

- **Theory 3: Considerations on primary containers and product properties**



- Vials, Ampoules, Syringes, Blow – Fill - Seal,
- 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



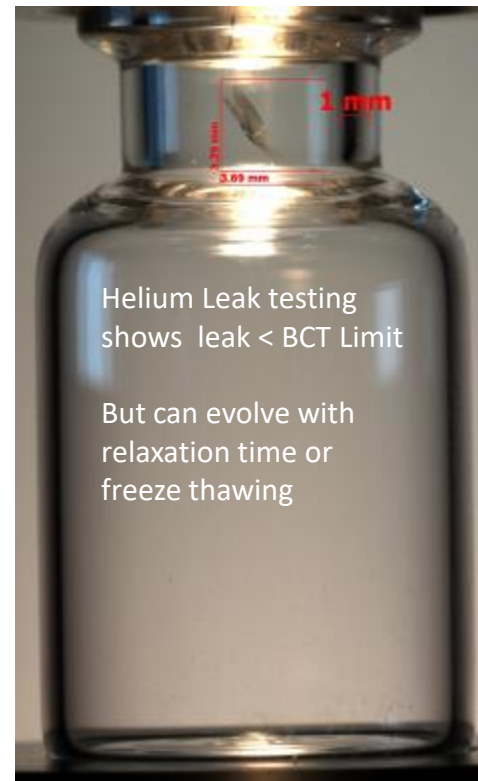
- Tubular glass



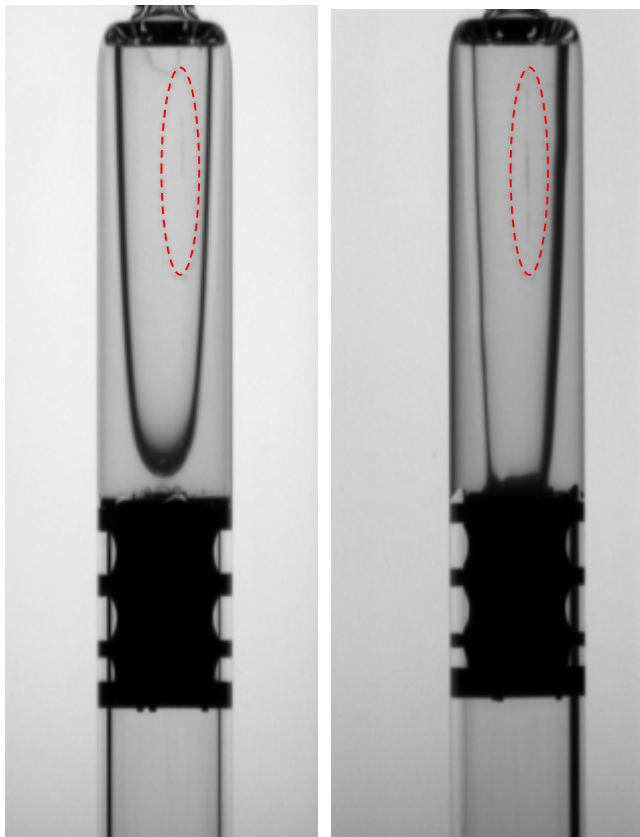
- Crossing crack



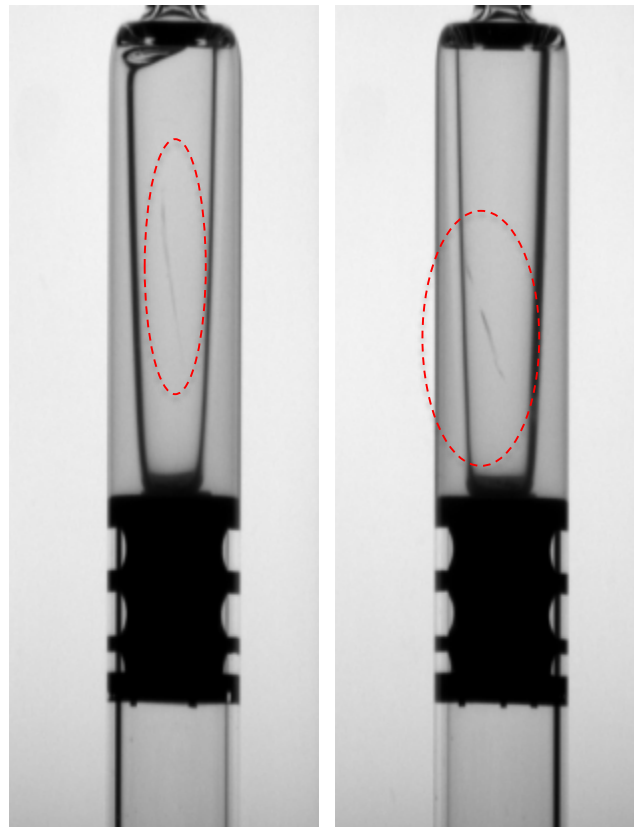
- Non Crossing crack



