

## IonScan-LS IMS: Fast, Efficient Cleaning Validation

Cleaning validation tests the efficacy of cleaning methods used in pharmaceutical research and manufacturing. It is a critical and time-intensive step. Process equipment must be cleaned after every stage in the drug development process and the equipment cannot be reused until the cleaning is validated. In cleaning validation, samples are taken from the equipment and analyzed for pre-determined thresholds of probable contaminants, in particular for active pharmaceutical ingredients (APIs) from previous batches.

The analysis method used in cleaning validation must be sensitive and selective in order to detect and identify trace contaminants, and quantitative to report the extent of the contamination. Ion mobility spectrometry (IMS) meets all of these criteria and it is fast, much faster than HPLC, the method most commonly used in cleaning validation.

Total Organic Carbon (TOC) is also used in cleaning validation. The disadvantage of TOC is that although it is fast, it is nonspecific, counting all organic carbon—even from harmless sources—against the pre-determined contaminant threshold.

The major disadvantage of HPLC is its speed. Each HPLC analysis takes about 10 minutes and when multiplied by the number of samples run to validate a cleaning method (typically 100-200), capital equipment may be quarantined for as much as two days while the cleaning validation is performed. A typical IMS analysis is done in less than a minute, resulting in a savings of more than a full day over

HPLC methods.

In addition to throughput rates, HPLC requires additional time for column equilibration and mobile phase preparation. Another significant factor in HPLC analysis is the handling and costs associated with the purchase and disposal of eluting solvents. IMS eliminates all of these elements, saving both time and money.

### The IonScan-LS Advantage

IonScan is well known in security and law enforcement for its trace determination capability, ease of use, and speed. The IonScan-LS IMS, designed particularly for the pharmaceutical industry, avoids the nonselective responses possible in TOC and eliminates most of the downtime associated with HPLC. Smiths Detection's IonScan-LS is the fastest method available for cleaning validation today. This instrument is fully compliant with the FDA's 21 CFR Part 11 regulation for electronic record keeping and it can be used to analyze a wide range of pharmaceutical compound. The IonScan-LS offers a choice of two different sample introduction methods: thermal desorption from a Teflon substrate and high performance injection (HPI). For many compounds, simply varying the desorption temperature offers the level of control needed for sample introduction. Other compounds can take advantage of the control parameters available with HPI; parameters such as hot or cold injection, split flow, large volume injection, and temperature and flow staging. By selecting the appropriate sample introduction method and

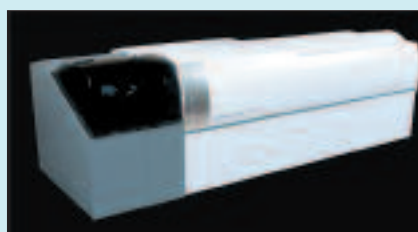
parameters, the IonScan-LS can be used to analyze samples—even in solvents of low volatility—over a concentration range of about three orders of magnitude.

Sensitivity, selectivity, regulatory compliance, speed. These qualities have brought IMS into numerous

major pharmaceutical companies for cleaning validation. In addition, the IonScan-LS is actively being investigated for other pharmaceutical applications such as dissolution and content uniformity testing.

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## LCMS-IT-TOF Liquid Chromatograph/Mass Spectrometer



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