



sartorius



GLP|GMP
(GAMP|FDA) ✓
Clean Rooms ✓
Qualification
(DQ|IQ|OQ|PQ|MQ) ✓
Explosion Protection ✓
Validation ✓
21 CFR Part 11 ✓



Source: Vima Cyclops ic

Qualified

Combined expertise for
the pharmaceutical and
cosmetics industries

This information will give you a representative sampling of the Sartorius Group's product range – weighing components and product solutions for sophisticated applications in the pharmaceutical and cosmetics industries. Offering you a performance spectrum from 0.1 µg to 1,500 t in combination with extensive services, we are ready and eager to support you as your expert partners.

pH meters...

... for professional electrochemical analysis in the pharmaceutical laboratory. Ideal operating and data management features. Choose from a range of modular-design versions to find the right meter for your requirements.

- Alert limits can be entered as parameters (Min, Max) to ensure reliable compliance with process limits.
- Manual input of buffers enables you to adapt an analysis to your matrix using customized buffers.
- Individual equipment qualification (OQ|PQ) of the electrode and the meter ensure maximum process reliability.
- All data generated are processed in compliance with CFR21 Part 11 using SPEXXIS.

Microbalances...

... feature the highest level of ergonomic operation for optimal functionality. Delivering amazingly quick response and lightning-fast, reliable and accurate results, these balances come standard with N.I.C.E., a built-in static electricity eliminator. It easily neutralizes electrostatic charges on samples or tare containers at the touch of a key. Another highlight is F.A.S.T., the flexible draft shield system that operates fully automatically at the touch of a key. Its three-part, motorized draft shield has "self-teaching" functions, enabling it to adapt independently to every weighing situation. **New: the SQmin function provides maximum support for weighing minimum sample quantities according to the USP.** GENIUS ... simply an incredibly intelligent balance ... right down to its extensive built-in bundle of applications ranging from weighing in percent to density determination to differential weighing, including backweighing.

Moisture analyzers...

... with analytical accuracy during measurements and **factory-certified EC type approval** on request. New: The Sartorius WDS400 is another option for water|moisture analysis

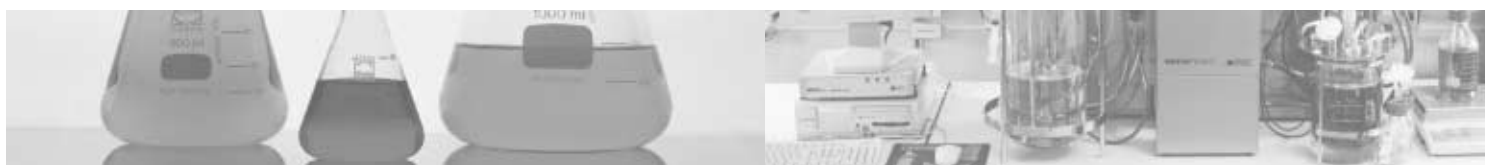
- Exceptionally small sample quantities (10...1,000 mg)
- Selective determination of different types of water

WDS offers considerable advantages and is an alternative to classic Karl-Fischer titration:

- No hazardous chemicals that have to be "carried out" of the lab and that cost lots of money to dispose of;
- Allows fractions of surface water, water of crystallization and capillary water to be analyzed in many samples;
- The sample does not decompose if the optimal temperature is selected. As a nitrogen atmosphere is used, oxidation is prevented. Thus, the dried product can even be used for further analyses, which saves time and money in pharmaceutical research.

Analytical balances...

... are ideal for laboratory use. With an extensive range of features, they offer the right solution for any weighing or application requirements. The plain-text prompts for optimal operator guidance in conjunction with the graphical display enable especially easy operation in any menu settings. With functions, such as the fully automatic calibration and adjustment feature isoCAL, input capability for alphanumeric sample IDs or ISO|GLP-compliant recording capability for printouts of all measured results, LA balances are perfect for meeting the requirements of monitoring the accuracy of measuring equipment. Sartorius' proprietary, patented monolithic weighing technology used in all models guarantees reliable weighing results over the long term and features incredibly fast response time.



