

# Conductivity measurement according to USP<645>



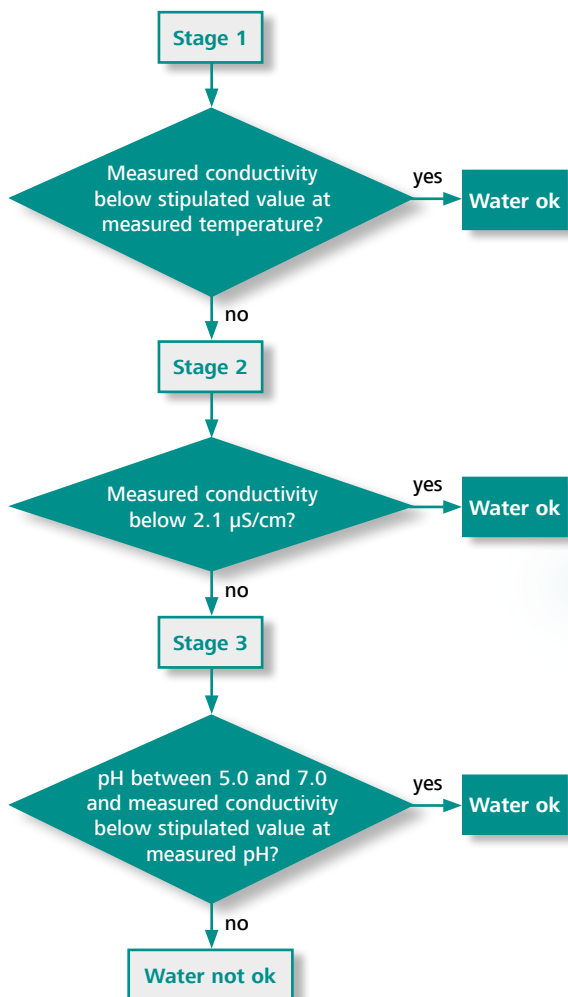
Automation increases reliability and productivity

## Measuring the conductivity of pure water using USP<645>

Pure water is important for our health and it is critical for pharmaceutical products. The requirements for purified water quality are especially high when it is used in such cases for injections, as diluent for active ingredients, or as sterile water.

Conductivity measures the purity of the water used in the pharmaceutical, biopharmaceutical, and microbiology sectors. It analyzes the amount of ions dissolved in the sample. Conductivity is an important quality parameter of purified water, and its measurement is stipulated in several standards, such as USP general chapter <645>.

USP<645> describes a three stage procedure to measure conductivity of pure water and water for injection.



Schematic of 3-stage analysis according to USP<645>.

Metrohm offers a **fully automated solution** for this measurement according to USP<645>. This solution reduces the risk of human error increasing the reliability of results.

### USP<645> defines a 3-stage test procedure

For the **stage 1 testing** the conductivity and temperature are measured. If the conductivity is lower at the measured temperature than the stipulated value, the test is passed.

If not, **stage 2 testing** has to be carried out. The water is tempered in an open vessel to 25 °C while stirring it to obtain a CO<sub>2</sub> equilibrium. The conductivity is measured. If the conductivity is higher than 2.1 µS/cm, testing according to stage 3 must be performed.

During the **stage 3 testing** a small amount of KCl is added to the sample to ensure a stable pH value. The measured conductivity in step two has to be lower than a stipulated limit for the measured pH value. If this value is exceeded, the testing failed, and the sample is not compliant.



Metrohm MATi 14 dedicated for conductivity measurements according to USP<645> in up to 28 samples.

# Automation reduces risks

Conductivity measurement according to USP<645> requires precise and thorough working, if the measurement is performed manually. Measurement or evaluation errors can result in batch rejections or even a production stop.

## Easy to use – How does automated water conductivity measurement work?

After filling the water into the sample beakers and covering them, the system carries out the measurement completely unattended. The evaluation, if the sample fulfills the requirements of USP<645> and after which stage, is automatically displayed.

The complete system is controlled by **tiamo™**, which allows you to work fully compliant with regulatory standards such as FDA 21 CFR Part 11.

## More safety through automation and data integrity

Using Metrohm's automated system for measuring water conductivity according to the USP norm not only reduces the risks of operator errors. System control by **tiamo™** ensures data integrity and compliance with regulatory standards such as FDA 21 CFR Part 11.

## Increase productivity

Automated conductivity testing frees up laboratory staffs, time and increases sample throughput.



## Literature

USP<645>, Water Conductivity

**Metrohm Application Bulletin AB-428,**

Automatic conductometry in water samples with low electrical conductivity in accordance with USP<645>

<https://www.metrohm.com/en/applications/AB-428>

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