

The Next Generation of Vials

Feature: Delamination under full control



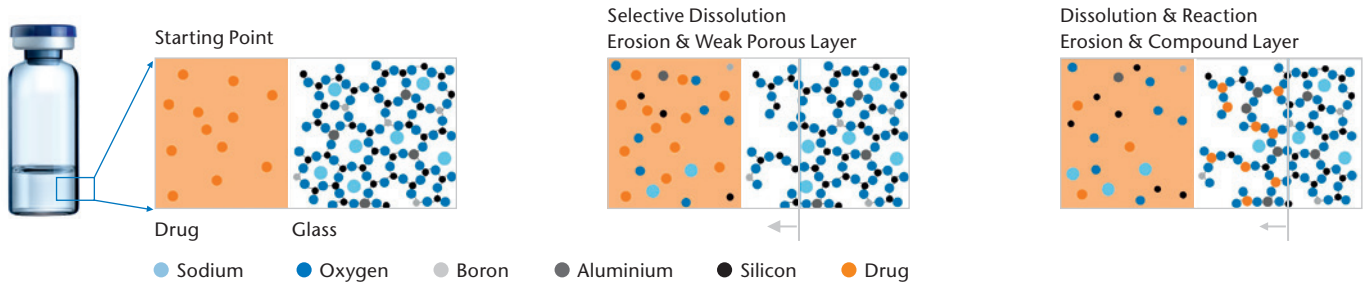
General Product Information

Recent achievements in the field of glass processing technology allowed for the development of highly delamination resistant Type I glass vials as a SCHOTT TopLine option. The region near the bottom of fully Delamination Controlled Quality vials particularly show a unique surface homogeneity and chemical stability. As a result the tendency of delamination is reduced. Delamination Controlled Quality vials comply with all current standards, such as Ph.Eur., USP and JP.

Physical & Chemical Product Properties

Standard converting processes lead 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.

Mechanisms of glass attack and delamination risk



Verifications

The improved properties of Delamination Controlled Quality vials have been tested using the following methods:

- 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
- Results of aging study with 2R vials after 12 weeks with 15% KCl-solution, at 60°C

Results:

- Stereo microscopy reveals colored diffusive areas in the region near the bottom of Standard Quality 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
- Delamination Controlled Quality vials do not show diffusive areas and have a high surface homogeneity (see SEM)

Time	T = 0		T = 12 weeks	
Standard Quality vial	 Stereo microscopy	 SEM	 Stereo microscopy	 SEM reaction zone, approx. 120 nm
	Quicktest® results: 8.0 µg/ml Na ₂ O		Reaction zone: YES	
Delamination Controlled Quality vial	 Stereo microscopy	 SEM	 Stereo microscopy	 SEM
	Quicktest® results: 3.5 µg/ml Na ₂ O		Reaction zone: NO	



Testing Information

SCHOTT has developed the “Dela Sample Kit” to be tested at the customer which combines primary packaging containers of two different quality steps using FIOLAX® glass (Type I borosilicate glass).

	Delamination Controlled Quality vials	Dela Test vials
USP <660> & EP 3.2.1.	complies	complies
SCHOTT Quicktest® limit value	complies	exceeds

Delamination Controlled Quality vials are produced with an improved production process to ensure that the glass surface in the delamination critical wall near the bottom area is homogeneous and therefore less susceptible to delamination. In addition, the SCHOTT Quicktest® is applied to certify that the set sodium limit is not exceeded ensuring that the tendency of delamination is minimized.

The **Dela Test vials** are produced in accordance with regulatory requirements such as EP 3.2.1 and USP <660> surface glass test purposely exceeding the limits defined by the SCHOTT Quicktest®, which is a measure for an increased vulnerability in the wall near the bottom area. This type of vial can be considered as vial with an increased risk of delamination and can therefore be used for positive testing.

Please note that SCHOTT does not recommend primary packaging containers with reduced surface alkalinity (low EP) value only to minimize the risk for delamination.

USP 1660 recommends predictive screening studies

Delamination of glass flakes in primary drug packaging has become a serious quality concern in recent years. Chapter <1660> of the United States Pharmacopeia (USP) therefore recommends performing predictive screening studies of the drug formulation with the glass container to evaluate the risk of delamination in an early stage of the drug development. The results of such predictive studies allow a graduated assessment of the delamination risk on the basis of early indicators of this phenomenon and help to select appropriate container/formulation systems to proactively prevent delamination.

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

Standard Quality vials can be replaced by SCHOTT Delamination Controlled Quality vials without the need for a new registration of the pharmaceutical product.

Improved delamination stability

Due to the revised surface homogeneity, SCHOTT Delamination Controlled Quality vials show greater delamination stability compared to Standard Quality vials.

Verified production quality

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

Ready-To-Order

The Delamination Controlled Quality vials are delivered in special trays with optional separators to avoid glass-to-glass contact. A standard Euro Pallet (1200 x 800 mm) contains 15 – 27 layers of 9 trays.

Capacity	2 R	4 R	6 R	8 R	10 R	20 R	30 R
Pieces/tray	344	344	186	186	154	99	99