



Confidence[®] Validation Services

SartoScale 25 Approach

Optimized Testing While Ensuring Existing High Standards

Our SartoScale 25 test approach enables bacterial challenge testing, chemical compatibility, and product integrity testing to be covered in a single run.

Reduced Sample Volume

Up to tenfold reduction in product volume needed for testing (as little as 0.5 L) thanks to automated testing with SartoScale 25.

Extended Process Knowledge

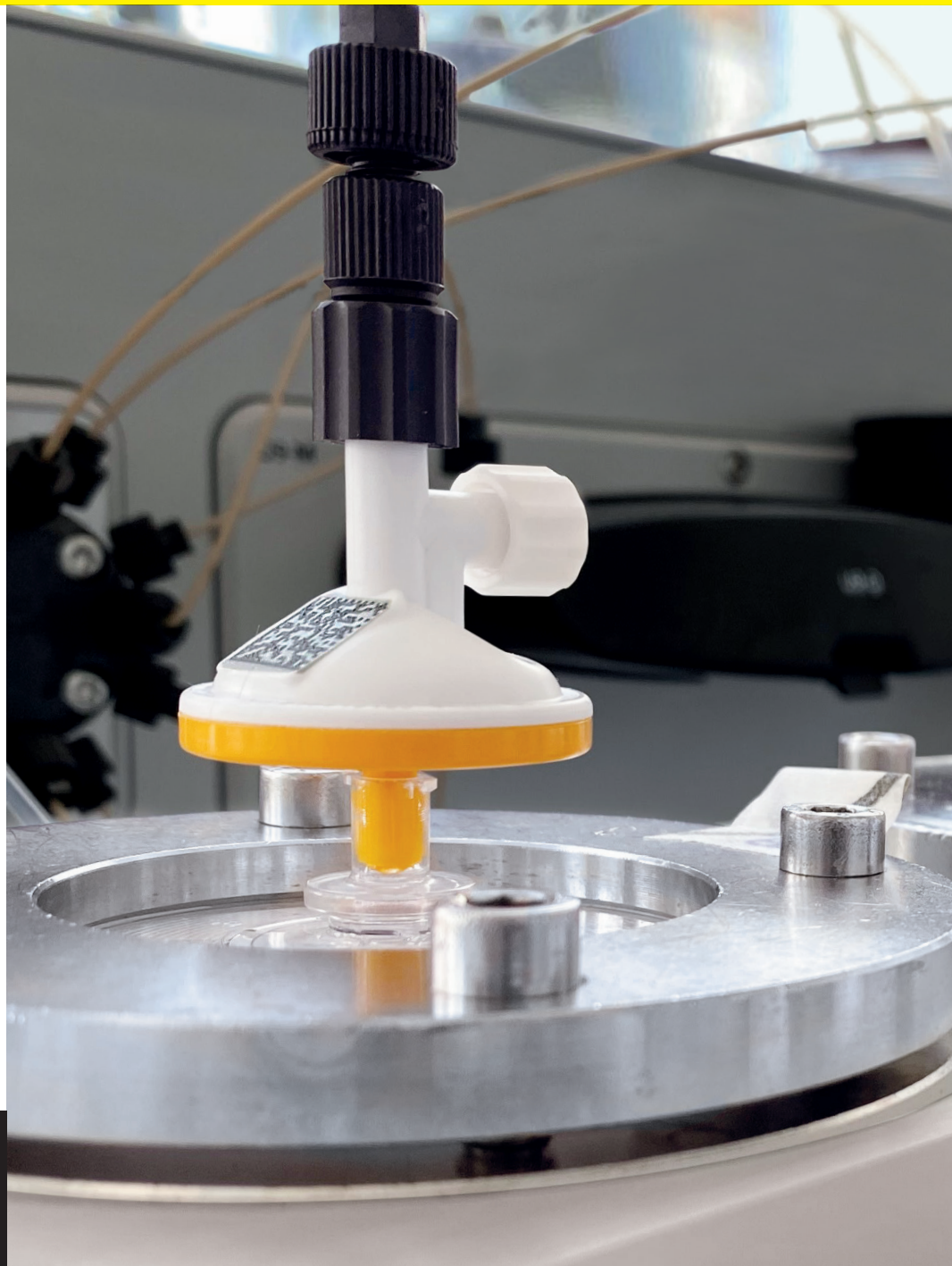
Capturing thousands of data-points in a single run including, but not limited to, pressure, flowrate, pH, and conductivity.

Complex Process Management

Simple simulation of complex start | stop filtration processes thanks to automated and highly customizable test run protocols.

Regulatory Compliance

Based on existing test procedures and in compliance with ASTM F838, PDA TR26, and ISO 13408.



New

Benefits

Up to 14 Test Elements Provides Flexibility

In standard validation, three SartoScale 25 filters, including a low bubble point filter, are tested separately. However, the automated test system can manage up to 14 SartoScale 25 test elements and apply separate filtration parameters so that a wide range of data can be collected. Consequently, four filter membranes can be tested simultaneously instead of just one, giving you greater flexibility without having to provide additional product.

Savings on Product

Assuming manufacturing costs of \$100 - \$200 per gram of monoclonal antibody (mAb) and a concentration of 150 - 200 g/L, a reduction of 2 - 5 L of final product needed for filter validation translates to cost savings of \$50,000 - \$200,000 per validation project.

Avoid Delayed Time to Market

This optimized approach allows you to include filter validation into your filter selection during process development. Thanks to the low volume required and the flexibility in setting parameters, you can validate multiple candidates at an early stage. This way, you avoid time pressure during commercialization.

