Supelco®
Analytical Products

save time—increase accuracy

Elemental Impurity Mixes as Certified Reference Material Standards for USP<232> and Ph. Eur. 9th Edition

Contamination of drug products with elemental impurities poses a risk to patient health. It is therefore critical to control, within acceptable limits, the levels of these impurities introduced into drug products through each step of the manufacturing process.

Effective January 1, 2018, the United States Pharmacopeia (USP), as well as the European Pharmacopeia (Ph. Eur) will adopt the ICH Q3D guidelines on specification limits for elemental impurities. These guidelines are documented in General Chapters <232> (Limits) and <233> (Procedures) in USP 40 NF35 (Second Supplement) and in the general chapter 5.20 of Ph. Eur. Supplement 9.3.

Elemental Impurity Mixes help to streamline your laboratory's ICP-OES/ICP-MS impurity analysis with accurate and consistent Certified Reference Materials for both calibration and quality control.

- All mixes produced and analyzed under the scope of ISO/IEC 17025, ISO Guide 34 and ISO/IEC 17034 accreditation
- Convenient concentrations according the the oral and parenteral PDEs given in USP <232> and Ph.Eur. 9.3, general chapter 5.20
- Inorganic mercury included in mix—no need for a separate solution
- COA included in each package
- COA with extended certification report

TraceCERT®
Traceable Certified Reference Materials

SIGMA-ALDRICH®

Certificate

Produced in house, accredited laboratory fulfilling ISO/IEC 17025 and ISO Guide 34

This certificate is designed in accordance with ISO Guide 31 [1].

Object of certification: **Element Impurities according to ICH Q3D, Standard 1**

Product No.: **19041** Lot: **BCBS7238V**

Composition: High-purity starting materials in 12% HNO_3 (prepared with HNO_3 suitable for trace analysis high-purity water, 18.2 MΩcm, 0.22 µm filtered).

Density at 20°C: ρ = 1067.4 kg·m^{-3} $u_c(\rho)$ = 0.5 kg·m^{-3}

Intended use: Calibration of ICP, AAS, spectrophotometry or any other analytical technique.

Storing and handling: This reference material shall be stored between 5°C and 30°C. The bott… be 20°C and shaken well before every use. If storage of a partially… cap should be tightly sealed and the bottle should be stored at re… refrigerator) to minimize transpiration rate.

Expiry date: **AUG 2020**

Certificate issue date: 16 SEP 2016

Bottle opening date:

Certified value traceable to SI unit kg and uncertainty according to ISO Guide 35 [2] and Eura…

Constituent	Certified values at 20°C and expanded uncertainty [$U = k u_c$;
Arsenic (As)	**14.05 mg kg^{-1} ± 0.06 mg kg^{-1} 15.00 mg**
Cadmium (Cd)	**4.68 mg kg^{-1} ± 0.02 mg kg^{-1} 5.00 mg**
Cobalt (Co)	**46.8 mg kg^{-1} ± 0.2 mg kg^{-1} 50.0 mg**
Lead (Pb)	**4.68 mg kg^{-1} ± 0.02 mg kg^{-1} 5.00 mg**
Mercury (Hg)	**28.1 mg kg^{-1} ± 0.1 mg kg^{-1} 30.0 mg**
Nickel (Ni)	**187.4 mg kg^{-1} ± 0.8 mg kg^{-1} 200.0 mg**
Selenium (Se)	**140.5 mg kg^{-1} ± 0.6 mg kg^{-1} 150.0 mg**
Silver (Ag)	**140.5 mg kg^{-1} ± 0.6 mg kg^{-1} 150.0 mg**
Thallium (Tl)	**7.49 mg kg^{-1} ± 0.03 mg kg^{-1} 8.00 mg**
Vanadium (V)	**93.7 mg kg^{-1} ± 0.4 mg kg^{-1} 100.0 mg**

