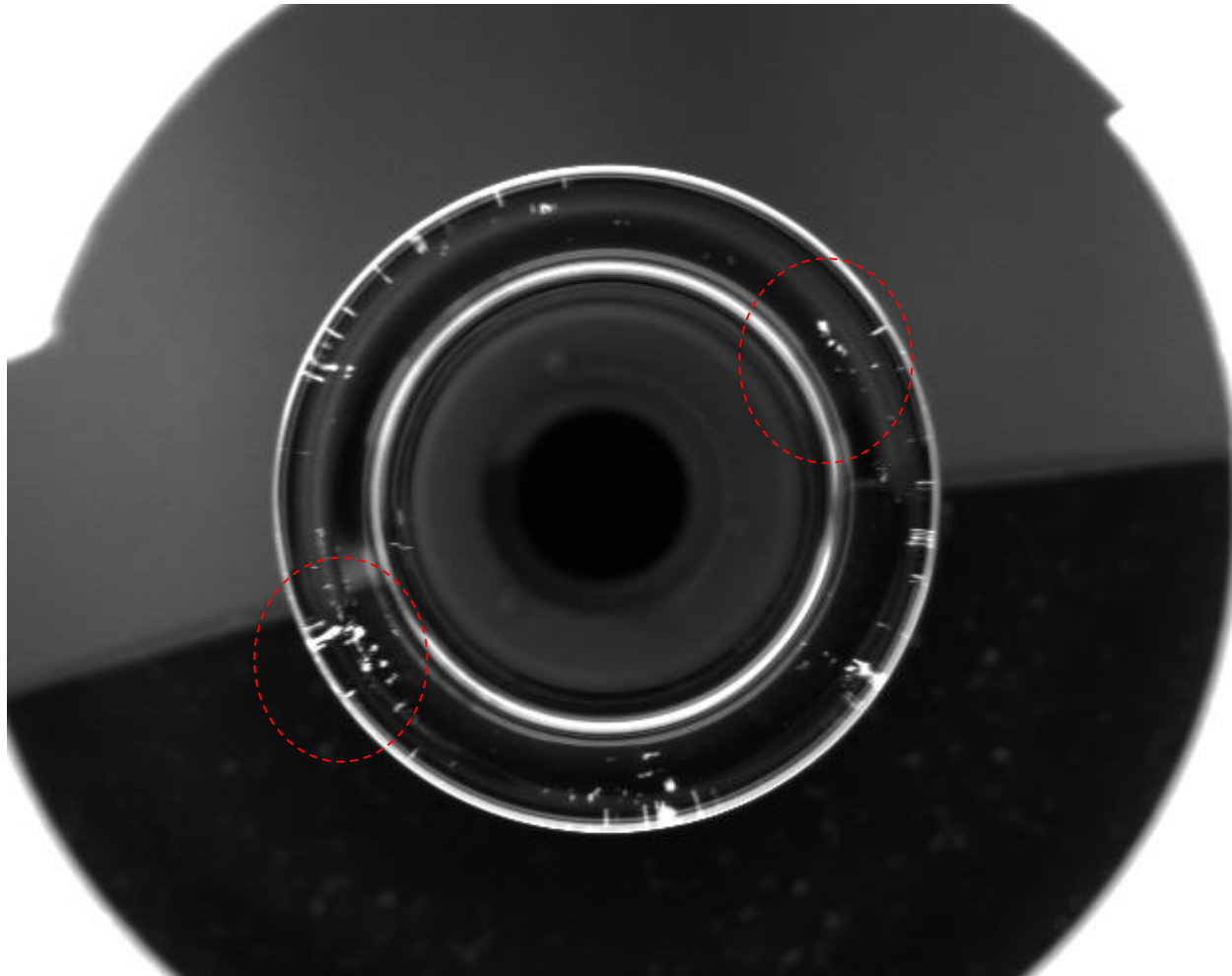


Normal





















Distortion due to waves

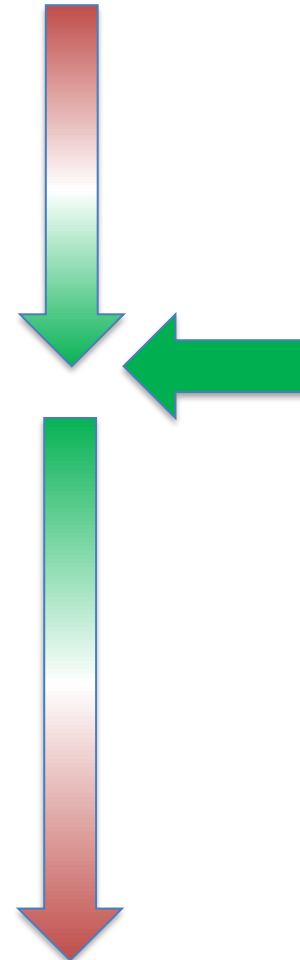






Plunger molding can also create darkness as not in contact to the glass

