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**Cleaning verification: A five parameter study of a Total Organic Carbon method development and validation for the cleaning assessment of residual detergents in manufacturing equipment**

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**Highlights**

- Five factors were identified affecting the development and validation of a TOC based analytical method to quantify trace residues of CIP100<sup>®</sup> and CIP200<sup>®</sup> detergents on the surface of manufacturing equipment during the cleaning verification stage. These factors were the concentration and volume of the diluent, extraction method, location for TOC sample preparation, and oxidant flow rate. Key experimental parameters were optimized to minimize contamination and to improve the sensitivity, recovery, and reliability of the method.

**Abstract**

A Total Organic Carbon (TOC) based analytical method to quantitate trace residues of clean-in-place (CIP) detergents CIP100<sup>®</sup> and CIP200<sup>®</sup> on the surfaces of pharmaceutical manufacturing equipment was developed and validated. Five factors affecting the development and validation of the method were identified: diluent composition, diluent volume, extraction method, location for TOC sample preparation, and oxidant flow rate. Key experimental parameters were optimized to minimize contamination and to improve the sensitivity, recovery, and reliability of the method. The optimized concentration of the phosphoric acid in the swabbing solution was 0.05 M, and

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