Sample Preparation for Analytical Quality Control

Solutions for Optimized Workflows and Accurate Results

Simplifying Progress

SARTORIUS

Sample Prep for Analytical Quality Control

Quality control (QC) is a critical step in highly regulated industries like pharmaceutical, biopharmaceutical, drug delivery, medical devices or cosmetics. Every manufacturer must demonstrate that their products are consistently manufactured, safe, effective, and pure. The number of tests that must be run by QC labs continues to rise to meet the ever increasing requirements of global regulatory agencies.

Your HPLC Chromatography, and Spectroscopy Results Can Only Be as Good as the Quality of Your Sample Preparation

High pressure liquid chromatography (HPLC) is one of the most common high-precision analytical methods used in QC labs to determine product concentration and purity. Its primary objective is to deliver reproducible and specific results. A sample must be optimally prepared before it can be injected directly into an HPLC column.

To accomplish this, your sample must be dissolved in the appropriate solvent. Elimination of particles from your samples prior to HPLC or other chromatographic analysis is essential in order to keep the integrity of your chromatography column reaching full operating life. Sample preparation is often tedious and time-consuming, but Sartorius has solutions to ease and speed your sample preparation workflow.

HPLC Sample Preparation With Sartorius

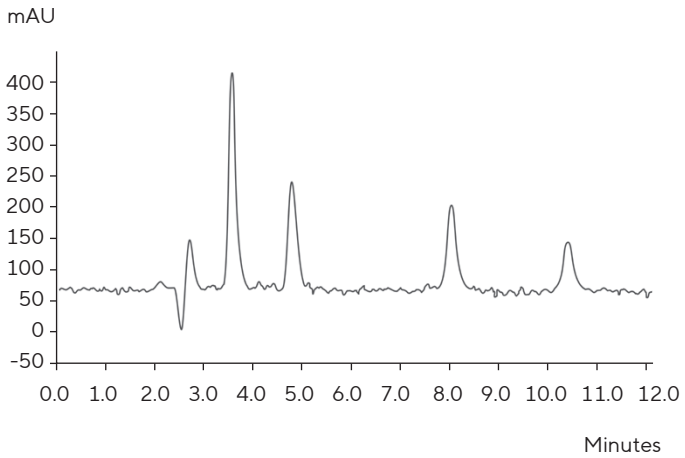
Clean Samples = Clean Results

Sample Preparation → Preparation of Standards and Solvents → Pipetting → Filtration

Identifying Problems During HPLC Analysis

Some effects of improper sample preparation are immediately visible in the chromatogram. Others gradually lead to deterioration of your results, ultimately requiring that you repeat entire series of chromatographic runs.

Chromatogram With Pronounced Background Noise and Peak Tailing

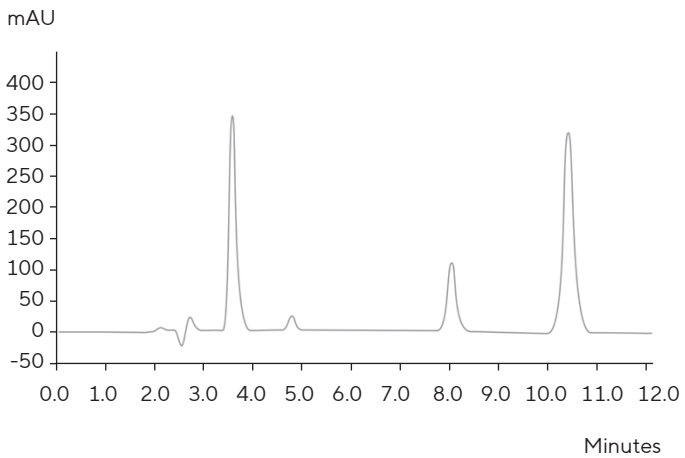


Using Sartorius products to prepare samples for HPLC prevents many common problems and permits higher analytical accuracy.

