ThermoFisher SCIENTIFIC

Pharma

Workflow solutions for pharmaceutical impurity analysis

Your roadmap on pharma quality control and quality assurance analytical solutions

Partnering with Thermo Fisher Scientific will enable your laboratory operations to become more profitable and productive. Learn more about our end-to-end solutions to support your GMP/GLP environment.

Counterion analysis

Accelerate the determination and quantification of inorganic anions and cations in pharmaceutical formulations. Screening and assaying of a broad variety of counterions and active pharmaceutical ingredients (APIs) is crucial for quality control (QC) of pharmaceutical salts to confirm identity of salt form and mass balance of the API.

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Volatile organic impurities and residual solvents

We have proven, simple, compliant workflows for organic volatile impurities that follow regulatory guidelines, such as pharmacopeial chapter USP <467> Residual Solvents, and ICH Q3C Guideline for Residual Solvents.

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Semi-volatile organic impurities

Semi-volatile organic pharmaceutical impurities are a complex range of chemicals that often require high selectivity and sensitivity analysis for identification and quantification.

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Non-volatile organic impurities

Impurity profiling is a critical quality control step in the production of pharmceuticals and biopharmaceuticals. This process is carefully regulated by bodies such as ICH and US FDA.

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Extractables and leachables

Extractable and leachable (E&L) testing methods, such as draft pharmacopeial chapters USP 1663 and USP 1664, demand carefully controlled extraction.

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Elemental impurities

Elemental impurities in pharmaceutical formulations can interfere with drug efficacy or have a toxic effect on the patient. A range of metal elemental impurities in pharmaceutical materials can be monitored using inductively coupled plasma-optical emission spectroscopy (ICP-OES), or ICP-mass spectrometry (ICP-MS).

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Nitrosamine impurities

Nitrosamine impurity analysis requires robust and sensitive analytical methods to ensure confidence in the obtained results. Our portfolio enables efficient and sensitive nitrosamine analysis, ensuring your exploratory and routine methods are performed as accurately and reliably as possible.

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Connect with us to ensure your pharmaceutical analysis is done with confidence

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