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Weighing Subject to the Requirements of "Good Manufacturing Practices" (GMP) – a Task for the Analytical Balance MSA125P-100-DI

White Paper

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Introduction

A lot of attention is paid to the weighing of substances during the production and | or testing of pharmaceutical products. It is generally seen as an essential step in determining quality and is therefore a key focal point for the operator, customers, clients and supervisory authorities. Pharmaceutical processes are accompanied by detailed quality assurance measures with comprehensive documentation. The binding regulatory requirements for this are provided by the rules of "Good Manufacturing Practices" (GMP) and "Good Laboratory Practices" (GLP).

When equipping a processing plant or a laboratory, these requirements directly state that the operator must have and provide documented proof of the suitability of the devices that they use. The terms "qualification of hardware" and "validation of software" are used. Against this background, particularly in quality-relevant weighing processes, it is necessary to use balances which have been specifically developed and designed by the manufacturer for GMP or GxP applications.

Sartorius Lab Instruments GmbH & Co. KG recognized the need for certain design criteria and functions for the use of balances in regulated operations at an early stage and meets the above mentioned requirements on the basis of decades of experience in hardware and software development. The implementation of binding quality requirements normal for the sector is a standard part of the "Cubis®" product ranges, both of which have been designed for the pharmaceutical industry. Products from these ranges are equipped with an Advanced Pharma Compliance (APC) design and function package which Sartorius Lab Instruments GmbH & Co. KG uses to ensure the basis for operation of the balances complies with regulations in areas based on GMP and GLP.

Sartorius Lab Instruments GmbH & Co. KG also relieves the burden on its customers by providing professional support and handling of quality assurance measures which need to be implemented by the operator. On request, the specialist department Advanced Pharma Compliance Services (APC Services) will monitor the entire life cycle of Sartorius products. This process starts with the software-supported selection of the right balance and accessory configuration based on the application, before moving on to the provision of performance and functional specifications, qualification and GAMP classification | validation of customer-specific software applications and those in the device itself, and concludes with actual balance operation. In this phase, APC Services cover maintenance, servicing, calibration | verification and re-qualification | validation and also provide documented data backup, decommissioning and disposal of the device. In this area, Sartorius Lab Instruments GmbH & Co. KG only offers sustainable solutions which can be smoothly integrated into the operator's risk, quality, environment and resource management.

A special feature fits in seamlessly here. Balances in the "Cubis®" range adapt to customer-specific processes. This is usually achieved using a combination of standard functions to produce simple process operations, known as tasks. Ideally, the contents of the Standard Operating Procedures (SOPs) which are normal in the pharmaceutical sector can be completely transferred into these tasks and therefore into the balance. If this is not the case, the customer can have complex applications programmed, installed, documented and validated by Sartorius Lab Instruments GmbH & Co. KG in the form of an app. This means that the balance undertakes and automates steps previously carried out manually and therefore makes a considerable contribution to quality assurance and to the repeatability of the processes.

The MSA125P-100-DI analytical balance is an example of 5/4/3-digit balances of the "Cubis®" range, which are equipped with automatic draft shield and ionizer. It is therefore ideally suited for use in regulated areas. It was developed for use in the pharmaceutical industry, has the APC functional standard and can be monitored by Sartorius Lab Instruments GmbH & Co. KG throughout the entire lifecycle of the balance with APC Services.

Design of the Balance

The MSA125P-100-DI analytical balance from the Cubis® range is designed for applications in pharmaceutical laboratories and production | clean rooms.

It is characterized by a modular design, which can be flexibly assembled to suit different ambient conditions. Display and operating units, weighing modules and an optional draft shield are available as individual components.

The surfaces of the MSA125P-100-DI are designed according to the fundamental requirements for hygiene and cleanability and therefore comply with the regulations of the EU-GMP guideline for use in clean rooms.

An integrated ionizer for eliminating electrostatic interactions and an automatic draft shield are technical functions which provide the basis for high repeatability of the weighing process and therefore lead to a considerable reduction in measurement uncertainty.

