PlasmaQuant MS in the Pharmaceutical Industry

Recommended configurations

Industry requirements

- Robust and reliable performance
- Matrix tolerance
- Easy operation
- Start-up routine
- Low maintenance
- 21 CFR Part 11 compliance

Regulations

USP 232/233, ICH Q3D

Instrument characteristics

- Temperature controlled sample introduction
- Robust plasma with exceptional hot and cool plasma capability
- Stable instrument performance even with changing matrices
- Throughput typically 20-30 samples per hour with standard sample introduction
- Unique interference management
- 21 CFR Part 11 compliance (user management, audit trail, electronic signature) incl. software validation

The control and characterization of pharmaceutical relevant materials and final products became a huge market for ICP-MS since the release of new regulations, e.g. USP 232/233 and ICH Q3D. Furthermore the growing market for food and dietary supplements offers high sales potential.
Pharmaceutical analysis is typically done in contract labs and pharmaceutical QC labs.

Sample types

- Nutrient solutions and dietary or food supplements
- Pharmaceutically relevant raw materials incl. active substances, binders and fillers (purity control)
- Pharmaceutical end products for characterization of toxic elements according to regulations

Recommended instruments

PlasmaQuant MS Q is the most suitable instrument for pharmaceutical QC control. It provides the fast and sensitive solution for the characterization of samples with moderate matrix concentration. In combination with HPLC it provides sensitive speciation analysis of Cr III and Cr VI and others.

PlasmaQuant MS S is recommended whenever sensitivity and more flexibility is required, e.g. in pharmaceutical research for lower limits of detection or specific applications using HPLC coupling.

With the flexible sample introduction system for aqueous samples and organic solvents the instruments are perfectly suited for pharma applications. Liquid sample types, dissolved or digested solids and samples solved in organic solvents are analyzed with ease.

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Application	Sample Introduction Kit	Sheath Gas / Aerosol Dilution	Nitrox	FAST Sample Introduction	Cones	PlasmaQuant MS		PlasmaQuant MS Elite	
							Q	S	
Clinical (urine, Blood,Serum)	Standard	Optional	Optional N_2	Optional	Nickel		✔	✔	
Infusion solutions	Standard	Optional	No	No	Nickel		✔	✔	
Dietary supplements	Standard	Optional	No	No	Nickel		✔	✔	
Raw materials and final products, liquids, pills/ tablets	Organic	Optional	Yes O_2	Optional	Nickel / Platinum		✔	✔	

When to choose which instrument

Rule of thumb:

- Sensitive analysis of organic matrices and moderate sample throughput → PlasmaQuant MS Q
- Lowest detection limits or specific requirements → PlasmaQuant MS Elite S

Nitrox mandatory when workig with organic solvents: allows the addition of nitrogen or oxygen to the plasma. Oxygen guarantees stable instrument performance when analyzing organic solvents. It is essential to use Pt tipped cones when applying oxygen.

In combination with HPLC all PlasmaQuant MS models guarantee fast and reliable speciation analysis far below current international limits.

Recommended basic configuration

- PlasmaQuant MS model
- Start Kit Organic
- Autosampler
- Chiller
- Nitrox
- Pt cones
- 21 CFR Pt. 11 package and validation package

Upgrades and accessories

- Fast/discrete sample introduction
- Aerosol Dilution
- HPLC

Benefits of upgrades and accessories

Autosampler: automated sample introduction provides the user with time for other activities. Combined with QC samples and defined response actions the automated sequence can run unattended or over night.

Fast/discrete sample introduction: autosampler upgrade that reduces sample or rinse delay times by 80 %, significantly increasing sample throughput.

Aerosol dilution: software controlled aerosol dilution option allowing the on-line dilution of samples such as nutriens solutions or dialysis solutions during sample introduction. Furthermore it is recommended when working with very low sample uptake and reduced nebulizer flow since an additional argon gas flow can stabilize the plasma conditions.

HPLC: by coupling an HPLC system for chromatographic separation of element species, e.g. the PQ LC, to the PlasmaQuant MS instruments, the species analysis of CrIII and CrVI required by pharmaceutical regulations can be performed. Other element species can also be characterized in this way.

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