LAB SERVICES

OVERCOMING YOUR PACKAGING CHALLENGES.

SGD PHARMA

Interactions such as extractables, leachables, breakage or delamination can compromise stability, reduce shelf life, and ultimately affect patients. To address these challenges, pharmaceutical companies require robust analytical support to select the right packaging, verify compliance, and accelerate product launch. SGD Pharma Lab Services provides this expertise through reliable testing dedicated to molded and tubular glass.

What makes Lab Services unique?

SGD Pharma Lab Services provides this expertise through a wide portfolio of tests, from pharmacopeia compliance studies to advanced investigations that help solve customer-specific challenges in molded and tubular glass.

- **Deep expertise in glass packaging**
  Over 100 years of know-how in molded and tubular glass.
- **Comprehensive analytical portfolio**
  From pharmacopeia compliance tests to advanced extractables, mechanical and surface studies.
- **Problem-solving approach**
  Advanced investigations to identify root causes of issues.
- **Regulatory testing**
  Standard pharmacopeia studies aligned with US, EU and JP requirements.
- **Tailored studies**
  Customized protocols designed to match customer-specific testing requirements.
- **Accelerated development**
  Reliable results that help reduce time-to-market for new drugs and packaging.

Our offer

Standard Quality Control	**Assessment of glass quality through composition, hydrolytic resistance, stress distribution, color, and light transmission, ensuring compliance with international pharmacopoeia standards.**	Pharmacopoeias Tests (USP 660 / EP 3.2.1 / JP 7.01): ▪ Light Transmission ▪ Hydrolytic Resistance ▪ Arsenic Tests (USP 211 method) Glass Testing: ▪ Chemical Composition ▪ Seedcount ▪ Homogeneity (local stress) ▪ Color (HunterLab standards)
Extractables Study	**Evaluation of glass chemical durability by measuring extractables under aggressive and ultra-pure water conditions, in line with USP 1660, ICH Q3D, or USP 232.**	**Extractables by ICP:** ▪ USP 1660: glycine, citric acid, KCl. ▪ After ultra-pure water attack (Internal method, with autoclave ageing as per USP 660 / EP 3.2.1) ▪ According to ICH Q3D: elemental impurities (e.g., heavy metals) in ultra-pure water.
External treatments Study	**Assessment of the impact of hot end treatments through quantification of tin extractables, using validated internal methods.**	▪ Hot End Treatment Test (Internal method developed and validated based on surface RH tests).
Delamination Testing	**Evaluation of delamination risk through pH variation, corrosion behavior, and particle release analysis in glass vials.**	▪ Glass delamination study: pH variation, corrosion (SEM / Blue methylene test), visible particles.
Mechanical properties	**Evaluation of glass breakage risks through root cause identification, stress mapping, and resistance testing under load, pressure, and thermal shock conditions.**	▪ Breakage analysis ▪ Glass stress analysis ▪ Mechanical tests (vertical load, thermal shock, internal pressure).
Particles Analysis	**Identification and evaluation of the impact of metallic, inorganic, and organic particles using SEM, optical microscopy, and FT-IR spectroscopy.**	▪ Scanning Electron Microscopy (SEM) and Optical Microscopy ▪ FT-IR spectrometer
Particles Counting	**Verification of compliance with pharmaceutical standards for particulate matter.**	▪ Dust Count in Vials (Counts particles inside vials to ensure cleanliness compliance)
Surface Characterization	**Imaging of glass surfaces to detect structural defects, assess vial-drug interactions, and evaluate surface quality.**	▪ Scanning Electron Microscopy (SEM) and Optical Microscope

Case study

01 *Addressing stability issues in hot climates*

Challenge

A pharmaceutical manufacturer observed stability issues in hot climate regions. The objective was also to explore shelf-life extension.

Outcome

The study identified optimal conditions to ensure product stability and proposed alternative packaging solutions.

02 *Optimizing vial choice for a new formulation*

Challenge

A pharmaceutical company developing a new product needed to identify the most suitable vial type to minimize headspace volume and reduce risks of oxidation and impurities.

Outcome

The study enabled the selection of the most appropriate vial, improving formulation protection. The company now plans to continue with complementary studies, including CCIT and delamination analysis.

03 *Extending shelf-life*

Challenge

Pharmaceutical companies often face product waste when the standard 6-year shelf life of glass containers is reached. Many requested support to extend this limit in order to maximize inventory use and reduce losses.

Outcome

The studies supported an additional 6-month shelf-life extension. This helped customers avoid unnecessary product disposal, optimize stock management, and strengthen regulatory submissions.

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For more information, please visit our website
www.sgd-pharma.com