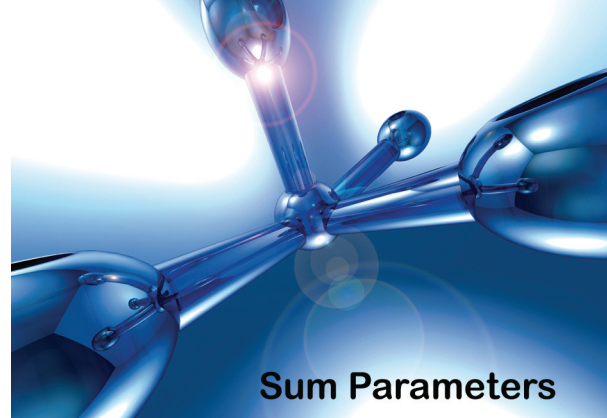


Application Note

Direct swab method procedure using TOC-V and SSM-5000A



Swab test in cleaning validation

A totally different application area of the SSM-5000A can be found in the pharmaceutical industry. The effective removal of residues in pharmaceutical production lines is a crucial prerequisite for production. A properly cleaned system prevents contamination and consequently the adulteration of the produced drug. This is especially important in the production of active agents in batch processes, as the system is used for different products and contamination of the next product must be prevented. Cleaning validation confirms the effectiveness of a cleaning procedure and assures that no residues remain.

Depending on the production- and cleaning process, there are different possibilities for sampling in order to effectively test the cleaning procedure. Recently the swab method has been gaining more importance. The advantages of the swab method are obvious as this is truly a surface sampling method. Insoluble compounds, baked-on residues or encrustations that cannot be easily removed via a rinsing solution, can be measured using the swab method. Traditionally, the swabs are subsequently extracted and the resulting solution is further analysed. However, when using the SSM-5000A module with glass-fibre swabs that do not contain any carbon, the swabs can be directly analysed.

Measuring system



TOC-V CSH with ASI-V and SSM-5000A

The solid sampling module (SSM-5000A) can be adapted for each model in the TOC-V series. After one-off installation, the system allows easy switching via the operating software between aqueous and solid samples without the need for system reconfiguration. The NDIR detector in the TOC-V series contains a tandem cell that consists of a long and a short cell. The long cell is typically used for water analysis and the short cell for solid sample analysis. In order to attain a higher sensitivity for the analysis of solids, the solid sample module can also be connected to the long, and therefore, more sensitive measuring cell. This can be realised via a switching valve. This way the system can be easily be used in cleaning validation without sacrificing the flexibility of easy switching between water and solid sample analysis modes.

Further equipment

- Two pairs of tweezers, one for the swabbing materials and one for the SSM sampling boat.
(carbon contamination should be burned out)
- 100µL syringe to load the standard solution onto the swabbing material
- Swabbing material:
Quartz microfibre filter ("ADVANTEC QR100, size 45mm" or "Whatman QM-A, 4,7cm, Cat No: 1851047")
- Standard solution:
1 or 0,1 % C-Glucose solution
(Depends of the final concentration)
- TOC-V with SSM-5000A
Measuring range: TC: 0,1 to 30mg/L C
(measuring with the short cell)
Installation of SSM high sense option
Measuring range: TC: 1 to 300µg/L C
(measuring with the long cell)
Carrier gas: pure oxygen

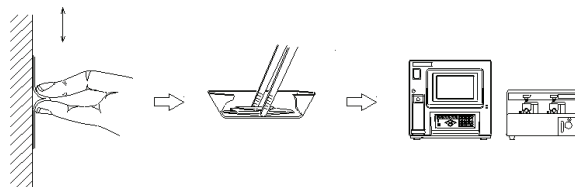
Preparation

Preliminary heat silica glass fibre filter paper at 600 °C for about 20 minutes to remove carbon impurities and store it in clean place.

Calibration

Fold the pre-cleaned swabbing material and put it in the SSM sample boat. Load the selected volume of the standard solution at the centre of the swabbing material. Put the sample boat into the sample change port, close its cover, wait until the ready signal appears and push the sample boat into the furnace.

Sample analysis



Hold the filter paper with a clean handling tool, wet it with approx. 0.4mL of high purity water, then swab a target surface.
Or, using two sheets of the filter paper put together and folded into two, hold the external paper with finger tips and swab with the inner paper.

Move the filter paper to the sample boat, and set it the calibrated instrument, and measure the carbon content.