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

**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.

**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 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

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.

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.

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.

Secondary Packaging Material
Long-term storage or accelerated storage of containers in combination with secondary packaging material. Determination of volatile or semivolatile organic contamination.
E&L + System Performance Tests (2)
Helping you to understand the performance of your container system

**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 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.

**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 reflectrometry system to map the thickness distribution of the silicone oil layer.
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.

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.

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.

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

One form of delamination is linked to a porous reaction layer

Corrosion effects: glass flakes

Setup for dye ingress test

Alkalinity test prior to vials being autoclaved
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 (MS²)
- 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
- 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:
Pharmaceutical Systems
SCHOTT AG
Hattenbergstraße 10
55122 Mainz
Germany
Phone: +49 (0)6131/66-7339
Fax: +49 (0)3641/2888-9125
pharma.services@schott.com
www.schott.com/pharmaceutical_systems