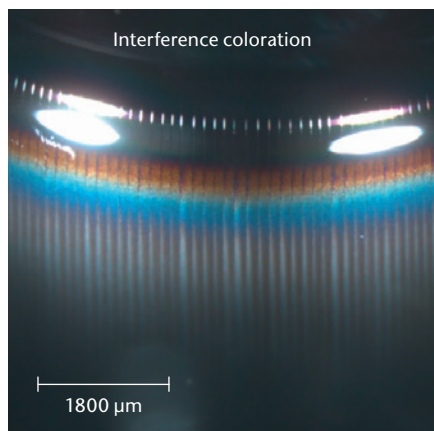# Chemical Durability Tests

Glass delamination in accordance with USP <1660>
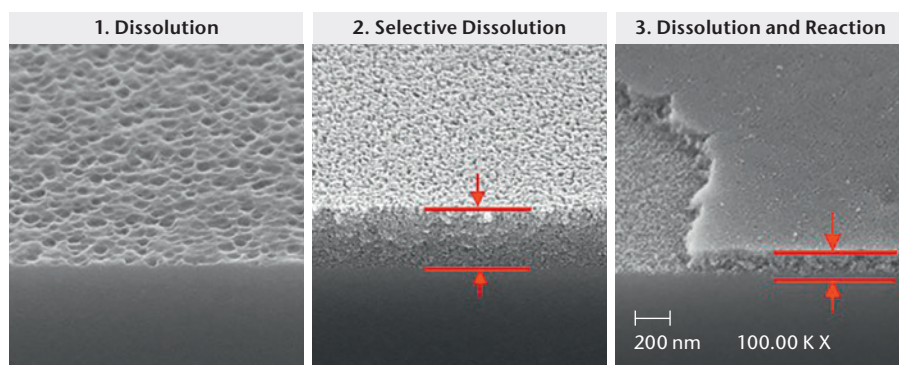

Flake-like particles by visual inspection

Interference coloration

1800 µm

Coloration ring by stereo-microscopy
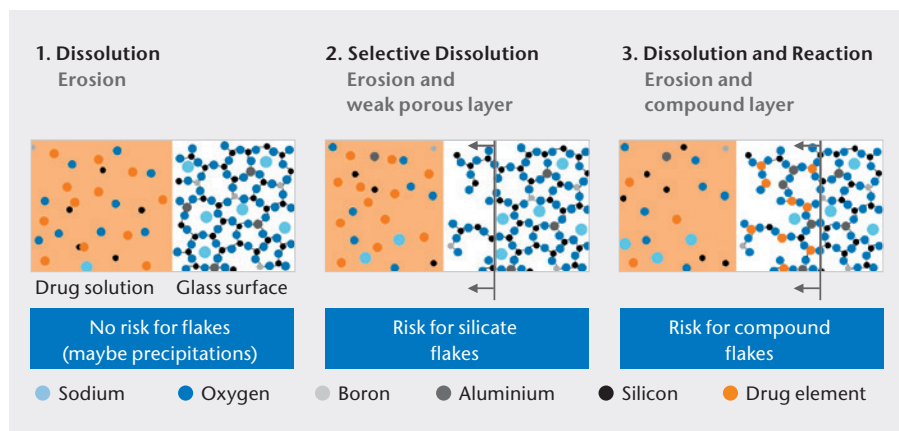
Container Inspection and Screening

- Glass delamination screening starts with visual inspection by eye and camera methods to detect flake-like particles.
- After emptying the container, stereomicroscopy is used to look for changed regions of a container for further surface analysis to determine the worst samples out of a sample set.

1. Dissolution	2. Selective Dissolution	3. Dissolution and Reaction

200 nm   100.00 K X

Element	Citrate buffer (pH 6.0)	Sodium bicarbonate (pH 8.0)	Phosphate buffer (pH 7.0)
B (mg/L)	2.1	2.0	1.1
Al (mg/L)	3.0	0.045	0.058
Si (mg/L)	20.1	8.2	9.2

Glass Delamination Confirmation

- SEM cross section analysis, in combination with ICP-OES/MS solution analysis, is used to determine the extent of attack of glass surface and confirm the mechanism of drug container interaction.

1. Dissolution **Erosion**	2. Selective Dissolution **Erosion and weak porous layer**	3. Dissolution and Reaction **Erosion and compound layer**
Drug solution Glass surface		
No risk for flakes (maybe precipitations)	Risk for silicate flakes	Risk for compound flakes

● Sodium   ● Oxygen   ● Boron   ● Aluminium   ● Silicon   ● Drug element

Drug Container Interaction

- SIMS depth profiling, SEM cross section analysis, and ICP-OES/MS solution analysis is used to determine the mechanism:
  1. Dissolution
  2. Selective dissolution
  3. Dissolution and reaction

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glass made of ideas