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Pharmaceutical Standards

Analytical Standards for USP <232>, <233>, <467>, and ICH/Global Compliance

SPEX CertiPrep's comprehensive experience in creating quality pharmaceutical standards will help you to comply with the guidelines set by the United States Pharmacopeia (USP) and the International Conference on Harmonization (ICH) to provide accurate, quantifiable results for the metal analysis in drugs, pharmaceutical substances and raw materials.

For additional product information, please visit www.spexcertiprep.com.

USP <232> and USP<233> Elemental Impurities

USP <232> outlines new limits and USP <233> outlines procedures in pharmaceutical products for arsenic, cadmium, lead, and mercury. The proposed procedures focus on the use of ICP-MS (Inductively Coupled Plasma-Mass Spectrometry) for the analysis of low level impurities.

SPEX CertiPrep is proud to offer Elemental Impurities Certified Reference Materials designed for use in USP <232> and USP <233>. These standards can be used as a calibration or check standard to verify Oral Daily Dose PDE, Parenteral Component Limit or Parenteral Daily Dose PDE.

Oral Elemental Impurities A

| Element | Concentration | Volume | Matrix | Part # |
|---------|---------------|--------|-----------------------------|-----------|
| Arsenic | 15 mg/kg | 125 mL | 5% HNO ₃ /1% HCl | USP-TXM2A |
| Cadmium | 5 mg/kg | | | |
| Lead | 5 mg/kg | | | |
| Mercury | 30 mg/kg | | | |

Precious Metal Impurities B (with Os)

| Element | Concentration | Volume | Matrix | Part # |
|-----------|---------------------------------|--------|---------|----------|
| Iridium | 100 mg/kg for each component | 125 mL | 15% HCl | USP-TXM3 |
| Osmium | | | | |
| Palladium | | | | |
| Platinum | | | | |
| Rhodium | | | | |
| Ruthenium | | | | |

Analytical Standards for USP <232>, <233>, <467> and ICH/Global Compliance

Precious Metal Impurities B (without Os)

| Element | Concentration | Volume | Matrix | Part # |
|-----------|---------------------------------|--------|---------|----------|
| Iridium | 100 mg/kg for each component | 125 mL | 15% HCl | USP-TXM4 |
| Palladium | | | | |
| Platinum | | | | |
| Rhodium | | | | |
| Ruthenium | | | | |

Oral Elemental Impurities C

| Element | Concentration | Volume | Matrix | Part # |
|------------|---------------|--------|---------------------|-----------|
| Chromium | 11,000 mg/kg | 125 mL | 5% HNO ₃ | USP-TXM5A |
| Copper | 3,000 mg/kg | | | |
| Molybdenum | 3,000 mg/kg | | | |
| Nickel | 200 mg/kg | | | |
| Vanadium | 100 mg/kg | | | |

Parenteral Elemental Impurities C

| Element | Concentration | Volume | Matrix | Part # |
|------------|---------------|--------|---------------------|-----------|
| Chromium | 1,100 mg/kg | 125 mL | 5% HNO ₃ | USP-TXM5B |
| Copper | 300 mg/kg | | | |
| Molybdenum | 1,500 mg/kg | | | |
| Nickel | 20 mg/kg | | | |
| Vanadium | 10 mg/kg | | | |

Parenteral Elemental Impurities D

| Element | Concentration | Volume | Matrix | Part # |
|---------|---------------|--------|-----------------------------|-----------|
| Arsenic | 15 mg/kg | 125 mL | 5% HNO ₃ /1% HCl | USP-TXM6A |
| Cadmium | 2 mg/kg | | | |
| Lead | 5 mg/kg | | | |
| Mercury | 3 mg/kg | | | |

USP <467> Residual Solvents

The USP General Chapter <467> Residual Solvents is a method widely used for identifying and quantifying residual solvents when there is no information available on what solvents are likely to be present.

SPEX CertiPrep now offers 35 analytes in dimethyl sulfoxide for Class 1, Class 2 and Class 3 solvents. Our products are manufactured and verified by our QC department to validate the Certificate of Analysis which accompanies each product.

5 Organic Volatile Impurities: Class 1 Solvents

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|-----------------------|----------|---------------|--------|--------------------|-----------|
| Benzene | 71-43-2 | 10,000 µg/mL | 1 mL | Dimethyl Sulfoxide | USP-RS-C1 |
| Carbon tetrachloride | 56-23-5 | 20,000 µg/mL | | | |
| 1,2-Dichloroethane | 107-06-2 | 25,000 µg/mL | | | |
| 1,1-Dichloroethene | 75-35-4 | 40,000 µg/mL | | | |
| 1,1,1-Trichloroethane | 71-55-6 | 50,000 µg/mL | | | |

