

Elemental Impurities Compliance Standards

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



Inorganic Ventures has added the following most-requested products to 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 | |
| IV-STOCK-65-500ML | | Volume: 500 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 | |
| IV-STOCK-66-500ML | | Volume: 500 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 | |
| IV-STOCK-67-A-500ML | | Volume: 500 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 | |
| IV-STOCK-68-500ML | | Volume: 500 mL | |
| Analyte | µg/mL | Analyte | µg/mL |
| Ag* | 150 | | |

| USP <232> / ICH Q3D Class 3 Oral Elemental Impurities | | | |
|--|-------|---------------------------------|-------|
| IV-STOCK-69 | | Matrix: HNO ₃ /tr HF | |
| IV-STOCK-69-125ML | | Volume: 125 mL | |
| IV-STOCK-69-500ML | | Volume: 500 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 | |
| IV-STOCK-70-500ML | | Volume: 500 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 |



* 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> 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 Guideline 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 are adding 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 | |
| IV-STOCK-38-500ML | | Volume: 500 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 | |
| IV-STOCK-41-500ML | | Volume: 500 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 | |
| IV-STOCK-40-500ML | | Volume: 500 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 | |
| IV-STOCK-60-500ML | | Volume: 500 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.