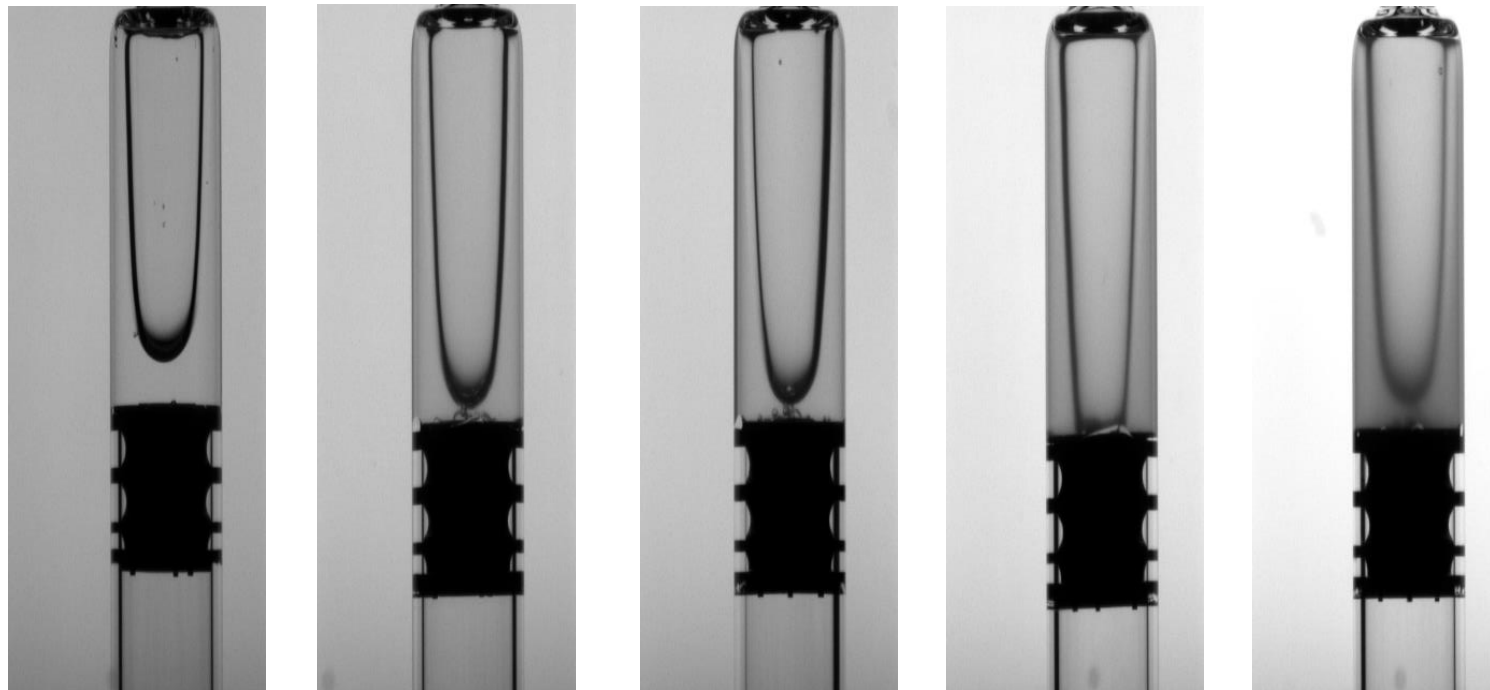
	Image 1	Image 2
735rpm		
2206rpm		
3350rpm		
3676rpm		
4412rpm (4 images)		
5000rpm		
5147rpm		
6618rpm		
7353rpm (4 images)		



