



PHARMACEUTICAL MANUFACTURING

Monitoring TOC in Pharmaceutical Waters

The pharmaceutical industry manufactures medicines, food ingredients, and supplements. Water used in the manufacture of these products must meet strict quality standards as documented by the US Pharmacopeia (USP). The USP specifies Total Organic Carbon (TOC) for the detection of organic contaminants in pharmaceutical waters - Purified Water (PW) and Water For Injection (WFI), and the analytical instrumentation that monitors these waters must meet USP standards.

Pharmaceutical Waters:

Since pharmaceutical products are largely intended for use in humans, the need to protect public health drives strict purity standards for Pure Water (PW) and Water for Injection (WFI). Monitoring contaminants at near-zero levels requires instruments that can pass a rigorous System Suitability Test (SST) and can be calibrated using USP-compliant methods.

USP specifies that TOC in Purified Water (PW) and Water For Injection (WFI) must be maintained at TOC levels ≤ 500 ppb (≤ 0.5 mg/L). Many pharmaceutical plants choose to monitor TOC online, which enables continuous, rapid recording of the water quality produced by the water filtration system.

Selecting an Appropriate TOC Analyzer:

To monitor TOC, USP does not specify the equipment or method to be used. Instead, the selected equipment must pass the challenges of a defined System Suitability Test .

The SST challenges the analyzer to measure two chemicals of different chemical compositions (but equal carbon content) and to respond with equivalent values for each. The USP's SST specifies solutions of sucrose (easy to oxidize) and benzoquinone (difficult to oxidize) as testing reagents. These two organic compounds challenge the analyzer's bond-breaking and oxidation capabilities. During the SST, reagent water is also analyzed to establish a baseline and suitable rates of recovery.

What is TOC? There are millions of organic compounds, so organic contaminants are detected as an aggregate rather than individually. Since all organic compounds contain carbon, measuring for carbon is a way to detect organic contaminants. A few carbon compounds are inorganic. To achieve a true TOC measurement, inorganic carbon compounds can be removed through acidification before measuring the sample.



A TOC Analyzer Designed for the Pharmaceutical Industry:

The QuickTOCtrace has been developed to measure TOC accurately and repeatably in the very low ppb ranges found in pharmaceutical waters. The analyzer utilizes a straight-forward differential conductivity method.

Advantages of the QuickTOCtrace

- No pre-filtration required
- A single, long-life UV light source
- Built-in SST procedure
- <30 second response
- Fast recovery time (< 3 minutes)
- Easy to use and maintain
- Simple annual calibration