- **Scratch :**
Metal parts contact

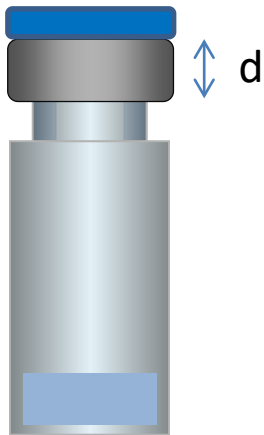


- **Crack:**
Glass to glass contact or thermal shock

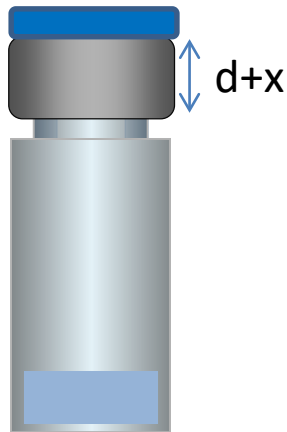


- Theory 3: Considerations on primary containers and product properties
- Defect definition is Key

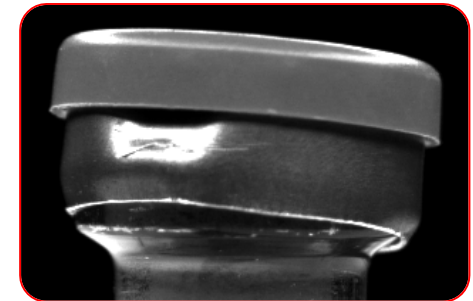
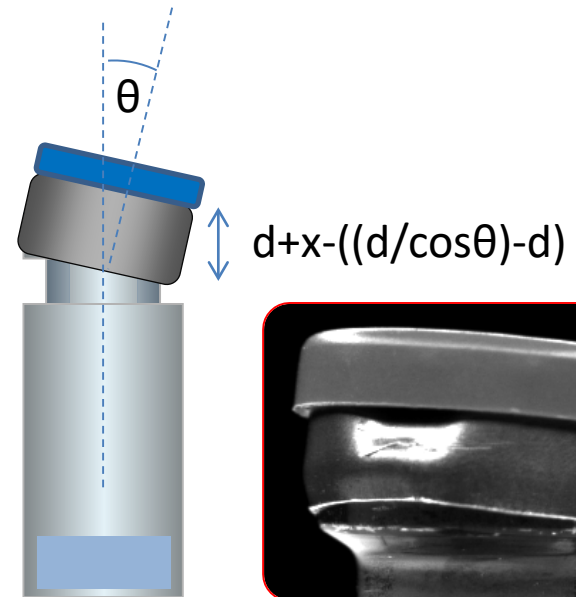
Conform crimp



