

Quality Assurance for
Initial Weight Procedures

White Paper

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Introduction

For more than 140 years Sartorius, now Sartorius Lab Instruments GmbH & Co. KG, has been providing high-quality weighing technology for laboratory and production environments. One of its key areas of expertise is the production of products specially tailored to the requirements of the pharmaceutical industry.

The balances in the Cubis® product range are designed for use in this very demanding environment based on the rules of "Good Manufacturing Practices" (GMP) and "Good Laboratory Practices" (GLP). Equipped with the "Advanced Pharma Compliance" (APC) design, function and service package, they use customer-friendly solutions to meet the process and quality requirements of the sector.

At Sartorius Lab Instruments GmbH & Co. KG, APC is expressed in a number of design criteria, functions and accompanying services which make a significant contribution to pharmaceutical quality assurance.

The term quality assurance includes all measures which are intended to guarantee previously defined quality requirements and ensure a constant product quality. Against this background, quality assurance in initial weight procedures means ensuring consistently accurate weighing results.

Pharmaceutical Quality Standard – A Fair Product Evaluation

A central criterion in the pharmaceutical industry is documented proof of suitability. Devices are qualified, procedures are validated.

Quality-relevant work steps, such as the measuring process itself, but also cleaning, calibration and maintenance, are described in Standard Operating Procedures (SOPs). In relation to initial weight procedures, this means that consistently precise weighing results are guaranteed at all times. Sartorius Lab Instruments GmbH & Co. KG supports these measures, if necessary, with comprehensive informative material, detailed document templates and accompanying services, and therefore ensures effortless integration of its products on the customer's premises.

The Sartorius Lab Instruments GmbH & Co. KG weighing technology also deals with work steps automatically. This is carried out using customer-specific programmed apps or tasks, which transfer normal process sequences in the pharmaceutical environment to the balances of the Cubis® range, and therefore fully standardize them.

The Right Value – an Indispensable Requirement

Regular calibration of the balances ensures the right measured value is produced. In order to do this, it is important to define the weights to be used, the tolerance limits, the sensitivity, the repeatability and the off-center load error in a test plan.

Sensitivity is understood to mean the change in the weight value divided by the load change on which this is based. The repeatability of the results provides information on how reliably the balance works and whether the determined weighing results can be repeatedly obtained in the same conditions. In order to obtain an ideal weighing result, the item being weighed should be placed in the middle of the weighing pan. To avoid the output of incorrect values, a test is carried out of how the balance performs when there is

an off-center load error. In order to do this, the item being weighed is intentionally placed in the corners of the weighing pan and the deviation in the measured value from the true value is determined. The weighing technology of Sartorius Lab Instruments GmbH & Co. KG counters this aspect with the balances in the Cubis® range: The "Q-Pan" function reduces a possible off-center load error caused by items not being placed in the center of the weighing pan. It also allows for the use of larger weighing pans.

Weighing Capacity, Minimum Initial Weight, Process Accuracy – a Matter of Course

The purpose of use, quality requirements and operating parameters are stipulated by the customer in specifications. On request, Sartorius Lab Instruments GmbH & Co. KG can provide support with initial versions of document templates. And it will respond directly and in a way that is compliant with individual specifications for the appropriate balance.

All balances are faced with the requirement of measuring masses that are as small as possible as accurately as possible and with the greatest possible level of repeatability. In order to do this, it is essential to know the minimum initial weight and the right weighing capacity of a balance. In relation to this, the measurement uncertainty of the balance must also be known. The absolute measurement uncertainty is defined as the value which limits a range of values within which the true value of the measurement lies with a specified probability (level of confidence). It always has the same dimension as the measurement itself, for example 100 ± 1 mg. In comparison, the relative measurement uncertainty, as the quotient of the absolute measurement uncertainty due to the true value (target value), is dimensionless but is usually stated as a percentage. The measurement uncertainty can be determined as part of a DAkkS calibration of the balance at the installation location, which is offered by Sartorius Lab Instruments GmbH & Co. KG. Depending on the model, the value can be entered on the balance and displayed at a later date. In order for there to be a sufficiently precise measurement, the measurement uncertainty of a balance must be less than the required weighing accuracy.

The minimum initial weight is the minimum value which must be weighed in order to be able to comply with a pre-defined process accuracy. Falling below this value would result in a deviation that is too large. This relationship can be explained using a diagram in which the minimum initial weight (in g on the X-axis) is logarithmically plotted against the process accuracy (in % on the Y-axis).

This diagram can then be used to determine the minimum weights for various process accuracies. In this case, process accuracy is only a clearer term for the expanded measurement uncertainty. This expanded measurement uncertainty is calculated by multiplying the relative measurement uncertainty with what is known as an expansion factor, which may vary depending on the classification of the process. The higher this expansion factor, the greater the level of confidence that the value of the measurement is within the stated value range. Based on the calibration guidelines EA-4/02 issued by the European Cooperation for Accreditation of Laboratories, in general an expansion factor of 2 is recommended if the level of confidence needs to be 95%.

The minimum initial weight is specified by Sartorius Lab Instruments GmbH & Co. KG for each balance in the Cubis® range and, if necessary, can be regularly checked as part of servicing. Weighing technology also makes daily life in the laboratory easier in this area. The SQ Min function can be used to monitor the minimum initial weight for selected balances in the Cubis® range. This is particularly necessary if substances are being weighed for volume determinations according to the United States Pharmacopeia (USP). According to USP Guideline 41, the measurement uncertainty in the initial weight process for volume determination must amount to a maximum of 0.1%. For industry, process accuracies of 0.5–5% are recommended for production processes, and 0.1–0.5% for laboratory processes.

The Right Location – an Absolute Necessity

Having the balance in the right location is essential for reliable weighing results. The balance should be placed in a closed, separate area with consistent ambient conditions, ideally separated from other process operations.

In this case, the installation location should minimize disruptive influences on weighing as much as possible. Accordingly, the balance must be on a base which is not subject to significant vibrations and which will not transmit any possible ground movements. Weighing tables from Sartorius Lab Instruments GmbH & Co. KG meet this criterion; they are designed so that a repeatable weighing result is ensured even in unsettled working conditions. If possible, the table should also be set up in a corner of the room in order to reduce vibrations as well as any disruptions caused by drafts. All models of the Cubis®

range meet the hygiene requirements for laboratory and production areas, and therefore allow for easy and simple cleaning. This requirement must also be complied with for the installation location. After installation, calibration and, if necessary, adjustment, the leveling of the balance must be checked on a regular basis. For this purpose, depending on the model, Sartorius Lab Instruments GmbH & Co. KG's weighing technology offers either automatic or manual leveling control, which draws attention to tilting of the balance. This guarantees permanently accurate weighing results.

Synopsis

Quality assurance for initial weight procedures means permanently guaranteeing consistently good weighing results.

Sartorius Lab Instruments GmbH & Co. KG meets this requirement using tailored applications, accompanying services and, in particular, innovative weighing technology. Integrated functions such as off-center load compensation, leveling control or the monitoring of the minimum initial weight

are just as much part of this as the option to transfer processes to the balance via apps and tasks. Balances in the Cubis® range are therefore specifically and optimally designed for use in the pharmaceutical sector.

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