

## Sample Preparation for Quality Control: Solutions for Optimized Workflows and Accurate Results



# Sample Prep for Quality Control

Quality control (QC) is a critical step in the pharmaceutical and biopharmaceutical industry. Every manufacturer must demonstrate that their drugs are consistently produced, safe, potent, and

## Your HPLC 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.

pure. The number of tests that must be run by QC labs continues to rise to meet the ever increasing QC requirements of global regulatory agencies.

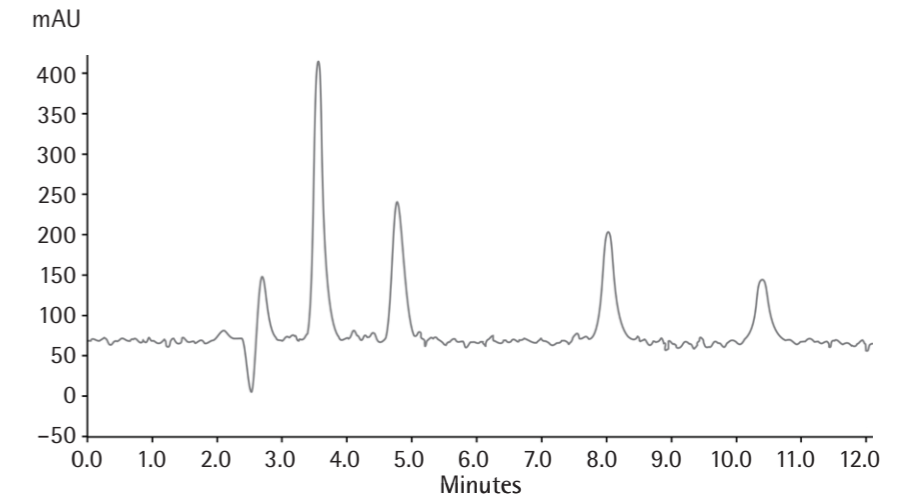
To accomplish this, your sample must be dissolved in the appropriate solvent. Even more important, it must also be free of particles to rule out interference during detection and to prevent blockage of your column. Sample preparation is often tedious and time-consuming, but Sartorius has solutions to ease and speed your sample preparation workflow.

HPLC sample preparation with Sartorius:  
Clean samples = clean results



## Identifying problems during HPLC analysis

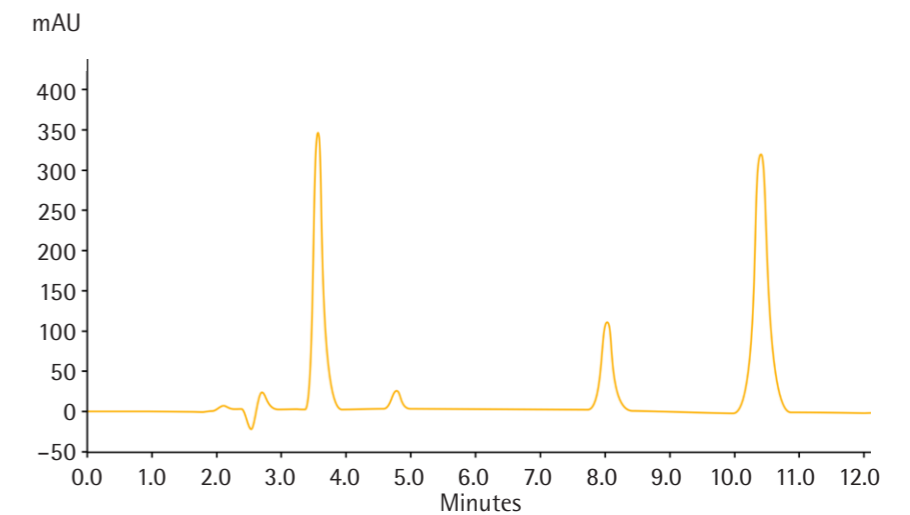
Some effects of improper sample preparation are immediately visible in the chromatogram. Others gradually lead to deterioration of your results, ultimately requiring that you repeat entire series of chromatographic runs.



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

Preparation of Solvents

Preparation of Standards

Pipetting

Filtration

HPLC Analysis

# Consistent Baselines and Fewer Ghost Peaks with Fresh Ultrapure Water

Tests have proven that up to 80% of the problems occurring during HPLC runs are attributable to inadequate 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 ultrapure lab water systems provide Type 1 water that is RNase, DNase, and endotoxin free. 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 can supply greater than 10 L per day.



## The arium® pro ultrapure water systems for volumes > 10 L/day

### Use in highly regulated areas

The arium pro system meets all requirements for Type 1 reagent-grade 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 pro systems provide excellent retention rates of RNases, DNases and endotoxins, as well as outstanding reduction of TOCs. The systems are highly suitable for analytical applications, such as cell cultivation and chromatography.

## The arium® mini UV ultrapure water systems for volumes of up to 10 L/day

### 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.

Freshly prepared on demand:  
Rely on Type 1 ultrapure water for  
consistency and reliability.

# Semi-automatic Preparation and Documentation of Highly Reproducible HPLC Calibration Standards with the Cubis® MSA 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.

## 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.

## Cubis® MSA individual system with Q-App software for HPLC standards

**Semi-automatic preparation of standard series**  
Customized Q-App software connects your Cubis® 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.

