



Inorganic Elemental Impurity Mixes According to ICH Q3D Guidelines

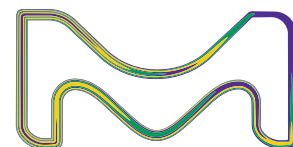
Metallic contamination in drug products, referred to as elemental impurities, may arise from several sources.

Because they pose a risk to patient health, due to toxicological effects, their levels should be controlled during the whole drug production workflow.

Since January 1st, 2018, USP and EP adopted the ICH Q3D guidelines for elemental impurities and implemented the limits in their general chapter USP<232>, <233> and EP 9.3, general chapter 5.20 and 2.4.20

We are offering different element mixes as certified reference materials with element ratios corresponding to the oral, parenteral and inhalation elemental concentration limits of the ICH Q3D guideline, so you can ensure the safety of your medicinal products.

- Produced in accordance to ISO/IEC 17025 and ISO 17034:
 - Values are traceable to at least two independent references (NIST[®] or BAM)
 - Expiry date
 - Storage Information
- Proper uncertainty calculation
- Special fluoropolymeric bottles and gas-tight aluminum foil bags provide extended stability
- Comprehensive documentation according to ISO Guide 31
- Unsurpassed level of accuracy and lot-specific value
- Convenient 100 mL package size
- All concentrations set according to the permitted daily exposure limits (PDE) as described in the ICH Q3D guideline.



Elemental Impurity Mixes:

		For oral application			For parenteral application			For inhalation application				USP <2232> dietary supplements	Non- regulated elements	USP<561> articles of botanical origin
Cat.No.		19041	73108	69729	89118	89922	07368	91496	92928*	93696	93679	93676	91529	18208
Matrix		12% HNO ₃	10% HCl	5% HNO ₃ <0.5% HF	12% HNO ₃	10% HCl	5% HNO ₃ <0.5% HF	12% HNO ₃	12% HNO ₃	10% HCl	5% HNO ₃ <0.5% HF	12% HNO ₃	4.8% HNO ₃ , 0.5% HF	12% HNO ₃
Element	Class	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L
As	1	15			15			2	2			15		20
B													100	
Ca													100	
Cd	1	5			2			3	2			5		5
Fe													100	
Hg	1	30			3			1	1			15		10
Pb	1	5			5			5	5			5		50
Co	2a	50			5			3	3					
K													100	
Mg													100	
Mn													100	
Na													100	
Ni	2a	200			20			5	5					
V	2a	100			10			1	1					
Ag	2b	150			10			7	7					
Al													100	
Au	2b		100			100				1				
Ir	2b		100			10				1				
Os	2b		100			10				1				
Pd	2b		100			10				1				
Pt	2b		100			10				1				
Rh	2b		100			10				1				
Ru	2b		100			10				1				
Se	2b	150			80			130	130					
Tl	2b	8			8			8	8					
Ba	3			140			70							300
Cr	3			1100			110							3
Cu	3			300			30							30
Li	3			55			25							25
Mo	3			300			150							10
Sb	3			120			9							20
Sn	3			600			60							60
W													100	
Zn													100	

*USP regulation for the Cd-limit in the inhalation mix 92928 will change on 1-Dec-2020. Replacement product is 91496.

Our high standards match yours.

Learn more about Supelco® ICH Q3D mixes:

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