



## Applications in pharmacy



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pharmacy



Quelle: Wacker Chemie AG

For the effective and precise detection of TOC trace contamination the multi N/C® pharma is just right!

Dependent on your requirements we offer flexibility with two models:

- multi N/C pharma HT
- multi N/C® pharma UV.

The TOC analyzer combines detection sensitivity, long-term stability and comfort of use in a perfect manner. An effective reduction and treatment of blank values, integrated into the N/C® pharma, provides for accurate results.

In combination with the FDA-compliant multiWin® Software, with integrated system suitability test, and comprehensive documentation (such as IQ, OQ, PQ etc.) it becomes easy for the user to meet the strict requirements of Pharm. Eur. or USP.

### TOC limit value verification in water for pharmaceutical use or for injection purposes

- NPOC analysis by catalytic high temperature combustion or by high power UV digestion
- Easy Cal function for multipoint calibrations from a single standard up to the lowest ppb range
- Detection limits of 2–4 ppb
- Flexible injection volumes up to 3,000 µl (pharma HT) or 20,000 µl (pharma UV)
- Flexibility in sample supply:
- APG 49: rack of 18 for 100 ml Schott flasks, rack of 49 for 100 ml vials, rack of 64 for 40 ml EPA vials with septum seal
- APG 21 for 50 ml vials
- APG 10 for 50 ml vials

# multi N/C® – Applications in pharmacy

## Swab eluate or last rinse, TOC or TN<sub>b</sub> during cleaning validation

- Use of certified polyester swabs or cotton swabs
- Extraction with ultrapure water directly in the sample vial with subsequent direct analysis on the EPA autosampler
- TOC and TN<sub>b</sub> are available as parameters in combination with a CLD detector

## Direct swab analysis in TOC cleaning validation

- Use of the swab module at the T furnace of the multi N/C® pharma HT for direct catalytic swab combustion at up to 950°C (only quartz fiber swabs)
- Quantitative detection also of compounds insoluble in water, e.g. fats
- Comfortable calibration using liquid standards



## Product control of protein solutions such as vaccines

- Catalytic high temperature combustion in combination with a CLD detector for TN<sub>b</sub> detection
- Calibration via a synthetic BSA standard of known TN concentration
- Implementation of smallest injection and rinsing volumes by way of direct injection and thus also suitable for lowest available sample volumes
- High reproducibility of measured values and comfortably automatable for up to 112 samples in a single sequence
- Recommended device especially for this application: multi N/C® 2100 S + autosampler APG 60

## Recommendations

|        |                      |  |
|--------|----------------------|--|
| Models | multi N/C® pharma HT | swab test module, autosampler APG 10, APG 21, APG 49, EPA (64) |
|        | multi N/C® pharma UV | autosampler APG 10, APG 21, APG 49, EPA (64)                   |
|        | multi N/C® 2100 S    | autosampler APG 60 (112)                                       |

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Subject to changes in design and scope of delivery as well as further technical development!