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

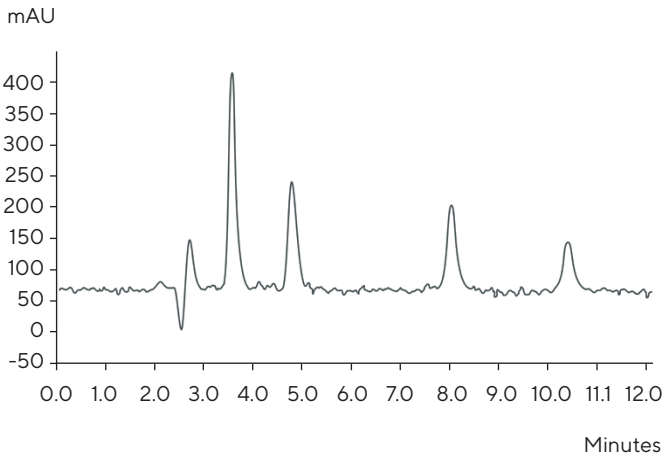
Clean Samples = Clean Results

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

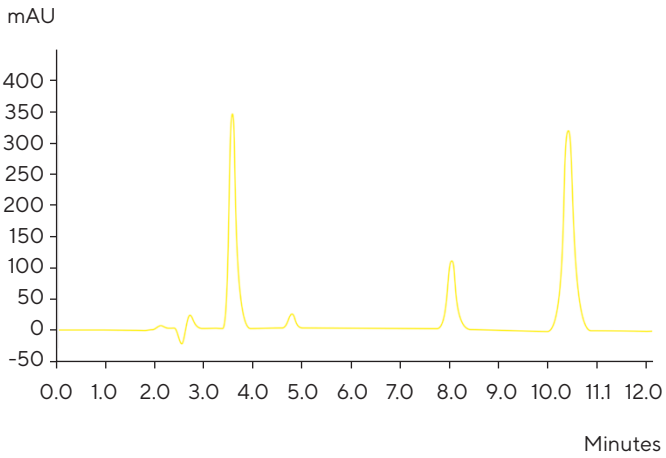


Using Sartorius products to prepare samples for HPLC prevents many common problems and permits higher analytical accuracy.

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



Pharma Compliant Weighing and Sample Management

Cubis® II 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® II 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 the 1st of July chapter 2.1.7 was added to the European Pharmacopoeia. After a transition phase of 6 months the new chapter becomes mandatory from 1st of January 2022 on and has to be followed by pharmaceutical companies producing drugs for the European market.

Ph.Eur. chapter 2.1.7 defines requirements on balances used for analytical procedures and performance checks like calibrations and tests to verify the precision and accuracy of the balance which have to be carried out regularly.

Repeatability and sensitivity measurements to determine the random and systematic deviation are also known from the US Pharmacopoeia (USP) chapter 41 and the tests are performed identical, but Ph.Eur. Chapter 2.1.7 has more stringent requirements. For example, in the sensitivity test the relative maximum permissible error of the test load must not exceed more than 0.05% according to Ph.Eur whereas according to USP 0.10% are acceptable. Furthermore Ph.Eur. Chapter 2.1.7 sets more stringent requirements on test loads used for performance checks.

Since USP Chapter 41 and Ph.Eur. Chapter 2.1.7 are not harmonized, pharmaceutical companies must check if they are affected by Ph.Eur. Chapter 2.1.7 and be aware of the implementation date.

Semi-Automatic Preparation and Documentation Of Highly Reproducible Calibration Standards for Chromatography and Spectroscopy With the Cubis® Dosing System

For quantitative HPLC, it is essential for you to prepare standard series with defined concentrations. Preparing a standard series can be labor intensive because it is nearly impossible to weigh a solid so accurately that a pre-defined volume of solvent may be used. The process can be complicated, error-prone, and expensive.

Semi-automatic Preparation of Standard Series
Customized Q-App software connects your Cubis® High capacity micro balance directly to your dispenser and will then accurately calculate the required solvent volume based on the quantity of solid weighed. With a weighing accuracy of up to five decimal places and a dispenser motor providing 48,000-step resolution, you can be sure that your solvent will be dispensed automatically with the highest precision.

Cubis® MSA Individual System With Q-App Software for HPLC Standards

Data Integrity and Paperless Lab
The Dosing Q-App provides an interface to the Thermo Fisher Chromeleon™ software*, permitting fully traceable documentation of all analytical data, including the details of your prepared standards.

Documentation of Test Procedures
The Q-App software will guide you step by step throughout your workflow and digitally document the entire process in a traceable, easy-to-understand record. Important parameters, such as purity, density and temperature of your solvent, will be automatically taken into account.