Not crimped

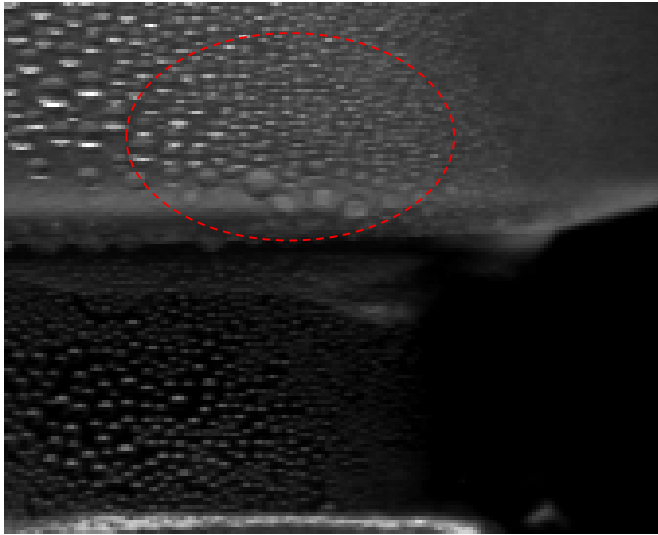


Partially crimped



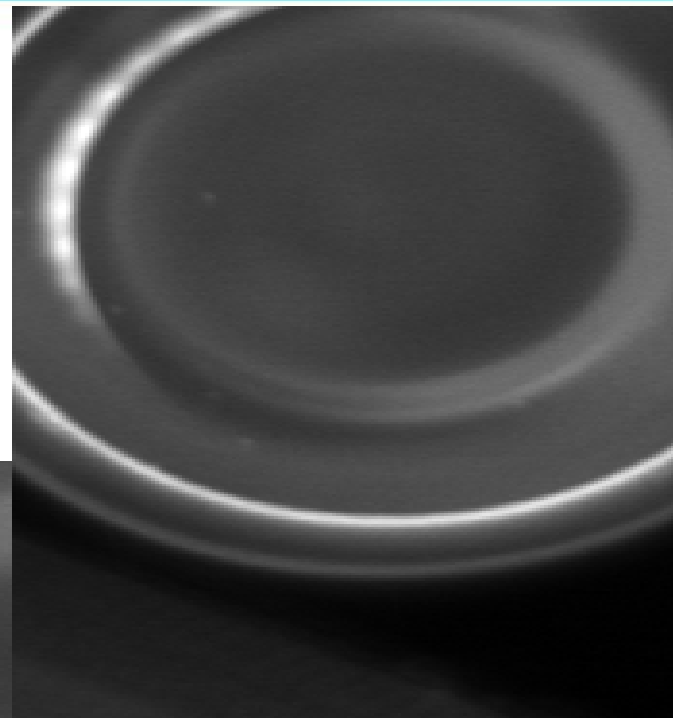
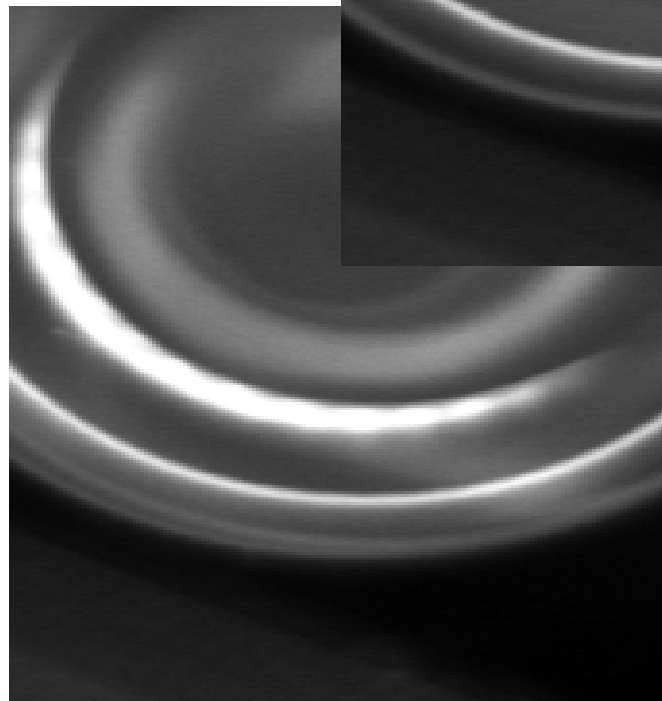
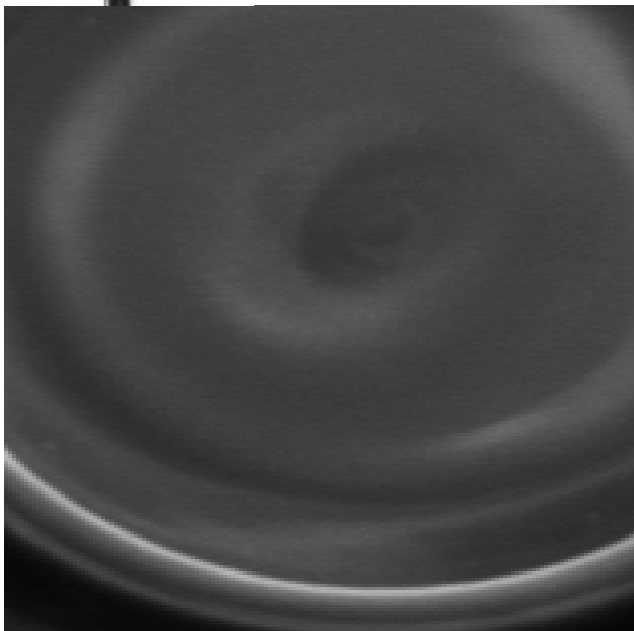
Defective crimping can be defined regarding cap height or angle

- Theory 3: Considerations on primary containers and product properties
- Condensation issues

