

DATA BULLETIN

*TOC determination for cleaning validation with the **acquray**[®] series*

TOC determination for cleaning validation is an FDA accepted tool, which has the great opportunity that it is not ingredient specific and delivers quantitative, fast results with a low detection limit.

The modular concept of the **acquray** series offers the opportunity to measure final rinse or swab samples depending on the desires and challenges of the respective laboratory. In case of final rinse analysis, the final rinsing solution is sampled and can be analyzed using the liquid TOC module if water has been used as a solvent. The use of organic solvents instead of water is possible, but high and fluctuating carbon blanks from the organic solvent would affect the results.

Table 1. Recovery of active substances dissolved in water, analyzed with the **acquray** TOC.

COMPOUND	CONC. [ppm C]	RECOVERY [%o]	RSD [%]
Acetanilide	2	98.5	0.87
acetylsalicylic acid	2	99.4	0.55
cystine	2	104.5	0.69
biotine	2	103.7	0.70
ciprofloxacin	2	32.2	0.50
atropine	2	37.3	0.84

The **acquray** TOC achieves accurate, precise results for different active substances dissolved in water and typically occurring in pharmaceutical industry (see Table 1). However, in case the compound is not or hardly soluble in water (like ciprofloxacin or atropine) an alternative would be swab analysis. Therefore, carbon concentrations on swabs made of glass fiber or quartz wool annealed at 400°C can be directly analyzed with the **acquray** solid module with great precision and accuracy (see Table 2).

OVERVIEW

acquray[®] is the perfect solution for TOC determination for cleaning validation as it covers TOC determination in liquid and solid samples with one instrument.



STANDARDS & REGULATIONS

FDA guide to inspections: validation
of cleaning processes
21 CFR 211.67 / 21 CFR 211.160 (b)
US Pharmacopeia USP 643

Table 2. Recovery of solid active substances analyzed with the **acquray** solid TOC module.

COMPOUND	CONC. [µg C]	RECOVERY [%]	RSD [%]
Acetanilide	357 - 431	100.9	0.71
acetylsalicylic acid	300 - 420	102.2	2.84
cystine	102 - 144	105.9	2.58
biotine	375 - 501	103.6	3.28
ciprofloxacin	230 - 482	101.1	0.78
atropine	309 - 442	101.9	1.95

Swab analysis with the **acquray** solid module shows excellent recovery for all substances.

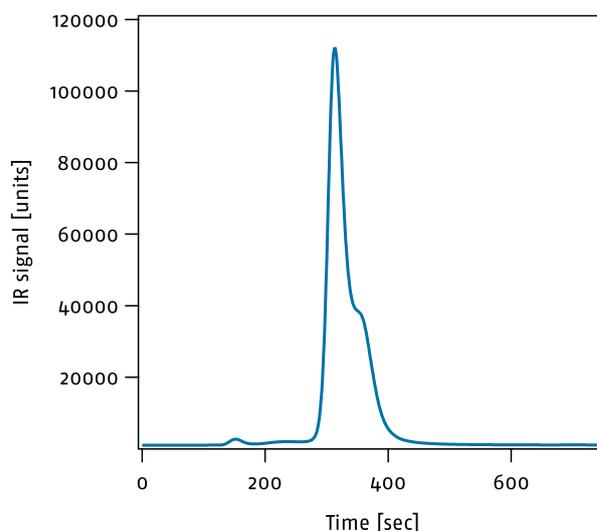


Figure 1. Cystine peak with 0.3149 mg sample weight.

Sensitivity

A sample weight of 0.3149 mg cystine (corresponding to 102 µg C) results in a well detectable peak that is clearly separated from the baseline (see Figure 1) as the limit of detection is 2 µg C for the **acquray** solid TOC module.

Conclusion

In summary, the **acquray** series with its liquid and solid TOC modules is the perfect solution for TOC analysis in cleaning validation as it covers TOC determination in final rinse and swab samples with one instrument.



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