Key benefits include:

- No blockage of your HPLC column
- Higher sensitivity of your HPLC column
- Higher accuracy
- Fewer false-positive peaks
- Less background noise
- No leachables

Chromatogram With a Stable Baseline And Symmetrical Peaks



Special QApps – Standard Preparation

Cubis® III with a completely configurable hardware and software offers a high-performance balance which supports unique connectivity demands and fulfills regulatory compliance requirements.

Compliance With Common Regulations

1. Comprehensive audit trail and alibi memory to ensure traceability: Extensive sorting, filtering and export options allow easy search of events. The results can be reviewed either on the balance or via network on your PC, without the need of an additional software.
2. Automatic backup and restore function and time synchronization
3. Documentation process which follows the ALCOA principles: Cubis® III ensures secure transfer of the results with the associated meta data
4. Extensive user and role management with electronic signatures: User can be either be managed on the balance in compliance with FDA CFR21 Part11 Part 2 or the balance can access your company's directory via LDAP for central user management.

Audit Trail & Alibi Memory	Technical Controls	User Management
Backup		Electronic Signatures
Safe Data Transfer		Time Synchronization

Sample Preparation → Preparation of Standards and Solvents → Pipetting → Filtration

Straightforward Connectivity Options
Connectivity options directly into laboratory IT environments without the need of installing an additional middle ware. Use of common IT standards simplify administration effort and reduces IT service costs.

1. Printouts on a laboratory printer or network printer
2. Transfer of files like PDFs on a file share or into a document management system
3. Complete bidirectional integration into your systems via REST webservices
4. Alternative connectivity options for example via RS3232

Eliminate Inaccuracies, Ensure the Highest Degree of Repeatability

1. Status Centre, more than just a green light: Comprehensive overview of all relevant status information always at your hand
2. Workflow support via intuitive software guidance makes your daily tasks faster and safer: Our QAPPs provide step-by step guidance and ensures that your results are always within the given specifications. All results are documented electronically, and the balance is logged if the specifications are not met.
3. Automatic touch free leveling: Thanks to the motorized feet your balance is always automatically leveled.
4. Automatic internal adjustement. The balance monitors changes of conditions and when necessary initiates the internal adjustment.

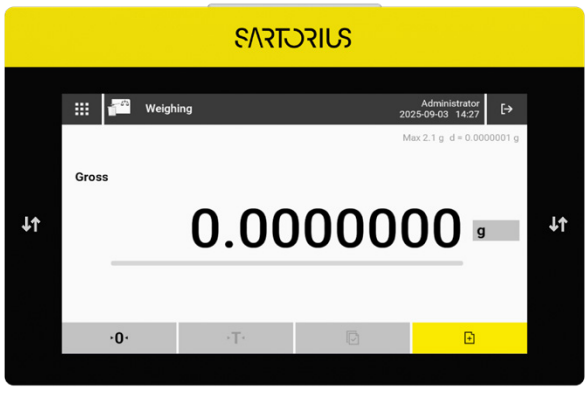
Ensure Compliance With the New Addition to European Pharmacopoeia: Chapter 2.1.7 “Balances for Analytical Purposes”

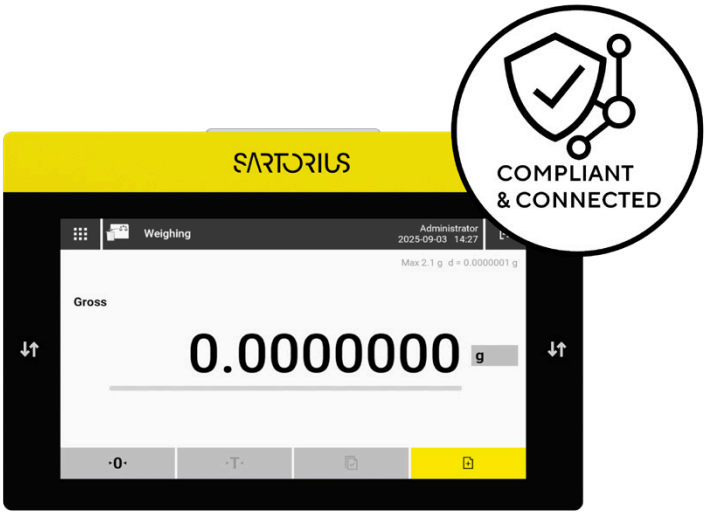
On 1 July, chapter 2.1.7 was added to the European Pharmacopoeia. After a six-month transition phase, the chapter became mandatory on 1 January 2022 and has since been required for all pharmaceutical companies producing drugs for the European market.