Reliable Planning of Simple Workflows
Forget delays caused by the need to take corrective steps. You no longer have to be prepared for the unexpected – thanks to the automated and fast preparation of 100% consistent standard series and reliable documentation.

* Dionex™ Chromeleon™ 7.2 Chromatography Data System (CDS) software is a trade mark of Thermo Scientific™

Simply Let Your Q-App Software Take Care Of Calculations And Documented Preparation Of HPLC Standards.

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

Cubis® High Capacity Micro Balances: Weigh Minimum Amounts of Sample Directly Into Heavy Flasks

Avoid Sample Transfer

Reliably Weigh Small Samples Directly in Large Sample Containers
Thanks to the high weighing capacity, you will no longer need to transfer samples and can weigh minimum amounts directly into large containers, such as long-necked flasks or HPLC bottles.

Weighing With the Highest Accuracy
The Cubis® High Capacity Micro Balance enables an extremely low sample weight, allowing you to comply with USP and FDA requirements.

No Additional Weighing Step Saves Time and Cost
Direct sample weighing into your flask eliminates the need of using weigh boats or paper.

Ergonomic Sample Weighing Without Sample Loss

Using the right sample holders or weighing pans completely eliminate the risk of sample loss and ensures high measurement accuracy.

Uncompromized Accuracy
Made of titanium, not only the highest material quality is guaranteed, but notably the repeatibility is not jeopardized because of the non-magnetic properties.

Great Variety of Choice
Selecting from numerous design variants you can make sure that the sample holder fits the balance and the application type you are looking for.

Convenient Usage
No more powder stuck to the weighing boat, weighing paper, etc. No more tip over. Thanks to ergonomic design weighing workflows can be executed much easier.

Adjustable sample holder

Extended weighing pans (50mm and 90mm)

Holder for titration vessels and round bottom flasks

Reliably Weigh Small Samples Directly Into Large Sample Containers of up to 250 mL

Consistent Baselines and Avoid Ghost Peaks With Fresh 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 highly pure 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 organic 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, NCCLS, ISO and USP 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.

The Arium® Smart Station simplifies your daily use of lab water and is designed for flexible remote dispensing of pure and ultrapure water directly at the point of use.

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.

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, ISO and USP 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 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® Nxt Electronic Pipette

Certified Reliability
Every Picus® Nxt electronic pipette is delivered with an accredited calibration certificate; ISO 8655 conformity method in ISO 17025 testing laboratory.

Unrivaled Precision
The electronic piston control and brake ensure accurate and precise pipetting results independent of the user's experience.

Easy Operation
The unique adjustment wheel enables exceptionally fast volume setting and menu navigation and makes it easy to prepare a protocol's calibration curve.

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

Chemical Stability
Chemically stable tips are suitable for pipetting solvents.

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 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.

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

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. Featuring a pore size of 0.2 µm or 0.45 µm and a selection of special membrane materials and diameters, the proven Minisart® with a polypropylene housing reliably removes particles.

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
Minisart® SRP with a hydrophobic coating-free PTFE featuring high chemical compatibility and minimum extractables to ensure excellent results.

