



SCHOTT
glass made of ideas

SCHOTT
pharma services

SCHOTT is an international technology group with more than 125 years of experience in the areas of specialty glasses and materials and advanced technologies. With our high-quality products and intelligent solutions, we contribute to our customers' success and make SCHOTT part of everyone's life.

SCHOTT pharma services provide analytical laboratory services for pharmaceutical packaging. Our unique combination of specialized analytics and expertise in materials, products, and processes enables us to support pharmaceutical companies in finding solutions for the most challenging packaging requirements.

SCHOTT pharma services

Specialized analytics for pharmaceutical packaging

SCHOTT pharma services specializes in the following area:

Chemical Durability

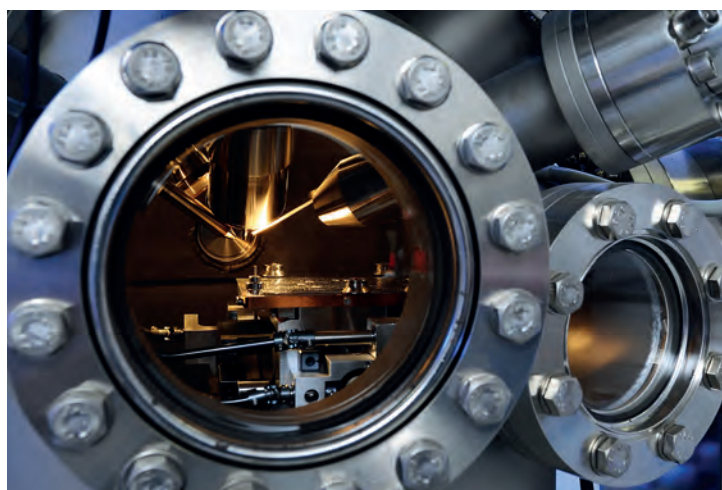
- Glass delamination screening
- Accelerated compatibility testing
- Particle analysis
- Pharmacopoeia testing (USP, EP, JP)

Mechanical Stability

- Fractography and breakage analysis
- Container strength testing
- Stress analysis

E&L + System Performance

- Extractables & Leachables
- Functionality testing
- Tungsten analysis
- Siliconization testing



Benefits:

Specialized Analytics

We are equipped with a unique set of **state-of-the-art analytical equipment** dedicated to the specific needs of glass and polymer packaging characterization.



Interpretation Skills

Our blend of expertise in **materials, products & processes** is key to correctly interpret analytical data and draw in-depth conclusions.

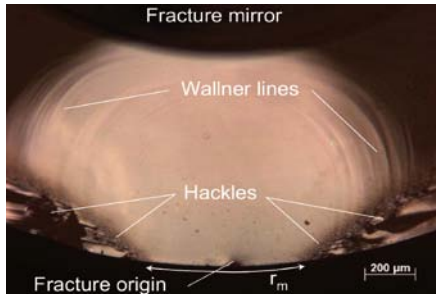


Comprehensive Solutions

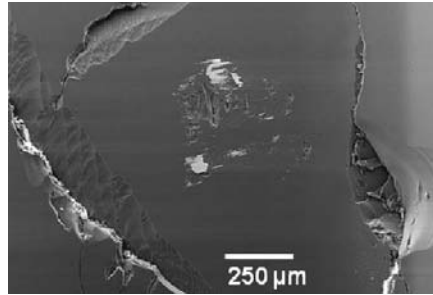
We find smart solutions to the most **challenging packaging issues** so they are avoided in the future.

Mechanical Stability Tests

The basis for selecting the packaging that best meets your specifications



Fracture surface of a broken syringe revealing fracture markings



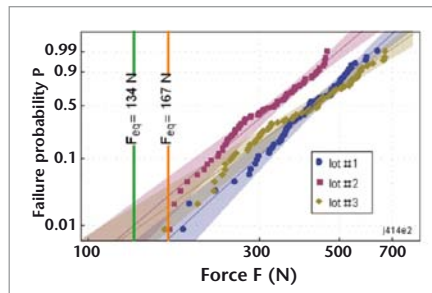
Contamination in the vicinity of the fracture origin as cause of breakage

Breakage Analysis – Fractography

Broken samples and cracks tell stories and leave behind clues. By applying optical and scanning electron microscopy we determine the origin and propagation of glass breakage. Clear evidence of the root cause can be drawn and the applied force that lead to the failure can be determined.



