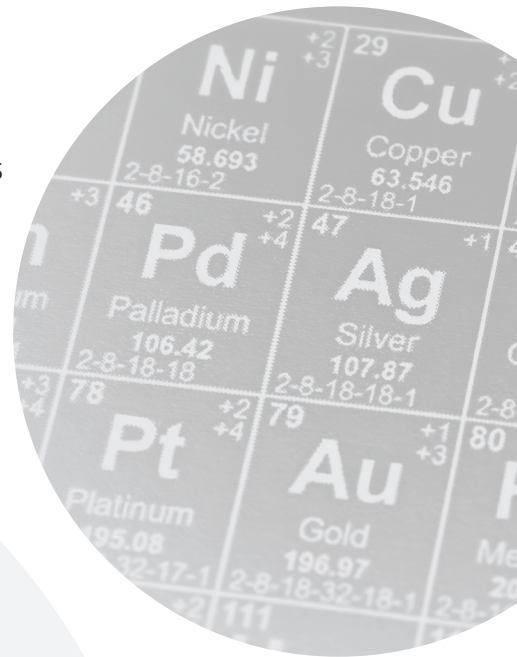




KYMOS

Elemental Impurities Analysis

- Compliance with ICH Q3D Guideline
- Analysis by ICP-MS of Drug Products, APIs, excipients and other sources
- Quality control and batch certificates under GMP



KYMOS
PHARMA SERVICES, S.L.

www.kymos.com
Kymos Pharma Services S.L.
Parc Tecnològic del Vallès
Ronda Can Fatjó, 7B
08290 Cerdanyola del Vallès
Barcelona, Spain

Phone (+34) 93 548 18 48
Fax: (+34) 93 170 29 99
info@kymos.es



PHARMAPROGRESS
a KYMOS company

www.pharmaprogress.com
Pharmaprogress S.r.l.
Via Alessandro Volta 12
60020 Camerata Picena
Ancona, Italy

Phone (+39) (0) 71 749 99 19
Fax (+39) (0) 71 749 63 41
info@pharmaprogress.com

REGULATORY FRAMEWORK

ICH Q3D on Elemental Impurities was published in September 2015. Immediately after, USP General Notices 5.60.30 made broadly applicable to drug products and dietary supplements the General Chapters <232>, <233> and <2232> from December 1, 2017. Finally, Ph. Eur. published in Supplement 9.3 an update of General Chapter 5.20 applicable from January 1, 2018. These new legal requirements represent a huge analytical effort for pharmaceutical industry from now on to the future.

STRATEGIC APPROACH

- Risk Assessment according to ICH Q3D in collaboration with our partner Azierta.
- Component approach based on analysis of potential sources: drug substance, excipients, manufacturing equipment, container, water.
- Drug product approach based on analysis of finished dosage forms.

IMPURITIES ANALYSIS

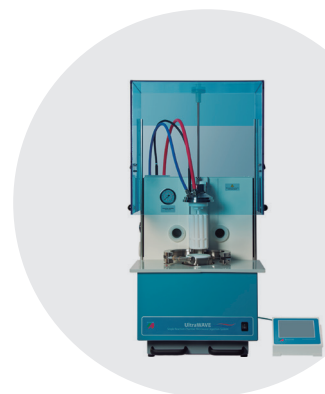
- Semi-quantitative screening method with specificity, recovery and LOD. Class 1 (Cd, Pb, As, Hg), Class 2A (Co, V, Ni), Class 2B (Tl, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt) and Class 3 (Li, Sb, Ba, Mo, Cu, Sn, Cr).
- Method validation according to Ph. Eur. and USP: Limit Test or Quantitative Test.
- Batch testing: routine analysis or established controls.

HIGH ANALYTICAL CAPACITY

KYMOS has an important capacity of sample analysis thanks to the availability of two Ion Coupled Plasma Mass Spectrometers (ICP-MS) Agilent 7700 and Agilent 7800 with high capacity autosamplers. Additionally, KYMOS is also well equipped for sample mineralization and processing by means of an Ultrawave MCLA1000 Milestone as well as a microwave oven Mars 5. An experienced team is fully dedicated to this service. Summarizing, back up instruments and dedicated team ensure narrow timelines at competitive prices.

OTHER RELATED SERVICES

- Pharmacopoeia compendial methods by Atomic Absorption using a Varian 240 FS with graphite furnace and hydride generator.
- Bionalysis of metals in biological fluids and tissues from preclinical and clinical studies of innovative drugs.
- Bioequivalence studies of metallic and organometallic compounds containing: strontium, lithium, platinum, iron, etc.



Partner for Risk Assessment:

azierta