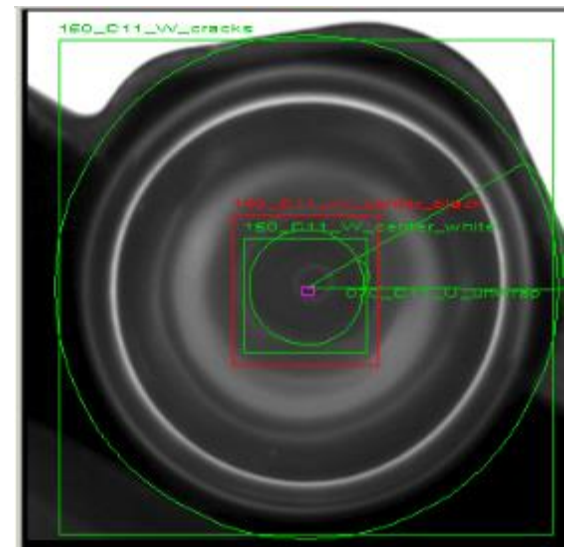
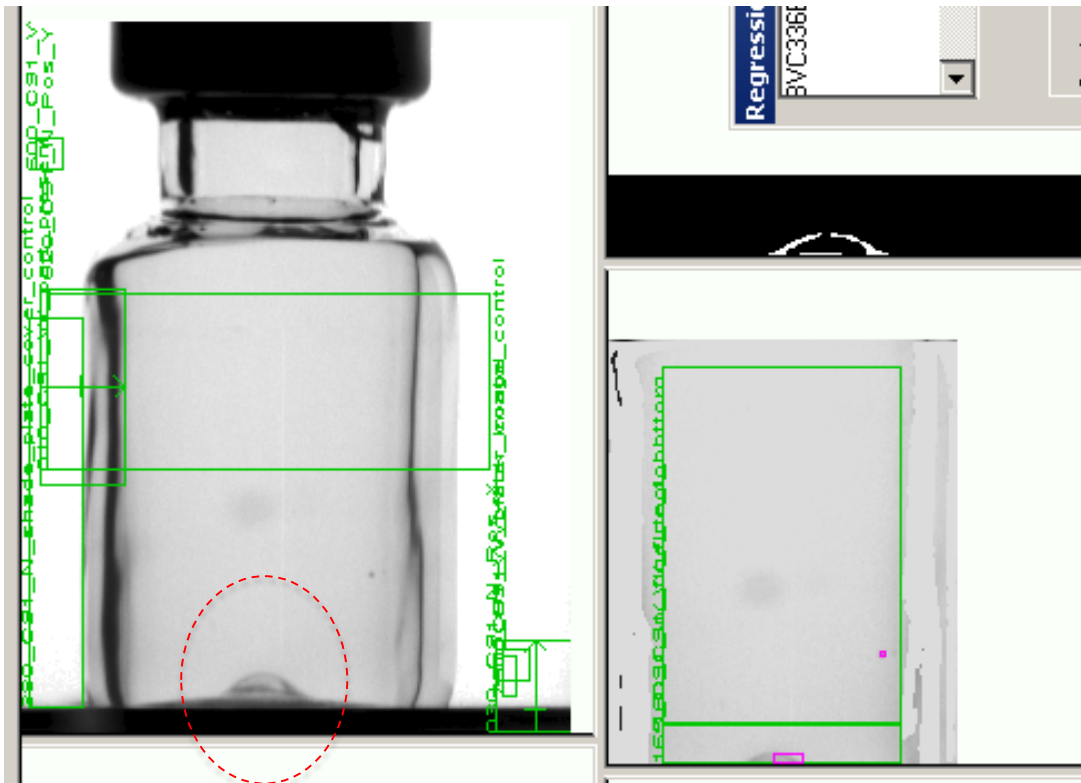


Micro droplet due to condensation will generate false rejects

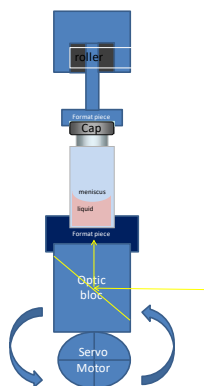
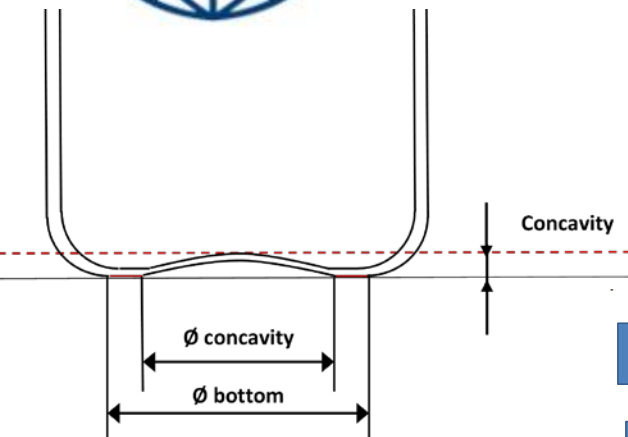
- Theory 3: Considerations on primary containers and product properties
- Glass Bottom shape



- Theory 3: Considerations on primary containers and product properties
- Bubble glass Bottom



- Theory 3: Considerations on primary containers and product properties
- Vial Heel shape => impact on fast rotation



Best case →

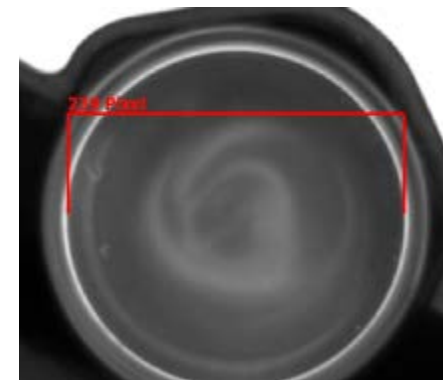


Worst case →

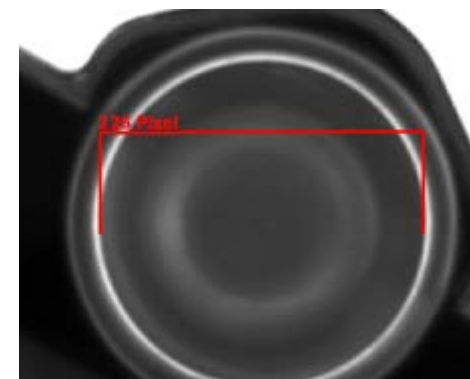


Vials are being rotated fast (3600t/min) from bottom, in order to obtain thin layer suspensions. And 'transparent' window for small particle inspection