Ph. Eur. chapter 2.1.7 defines the requirements for balances used in analytical procedures as well as the performance checks—such as calibrations and tests to verify precision and accuracy—that must be carried out regularly.

Repeatability and sensitivity measurements to determine random and systematic deviations are also known from the U.S. Pharmacopoeia (USP) chapter 41, and the tests are performed in the same way. However, Ph. Eur. chapter 2.1.7 includes more stringent requirements. For example, in the sensitivity test, the relative maximum permissible error of the test load must not exceed 0.05% according to Ph. Eur., whereas 0.10% is acceptable under the USP. Furthermore, Ph. Eur. chapter 2.1.7 specifies stricter requirements for the test loads used during performance checks.

Since USP chapter 41 and Ph. Eur. chapter 2.1.7 are not harmonized, pharmaceutical companies must evaluate whether they fall under the scope of Ph. Eur. chapter 2.1.7 and ensure ongoing compliance with its requirements.





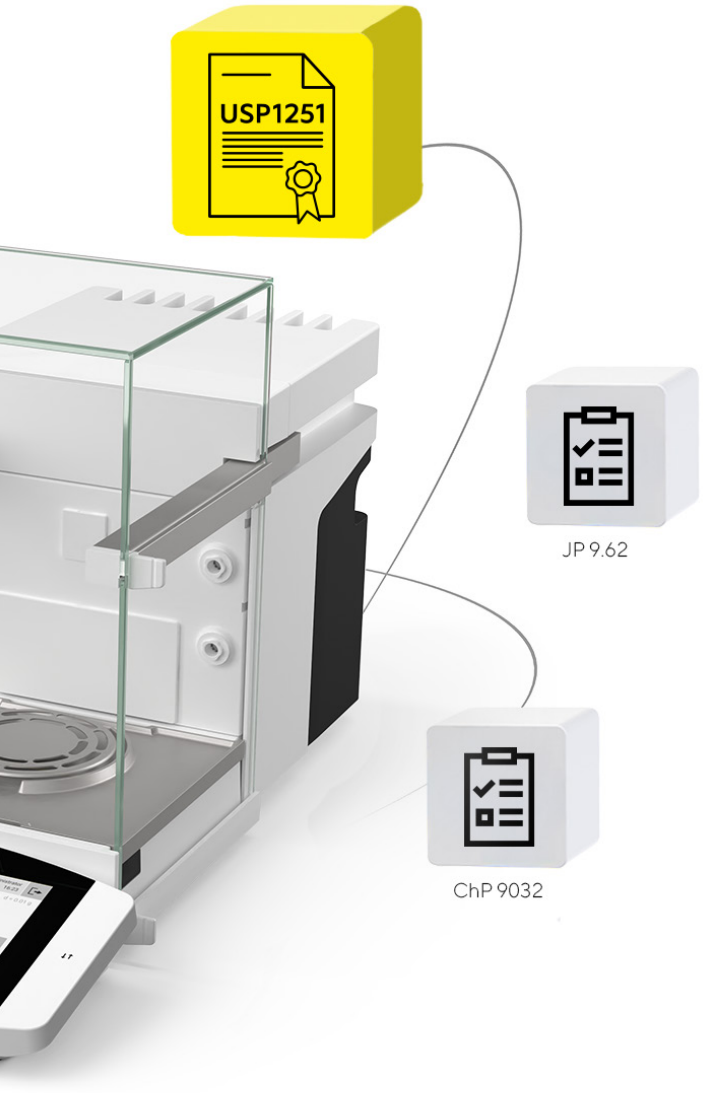
Pharma Compliant Weighing and Sample Management

Preparation of standards and buffers

The application standard preparation is used to prepare standards or buffer solutions of known concentration. During the task setup, for documentation purposes the system devices (balance, thermometer, density meter and printer) can be set. Furthermore, the permissible sample weight tolerances in percent and the mode for samples out of tolerances can be defined. If the sample weight is below or above the set tolerance, the user either a) cannot accept the weight value, or b) must enter the set password to take over the weight value, or c) can accept any value, even if the weight is out of tolerance.

