Pharmaceutical applications

ALS Scandinavia offers specialized services for the pharmaceutical industry, with applications in development as well as in production. Our services range from occasional analyses to full-scale projects, including customized method development and validation to meet customer-defined specifications.

To date we have developed and validated over 70 analytical methods for the entire spectrum of pharmaceutical sample types and analytes, ranging from bulk matrix elements (Pd, S) to trace residues (B, Pd). In cooperation with subcontractors, we can also provide pharmacopoeia analyses. We are committed to close cooperation and communication to guarantee your satisfaction with our services. ALS Scandinavia AB has an FDA approval.

Capabilities

ALS Scandinavia's in-house analytical capabilities include:

- Elemental analyses down to µg/kg or even ng/kg levels by atomic mass spectrometry (ICP-SFMS), see Table 1
- Particle analyses by scanning electron microscopy (SEM), see Table 2

Our application of ICP-SFMS in a Class 10000 clean room environment minimizes sample consumption, preserving valuable material. As little as 50 mg is needed to check for residues from precious metal catalysts in an API.

ICP-SFMS also facilitates the use of stable isotopes as non-radioactive tracers for experimental studies in vivo or in vitro. See our dedicated website www.human-analysis.com for further information and scientific publications.

SEM is used to determine the bulk composition of single particles occurring as impurities in raw materials or products. This kind of information can assist in identifying the point in the production process at which the particles have been introduced.

Screening analysis

Issues involving trace elements are sometimes non-specific regarding which elements are of interest. In such cases, a screening analysis (Table 1) may be an attractive proposition. More than 70 elements are measured simultaneously with good accuracy, very high sensitivity and without excessive costs. Application to raw materials, APIs, excipients, finished products and packaging often reveals the presence of unwanted and unexpected contaminants, providing an invaluable troubleshooting tool.

Quality

ALS Scandinavia's quality management system is ISO17025 compliant. As your subcontractor, we will meet all your requirements regarding sample handling according to GMP, ICH Q2(R1) validation of methods and confidential information management.

ALS Scandinavia has recently acquired EU GMP certification after an inspection by the Swedish Medical Products Agency. We are regularly audited by pharmaceutical companies and we participate in various inter-laboratory comparison programs on a routine basis.

It may also be good to know that our laboratory has considerable back up capacity in house. In other words, your samples are not dependent on the availability of any one instrument. Together with a well-developed organization this enables high productivity, and ensures that your results are delivered on time – every time.

Table 1. Trace elements in pharmaceuticals

Package	Elements
Elements in solutions	Al, As, Ba, Ca, Cd, Co, Cr, Cu, Fe, Hg, K, Mg, Mn, Na, Ni, Pb, S, Zn
Elements in drugs or APIs	Al, As, Ba, Ca, Cd, Co, Cr, Cu, Fe, K, Mg, Mn, Na, Ni, P, Pb, Si, Ti, V, Zn
Screening analysis	Ag*, Al, As, Au*, B*, Ba, Be, Bi*, Br*, Ca, Cd, Ce*, Co, Cr, Cs*, Cu, Dy*, Er*, Eu*, Ga*, Gd*, Ge*, Hf*, Hg*, Ho*, I*, Ir*, La*, Li, Lu*, Fe, K, Mg, Mn, Mo, Na, Nb*, Nd*, Ni, Os*, P, Pb, Pd*, Pr*, Pt*, Rb*, Re*, Rh*, Ru*, S, Sb*, Sc*, Se*, Si, Sm*, Sn, Sr, Ta*, Tb*, Te*, Th*, Ti, Tl*, Tm*, U, V, W*, Y*, Yb*, Zn, Zr*
USP 232 elements	As, Cd, Cr, Cu, Hg, Ir, Mn, Mo, Ni, Os, Pb, Pd, Pt, Rh, Ru, V

* only qualitative results are reported for these elements

Table 2. Other analyses of pharmaceutical products

Package	Method
Qualitative analysis of particles in dust	SEM
Particle size distribution	SEM
Semi-quantitative analysis	SEM-EDS*
Custom analysis – client defined	SEM
Image of material	SEM

* scanning electron miscroscopy with energy-dispersive sector