Supplier A



Supplier B



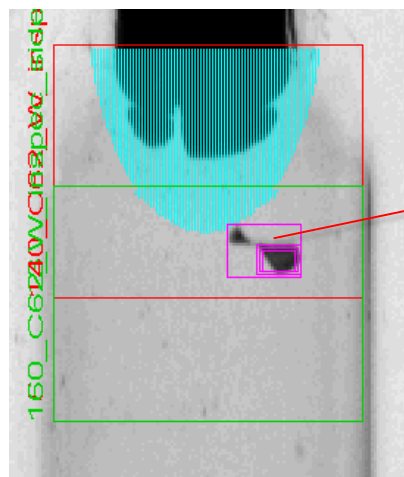
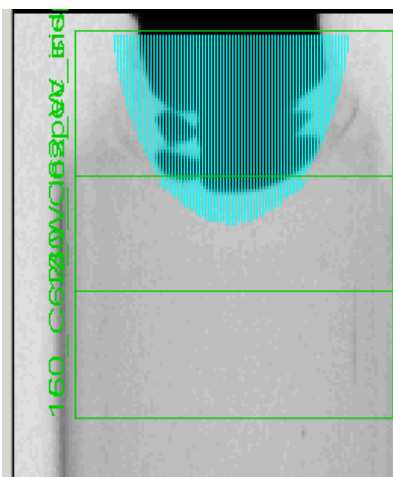
- Theory 3: Considerations on primary containers and product properties
- Vial Shoulder



- Theory 3: Considerations on primary containers and product properties
- Vial Shoulder

Practical impact of primary packaging impact

Shoulder inspection tool and longer stopper impact

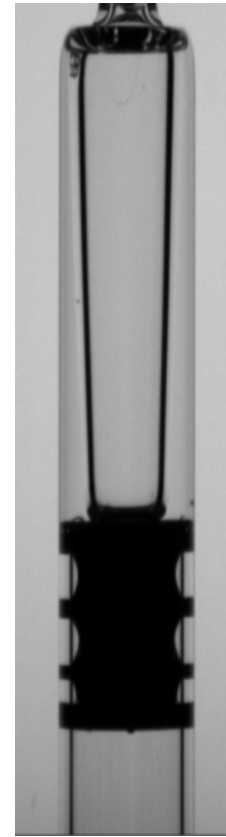


With the mask present for reflects of stopper (blue) the crack control windows is reduced

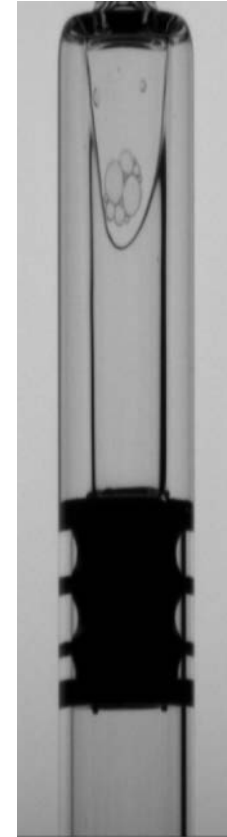
Supplier A
Round shoulder
No reflects

Supplier B
Wave shoulder
many stopper reflects

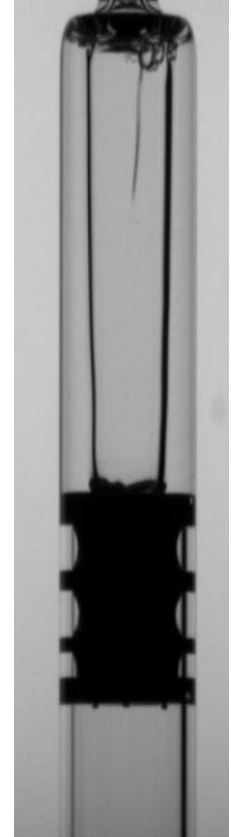
- Theory 3: Considerations on primary containers and product properties
- Syringe perpendicularity