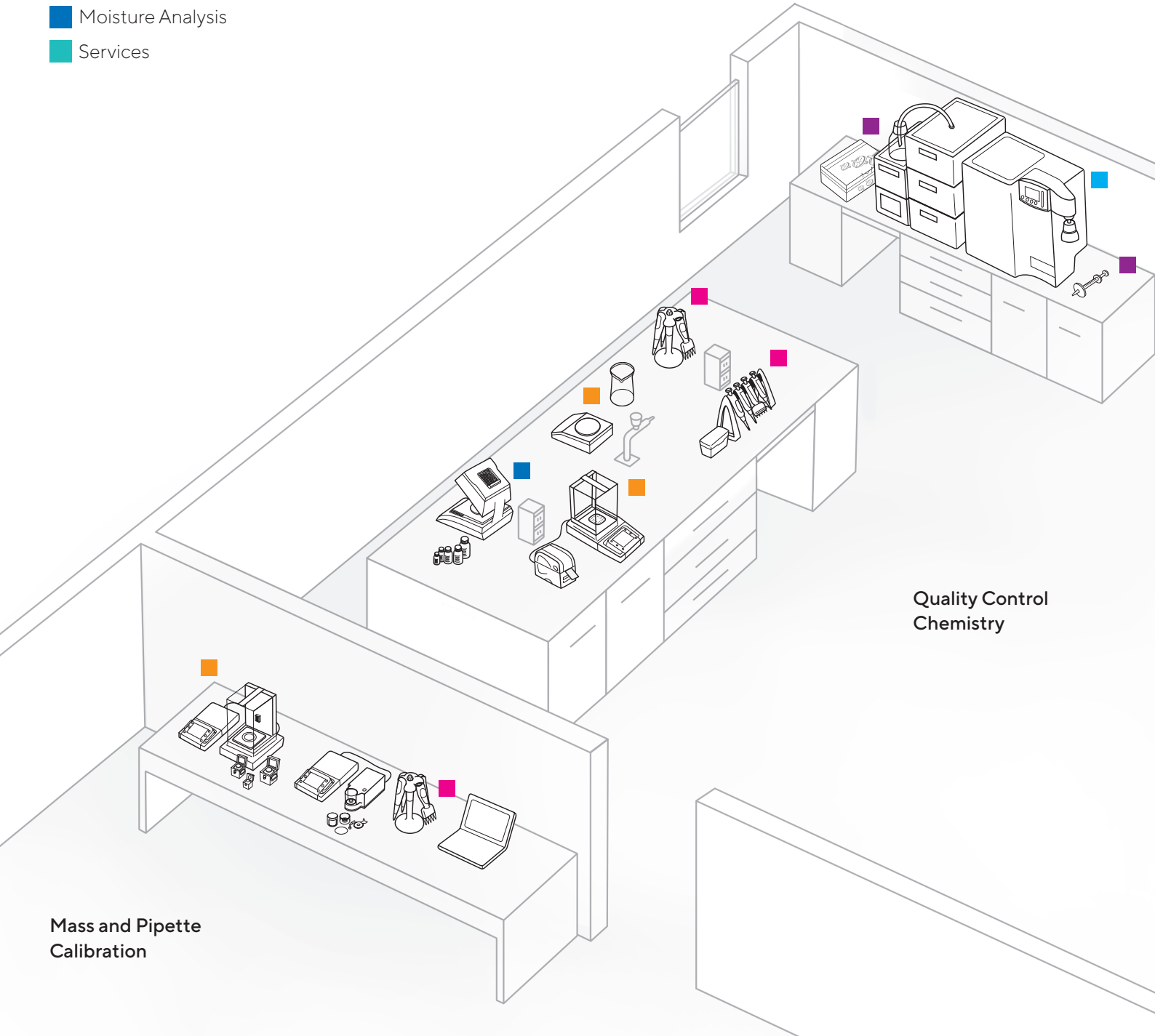
Rely on Over 30 Years of Proven Minisart® Quality for All Your Filtration Needs.

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.

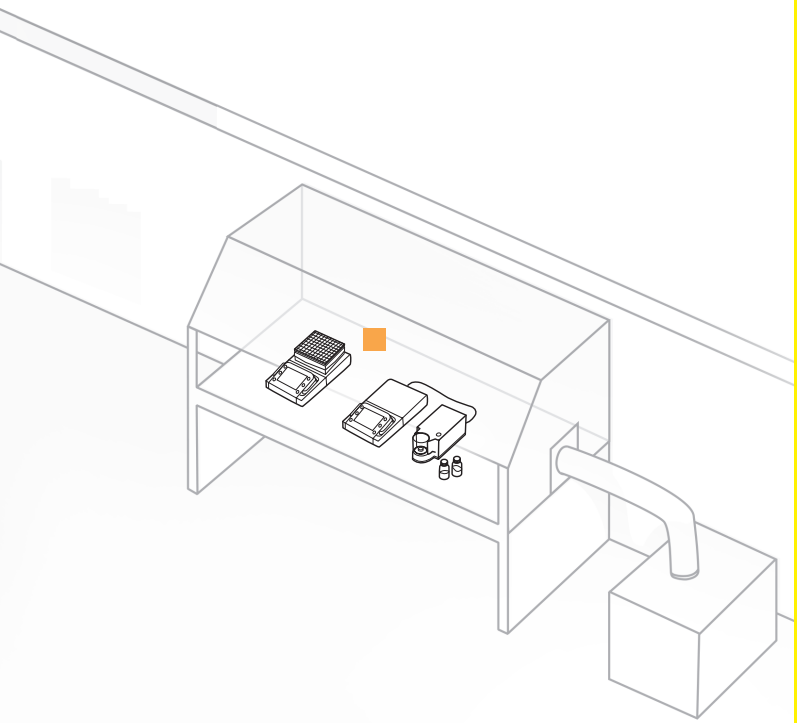
- Laboratory Weighing
- Laboratory Filtration
- Laboratory Water Purification
- Liquid Handling
- Moisture Analysis
- Services

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



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

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