

Peak TOC and Average TOC Derived Measurements

Compendial Pharmaceutical Waters such as Purified Water and Water for Injection are commonly produced and used continuously as part of the pharmaceutical manufacturing process. Because of this process of continuous usage, demonstration of compliance with TOC regulatory requirements and Pharmacopeia guidelines can become challenging due to the dynamic nature of the data collection of a continuous measuring system. Mettler Toledo Thornton has developed two derived TOC measurements to assist with quality assurance associated with TOC compliance verification.

Peak TOC

Pharmacopeia standards and regulatory requirements establish maximum allowable limits for impurities in pharmaceutical waters, including limits for TOC concentration. By monitoring the TOC measurement, and tracking the maximum TOC concentration observed during the production period, a single data point can be used to demonstrate TOC compliance.

The peak TOC measurement is a measurement of the highest TOC concentration observed by the 5000TOCi Sensor during the past 1 to 24 hours of normal operation (as configured by

the user), exclusive of calibration and SST cycles. Peak TOC is an optional reporting measurement designed to provide complete knowledge of the highest TOC value observed during the user-selectable time period ranging from 1 to 24 hours, providing a 'worst case' TOC concentration which may be used to demonstrate that TOC concentrations have never exceeded regulatory requirements during this time period.

Average TOC

The average TOC measurement is an optional time-weighted TOC measurement over a user-selectable time period ranging from 1 to 24 hours, providing an indication of the overall water quality during the selected time period. In many applications, pharmaceutical water may be produced and held in a storage tank to be used intermittently or to meet peak usage rates that may exceed the maximum water system output. Dependent upon the tank size and usage, the total water turnover time may range from one hour to one day.

The Average TOC measurement will provide an indication of the total water quality over the selected time period. For practical application, the time period should be set to the approximate turnover time calculated as:

$$\frac{\text{Average Tank Volume}}{\text{Volumetric Flow Rate}}$$

The Average TOC measurement can be used as a representation of the TOC concentration of the batch of water produced over the last 1-24 hours.

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Mettler-Toledo Thornton, Inc.

36 Middlesex Turnpike,
Bedford, MA 01730 USA
Tel. +1-781-301-8600
Fax +1-781-301-8701
Toll-Free: 1-800-510-PURE (US and Canada only)
thornton.info@mt.com