For each product fill level/viscosity DOE to conduct to find optimum image stability

Grouping products into families

1. Main aspect is viscosity, since viscosity sets rotation speed
2. Transparency can be compensated with light intensity to get equal images



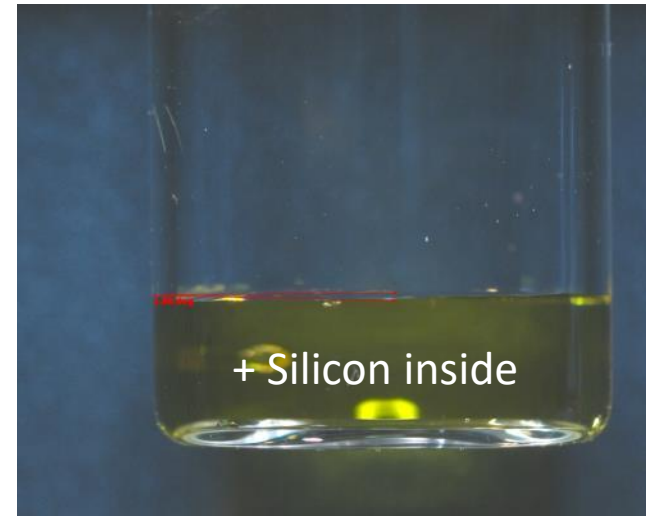
Product A

Product B

Product C

Product D

Product E

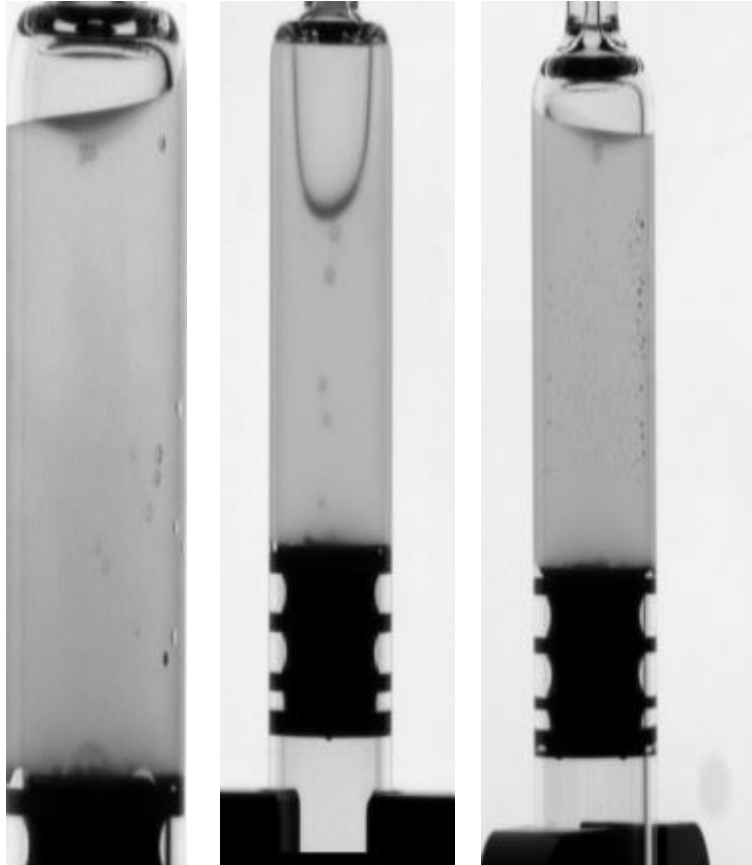


- Product Opacity

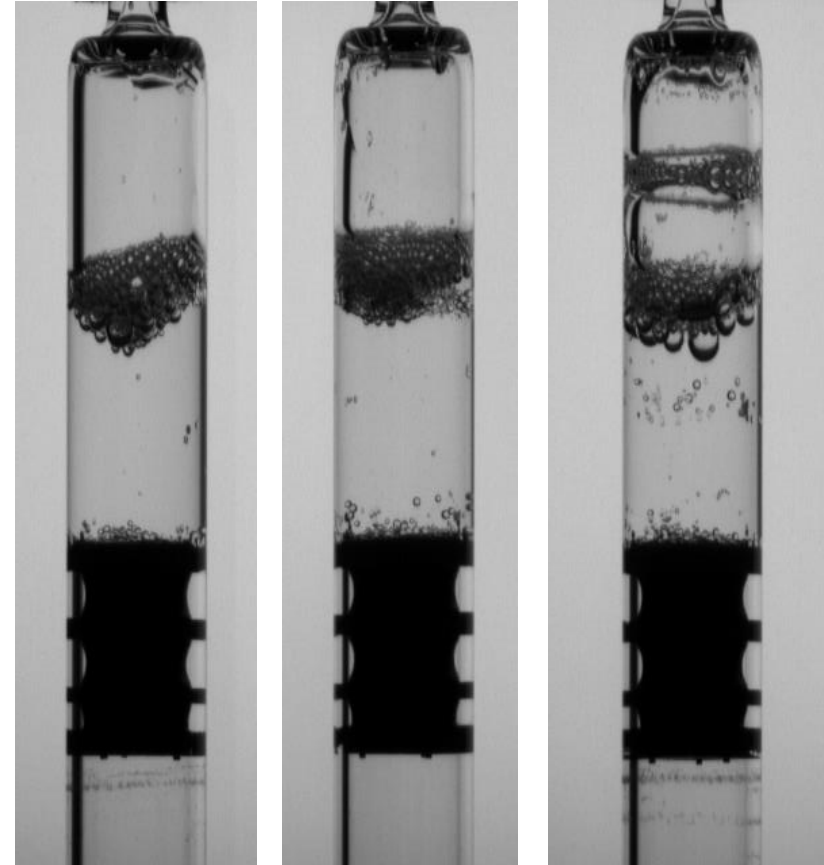


© Copyright PDA Author Romain Veillon

Product micro bubbles



Foaming



- Lyo product aspects

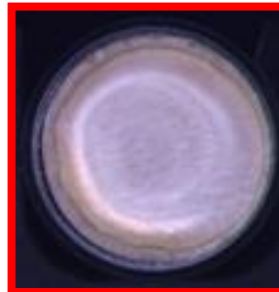
Conform



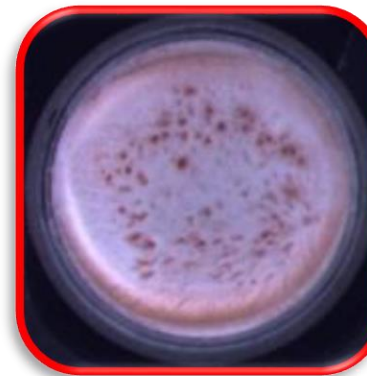
Conform with slight color change side



Fail



Fail



Fail



Key take away:

container	molded vs elongated glass
	reflects / geometry
	condensation
	fill level
	silicon
	Lyo defects
	opacity.....



RECAP

You have learnt

AVI

-



AVI

-