Normal



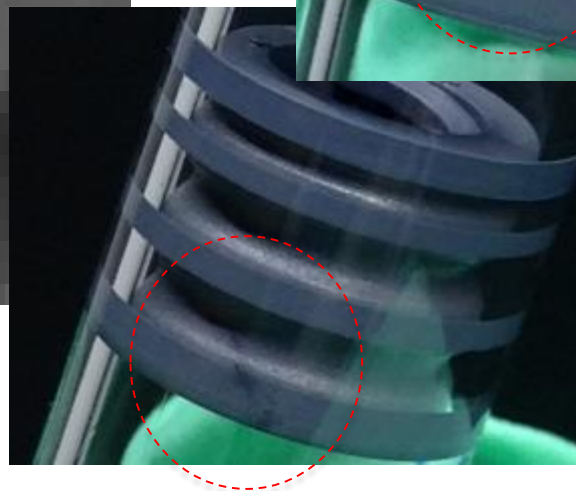
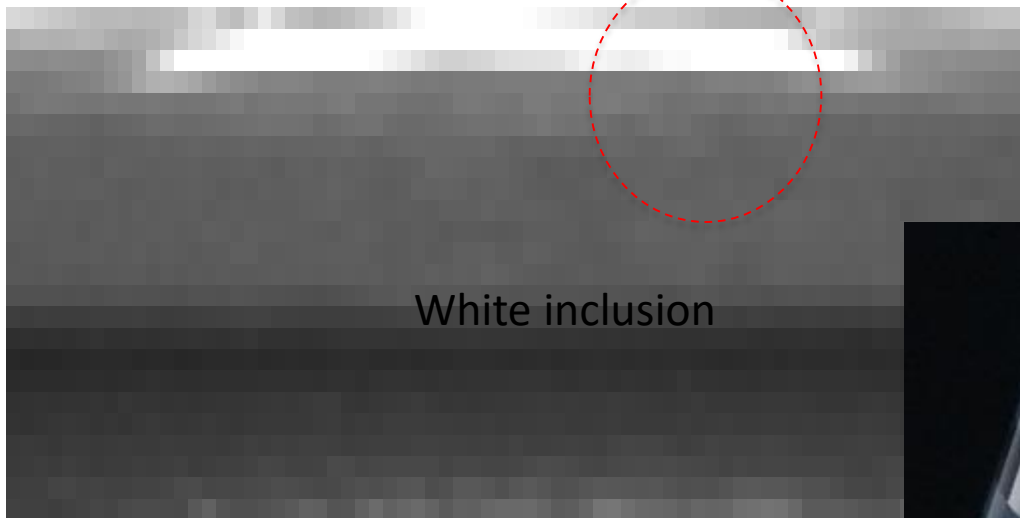
Distortion due to waves



- Theory 3: Considerations on primary containers and product properties
- Air bubbles on flange





















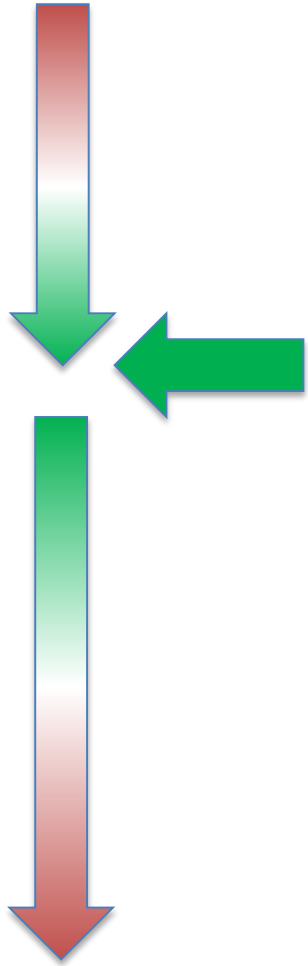
- Theory 3: Considerations on primary containers and product properties
- Plunger inclusion / molding



Dark inclusion

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

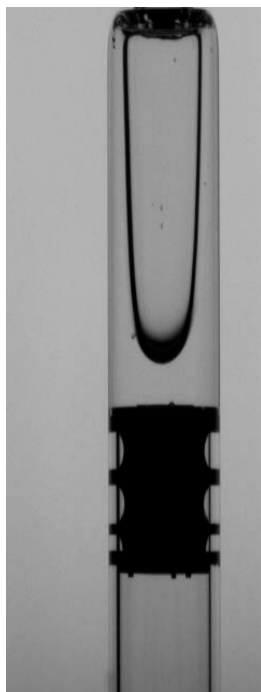
	Image 1	Image 2
735rpm		
2206rpm		
3350rpm		
3676rpm		
4412rpm (4 images)		
5000rpm		
5147rpm		
6618rpm		
7353rpm (4 images)		



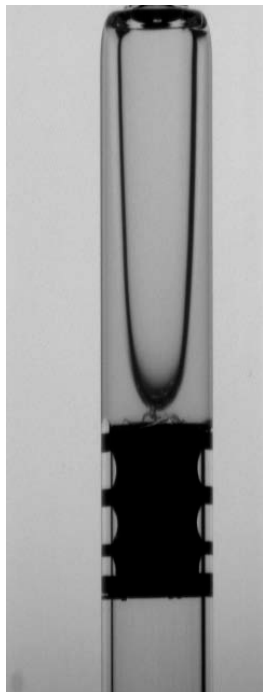
For each product fill level/viscosity DOE to conduct to find optimum image stability

