




## A new dimension of safety

They are small. If not tiny. Sometimes they are even barely visible. In fact, it can take weeks, months or years before they appear: minute glass flakes, which might detach from the inner surface layers of pharmaceutical vials during a drug's shelf life. This phenomenon is known as "delamination." It is rare and only occurs under certain circumstances. But it still poses a danger for patients if glass flakes are injected into the bloodstream.

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### Challenge



A single recall can cost a pharma company up to

**250 million US Dollars**

The US Food and Drug Administration (FDA) reacted by implementing recalls. For the respective manufacturers, this seemingly minor occurrence can then have costly consequences.

There is good news, however. New packaging concepts help bring delamination under control with SCHOTT offering perhaps one of the most innovative ones.

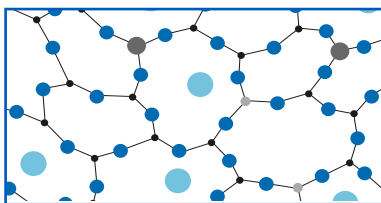


## Optimized step-by-step

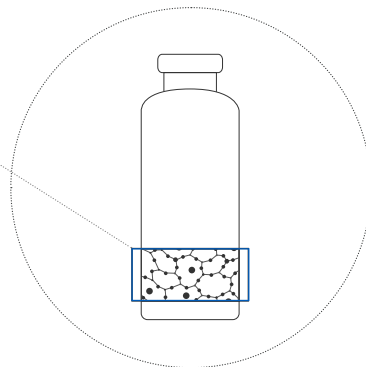
Delamination is nothing new for the pharmaceutical industry, and the use of glass as a packaging material has never been questioned. On the contrary; pharma glass offers very high chemical resistance – and thus is perfectly suitable for storing medications safely.

Yet, there is still a risk of unfavorable interactions under certain conditions. The glass surface of the container and the drug interact and can cause glass delamination over time.

It is this very process that SCHOTT has investigated very thoroughly. Based on its findings, the company has launched two unique innovations:

