

cleaning validation from HPLC to TOC: three factors to consider



Total Organic Carbon (TOC) analysis is often preferred over traditional, product-specific methods for cleaning validation due to its speed, simplicity, and ability to enhance process understanding.

HPLC vs. TOC

TOC analysis offers several benefits over HPLC, including:

- Better process understanding
- Faster sample analysis
- Simpler method development
- Greater productivity
- Opportunity for at-line and online efficiency gains
- Lower operating costs

Here are 3 factors to consider to help you get started with TOC:

1 Cleaning process/sample compatibility

Does the existing cleaning cycle use a final aqueous rinse?

Understanding your current process will help determine if an aqueous final rinse is possible.

2 Cleaning limit acceptance criteria

Is the acceptance criteria limit within the linear dynamic range of the TOC analyzer?

Convert existing specific product limits to TOC limits using the percent carbon in the chemical formula to determine if they are within the range of the instrument.

3 Product recovery/solubility

Are your compounds soluble enough for TOC?

Even traditionally insoluble or difficult-to-solubilize compounds such as ibuprofen, starch, and lidocaine can often be recovered by TOC with little or no pretreatment.

TOC may be a great match for your CV program.

To learn more, visit geinstruments.com/industries/cleaning-validation-and-verification

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