Broken vial after burst pressure test



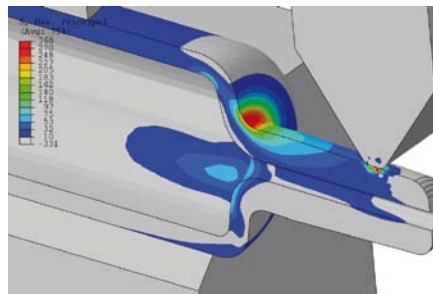
Probability of flange breakage in auto injector for different drive springs

Strength Testing

Strength testing predicts the probability of fractures to glass containers. Samples of different manufacturers and different lots can be compared and evaluated. Burst pressure testing reveals the weakest spot of a container, while specific tests target critical areas like the flange or cone.



Stress distribution in vial that was not completely relieved after hot forming



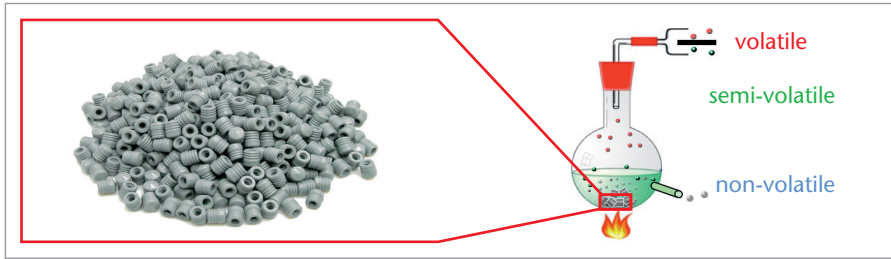
Simulation: Stress distribution in flexural loading of the syringe cone

Stress Analysis

It is said that glass, as a brittle material, retains a memory. Any mechanical impact such as glass to glass contact, that it experiences will be saved as a surface defect. These defects do not heal and consequently the accumulated damages enhance the probability of breakage. Advanced analytical methods can reveal the inherent stress in order to determine weak spots.

E&L + System Performance Tests (1)

Helping you to understand the performance of your container system

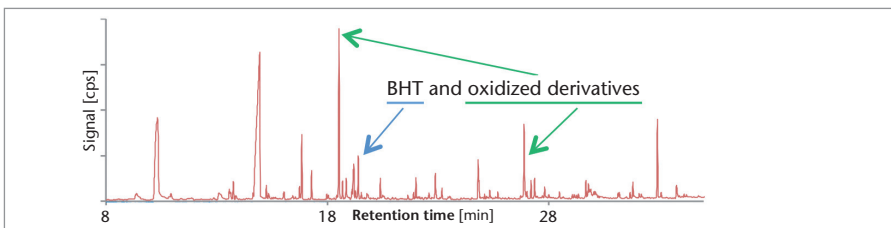


Typical stoppers used as primary packaging material

Extraction of container closures

Extractables Study

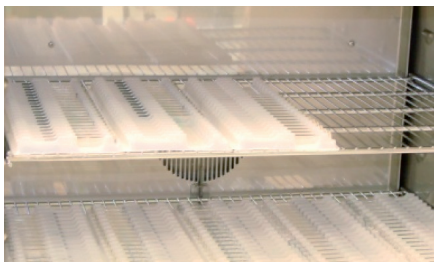
Customer oriented extractables studies for determination of inorganic (including cations and anions) and organic substances extracted out of primary packaging materials. These substances are potentially hazardous directly or after interaction with the drug formulation.



Chromatogram of leachables testing with an antioxidant in different oxidation states

Leachables Study

Determination of leachables and cross reaction products after storage in different containers under standard conditions. All analyses are performed with state-of-the-art equipment.



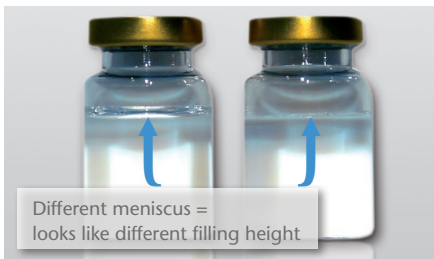
Storage under accelerating conditions (e.g. higher temperature)



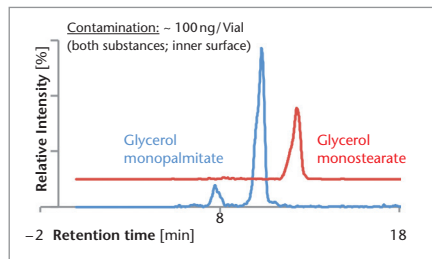
Inspection of stored containers

Accelerated Leachables Study

Determination of leachables after storage under accelerated conditions. First information about leachables after a few weeks compared to stability storage times of up to 36 months.



