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Laboratory Balances of the Cubis® Balance Range Meet the Requirements of the Pharmaceutical Industry for Cleanability

White Paper

turning science into solutions

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Introduction

For more than 140 years Sartorius, now Sartorius Lab Instruments GmbH & Co. KG, has been providing high-quality laboratory and production technologies. One of its core competencies is the production of laboratory balances developed to be process-oriented.

The balances in the Cubis® product range have been designed specifically for use in the very demanding environment governed by the rules of "Good Manufacturing Practices" (GMP) and "Good Laboratory Practices" (GLP) and are equipped with an "Advanced Pharma Compliance" (APC) design and function package for use in the pharmaceutical industry.

The process of weighing is of key importance for the production of pharmaceutical products, During this process, the raw materials are prepared for further processing according to the specified requirements. This step is fundamental to determining quality because it is almost impossible to correct errors at a later date.

A further important aspect is the avoidance of contaminations resulting both from the experimenter and from the material that is used.
The employees involved in production must not be exposed to any substances which might be hazardous to health, and the item being weighed must also not be contaminated with microorganisms or foreign particles | previously weighed substances.

This requires a device design which ensures easy and highly-efficient cleaning. The pharmaceutical industry has dedicated hygiene regulations in order to meet this requirement. These are reflected, inter alia, in the EU Machinery Directive 2006/42/EC of 2009, the guidelines of the European Hygienic Engineering & Design Group, and the standards of the 3A Sanitary Standards Inc. Organization.

Sartorius Lab Instruments GmbH & Co. KG deals with this aspect via the APC design package which has been introduced to the Cubis® range. This pays the utmost attention to the requirements for the cleanability of the balances.

Stainless Steel is the Material of Choice

In the pharmaceutical sector, stainless steel is the material of choice for system and equipment building due to its longevity and corrosion resistance. According to the standard DIN EN 10020, alloyed or unalloyed types of steel with a high level of cleanliness are known as "stainless steel". This is achieved using special manufacturing procedures and results in high mechanical strength properties.

There are various types of stainless steel which differ in terms of their chrome, nickel, molybdenum, titanium and niobium contents. Generally speaking, the chrome content, which is responsible for corrosion resistance, is above 12% in these steels.

Due to the reaction of chrome with the oxygen in the air, spontaneous passivation results in a chrome oxide layer on the surface of the metal that is just a few angstrom thick and separates the metal from the atmosphere. This prevents oxidation of the metal and stops corrosion. In the event of damage to this passivation layer, for example due to mechanical influences,this layer will be replaced by the spontaneous new formation of chrome oxide. In addition to chrome, other possible noble metal components such as molybdenum, titanium and nickel are also capable of forming this kind of passivation layer. Therefore stainless steel compounds which are free of separation, and which do not have a poor level of chrome or other components due to intermetallic phase formation, have the greatest corrosion resistance.

For this reason, Sartorius Lab Instruments GmbH & Co. KG only uses non-rusting austenitic stainless steel (material number 1.4401, standardized short name X5CrNiMo17-12-2) with a chrome content of 16.5 – 18.5%, a nickel content of 10 – 13% and a molybdenum content of 2.0 – 2.5% for the production of balances in the Cubis® range. Due to its high molybdenum content, this stainless steel also offers good resistance to media which contain chlorine and non-oxidizing acids.

Stainless Steel Balance Surfaces: Roughness and Polishing Process

It is particularly important that the surfaces of the balance are easy to clean. Accordingly, these surfaces must have a high resistance to the cleaning agents and detergents used during cleaning. They should be made of a non-adsorbent material and have a suitably low surface roughness. The mean roughness "Ra" is used to express the surface roughness. It specifies the average distance of all measured points on the surface of a profile to the center line and is expressed in µm.

In this case, the center line (x) is defined as the reference length (l) which cuts the profile so that the total of the profile deviations (z) is minimal. Therefore, the Ra value corresponds to the arithmetic mean of the deviation from the center line and is calculated as follows:

$$R_a = \frac{1}{l} \int_0^l |z(x)| dx$$

Large even surfaces which may come into contact with the product may have a maximum average roughness of 0.8 µm and must be free of any damage such as cracks, brush strokes, grooves or fissures. But even surfaces which do not come into contact with the product must be smooth enough so that they can be cleaned thoroughly and easily.

In order to obtain these surfaces, it is general practice to carry out a final electropolishing subsequent to grinding processes with increasingly fine grain sizes. This is an erosive procedure and is particularly suitable for metal parts which are not suitable for mechanical smoothing due to their shape.

For the electropolishing, the part to be smoothed is switched as an anode in a direct-current circuit within a special electrolyte bath. This results in removal of the metal ions from the surface of the anionic part to the cathodes which are also in this electrochemical cell. The electrolyte solution itself does not attack the stainless steel. In the direct surroundings of the surface, a polishing film is formed, which levels the surface on a microscopic level, therefore smoothing it. This also leads to reduced roughness.

Normally the average roughness of electropolished stainless steel surfaces is in the range of 0.2 to 0.3 µm. Electropolishing is not only effective in the microscopic range. At the macroscopic level, higher local current strengths have an effect on corners and edges, which increases removal and results in very fine deburring. The removal has completely no-load, meaning that a zero-potential and metallically clean surface is produced. The accumulation of chrome and nickel on the surface also favors the formation of a passive layer, which forms due to spontaneous passivation when the current is switched off as a result of the oxygen present in the polishing film near the surface.

The advantage of a very smooth surface is obvious: Deposits, which could result in contact corrosion, are avoided This means that stainless steel treated in this way has a particularly long life cycle.

The balances in the Cubis® range exclusively use electropolished stainless steel with an average roughness of 1.6 µm. This high-quality, outstandingly smooth stainless steel is particularly resistant and is optimally suitable for easy cleaning.

Functional Design Features

A hygienic design is obligatory when designing devices and systems for the pharmaceutical industry. In principle, this also applies for balances and includes the aspects relating to the cleanability of the models already discussed above.

Against this background, the pharmaceutical balances of the Cubis® range are designed and constructed with the specific APC Design. They have clear shapes and surfaces made of electropolished stainless steel. A shield plate also ensures that no contaminations can get inside of the balance. Some models also have a liquid outlet which offers additional protection against contamination. The display and the control keys integrated into the surface are also smooth, resistant to cleaning agents and easy to clean.

The Cleaning Process: Guarantees Perfect Cleanliness

In a regulated environment, cleaning processes must be shown to be suitable for their use and detailed instructions | descriptions must be provided.

Sartorius Lab Instruments GmbH & Co. KG covers this aspect with a cleaning process tailored to the Cubis® balance range. The process is described in a standard operating procedure, which can also be provided on request in addition to the documentation of the development and testing for the decrease in example substances.

The cleaning agent referenced for the process has a defined composition and can be procured, with a certificate concerning all of the contents, from Sartorius Lab Instruments GmbH & Co. KG.

Synopsis

Cleanliness is one of the most important requirements in pharmaceutical operations.

Sartorius Lab Instruments GmbH & Co. KG has designed the balances in the Cubis® range with the APC design package so that they can easily comply with the high hygiene standard required in the pharmaceutical industry. In addition to this, Sartorius Lab Instruments GmbH & Co. KG provides suitable processes and cleaning agents for the devices.

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