

In the pharmaceutical industry, predictability and highest accuracy are critical for a good performance of elemental analysis. Compliance to strict regulations can only be reached with very rugged instrumentation and unconditionally reproducible instrument behavior. UNICUBE® is your solution when it comes to demanding applications in pharmaceutical elemental analysis. It can be supplied with 21 CFR part 11 software compliant to GLP guidelines. As all temperatures, gas flows and pressures are digitally controlled (no manual valves), it is the only instrument on the market which is fully compliant with 21 CFR part 11 and GLP.

Different pharmaceutical substances were weighed into tin boats and analyzed with a standard method on the UNICUBE. The theoretical and analyzed CHNS content and the absolute standard deviation of the analyses are presented in the table below. Please note that some substances were not available in >98 % purity.

SAMPLE	(n=5)	C [%]	H [%]	N [%]	s [%]
biotine	theory	49.16	6.60	11.47	13.13
≥99 %	analysis	49.21 ± 0.09	6.64 ± 0.01	11.49 ± 0.03	13.11 ± 0.05
D-cysteine	theory	29.74	5.82	11.56	26.47
≥99 %	analysis	29.76 ± 0.06	5.85 ± 0.01	11.65 ± 0.01	26.51 ± 0.02
aspirin ≥99 %	theory analysis	60.00 60.16 ± 0.01	4.48 4.50 ± 0.01		
carbimazole	theory	45.15	5.41	15.04	17.22
≥98 %	analysis	44.98 ± 0.05	5.26 ± 0.05	15.15 ± 0.04	17.18 ± 0.09
ciprofloxacine	theory	61.62	5.48	12.68	
≥98 %	analysis	62.06 ± 0.08	5.53 ± 0.05	12.73 ± 0.06	
atropine	theory	70.56	8.01	4.84	4-71
≥99 %	analysis	71.08 ± 0.01	8.09 ± 0.02	4.84 ± 0.01	

UNICUBE offers high analytical performance combined with innovative technology and unprecedented usability. With UNICUBE, elemental analysis is fully compliant to pharmaceutical regulations and straightforward at the same time. Enjoy tool-free maintenance and extraordinary instrument uptime due to functional design and experience the lowest noise emission in the industry.

INSTRUMENT:

UNICUBE® with 21 CFR part 11 software

DETAILS:

mode: CHNS

sample: <1-5 mg pure chemicals



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