

SCHOTT Vials DC (Delamination Controlled)



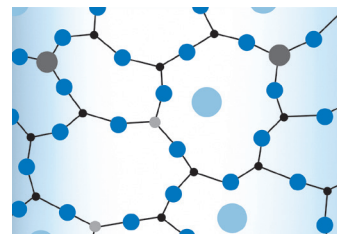
General Product Information

Recent achievements in the field of glass processing technology allowed for the development of highly delamination withstanding Type I glass vials as a SCHOTT TopLine option. The region near the bottom of SCHOTT Vials DC particularly show a unique surface homogeneity and chemical stability. As a result, the liability of this region to delamination is improved. SCHOTT Vials DC comply with all current standards, such as Ph.Eur., USP and JP.

Established and registered products can be filled into SCHOTT Vials DC vials without the need of a new registration of the pharmaceutical product.

Physical & Chemical Properties

Conventional converting processes leads to inhomogeneities on the surface of the glass composition near the inner bottom region of the vial. This zone is highly sensitive to delamination. By using enhanced processing techniques SCHOTT is able to reduce the tendency of delamination.



- Sodium
- Oxygen
- Boron
- Aluminium
- Silicon

Verifications

Surface homogeneity and improved delamination stability

Method:

- Corrosive stressing of the vial
- Analysis of the region near the bottom of the vial by Scanning Electron Microscopy (SEM) with the use of cross section polarized light microscopy.

Autoclaving 4h

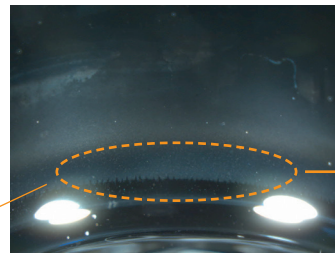
Inspection



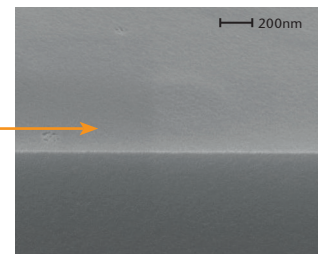
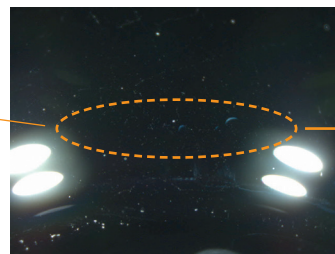
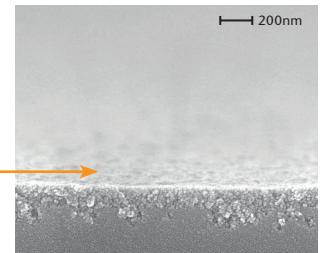
Conventional Type I glass

SCHOTT Vials Delamination Controlled

Optical Stereomicroscopy



Scanning Electron Microscopy



Result:

- Polarized light microscopy reveals colored diffusive areas in the region near the bottom of conventional Type I glass vials
- SEM and various additional studies proved that the extent of the colored diffusive areas correlate with an increased delamination risk
- Under the same test conditions, SCHOTT Vials DC do not show diffusive areas and have a high surface homogeneity (see SEM)



Product Information

Under laboratory conditions the glass corrosive autoclaving step is followed by stereomicroscopy. For production control, stereomicroscopy is replaced by AAS, sodium content determination. The sodium content correlates with the intensity of the colored diffusive area.

SCHOTT Delamination Quicktest

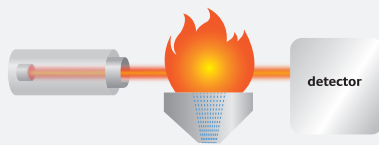
**Autoclaving
Empty head first**
t= 4 h
at 121°C



**Autoclaving
Filled with H₂O**
t= 2 h
at 121°C



AAS (Atomic Absorption Spectroscopy)



Replaces
stereo-
microscopy



Standardized production quality monitoring

Stage 1

Autoclaving induces glass stress in bottom up empty vials. Vials with poor surface homogeneity will be more affected than vials with high homogenous surfaces.

Stage 2

Autoclaving vials filled with water will extract ions similar to ISO 4802.

Stage 3

The extraction solution of stage 2 is analyzed by Atomic Absorption Spectroscopy (AAS) to determine the amount of sodium.

The routinely conducted SCHOTT Delamination Quicktest monitors the product quality and certifies that SCHOTT Vials DC do not exceed the set sodium limit ensuring that the tendency of delamination is reduced.

Verifications

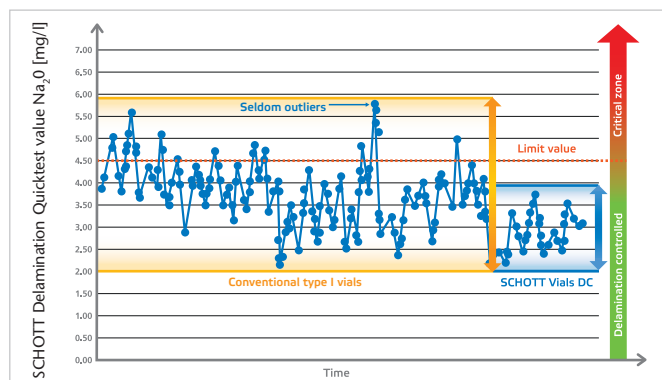
Homogeneity

Method:

SCHOTT Delamination Quicktest

Result:

SCHOTT Vials DC, 2R, have a certified limit of less than 4.5 Na₂O mg/l



Value-adding Product Benefits and Services

Optimized total cost of ownership

High quality vials with low delamination risk ensure a consistent, superior performance throughout the product life cycle.

High glass surface homogeneity and quality

The new processing technique achieves unique glass homogeneity and vial to vial reproducibility.

Applicable to registered products

Conventional vials can be replaced by SCHOTT Vials DC without the need of a new registration of the pharmaceutical product.

Improved delamination stability

Due to the revised surface homogeneity there is a delamination stability of SCHOTT Vials DC compared to conventional vials.

Verified production quality

The stability of the production process is routinely inspected by the patented SCHOTT Delamination Quicktest.

Packaging

- SCHOTT Vials DC are delivered in special trays with optional separators to avoid glass to glass contact
- A standard Euro Pallet (1200 x 800mm) contains 15-27 layers of 9 trays each

Capacity	2 R	4 R	6 R	8 R	10 R
Pieces / tray	344	344	186	186	154