

Elemental Impurities Compliance Standards

USP <232> and ICH Q3D have gotten together.
Do you have it together?



Inorganic Ventures has the following most-requested products in our stock catalog.

USP <232> / ICH Q3D Class 1 Oral Elemental Impurities			
IV-STOCK-65		Matrix: HNO ₃	
IV-STOCK-65-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
As	15	Hg	30
Cd	5	Pb	5

USP <232> / ICH Q3D Class 2A Oral Elemental Impurities			
IV-STOCK-66		Matrix: HNO ₃	
IV-STOCK-66-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
Co	50	V	100
Ni	200		

USP <232> / ICH Q3D Class 2B Oral Elemental Impurities			
IV-STOCK-67		Matrix: HCl	
IV-STOCK-67-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
Au	100	Rh	100
Ir	100	Ru	100
Os	100	Se	150
Pd	100	Tl	8
Pt	100		

USP <232> / ICH Q3D Class 2B			
IV-STOCK-68		Matrix: HNO ₃	
IV-STOCK-68-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
Ag*	150		

* Silver has been separated from the other Class 2B elements due to long-term stability concerns. However, IV-STOCK-68 can be combined with IV-STOCK-67 at working levels. Contact Technical Support or visit our Technical Forum for more information regarding Ag in HCl matrices.

USP <232> / ICH Q3D Class 3 Oral Elemental Impurities			
IV-STOCK-69		Matrix: HNO ₃ /tr HF	
IV-STOCK-69-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
Ba	140	Mo	300
Cr	1100	Sb	120
Cu	300	Sn	600
Li	55		

USP <232> / ICH Q3D Oral Elemental Impurities			
IV-STOCK-70		Matrix: HCl	
IV-STOCK-70-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
Ag	15	Ni	20
As	1.5	Os	10
Au	10	Pb	0.5
Ba	140	Pd	10
Cd	0.5	Pt	10
Co	5	Rh	10
Cr	1100	Ru	10
Cu	300	Sb	120
Hg	3	Se	15
Ir	10	Sn	600
Li	55	Tl	0.8
Mo	300	V	10



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USP <232> and ICH Q3D Products

The United States Pharmacopeia (USP) and the International Conference on Harmonisation (ICH) both specify limits for elemental impurities in drug products. The USP specifications are detailed in General Chapter <232>, and the ICH limits are provided in the Guidelines for Elemental Impurities Q3D.

Prior to 2016, USP <232> specified 15 elements for consideration as impurities in drug products, whereas ICH Q3D specified the same 15 elements and also included nine additional elements. As of 2017, USP <232> and ICH Q3D have been fully aligned with respect to elements, element concentrations, and toxicity classification.

Inorganic Ventures is staying on top of the revisions being made in regards to USP <232> and ICH Q3D. We have added six of the most requested products to our stock catalog. However, customs are our specialty, so if you don't see a product that is exactly what you need, contact us.

USP <232> Precious Metals Elemental Impurities			
IV-STOCK-38*		Matrix: HCl	
IV-STOCK-38-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
Ir	100	Pt	100
Os	100	Rh	100
Pd	100	Ru	100

USP <232> Parenteral Elemental Impurities			
IV-STOCK-41*		Matrix: HNO ₃	
IV-STOCK-41-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
As	1.5	Mo	10
Cd	2.5	Ni	50
Cu	100	Pb	5
Hg	1.5	V	10

USP <232> Oral Elemental Impurities			
IV-STOCK-40*		Matrix: HNO ₃	
IV-STOCK-40-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
As	1.5	Mo	100
Cd	25	Ni	500
Cu	1000	Pb	5
Hg	15	V	100

USP <232> Drug Substance and Excipients			
IV-STOCK-60*		Matrix: HCl	
IV-STOCK-60-125ML		Volume: 125 mL	
Analyte	µg/mL	Analyte	µg/mL
As	1.5	Os	10
Cd	0.5	Pb	0.5
Cr	1100	Pd	10
Cu	300	Pt	10
Hg	3	Rh	10
Ir	10	Ru	10
Mo	300	V	10
Ni	20		

*Pre-December 2015 limits.