Laboratory water purification systems for ultrapure water...

... in line with your various applications, you can choose from a complete array of products ranging from a reverse osmosis system, arium® 611 DI, a basic type I water purification system, to arium® 611 with an integrated UV lamp and ultrafilter for producing reagent grade water. These units deliver the highest water quality with exceptionally low TOC at levels < 1 ppb, and reduce endotoxins to < 0.001 EU/ml, all at flow rates up to 1.7 l/min and with a long cartridge in-service life. Sartorius delivers amazing performance for smooth-running production processes. From incoming goods to outgoing goods inspection, we offer rugged, modular weighing equipment – all the way to customized configurations. See for yourself!

Platform scales – compact or modular...

... are designed to meet the most stringent requirements placed on the pharmaceutical and cosmetics industries. This is a whole new generation of industrial scales and weighing equipment. Rugged, flexible and modular, the series features weighing capacities from 3 kg to 3,000 kg, and selectable resolutions of 3,000 e, 2×3,000 e, 15,000 d and 30,000 d. Combics also offers you a choice of IP65, IP67 and IP68 protection ratings. Stainless steel versions are available in AISI 304 or AISI 316 Ti and with various surface finishes. Depending on your specifications, they can be used in

Zone 1, 2, 21 or 22. Four indicators – display and control units – are supplied. They feature large keys, clear, easy-to-read digits, +/- LEDs for checkweighing or classification, and multifunctional ABC keys.

Pallet scales...

... for heavy loads are highly versatile for applications, such as use as a compact weighing solution in production sequences and for checking the weights of IBCs* before and after a blending step. Special guide bars ensure safe loading of the scale. Their carrying handle and rollers make them easy to transport, e.g., for cleaning a room. The scales are available in your choice of surface finishes all the way to cleanroom Grade A. Protected according to IP68, rugged and industry-compatible, they can be used in Zones 1, 20 and 21 or 2 and 22 hazardous areas.

* IBCs = intermediate bulk containers

Flat-bed scales...

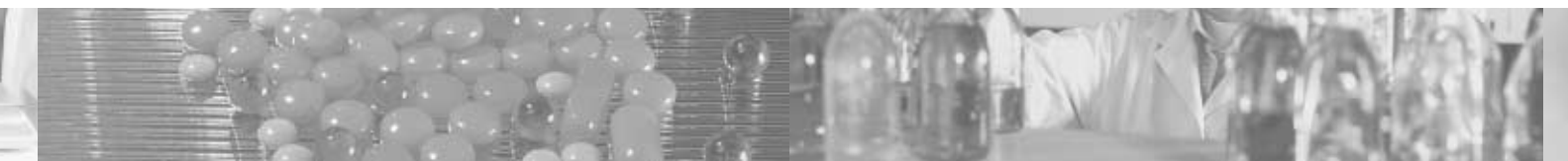
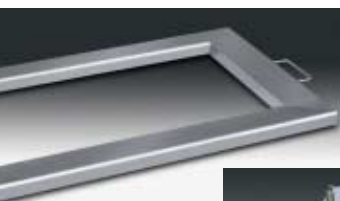
... the premium series for heavy loads; specially designed for clean rooms – without any weld seams on the surface in contact with the pharmaceutical; underside sealed as far as possible; patented mechanism that meets the latest accident prevention standards for lifting and lowering heavy loads. The scales' ultra-low profile minimizes the effort of loading containers. Suitable for clean rooms up to Grade A (RA ≤ 0.4 µm); IP68 protection; rugged; industry-compatible; and can be used in Zones 1, 20 and 21 or 2 and 22 hazardous areas.

Precision scales...

... The Premium Line combines the highest accuracy with the ultimate in functionality and operating convenience thanks to the incorporation of high-resolution weighing technology based on the principle of electromagnetic force compensation. Easy-to-understand text prompts shown on the graphical display make it a breeze to run the many application programs and extra functions ... plus, the Factory series scales are also available in Ex versions. Reproducible weight readouts and easy integration into quality assurance systems make these scales the series of choice for use in the pharmaceutical industry.