Grouping products into families

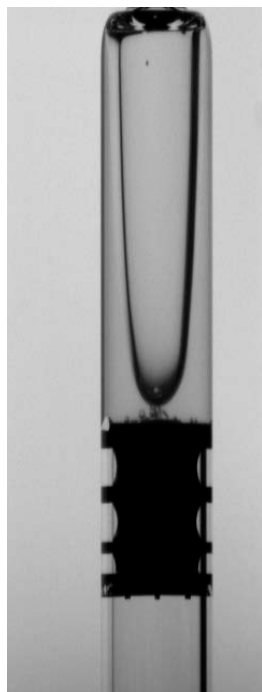
1. Main aspect is viscosity, since viscosity sets rotation speed
2. Transparency can be compensated with light intensity to get equal images



Product A



Product B



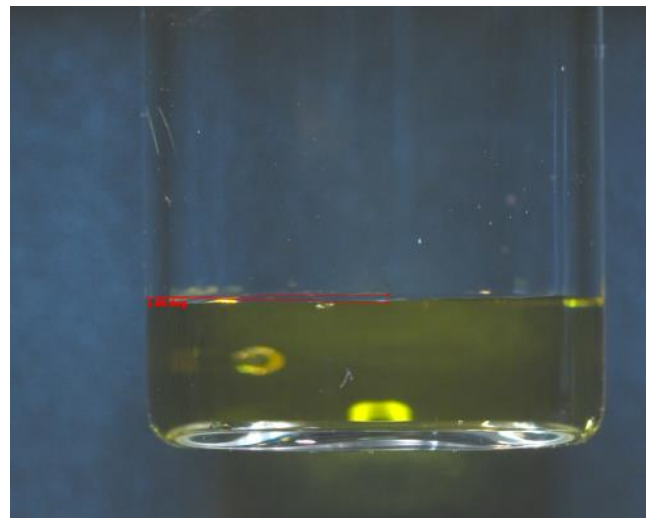
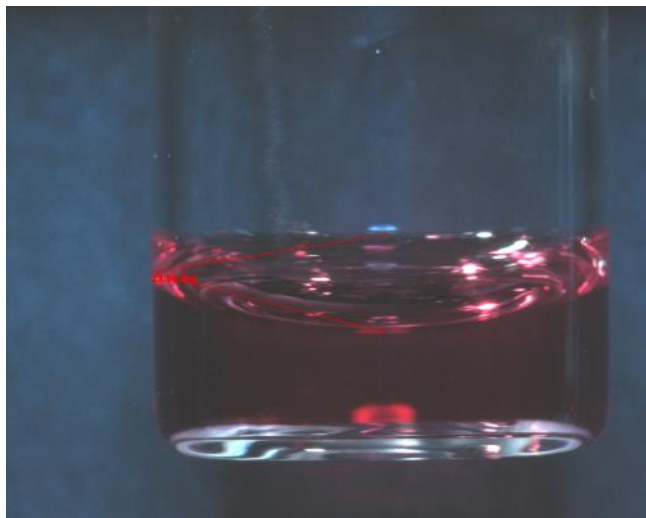
Product C



