

Chemical analysis by ICP-MS (inductively coupled plasma mass spectrometry)

Inorganic chemical analysis plays an important role in guaranteeing the safety and performance of countless materials and products. In particular, medical devices in contact with the human body must comply with strict maximum limits of potentially harmful elements such as heavy metals. ICP-MS is an extremely sensitive technique that allows simultaneous quantification of 70 elements down to trace levels in the µg/L or sub-µg/L range, and can therefore handle a large variety of analytical challenges.

At RMS Foundation, we offer services in various areas including the MedTech, pharma, chemical and machine industry. ICP-MS can be applied to most engineering materials including metallic alloys, ceramics, polymers as well as natural materials and liquid samples, if necessary with a chemical digestion process prior to analysis.

The following examples highlight ICP-MS analyses that were tailored to meet medical device regulatory requirements. The methods were material-specifically validated in internal studies as well as round robin comparisons in order to guarantee accurate results.

The periodic table shows elements detectable by ICP-MS highlighted in green. These include: H, Li, Be, Na, Mg, K, Ca, Sc, Ti, V, Cr, Mn, Fe, Co, Ni, Cu, Zn, Ga, Ge, As, Se, Br, Kr, Rb, Sr, Y, Zr, Nb, Mo, Tc, Ru, Rh, Pd, Ag, Cd, In, Sn, Sb, Te, I, Xe, Cs, Ba, La, Hf, Ta, W, Re, Os, Ir, Pt, Au, Hg, Tl, Pb, Bi, Ce, Pr, Nd, Pm, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, Lu, Th, U.

Green: elements detectable by ICP-MS.

Trace elements in bone graft substitutes: RMS Foundation offers a standardized method to demonstrate compliance of implantable calcium phosphate materials with the maximum trace element limits specified in ISO 13175-3 as well as ASTM F1088, F1185 and F1581. Specifically, 10 heavy metals are quantified including arsenic, cadmium, mercury and lead (with limits as low as 3 mg/kg), along with a simultaneous screening for 50 additional elements to identify potential impurities at levels greater than 1000 mg/kg.

Dissolution testing of bone graft substitutes: An *in vitro* dissolution test has been defined to characterize degradable calcium phosphates according to ISO 13175-3. This test provides the Ca release along with pH changes during dissolution of test specimens in a buffer solution.

Element	Concentration in mg/kg	ICP-MS		Specification in mg/kg
		in mg/kg	in mg/kg	
< LOD	0.50	-	-	≤ 3 [†]
< LOD	0.09	-	-	≤ 5 [†]
< LOD	0.18	-	-	≤ 5 [†]
< 0.43	0.13	0.43	-	≤ 30 [†]
< 2.3	-	-	-	≤ 50 [†]
< LOD	4	-	-	≤ 400 [†]
< 6.4	1.6	6.4	-	≤ 50

Ag, Cu and Mo

[†] European Pharmacopoeia - 01/2017:1052
[†] ISO 13175-3:2012, ASTM F1088-04a (2010), ASTM F1185-03 (2014) and ASTM F1581-08(2012)

95% confidence level

The results comply with the material specification

Test certificate demonstrating compliance with trace element limits in international standards.

Leachables and extractables in compliance with ISO 10993: As part of the biological evaluation of medical devices, products must be tested for surface contaminants in «leachable» and «extractable» studies. RMS Foundation offers incubation tests according to ISO 10993 followed by ICP-MS analysis of more than 60 trace elements released into solution. For additional services in compliance with ISO 10993, please refer to our previous Newsletter 25.

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Equipment:

Agilent 7700x ICP-MS

Our offers for inorganic analysis:

- Quantitative analysis of the chemical composition of materials
- Detection of trace elements
- Quantification of degradation products in solution
- Quantification of leachables and extractables

Sample requirements:

A few hundred milligrams (solid samples) or one millilitre (liquids) is usually sufficient for ICP-MS analysis.

Complementary inorganic techniques available at RMS Foundation:

X-ray fluorescence (XRF) and energy-dispersive X-ray spectroscopy (EDX).

Discuss your questions with us! We are happy to advise you.

Contact for ICP-MS analysis:

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More information as well as our service catalogue can be found on our website.

RMS Foundation has been certified according to ISO 9001 and is an ISO/IEC 17025 (type C) accredited laboratory.

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