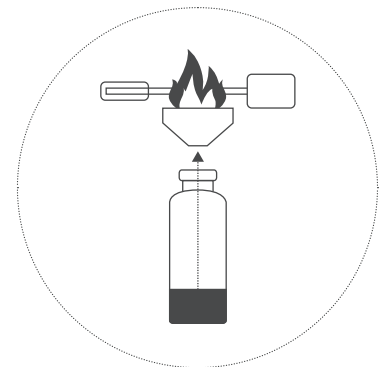


Unique homogeneous inner glass surface ensures chemical stability



### SCHOTT Vials DC (Delamination Controlled)

Pharmaceutical vials that minimize the risk of delamination

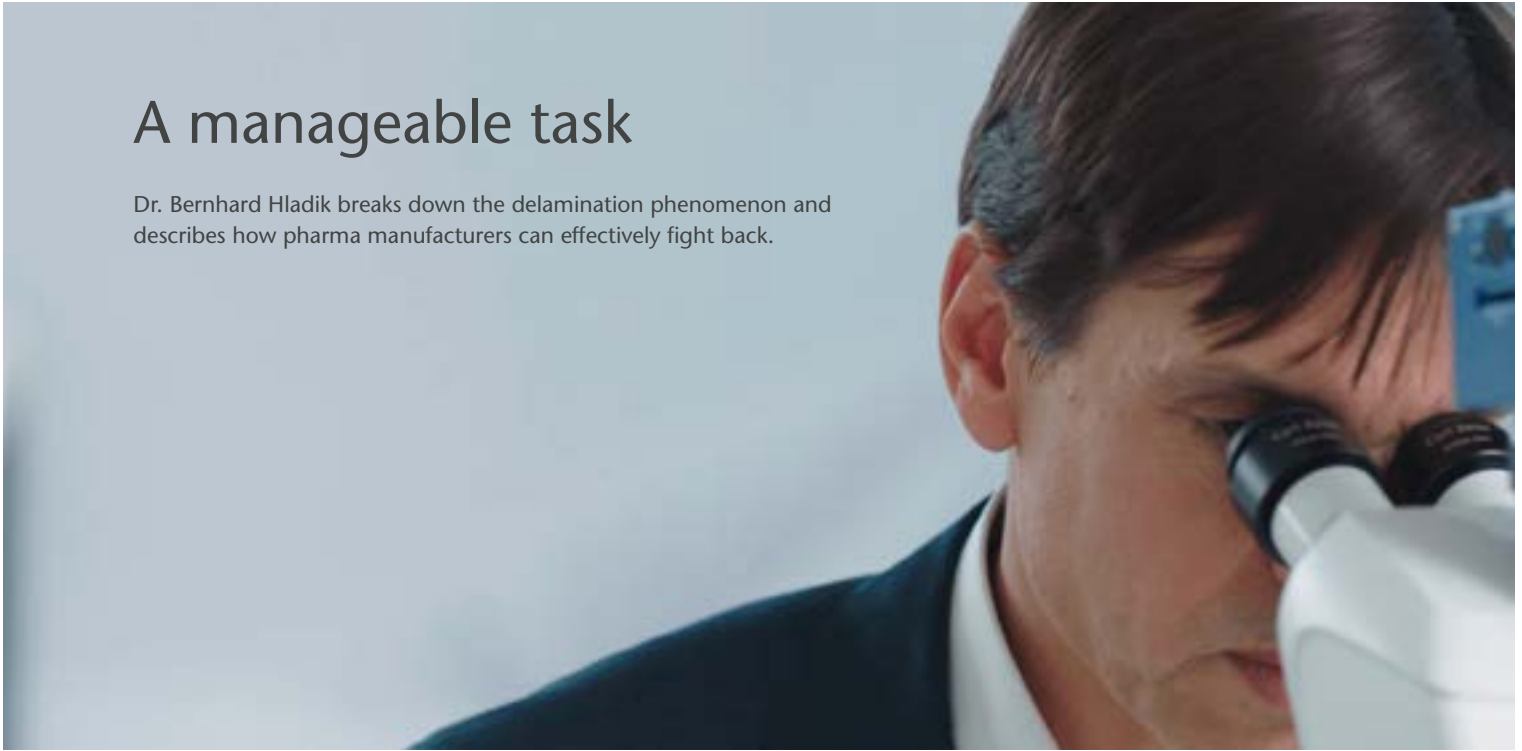


### SCHOTT Delamination Quicktest

A time lapse test process that monitors this property.

## A manageable task

Dr. Bernhard Hladik breaks down the delamination phenomenon and describes how pharma manufacturers can effectively fight back.



“Why does glass delaminate in the first place? A lot of research has been done to learn what causes this. Conventional converting processes can lead to inhomogeneous surfaces inside a vial and thus make the glass more vulnerable. With this in mind, we have developed a way to produce vials to ensure that this problem will not occur later on.”

— Dr. Bernhard Hladik, Senior Product Manager responsible for SCHOTT Vials DC

## Under Control

Every new process in the pharmaceutical industry needs to be validated, which ends up costing pharma companies a lot of time and money. This is why SCHOTT concentrated on solving this problem without actually making any significant changes.

When it comes to SCHOTT Vials DC, we have optimized established production processes to the point where they consistently lead to highly homogeneous inner surfaces in the vials.



## It's the material that matters.

FIOLAX® Type I glass with high hydrolytic resistance.



The first step is to select the right type of glass by focusing on its chemical and hydrolytic resistance.

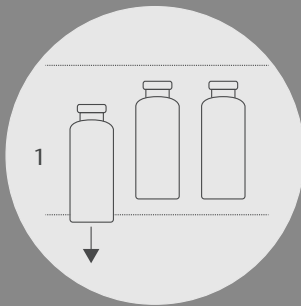
This criterion is met by the glass tubing known as FIOLAX®, a pharmaceutical glass product that was invented by SCHOTT more than a century ago and has since become the de facto standard in the pharma industry. Its exceptional properties are the basis for SCHOTT Vials DC – with the benefit of higher safety.

# Knowing the limits

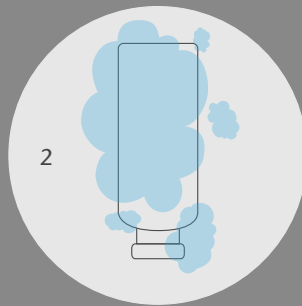
SCHOTT was able to determine the measurable risk of delamination by performing a simple trick. The vials were turned upside down and then stressed using hot water vapor. The resulting critical zones were then measured conventionally by using stereomicroscopy. Drawbacks: this requires the trained eye of a professional and is not objective. Furthermore, it takes time. Too much time, in fact, to be able to intervene in the current production setup.

Through rigorous research, SCHOTT has developed an even quicker objective test method: the SCHOTT Delamination Quicktest

random samples from production



treatment with water vapor



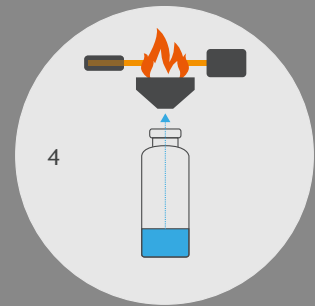
4 hours  
121 °C  
in an autoclave

sodium extraction



2 hours  
121 °C  
in an autoclave

quantification of sodium content



flame spectrometry

## Results obtained within 8 – 10 hours

The key feature? Thanks to this robust statistical process, it is now possible to determine a threshold value for the risk of delamination. Thus, 4.5 mg of sodium oxide per liter is the limit for a 2 mL vial. If the value is lower, the vial is able to withstand the onset of delamination.

We monitor the limit by performing random checks on the current production. In the event that an alarming value is reached, we can intervene very quickly.



## New Dimensions

The concept is receiving a lot of attention from the pharma industry. No wonder, given that SCHOTT Vials DC have proven their performance in various screening studies.

“Delamination Controlled” vials with a standard ISO size of 2 to 10 milliliters are currently available from stock. They can even be used with approved medications without having to undergo new registrations with the respective authorities. We can even develop individual formats to meet specific needs. In fact, we have proven this flexibility in recent customer projects.



Let's make medications even safer.

## What's your next milestone?

### Contact

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Downloads



Data sheet Vials DC



Minimize delamination risk  
(World Pharma Frontiers)

Links



More about delamination



More about SCHOTT Vials and Pharmaceutical  
Packaging