Users with the role right to create or modify tasks have access to the application's sample management. The sample management offers a solvent, component and sample library that can be edited by this user group. Solvents are defined by name and density and components by name, molecular weight, and purity. Newly created solvents or components are added to the corresponding libraries and by combining a solvent and at least one component, as well as entering the desired final concentration, the composition for the standard solution can be defined and saved in the sample library. The target concentration can be selected as a weight unit per volume or molar concentration. For the preparation of mixed standards or buffers, up to 20 components can be selected for each sample.

Sample Preparation → Preparation of Standards and Solvents → Pipetting → Filtration



The user without the right to create or change tasks may only prepare standard solutions from stored samples. The user selects a sample from the library and is guided through the process by the software. On the basis of the volume entered by the user, the software automatically calculates the quantities of components to be weighed in and provides direct visual feedback by means of a graphic tolerance bar as to whether or not the weight is within the specified tolerance. Based on the components weights measured by the balance, the software application calculates the amount of solvent required to achieve the desired target concentration.

Finally, the effective added solvent weight is determined gravimetrically, converted to volume using the density, and using this value the effective final concentration of the standard solution is calculated. Finally, the software application creates a comprehensive report that can be printed out in standard or GLP format including a list of the system devices used during the procedure. In addition, the application allows the printing of labels that can be attached to the used vessels.

Reliable Analytical Results with Freshly Produced Ultrapure Water

Tests have proven that up to 80% of the problems occurring during HPLC and other chromatography analysis can be avoided by improving the water quality. This is why the use of a ultrapure mobile phase is essential for ensuring the highest analytical-grade quality. The eluents must be especially pure in terms of their physical and chemical properties and must not contain any kind impurities or particles. Even purchased HPLC-grade water is frequently found to have a high total organic carbon (TOC) level.

The Arium® Mini Plus UV and Arium® Pro UV ultrapure lab water systems provide Type 1 water that reduces TOC to a minimum. With either Arium® system, you are guaranteed on-demand, reagent-grade water that meets all requirements according to the ASTM, CLSI and ISO standards – without the need to find storage for numerous water bottles. Choose the system that meets your needs: the Arium® Mini Plus UV can supply up to 10 L of ultrapure water per day, while the Arium® Pro UV can supply up to 100 L per day.

Due to its small footprint and height-adjustable arm, the Arium® Smart Station can easily integrate into any lab environment. Connect up to 3 Arium® Smart Stations to your ultrapure water system, with up to 4 meters between each units, which can save costs and valuable lab space. Furthermore, Arium® Smart Station ensures transparent tracing and documentation of your lab water product quality.

Freshly Prepared On Demand:

Rely on Type 1 ultrapure water for consistency and reliability.

Sample Preparation → Preparation of Standards and Solvents → Pipetting → Filtration

The Arium® Ultrapure Water Systems for Efficiant and Secure Operations

Constantly Low Conductivity
ASTM Type 1 water increases the sensitivity of analytical results and minimizes chemical ion interference.

Consistently Low TOC Levels
Minimum TOC levels avoid chromatogram background noise and ghost peaks.

Reliable Process Stability
A variety of services are offered, such as installation, equipment qualification (IQ | OQ), preventative maintenance, to ensure consistently reliable water quality along the entire life cycle of the system.

The Arium® Pro UV Ultrapure Water Systems for Volumes up to 100 L/day

Use in Highly Regulated Areas
The Arium® system meets all requirements for Type 1 reagentgrade water according to the ASTM, NCCLS and ISO standards.