Balance Parameters

The general suitability of the balance for pharmaceutical processes is also based on the modular composition, which makes it possible to guarantee the correct measuring range according to the requirements of the EU GMP guidelines and the necessary accuracy.

This is also supported by the fact that the non-automatic balance has the option for weighing in two different weighing areas with different readabilities and maximum capacities.

The balance has the following specifications:

Table 1: Specifications of the balance Cubis® MSA125P-100-DI

Parameter	**Value | Unit**
Readability	0.01 | 0.1 mg
Weighing Capacity	60 | 120 g
Repeatability ≤ ± mg	0…60 g: 0.015, 60…120 g: 0.06
Linearity	0.15 mg
Optimal starting point of the operating range* USP39-NF41	8.2 mg
Typical stabilization time	≤ 2 s
Measurement time	≤ 6 s
Weighing plate	85 × 85 mm

Depending on the relevant application, further requirements can be specified for the balance in the User Requirement Specification (URS).

* According to USP Chapter 41, to optimal operating range is defined from 820d to maximum weighing capacity.

Balance Qualification

Equipment which is used in the manufacturing and/or testing of active ingredients and medical products must be deemed adequate as a matter of course. The requirements for qualification are stipulated in Annex 15 of the EU GMP Guideline.

On request, Sartorius Lab Instruments GmbH & Co. KG will provide specific property (performance specifications sample, functional specifications) and qualification documents (risk analysis, DQ/IQ/OQ) in a required format or in hard copy for this balance or for any device configuration of the "Cubis®" balance range.

If necessary, as part of Advanced Pharma Compliance Services, Sartorius Lab Instruments GmbH & Co. KG offers the complete conduct and documentation of the qualification as a separate service. In this case, providing it is deemed necessary, it is also possible to provide support with the performance qualification phase following detailed agreement.

The validation of software components in GAMP categorie 3 and the compilation of customer-specific tasks will be considered during the qualification. The valid status of the applications installed on the device will be proven and documented based on risk using suitable tests. The quality-assured development of the software is dealt with internally at Sartorius and is incorporated into the entire documentation. The validation of complex customer and application-specific programmed applications in GAMP category 5 can also be included in the qualification and validation work according to separate agreement.

Balance Cleanability

In order to avoid contamination by the item being weighed, requirement-compliant cleaning of all relevant parts of the balance is supported.

All surfaces of the balance can be removed, are easy to clean and are resistant to cleaning agents and disinfectants. The weighing pan and draft shield windows can also be removed. This also ensures the cleanability of the areas under the balance socket.

On request, Sartorius Lab Instruments GmbH & Co. KG will provide detailed cleaning instructions and suitable cleaning agents (including their composition).

During commissioned studies, which were carried out at an independent center for research services, it was shown that the balance could be sufficiently cleaned at all critical points in the event of contamination with lipophilic and hydrophilic substances.

Balance Software

The software integrated into the "Cubis®" balance range makes a verifiable contribution to reducing the risk of defective weighing.

In this case an integrated user management system (Q-Guide) or the ability to produce user profiles help to prevent handling errors and lead to high applicability based on the relevant process. In addition, Q-Com enables reliable and secure data transfer or data exchange between several interface inputs.

In relation to handling quality-relevant data, the ability to save the identity of the user, the audit trail function and the possibility to print out the electronic data ensures a high level of reliability, security and traceability for the generated data.

Synopsis

The MSA125P-100-DI is a highly precise analytical balance with proven suitability for use in an environment governed by GMP.

The hygienic design considerably reduces the risk of contaminations and ensures cleanability in compliance with requirements. The modular structure of the balance ensures compliance with the necessary level of accuracy whilst at the same time having a highly variable measurement range. Sartorius Lab Instruments GmbH & Co. KG provides comprehensive support for qualification and validation work, and can carry out this work in full if necessary.

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