

ASK THE EXPERT

Real-Time TOC Sensors Improve Control over Organics in Pharmaceutical Water Systems



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Pharmaceutical plants rely on TOC measurements to ensure their water is safe for use in the manufacture of products that are intended for human use. If left unchecked, organic impurities can rise to levels that result in noncompliance with regulatory guidelines and product recalls. Batch-style and offline TOC measurements generate intermittent data, creating a risk that a contamination excursion gets missed. Fortunately, real-time TOC sensors can be utilized at appropriate locations throughout a pharmaceutical plant, allowing personnel to monitor water system health and to take corrective actions before organic contaminants lead to expensive ramifications. Maura Rury, Global Product Manager with Mettler Toledo

Process Analytics, explains how using real-time TOC sensors to monitor organics helps maximize the overall health of the water system.

Why are TOC measurements crucial in the pharmaceutical industry?

Water is one of the most highly used solvents in pharmaceutical manufacturing. Whether it is used as a raw material, a solvent, a cleaning agent or is the final product itself, high-purity water is critical to pharmaceutical production. If organic contaminants are present in the process water during manufacturing, these compounds can be transferred into the final product, resulting in consumer goods that are ineffective or unsafe for consumption. Accurate and reliable TOC

measurements are crucial for ensuring the purity — and therefore, the quality and safety — of the water used for manufacturing meets pharmaceutical requirements.

What are the challenges associated with batch-style or offline TOC measurements?

Batch-style TOC measurements reduce the frequency of data collection, eliminating a plant's ability to act quickly in the event of an excursion. These infrequent measurements allow intermittent excursions to go

undetected, increasing the risk for organic contaminants to build up in the water system.

Offline TOC measurements always produce results that are higher than those from online systems due to contamination introduced during collection and transport. These biased results can produce false positives and trigger corrective actions that are not warranted. Such false positives reduce the plant's ability to maintain strict control over the organic contaminant levels in the water system and increase the risk of using contaminated water for manufacturing purposes.

How do real-time TOC sensors alleviate the frustration of intermittent or offline measurements?

Uninterrupted monitoring of organic contaminants allows a pharmaceutical plant to identify longer-term trends as well as short-lived excursions and make confident, effective decisions to maximize control over the water system. Maintaining full transparency of the "health" of the water system reduces the risk of releasing contaminated water for use in production.

The lengthy measurement delays from a batch-style system and the delays and contamination risks introduced with offline testing are eliminated with an online, real-time TOC sensor. Measurements never have to be repeated because results will never be questioned or second-guessed. These plants can focus on manufacturing, knowing that they have full control over the organic contaminants in their water.

Do you have any examples of customers who have benefitted from this technology?

We have many pharmaceutical customers who have found real-time TOC measurements beneficial to their process. In one example, a pharmaceutical plant was using a batch-style TOC analyzer to release water for use in production. During a sanitization cycle with ozone, the TOC sensor became overwhelmed from exposure to ozone and could not resume reporting TOC measurements for nearly an entire day after the sanitization was complete. To avoid the risk of releasing contaminated water, the plant grabbed

samples for offline testing in the laboratory, which was an inefficient and error-prone approach to TOC data collection. After switching to real-time TOC sensors, this plant resumed reporting TOC measurements within an hour of the ozone dissipating from the water.

In another example, a batch-style TOC analyzer missed a short-term excursion, causing a mid-size pharmaceutical manufacturing facility to use contaminated water in its production process. The organic contaminants that reached the final product were caught before the product was distributed to consumers; however, the product recall reduced the company's operating profits and their confidence in maintaining a regulatory compliant water system. After installing real-time TOC sensors, this company never missed another excursion.

Are there additional frustrations alleviated with this TOC technology?

The simplicity of this design minimizes the number of hours spent doing service and maintenance, which maximizes the amount of time the TOC sensor spends measuring organic contaminants in your water system. How would a real-time TOC sensor be beneficial if it was always offline for maintenance? Maximizing the sensor's uptime provides you with optimal control over your water system and any potential excursions that may occur.

Another advantage of this design is its robustness to extreme water conditions, particularly those generated during a sanitization cycle. Thermal sanitization and ozonation are commonly used approaches for managing a water system from a microbial perspective. Both techniques have the potential to negatively impact any analytical device, including a TOC sensor. The strength of this design allows the sensor to remain online during a sanitization, with only a brief hold on reporting TOC measurements until after the cycle is complete. The sensor does not require calibration, maintenance or intervention of any kind, and may resume reporting TOC measurements as soon as the water system is sanitized.

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