Reliability Guaranteed
Highly visual and audio signals easily display maintenance cycles, alerts and alarms if any limits are exceeded, as well as cartridge change-out intervals.

The Highest Water Quality
The Arium® systems provide outstanding reduction of TOCs and are highly suitable for analytical applications, such as chromatography HPLC, LCMS or ICP-MS.

The Perfect Balance Of Convenience, Reliability, And Ergonomics

Sample Preparation > Preparation of Standards and Solvents > Pipetting > Filtration

Safe and Reliable Pipetting

Using inadequate tools to pipette solvents can lead to unintentional consequences like aerosol contamination of your sample or pipette or dissolution of the tip by the solvent. Our pipettes and tips are highly durable and suitable for pipetting most solvents. When pipetting solvents reverse pipetting mode usually yields more accurate and repeatable results. Reverse pipetting mode has the excess volume on top and the evaporation takes place from this extra volume. This also applies electronic pipette pipetting modes, like multi-dispensing. Pipetting with constant but rapid speed helps to eliminate evaporation effect.

Picus® 2 Electronic Pipette

Ease of Use
The Picus® 2 pipettes ensure reliable and repeatable pipetting results and feature an unbeatable ergonomic design that is kind to your hand. Anyone can use Picus® 2; it is intuitive like a mechanical pipette, while also offering more advanced options for experienced users.

Speed up Work
Picus® 2 saves you time in the lab with a wide selection of pipetting modes and customizable programs for every need. Save the most frequently used modes with specified settings on your device for quick and easy access. To enhance compliance, you can rely on safety features like password protection and calibration reminders.

Connect for the Future
By connecting Picus® 2 to your mobile device, you can use the Sartorius pipetting mobile app to seamlessly run sample preparation workflows and automatically adjust the pipette setting, taking your productivity to the next level.

Tacta® Mechanical Pipette

Effortless Pipetting
The Tacta® mechanical pipette is perfectly balanced to meet all your needs during pipetting. Its ergonomic design and low weight ensure easy and convenient handling.

Volume Adjustment Lock
Optilock, a unique Sartorius feature, provides flexibility for volume adjustment and locking – reliably preventing accidental volume changes during pipetting.

Easy Calibration and Adjustment
Easy calibration and adjustment provide the end user with a simple way of adjusting the pipette to liquids of varying viscosities to ensure accurate results.

High Quality Tips

Pure Quality
Tisp are manufactured using a fully automated process in ISO class 8 cleanroom conditions to ensure purity. Strict standards, followed from R&D to production: ISO 9001, ISO 140001, and ISO 13485.

SafetySpace® Filter Tips
The additional space between the sample and the filter virtually eliminates the risk of an expensive or a contagious sample permeating the filter.

The Right Membranes to Filter Samples with Special Properties or Low Volumes

If you need to filter HPLC samples that have special properties or small volumes, the use of syringe filters is the method of choice. Minisart® syringe filters optimized for sample preparation consist of a PP housing and membrane components featuring maximum chemical compatibility and minimum extractables to ensure excellent results. Due to the typical range of volumes from less than 1 mL to 100 mL these filters are available in three different diameters with an effective filtration area of 0.07 cm^2, 1.7 cm^2 and 4.8 cm^2.

Minisart® Syringe Filters
Minisart® RC with a regenerated cellulose membrane has been optimized for aqueous solutions and solvents. Its especially high chemical compatibility permits it to be used in a wide variety of applications. Minisart® RC is resistant to DMSO, other amides, ketones, esters and ether compounds.

NY Membrane for Alkaline Aqueous Solutions and Solvents
Minisart® NY with a nylon membrane and Minisart® GF+NY with a high-purity glass fiber prefilter and nylon membrane are optimally designed for the filtration of alkaline aqueous solutions and solvents. Their unique purity compared with other common polyamide membranes ensures clean samples.

PTFE Membrane for Aggressive Chemicals
Our coating-free hydrophobic PTFE membrane used in Minisart® SRP is suitable for venting applications and applications with either very low or very high pH level.

Rely on Over 30 Years of Proven Minisart® Quality for All Your Filtration Needs.

