



Elemental Impurities in Pharmaceuticals Standards ICH Q3D, USP 232, 233, 2232 and Ph. Eur. 520

Reagecon has responded to the changes in the test methods of all the major Pharmacopoeias by developing an outstanding and complete range of ultrapure Elemental Impurity Standards.

The products are formulated specifically for ICP-OES, ICP-MS or any Atomic Absorption technique. These Standards are offered in exactly the concentrations mandated in the Pharmacopoeias as being the permitted daily exposure limits (PDE's), depending on whether ingestion route is Oral, Parenteral or Inhalation.

A complete range of appropriate Standards is offered by Reagecon.

Standards for Elemental Impurities in Pharmaceuticals as applied to:

- ✓ ICH Q3D
- ✓ USP <232>, <233>, <2232>
- ✓ EP General Test 520 (General Method 2.4.20)
- ✓ Chinese Pharmacopoeia
- ✓ Japanese Pharmacopoeia
- ✓ Other Pharmacopoeia

These products can be used for instrument calibration, instrument qualification, quality control or method validation.

All of the products are manufactured in an ISO 7 clean room environment, using pure materials (where possible) of either 99.995 or 99.999% purity.

The products are certified gravimetrically and verified using a state of the art ICP-MS instrument.