Vials with different meniscus, but same filling volume causing problems in inspection system



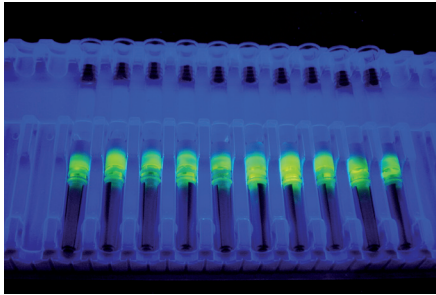
Chromatogram of an extract from a vial with bad wetting behaviour

Secondary Packaging Material

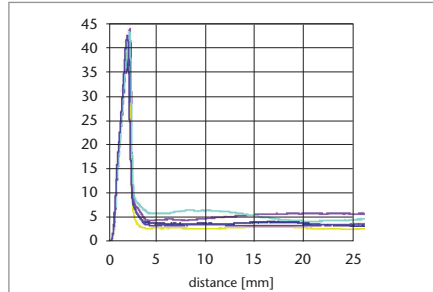
Long-term storage or accelerated storage of containers in combination with secondary packaging material. Determination of volatile or semi-volatile organic contamination.

E&L + System Performance Tests (2)

Helping you to understand the performance of your container system



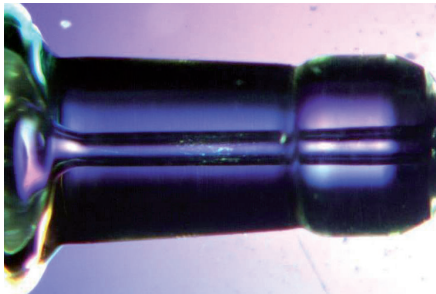
Fluorescent dye to verify container closure integrity



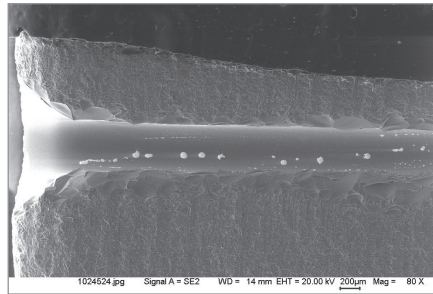
Testing breakaway and gliding forces of syringes

Functionality Testing

Container closure integrity, permeability, leakage, dye ingress, axial compression, and functionality tests including breakaway and gliding forces, tip cap removal, tip cap leakage, needle penetration, or pull force tests are performed on a routine basis.



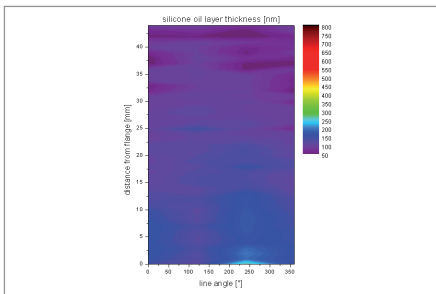
Tungsten particles in needle channel by Stereo Microscopy



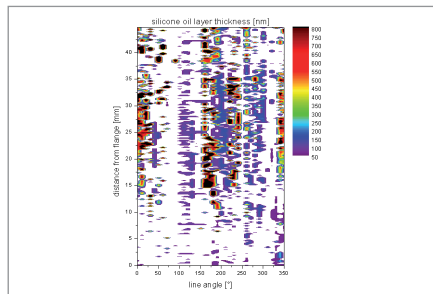
Tungsten particles in needle channel by Scanning Electron Microscopy

Tungsten Analysis

Tungsten residues in syringes are a major concern for biotech products. In order to assess potential risks we offer comprehensive characterization of tungsten contamination and also provide spiking solutions to test the actual effect on the drug product.



Adequately distributed silicone oil



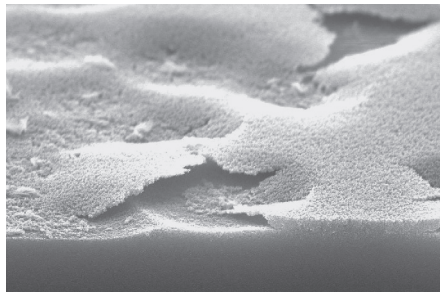
Inadequately distributed silicone oil

Siliconization Testing

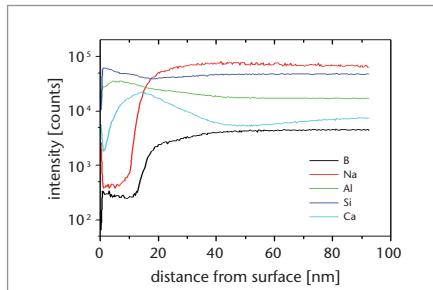
Free silicone (i. e. small silicone oil droplets detachable from the silicone layer) is quantified by wet chemical methods. The total amount of silicone is determined by Soxhlet extraction and spectroscopy. We use a reflectometry system to map the thickness distribution of the silicone oil layer.