Sample Preparation → Preparation of Standards and Solvents → Pipetting → Filtration

The Power of Simplicity: Filter 8 HPLC Samples Simultaneously

Clarification by filtration to remove particles from samples decisively impacts the separation efficiency of your HPLC column and thus the reliability of your results.

Claristep® Filtration System
Total ease of use Claristep® is a filtration system designed to save you both time and effort. Thanks to the patented design of the Claristep® station, you can now quickly and easily filter up to eight 60 µL to 600 µL HPLC samples in parallel using one hand – without the need for AC power, vacuum pumps or syringes.

Gentle Filtration
Claristep® filter units with regenerated cellulose membranes have been optimized for organic and aqueous solutions and provide maximum chemical resistance and compatibility. Just pipette each sample into the reservoir on top of every filter. A light press on the station lid will close all 8 filter unit caps. This works like a self-filtering system. The samples pass through the membrane filters, available in a choice of 0.2 µm or 0.45 µm pore size, and are collected directly in your sample vials.

Watch video to see how easy filtration is with Claristep®
Claristep®

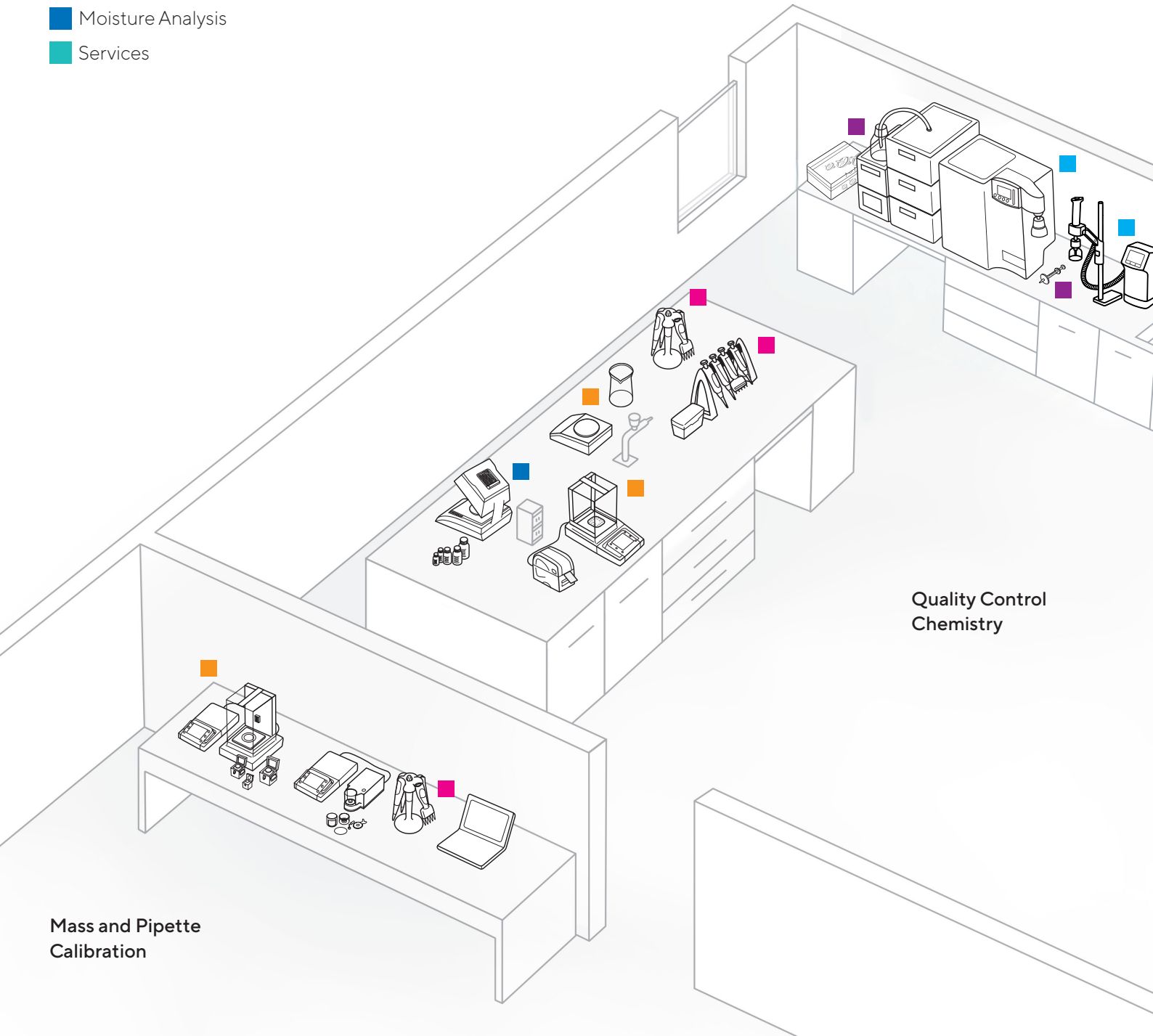
Save Time With Parallel Filtration of Your Samples.

