Conductivity Measurement – The Mark of Quality in Highly-Purified Water

The pharmaceutical industry is an industry in which highly sensitive products are manufactured using equally sensitive processes. The smallest process variations can have serious effects — and not only on manufacturing costs. With the help of suitable measurement and control technology, processes have become considerably more reliable, monitoring has improved, and quality standards have been raised. This can be seen with highly-purified water, for example.

In most pharmaceutical processes, the parameters of temperature, pressure, pH value, conductivity, level, humidity, oxygen, and flow are recorded, monitored, and/or controlled. This is required for the standardization, validation, and optimization of the processes. In this context, the implemented measurement technology can be highly variable. Measuring devices used within the pharmaceutical industry must therefore meet the most varied requirements regarding materials, design, and in particular, process stability.

The quality of highly-purified water is described in standards and recommendations, for example from ASTM International (orig. the American Society for Testing and Materials), Pharmacopoea Europaea (Ph. Eur.), The United States Pharmacopeia (USP), and in DIN or ISO standards. All standards mentioned require an appropriate quality control. The method proven to be the most reliable and most widely accepted is conductivity measurement.

The measurement in highly-purified water is performed with conductivity sensors that work according to the two-electrode method. In this application, the electrodes are arranged concentrically, whereby the outer electrode shields the inner electrode. As the electrolytic conductivity of a liquid is highly dependent on the temperature, the measured value is usually based on the internationally recognized reference temperature of 25 °C (temperature-compensated). The special evaluation procedure "Water Conductivity <645>" (acc. to USP) for conductivity measurement in highly-purified water is an exception. Here, corresponding transmitters are available for which temperature compensation can be switched off.

A two-electrode sensor uses two conductive measuring electrodes which are made of stainless steel or titanium and arranged in a specific geometry for measurements in highly-purified water. The distance between the sensor surfaces (l) in relation to the effective measuring surface (A) is called the cell constant K, with the unit [1/cm]. This cell constant must amount to K = 0.01 for highly-purified water. In reality, most sensors are designed co-axially; that is, both measuring electrodes are arranged concentrically. Furthermore, a probe is usually integrated in these sensors to record the temperature of the medium. An external electronic transmitter supplies the two-electrode sensor with an alternating voltage. An alternating current is set according to the electrical resistance of the measurement solution (purity level). This is converted by the transmitter into the value for the conductivity of the measurement solution, taking into account the cell constant and potentially the temperature of the measurement medium.

Temperature compensation conforming with ASTM International avoids potential measurement errors occurring due to incorrectly set temperature coefficients. However, an inaccurate cell constant may cause systematic measurement errors. Highly-purified water conductivity sensors may also deviate from the nominal cell constant K = 0.01. Unfortunately, there are no test or calibration liquids which can be used practically for conductivity in highly-purified water, that is, for values below 10 µS/cm. Liquids with these conductivity values do not produce stable reference values, as they immediately absorb carbon dioxide from the air and change.

Therefore, the highly-purified water conductivity sensors need to be used with an accurately measured cell constant. For this purpose, the manufacturer provides a test certificate, such as the so-called "ASTM test certificate", in which each cell constant is entered accurately to several decimal points. During the startup of the measuring point, only this accurate cell constant then needs to be programmed into the transmitter. The sensor is then ready for measurement.

Tried and tested for many years, yet still modern

The optimized conductive JUMO tecLine CR conductivity sensor in a stainless steel version meets all the requirements of the pharmaceutical industry. Here, the deciding factors for good measurement results are the cell constants of the sensors. There are two variants with the cell constants K = 0.01 or 0.1. It is essential to use a measuring cell with a cell constant of K = 0.01 when measuring highly-purified water of the highest quality (below 1 µS/cm).

In the new version, the electrode shaft has been optimally adjusted to meet the process conditions of the pharmaceutical industry. Thanks to a clever shortening of the active measurement electrodes, the new JUMO tecLine CR conductivity sensor also allows for insertion into smaller pipe diameters. Since the electrolytic conductivity is highly dependent on temperature, the temperature must be taken into account during the evaluation. For this purpose, a Pt1000 sensor is integrated into the JUMO tecLine CR conductivity measuring cells. During the measurement process, the sensor records the medium temperature, which is then appropriately compensated in downstream measuring amplifiers.

The parts of the sensor which come into contact with the medium are manufactured out of stainless steel 1.4435 (316L) to electropolished quality (Ra < 0.8 µm). For these, acceptance test certificates according to DIN EN 10204 3.1, as well as roughness certificates (according to Ph. Eur or ASTM International), can be provided. Seals and plastics used by JUMO meet the requirements of the FDA and are physiologically harmless.

Figure 1: the JUMO tecLine CR conductivity measuring cell

Summary

The manufacture of highly-purified water is among the most important processes in the manufacture of drugs and pharmaceuticals. In order to guarantee the quality of the highly-purified water, the conductivity must be continuously recorded and monitored. This guarantees uniform quality and high process reliability. Co-axially designed two-electrode sensors, together with an external transmitter, provide the best requirements for reliable measured values.

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