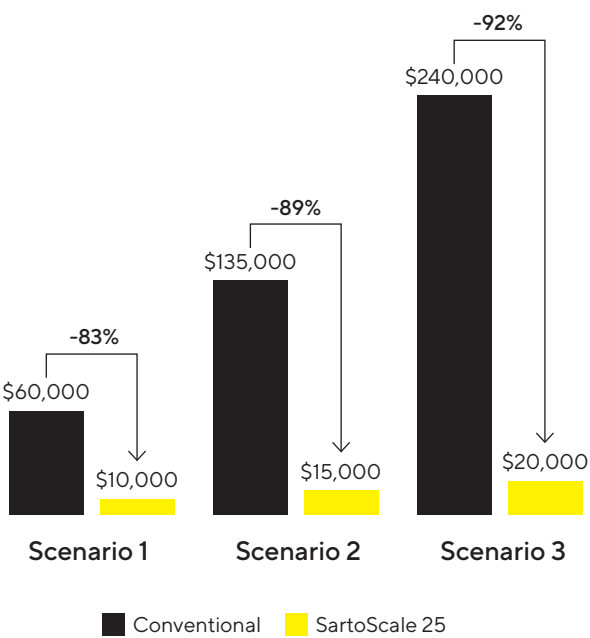


Figure 1: Product savings in three different scenarios, taking into account COGS and the amount of product needed for validation.
Scenario 1: COGS \$100/g, 3 L product volume
Scenario 2: COGS \$150/g, 4.5 L product volume
Scenario 3: COGS \$200/g, 6 L product volume

Comparison Between Conventional and SartoScale 25 Approaches

BCT CC PIT	Conventional Approach	SartoScale 25 Approach
Sample volume	3 - 6 L	0.5 L
Data recording	Sporadic (P, v)	Continuous (P, V, v, pH, Con.)
Test filter	Disc or capsule	SartoScale 25 mm (disc)
Maximum # test filter	3	14
Test parameter control for each test filter	■	■
Compliance PDA TR26/ASTM F838	■	■

Technical Information on Test Setup

Data Integrity

Data recording and monitoring are essential features of the test system. For liquid filtration, we combine established test equipment: a Sartocheck® 5 Plus integrity tester and a fast protein liquid chromatography (FPLC) platform. Both instruments support full data integrity throughout the test. All activities are logged in audit trails. In addition to the automated system, the operator ensures high quality throughout the validation run by performing all sampling, controls, and microbiological testing.

SartoScale 25

Thanks to the SartoScale 25, we have a downsizing of near process sterile filters as it has the same housing materials, pre-filters, and nonwovens. The membrane surface ratio and flow characteristics between the SartoScale 25 and the analytical filter allow optimized pressure regime and reduced backpressure effects even at high flow rates.

Test System Components

Component	Specification
SartoScale 25	Test filter Ø 25 mm
Analytical Filter	Ø 47 mm, 0.45 µm pore rating
Pump A B	Piston pumps
Mixer	5 mL chamber magnetic stirrer
Sartocheck®	Sartocheck® 5 Plus

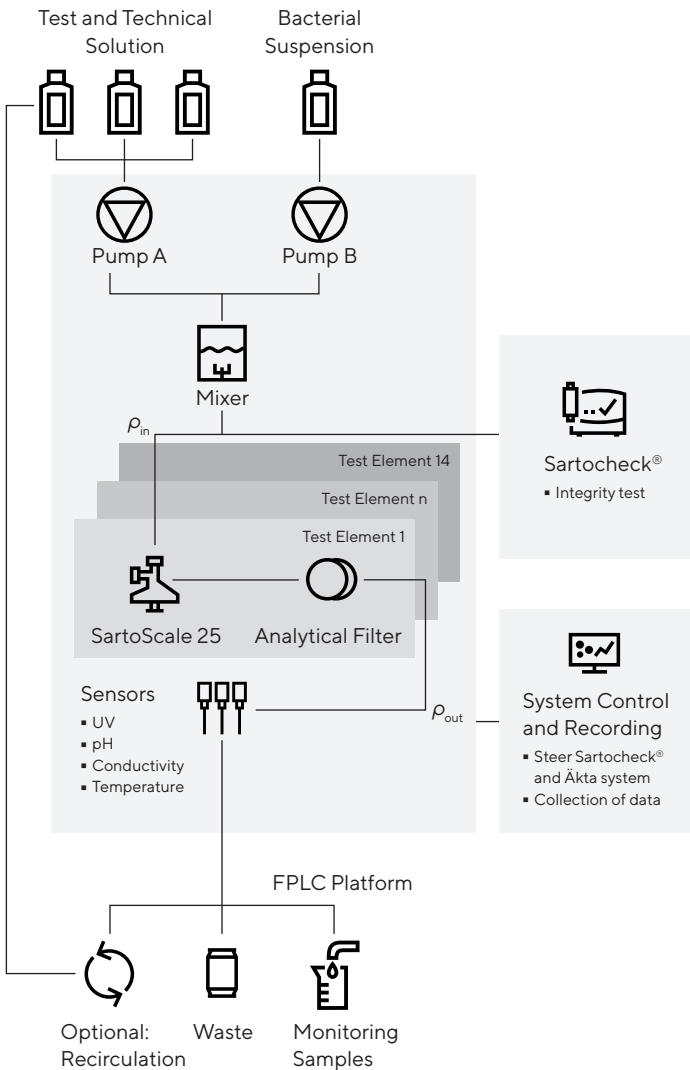


Figure 2: Schematic setup of the SartoScale 25 automated test system.

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