Chemical Durability Tests

Screening packages to assess and avoid potential risks



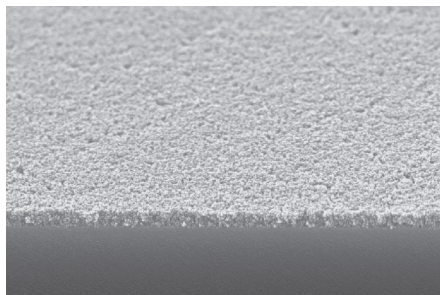
Delamination of the container wall by Scanning Electron Microscopy



Elemental composition of surface near layer with B, Na depletion due to chemical attack

Delamination Screening

Do you see a risk of glass delamination for your products? We have developed a delamination screening package aligned with USP 1660 guidance to assess the likelihood for delamination occurring during the shelf life of your product. A combination of tests which investigates the solution, the container surface, and the surface near region allow for risk assessment.



One form of delamination is linked to a porous reaction layer



Corrosion effects: glass flakes

Accelerated Compatibility Testing, Spiking Studies

After only a few days instead of months or years, tailored accelerated stress tests can reveal the suitability of the given formulation or placebo with the intended container. Spiking studies are performed to assess the impact of leached compounds on particle formation or aggregation.



Setup for dye ingress test



Alkalinity test prior to vials being autoclaved

Pharmacopoeia and Industry Standards Testing

Standardized testing with pharmacopoeia (US/EP/JP) and industry body (ISO, DIN, ASTM) methods is routinely required. We offer many tests including alkalinity, hydrolytic resistance, glass composition, transmission, needle conformity, stopper conformity, and particulate counting.

State-of-the-Art Analyses

Highly sophisticated and precise analysis methods for your support

Below you will find a selection of our analytical testing methods:

E&L and System Performance Tests

- GC-MS Gas Chromatography – Mass Spectrometry
- GC-FID Gas Chromatography – Flame Ionisation Detection
- HS-GC Headspace – Gas Chromatography
- TD-GC Thermal desorption – Gas Chromatography
- LC-MS-IT-TOF Liquid Chromatography with high resolution Mass Spectrometry (MSⁿ)
- LC-DAD Liquid chromatography with UV/VIS detection
- IC Ion Chromatography
- ICP-OES Inductive Coupled Plasma – Optical Emission Spectrometry
- ICP-MS Inductive Coupled Plasma – Mass Spectrometry
- F-AAS, GF-AAS, HG-AAS Atomic Absorption Spectrometry
- Hot Gas Extraction Methods for C, O, S, N Determination
- Transmission, Reflection, Remission, Absorption in UV-VIS-IR Range
- FTIR- and Raman-Microscopy

Mechanical Stability Tests

- Fractography, Crack Origin, Fracture Mirror, Stress-optical Measurements
- Statistical Analysis of Strength Data
- Indentation Measurements (Knoop, Vickers, Martens)
- Micro- and Nano-hardness, Fracture Toughness
- Crack Initiation Load, Elastic and Plastic Indentation
- Static Strength, Tension-compression (uniaxial)
- Bending, Bursting (hydrostatic)
- Dynamic Strength, Notch Test, DCDC (crack growth)
- Thermal Shock, Climate Testing
- FEA Finite Element Analysis

Chemical Durability Tests

- ToF-SIMS Secondary Ion Mass Spectrometry
- SEM Scanning Electron Microscopy
- AFM Atomic Force Microscopy
- LiMi, WLI Light Microscopy
- EDX Energy-dispersive X-Ray Spectroscopy
- F-AAS, GF-AAS, HG-AAS Atomic Absorption Spectrometry
- ICP-OES, Spark-OES Atomic Emission Spectrometry
- ICP-MS, Laser Ablation ICP-MS
- Stress-optical Coefficient and Stress-induced Birefringence
- Spectral and Temporal Resolved Fluorescence, Phosphorescence
- Light Scattering UV-VIS-NIR
- Solarisation Tests (DUV, UV, Solar)
- Wet Chemistry, Gravimetry, Titration, Photometry
- Surface Tension and Contact Angle Measurements



**Accredited according
to DIN EN ISO 17025:**



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