DATA BULLETIN

elementar
EXCELLENCE IN ELEMENTS

*System suitability of the **acquray**® TOC and vario TOC cube for pharmaceutical applications*

According to the European Pharmacopeia (EP 2.2.44) and the US Pharmacopeia (USP 643), the system suitability of a TOC analyzer has to be tested by comparing the recovery of a hard digestible compound, which is 1,4-benzoquinone, and an easy digestible compound, which is sucrose. Both compounds should have a concentration of 0.5 mg/l carbon to cover the requirements of bulk water (USP) or water for pharmaceutical use in general (EP).

To achieve the required concentration, 1.19 mg sucrose and 0.75 mg benzoquinone have to be dissolved in 1 Liter ultra pure water. For this purpose, either an adequate balance or larger water volumes should be used. Additionally, it is recommended to sterilize all required laboratory equipment thoroughly. The reagent water should have a concentration < 0.1 mg/l.

The Pharmacopeias allow oxidation techniques using UV/persulfate as well as high-temperature combustion. Consequently, both the **acquray** TOC (UV/persulfate) and the vario TOC cube (high-temperature combustion) are suitable techniques.

For the test of the **acquray** TOC, an injection volume of 7 ml in TC mode was defined. To test the suitability of the vario TOC cube, the NPOC mode was used with an injection volume of 1 ml. The combustion temperature was 850°C and a platinum catalyst was used. Both instruments met the system suitability test with great reproducibility (Table 1, 2).

OVERVIEW

Automatic system suitability test of **acquray**® TOC and vario TOC cube with an immediate interpretation of the results.

STANDARDS & REGULATIONS

e.g.
European Pharmacopeia EP 2.2.44
US Pharmacopeia USP 643

Table 1. Results of the system suitability test for the **acquray** TOC.

COMPOUND	CONC. [ppm C]	RECOVERY [%]	RSD [%]
sucrose	0.5	100.4	0.57
1,4-benzoquinone	0.5	99.0	1.21

Table 2. Results of the system suitability test for the vario TOC cube.

COMPOUND	CONC. [ppm C]	RECOVERY [%]	RSD [%]
sucrose	0.5	99.2	0.92
1,4-benzoquinone	0.5	102.0	1.13

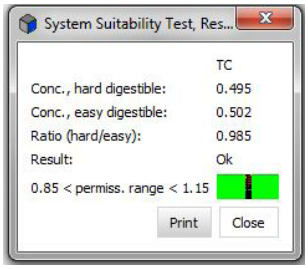

Figure 1. Screenshot of the system suitability test evaluation feature of the **acquray** TOC

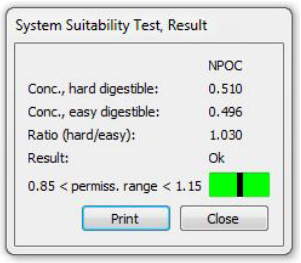

Figure 2. Screenshot of the system suitability test evaluation feature of the vario TOC cube

Conclusions

The evaluation of the system suitability test can be conducted automatically via the software of both analyzers with an immediate interpretation of the results (see Figure 1 and 2). The results and features confirm the suitability of both analyzers for laboratories in the pharmaceutical industry, which need to determine and evaluate the TOC concentration in any water involved in the production and research of pharmaceutical products.

Elementar – your partner for elemental analysis
Elementar is the world leader in high performance analysis of organic elements. Continuous innovation, creative solutions and comprehensive support form the foundation of the Elementar brand, ensuring our products continue to advance science across agriculture, chemical, environmental, energy, materials and forensics markets in more than 80 countries.

Elementar Analysensysteme GmbH
Elementar-Straße 1 · 63505 Langenselbold (Germany)
Phone: +49 (0) 6184 9393-0 | info@elementar.de | www.elementar.de

04 / 2018 A