Product D



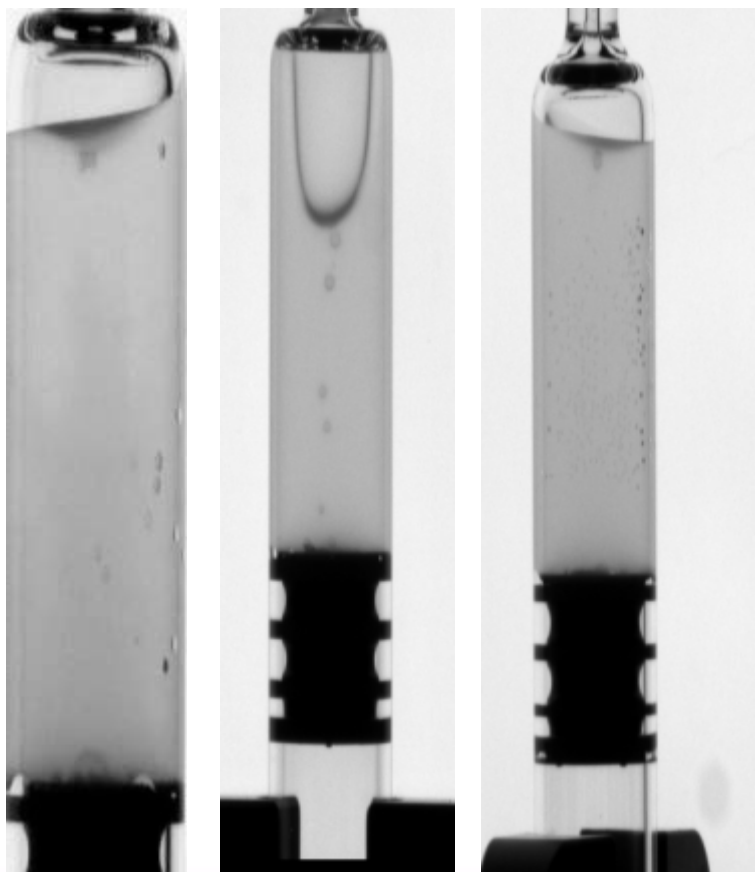
Product E



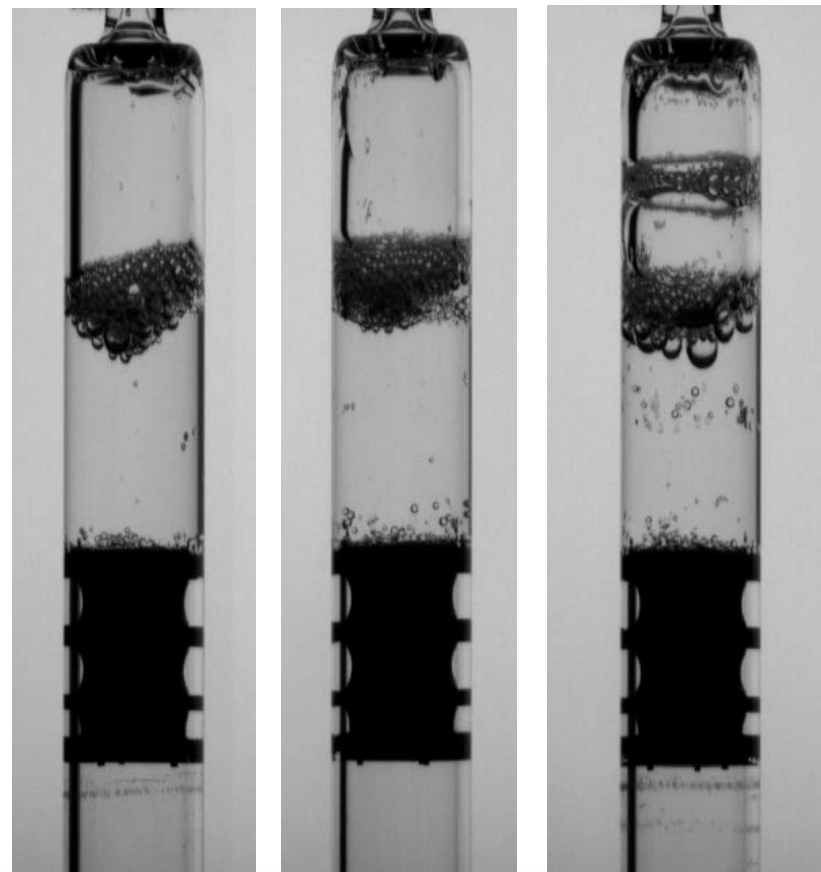
- Product Opacity



Product micro bubbles



Foaming



- Lyo product aspects

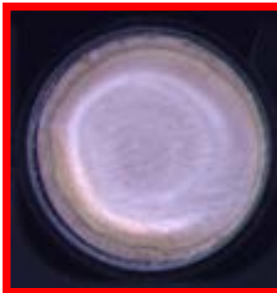
Conform



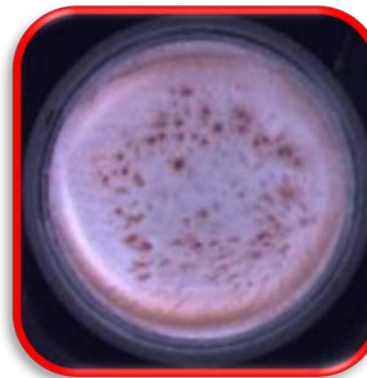
Conform with slight color change side



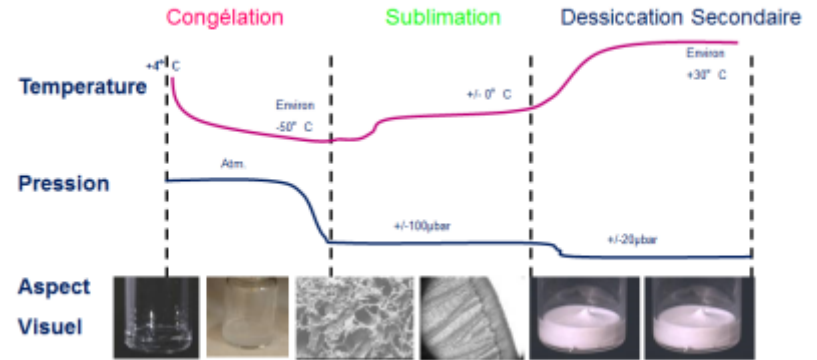
Fail



Fail



Fail



Key take away:

- In this section you have learnt:

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