Accurate Results with Sartorius

Discover the Potential of Your QC Lab
Whatever your area of expertise, Sartorius offers unique solutions for quality control in the lab. Our products and services are tailored to meet your application-specific needs. Browse the sections below that apply to your field of interest to find out how we can help you with your daily QC procedures.

- Laboratory Weighing
- Laboratory Filtration
- Laboratory Water Purification
- Liquid Handling
- Moisture Analysis
- Services

Services for Your Laboratory
- Installation
- Extended warranty
- GMP | GLP qualification (IQ | OQ)
- Calibration services
- Preventive maintenance
- Service contracts
- User training | Laboratory Academies

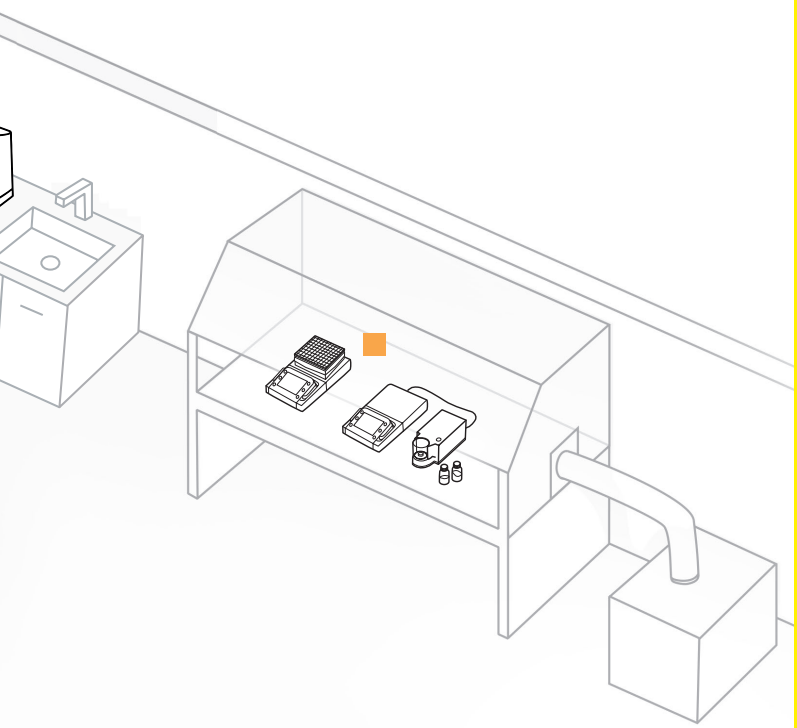


Quality Control Chemistry

Mass and Pipette Calibration

Analytical Sample Preparation With Sartorius

Because every detail counts in highly sensitive analyses.



Find out more
For more information, please visit
www.sartorius.com/sampleprep-qc

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Strasse 20
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Corporation
3874 Research Park Dr.
Ann Arbor, MI 48108
Phone +1 734 769 16006

For further contacts, visit
www.sartorius.com

Status: 07 | 2026 HPLC-Pharma-QC-Brochure-en-Sartorius