Certificate page 1 of 3

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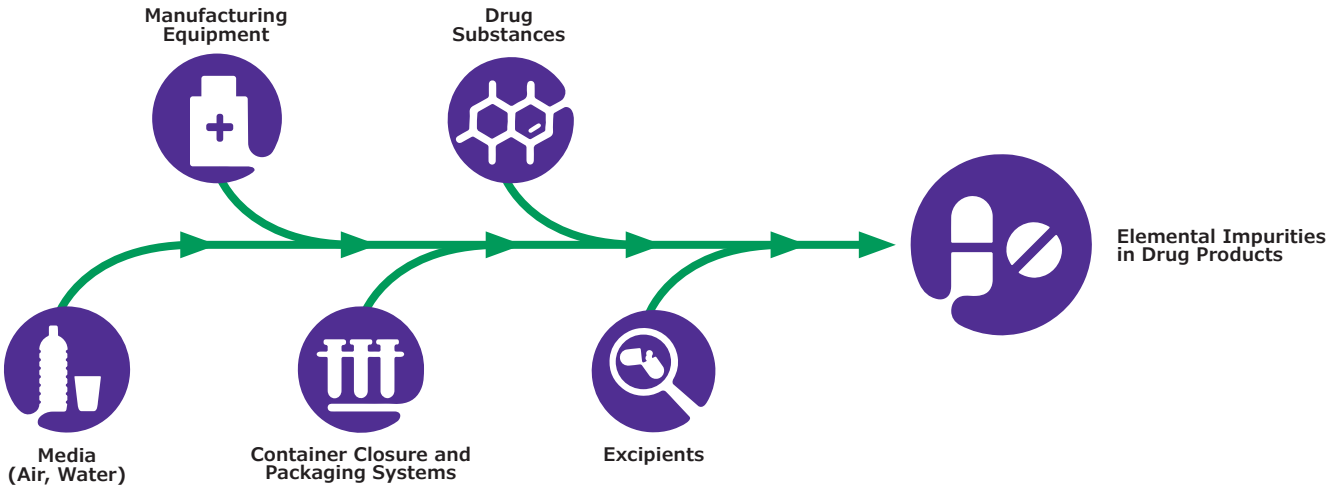
MERCK

Multi-Element Impurity CRM Mixes according to ICH Q3D guideline

		Elemental Impurities Mix According to ICH Q3D Oral			Elemental Impurities Mix According to ICH Q3D Parenteral		
	Cat. No.	**19041**	**73108**	**69729**	**89118**	**89922**	**07368**
	Matrix	12% HNO3	10% HCl	5% HNO3 + <0.5% HF	12% HNO3	10% HCl	5% HNO3 + <0.5%
Element	**Class**						
Ag	2B	150 mg/L			10 mg/L		
As	1	15 mg/L			15 mg/L		
Au	2B		100 mg/L			100 mg/L	
Ba	3			140 mg/L			70 mg/L
Cd	1	5 mg/L			2 mg/L		
Co	2A	50 mg/L			5 mg/L		
Cr	3			1100 mg/L			110 mg/L
Cu	3			300 mg/L			30 mg/L
Hg	1	30 mg/L			3 mg/L		
Ir	2B		100 mg/L			10 mg/L	
Li	3			55 mg/L			25 mg/L
Mo	3			300 mg/L			150 mg/L
Ni	2A	200 mg/L			20 mg/L		
Os	2B		100 mg/L			10 mg/L	
Pb	1	5 mg/L			5 mg/L		
Pd	2B		100 mg/L			10 mg/L	
Pt	2B		100 mg/L			10 mg/L	
Rh	2B		100 mg/L			10 mg/L	
Ru	2B		100 mg/L			10 mg/L	
Sb	3			120 mg/L			9 mg/L
Se	2B	150 mg/L			80 mg/L		
Sn	3			600 mg/L			60 mg/L
Tl	2B	8 mg/L			8 mg/L		
V	2A	100 mg/L			10 mg/L		

Potential Sources of Elemental Impurities



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