"X-Family" controllers...

... a new generation offering maximum flexibility and operating convenience. They are available for installation in control panels, a 19" rack or in an IP65 universal enclosure. Plus, they are equipped with various application packages for single-component and multi-component batching, recipe management, continuous discharge of materials, etc. They ensure programmability in compliance with IEC 6113, have a powerful, integrated PLC function, and can be networked via Ethernet, Profibus-DP, Device Net and Interbus-S interfaces. The controllers can be universally used as they can be connected via serial interfaces and through analog and digital I/O ports. Various software packages expand their functionality and allow simple connection to PCs. Thanks to their modular design, the X-Family controllers offer a product solution for nearly any application.



Formula and recipe management systems...

... enable easy and direct management of data. They serve as central operator workstations for batching applications in automated processes and feature easy operation through their familiar Windows-based user interfaces. Control of several parallel formulation processes is no problem. All production data are automatically generated and archived. To simplify communication, various user languages are already implemented. The systems can also directly communicate with the X-Family system controllers for all applications.

Fill level control...

... a compact and neat solution to big and messy problems in fill level control of tanks. Our level-by-weight control cell does not come in contact with your product and thus features the ideal hygienic design. The cell provides the highest economy and precision under any conceivable circumstances, regardless of the liquid or material filled in tanks and the ambient conditions.

Load cells...

... are ideal for any tank size. In combination with Sartorius installation kits, they constitute the perfect unit. Whether you have tanks, stirrers or dissolvers, with Sartorius technology and products, you can convert any type of vessel into a scale. The load cells' high-grade stainless steel allows them to be

used in the widest variety of installations. Especially for the pharmaceutical and cosmetics industry, Sartorius offers each load cell type in an intrinsically safe version.

Metal detectors...

... with 3-band multifrequency sounding up to 1 MHz. Whether you need to check for metal particles in blister-packaged tablets, or pills in cardboard boxes or in medications sealed in plastic bottles or even unpackaged medications, Discovery PLUS immediately adjusts itself to maximum sensitivity to accommodate changing products. Fuzzy logic recognizes the product profile and evaluates the product's conductivity ... generating 100% traceable documentation of the process data. The OBSERVER has been specially designed for final quality control of tablet blister packages, allowing metal contaminants (iron and AISI 304 stainless steel) in aluminum blister packages to be detected. Until now, metal detectors could only be used in the middle of a production process to check individual tablets in the pharmaceutical industry. However, for this industry, detection of such small foreign metal particles in tablet blisters is even more important in final quality control.

Compact checkweighers...

... make it even easier for you to start with in-line monitoring. You can even comply with the requirements for legal metrology. Our compact checkweighers feature 2 weighing ranges (0-3 kg, e = 1 g | 0-6 kg, e = 2 g). They're highly flexible for adapting to a variety of weighing table or bench dimensions - up to 500 x 300 mm. In addition, these checkweighers are protected according to IP65 and have a maintenance-free motor and trend controller software. They can be

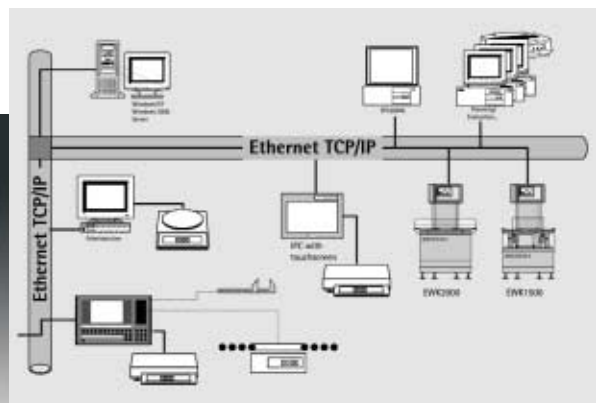
connected to the quality control system Sartorius ProControl for Windows (SPCfWin). As a result, they are the stainless steel checkweighers of choice in the pharmaceutical and cosmetics industries.

SartoPac Basic...

