



Applications in 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 3,000µl (pharma HT) or 20,000µl (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_b 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

Direct swab analysis in 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
- Quantitative detection also of compounds insoluble in water, e.g. fats
- TOC and TN_b are available as parameters in combination with a CLD detector
- 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_b 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!