





<u>Chemica</u>

Elemental impurities analysis in pharmaceutical products according to USP

In the United States Pharmacopeia (USP) edition 38 and its supplements, the colorimetric manual determination of heavy metals (Chapter <231> Heavy metals) is replaced by analysis of metal impurities by ICP-OES and ICP-MS (Chapter <232> *elemental impurities limits* and <233> *elemental impurities procedures*).

This change will be applied on the 1st december 2015.

CARLO ERBA Reagents offers multi-element standards for ICP for heavy metals analysis in pharmaceutical products according to USP.

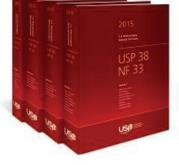
Benefits :

- Traceability to SRM® of NIST for raw material
- Produced from raw material ≥ 99.99%, ultrapur acid and deionized water 18MOhms
- Raw material concentration controlled by ICP-OES
- · Certificate of analysis with batch number and shelf life
- Impurities controlled by ICP-OES
- · Bottles leached with acids to eliminate any contamination material
- Minimum shelf life : 24 month sealed bottle and 12 months opened bottle
- · Preparation time saving
- Handling of some reagents avoided

Product	Composition	Matrix	Pkg	Code
Multi-element for ICP according USP <232> Oral elemental impurities	8 elements : Cd 25mg/l; Pb 5mg/l; As 1.5mg/l; Hg 15mg/l; Mo 100mg/l; Ni 500mg/l; V 100mg/l ; Cu 1000mg/l	HNO3 7%	100 ml	506110
Multi-element for ICP according USP <2232> Dietary supplement	4 elements : Cd 5mg/l; Pb 10mg/l; As 15mg/l; Hg 15mg/l	HNO3 7%	100 ml	506120
Multi-element for ICP according USP <232> Parenteral elemental impurities - Precious metals	6 elements : Ir 10 mg/l, Pt 10 mg/l; Os 10 mg/l; Rh 10 mg/l; Pd 10 mg/l; Ru 10 mg/l	HCI 15%	100 ml	506130
Multi-element for ICP according USP <232> Parenteral elemental impurities	8 elements : Cd 2.5mg/l; Pb 5mg/l; As 1.5mg/l; Hg 1.5mg/l; Mo 10mg/l; Ni 50mg/l; V 10mg/l; Cu 100mg/l	HNO3 7%	100 ml	506140
Multi-element for ICP according USP <232> Oral elemental impurities - Precious metals	6 elements : Ir 100 mg/l, Pt 100 mg/l; Os 100 mg/l; Rh 100 mg/l; Pd 100 mg/l; Ru 100 mg/l	HCI 15%	100 ml	506150

CARLO ERBA Reagents S.A.S.

Chaussée du Vexin 27106 Val de Reuil Cedex - FRANCE









In addition, CARLO ERBA Reagents offers 2 complete ranges for the preparation of the samples analyzed by ICP-OES and ICP-MS, preparation of calibration solutions and labware cleaning and pre-leaching. Their high purity guarantees maximum reliability in the final result.

Our reagents are produced by sub-boiling or double sub-boiling in order to guarantee a minimum level of impurities in the scale of ppt and are packaged in dedicated clean rooms.

SUPERPUR	ULTRAPUR
Metal trace analysis at ppb level	Metal trace analysis at ppt level
 Up to 65 elements certified with concentration < 1 ppb Packaged in PEHD to avoid leaching from glass PEHD bottles : more safety with 45mm necksize to adapt a dispenser Dropper cap for hydrofluoric acid Available in 500ml, 11 and 2.51 	 Up to 65 elements certified with concentration < 10 ppt Packaged in FEP bottles (Fluorinated ethylene propylene) or PFA (perfluoroalkoxy polymer resin) depending on the molecule, after several cleaning steps Available in 500ml

Product	Pkg	Code
	500ml	401405
Acetic acid glacial	11	401406
	2.51	401407
	500ml	403915
Hydrochloric acid 34-37%	11	403916
	2.51	403917
Hydrofluoric acid 47-51%	500ml	405716
	500ml	408115
Nitric acid 67-69%	11	408116
	2.51	408117
	500ml	410405
Sulfuric acid 93-98%	11	410406
	2.51	410407
Ammonia 20-22%	500ml	420175

Product	Pkg	Code
Acetic acid glacial	500ml	401405
Hydrochloric acid 32-35%	500ml	403891
Hydrofluoric acid 47-51%	500ml	405611
Nitric acid 67-69%	500ml	408051
Sulfuric acid 93-98%	500ml	410351
Ammonia 20-22%	500ml	420161
Water	500ml	412185
Hydrogen peroxide 30-32%	500ml	412051



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