... provides the compact, fast basis for reliable average weight control of prepackaged products. Located right at the production line or in your quality assurance lab, it enables you to check, document and evaluate up to 100 products within a minimum of space. Moreover, in the SPC mode, you can monitor your process within user-definable limits (two -T limits and two +T limits). At the press of a key, you have instant access to all main functions. SartoPac Basic facilitates entering real product names and lot numbers. The isoTEST function with its self-testing, calibration, adjustment and documentation capabilities makes SartoPac Basic the ISO-compliant test equipment you can rely on ... even in hazardous areas.

Statistical process control...

... reflected by our SPCfWin acronym. This software makes essential inline checkweighing and monitoring functions simple and "compatible": statistical process control, average weight control or checking the net weight of prepackaged products, and attribute testing. The configurable capabilities of SPCfWin allow easy custom-tailored process evaluation. SPCfWin offers you unbeatable graphical evaluation functions and affordable archiving over the years - your "system for proof of compliance" of your production processes. Sartorius ProControl for Windows is easy to integrate into any data-processing environment.



GLP | GMP

Quality management in the pharmaceutical industry is precisely defined by comprehensive international standards and regulations (e.g., GLP, GMP) the majority of which have been harmonized. The requirements for controlling the accuracy of measuring and test equipment that are stated by these quality systems are very similar. One of their key requirements is that the accuracy of a measuring instrument must maintain the tolerances appropriate for the task. Sartorius products meet these prerequisites to a high degree, even fully automatically to some extent. This applies to calibration, adjustment and compliance with the minimum sample quantity, or, for example, automatic calculation of the uncertainty of measurement at each work area.

Clean rooms – where every little speck of dust can become a big problem

From production of active ingredients to manufacture to quality control, clean rooms play a central role in the pharmaceutical industry. Even the slightest deviations in APIs can have fatal consequences just as can microbial contamination. The development of highly effective active ingredients always leads to ever-increasing standards in processing these substances with regard to product and consumer safety. A growing number of processes take place in rooms with controlled environmental conditions. These clean rooms

are subject to conformance with strict standards. Compliance with internationally valid requirements (GMP guide for making sterile products, EN ISO 14644) and technical standards must be considered right during the planning stage. Every clean room has the individual task of meeting specific requirements of air cleanliness and climate. For this reason, our product solutions are focused on your processes. Implementation, qualification and, where required, validation are part of our integrative offer of services.

Qualification (DQ | IQ | OQ | PQ | MQ)

To support quality management, we offer you comprehensive services for equipment qualification. We will be happy to supply you with our design qualification (DQ), installation qualification (IQ), operation qualification (OQ), performance qualification (PQ) and maintenance qualification (MQ) documents, which the corresponding legal regulations or standards (GLP | GMP, FDA, etc.) require. On request, we will perform all these services for you. Our qualified service staff will provide professional consulting, installation, instruction and staff training services, and perform repair, maintenance and requalification services.

Approvals for explosion protection

In production processes, explosive atmospheres cannot be entirely avoided. For this reason, manufacturers of weighing equipment are also required to supply apparatus suitable for use in various hazardous areas (Zones) and for groups of substances (gases & dust). In Europe, the ATEX Directive 94/9/EC has been obligatory since July 1, 2003. This Directive ensures standardized safety levels, both on the part of the equipment manufacturer and on the part of the operator. For many years, Sartorius has been an ATEX-, FM- and CDA-certified manufacturer, and has international approvals for the entire range of its products. To help you provide the mandatory documents for explosion-protected equipment, we supply "Verification of Intrinsic Safety" documents along with our explosion-protected equipment at no extra cost. This will save you considerable time and expense in verifying the compatibility of individual components from different manufacturers.

Electronic records and signatures 21 CFR Part 11

Today, electronic collection, recording and processing of data is part of routine work in pharmaceutical laboratories. To regulate the use of paperless systems in the pharmaceutical industry to ensure their equivalency to systems where paper is used, the FDA issued the law 21 CFR Part 11. Within our range of products, you will find hardware and software that satisfy the requirements of this law and that will help you design your electronic process in compliance with 21 CFR Part 11.



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