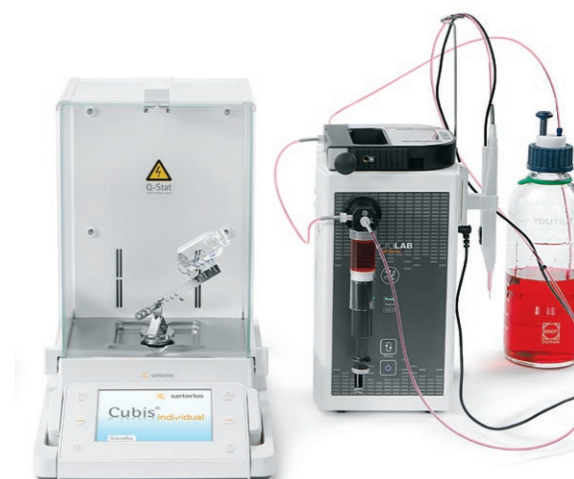
## Documentation of test procedures

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.

## Preparation of standards—ingeniously simple and highly precise



Simply let your Q-App software take care of calculations and documented preparation of HPLC standards.

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



**Step 1:** Weigh the compound



**Step 2:** Measure the density of solvents



**Step 3:** Dispense the exact amount of solvent



**Step 4:** Check the achieved results gravimetrically



**Step 5:** Print the results in GLP or label form on self-adhesive paper



**Result:** Standard solution of a defined concentration

# Avoid Sample Transfer with Cubis® High Capacity Micro Balances: Weigh Minimum Amounts of Sample Directly into Heavy Flasks

## Forget the inconvenience of transferring samples

Are you still weighing your expensive samples in small sample containers, weigh boats, or paper before transferring them to a large flask or other container? Do you find that you then have to either lower the container right into the solvent or use a brush to remove residue still clinging to the container so you won't lose any of your sample? This procedure is not only tedious but is also a major source of error. Besides risking sample contamination, you can't be sure whether you have quantitatively transferred your entire sample into a vessel.

Reliably weigh small samples directly into large sample containers of up to 250 ml

## Avoid transfer errors and sample loss: reliably weigh small samples directly in large sample containers

Based on the high weighing capacity, you will no longer need to transfer samples and can weigh minimum amounts directly into relatively heavy containers, such as longnecked flasks or HPLC bottles.

## No more wasting expensive samples: accurately weigh small amounts

The new Cubis High Capacity Micro Balance enables an extremely low sample weight, allowing you to comply with USP and FDA requirements.

## Save costs by eliminating the need for weigh boats and paper

Since challenging sample transfer is no longer required, you will not only save time, but also the cost of purchasing weigh boats and paper, as well as the expense of subsequent disposal.

# Always the Right Position for Optimal Manual Dosing

We have designed a flexible sample holder so that you can always position your containers for preparing stock solutions or reference standards to allow optimal manual dosing. This holder will enable you to easily dispense even the smallest quantities. Whether you use long-necked round-bottom flasks, cylindrical HPLC bottles or test tubes, you can adjust the titanium sample holder to the size of your vessel. The angle and position can be adjusted for ergonomic and reliable dosing.

## Increase user safety by omitting a risky step

When you transfer samples, tiny airborne particles can be released as a result of spillage or brushing. This can unnecessarily endanger your employees, particularly when they work with toxic substances. Sartorius enables direct weighing into containers, which protects all users from exposure to particles. The risk of spillage when a sample is added into small containers using a spatula is also reduced as larger sample containers also have wider openings.



## Flexible sample holder and weighing pan enable use of various vessels



A flexible titanium sample holder comes standard with the Cubis® High Capacity Micro Balance. This holder can be quickly positioned to accommodate different container sizes, such as long-necked flasks or HPLC bottles.



The extended space on our large 50 mm diameter weighing pan is ideal for vessels requiring a larger support area to prevent them from tipping over.

We will actively support you by offering seminars, training courses, helpful information, and valuable tips so you can obtain the best performance from your high capacity microbalance.

# 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 designed for pipetting solvents, and their chemical stability makes them compatible with various solvents. All Picus® Nxt pipettes are certified according to international standards, for the highest level of reliability.



The perfect balance of convenience, dependability, and ergonomics

## Picus® electronic pipette

### Certified reliability

Every Picus Nxt electronic pipette is delivered with a certificate of calibration that meets the strictest requirements of ISO 17025 and ISO 8655.

### Unrivalled 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. The most common filtration method is to use syringe filters. They're great if you have a small number of samples, but when you have to filter many samples, this can quickly turn into a tedious—and strenuous—chore.

### 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 the video to see how easy filtration is with Claristep®:



Save time with parallel filtration of your samples.



## 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, without adding any extractables or leachables to your sample.

### Minisart® syringe filters

#### RC membrane for aqueous solutions and solvents

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 especially alkaline aqueous solutions and solvents

Minisart® NY with a nylon membrane and Minisart® GF+NY with the purest 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 PTFE membrane has been optimized for filtration of especially aggressive chemicals. The membrane without any coating whatsoever guarantees absolutely leachable-free clarification of samples.



Rely on over 30 years of proven Minisart® quality for all your filtration needs.



Preparation of Solvents

Preparation of Standards

Pipetting

Filtration

HPLC Analysis

For more information about filtration systems, visit us at [www.sartorius.com/sampleprep-qc](http://www.sartorius.com/sampleprep-qc)

# Accurate HPLC 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

HPLC sample preparation with Sartorius:  
Because every detail counts in highly  
sensitive analyses.



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Contact your Sartorius sales specialist today—you'll be convinced.

For further information, visit [www.sartorius.com/sampleprep-qc](http://www.sartorius.com/sampleprep-qc)



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