Analytical Standards for USP <232>, <233>, <467> and ICH/Global Compliance

15 Organic Volatile Impurities: Class 2 Solvents

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|--------------------------|----------|---------------|--------|--------------------|------------|
| Acetonitrile | 75-05-8 | 2,050 µg/mL | 1 mL | Dimethyl Sulfoxide | USP-RS-C2A |
| Chlorobenzene | 108-90-7 | 1,800 µg/mL | | | |
| Cyclohexane | 110-82-7 | 19,400 µg/mL | | | |
| cis-1,2-Dichloroethene | 156-59-2 | 4,700 µg/mL | | | |
| trans-1,2-Dichloroethene | 156-60-5 | 4,700 µg/mL | | | |
| 1,4-Dioxane | 123-91-1 | 1,900 µg/mL | | | |
| Ethylbenzene | 100-41-4 | 1,840 µg/mL | | | |
| Methanol | 67-56-1 | 15,000 µg/mL | | | |
| Methylcyclohexane | 108-87-2 | 5,900 µg/mL | | | |
| Methylene chloride | 75-09-2 | 3,000 µg/mL | | | |
| Tetrahydrofuran | 109-99-9 | 3,450 µg/mL | | | |
| Toluene | 108-88-3 | 4,450 µg/mL | | | |
| m-Xylene | 108-38-3 | 6,510 µg/mL | | | |
| o-Xylene | 95-47-6 | 980 µg/mL | | | |
| p-Xylene | 106-42-3 | 1,520 µg/mL | | | |

8 Organic Volatile Impurities: Class 2 Solvents

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|-------------------------------|----------|---------------|--------|--------------------|------------|
| Chloroform | 67-66-3 | 60 µg/mL | 1 mL | Dimethyl Sulfoxide | USP-RS-C2B |
| 1,2-Dimethoxyethane | 110-71-4 | 100 µg/mL | | | |
| n-Hexane | 110-54-3 | 290 µg/mL | | | |
| 2-Hexanone | 597-78-6 | 50 µg/mL | | | |
| Nitromethane | 75-52-5 | 50 µg/mL | | | |
| Pyridine | 110-86-1 | 200 µg/mL | | | |
| 1,2,3,4-Tetrahydronaphthalene | 119-64-2 | 100 µg/mL | | | |
| Trichloroethene | 79-01-6 | 80 µg/mL | | | |

8 Organic Volatile Impurities: Class 2 Solvents

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|--------------------------|----------|---------------|--------|--------------------|------------|
| N,N-Dimethylacetamide | 127-19-5 | 5,450 µg/mL | 1 mL | Dimethyl Sulfoxide | USP-RS-C2C |
| N,N-Dimethylformamide | 68-12-2 | 4,400 µg/mL | | | |
| 2-Ethoxyethanol | 110-80-5 | 800 µg/mL | | | |
| Ethylene glycol | 107-21-1 | 3,100 µg/mL | | | |
| Formamide | 75-12-7 | 1,100 µg/mL | | | |
| 2-Methoxyethanol | 109-86-4 | 250 µg/mL | | | |
| 1-Methyl-2-pyrrolidinone | 872-50-4 | 2,650 µg/mL | | | |
| Tetramethylene sulfone | 126-33-0 | 800 µg/mL | | | |

2 Organic Volatile Impurities: Class 3 Solvents

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|-------------|---------|-----------------------------------|--------|--------------------|------------|
| Acetic acid | 67-19-7 | 1,000 µg/mL for each component | 1 mL | Dimethyl Sulfoxide | USP-RS-C3B |
| Formic acid | 64-18-6 | | | | |

Analytical Standards for USP <232>, <233>, <467> and ICH/Global Compliance

24 Organic Volatile Impurities: Class 3 Solvents

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|---|-----------|-----------------------------------|--------|--------------------|------------|
| Acetone | 67-64-1 | 1,000 µg/mL for each component | 1 mL | Dimethyl Sulfoxide | USP-RS-C3A |
| Anisole | 100-66-3 | | | | |
| 2-Butanone | 78-93-3 | | | | |
| 1-Butanol | 71-36-3 | | | | |
| 2-Butanol | 78-92-2 | | | | |
| Butyl acetate | 123-86-4 | | | | |
| tert-Butyl methyl ether | 1634-04-4 | | | | |
| Ethanol | 64-17-5 | | | | |
| Ether | 60-29-7 | | | | |
| Ethyl acetate | 141-78-6 | | | | |
| Ethyl formate | 109-94-4 | | | | |
| n-Heptane | 142-82-5 | | | | |
| Isobutyl acetate | 110-19-0 | | | | |
| Isopropyl acetate | 108-21-4 | | | | |
| Isopropyl benzene | 98-82-8 | | | | |
| Methyl acetate | 79-20-9 | | | | |
| 3-Methyl-1-butanol | 123-51-3 | | | | |
| 4-Methyl-2-pentanone | 108-10-1 | | | | |
| 2-Methyl-1-propanol | 78-83-1 | | | | |
| n-Pentane | 109-66-0 | | | | |
| 1-Pentanol | 71-41-0 | | | | |
| 1-Propanol | 71-23-8 | | | | |
| 2-Propanol (Isopropanol, Isopropyl alcohol) | 67-63-0 | | | | |
| Propyl acetate | 109-60-4 | | | | |

USP <467> Residual Solvent Singles

| Compound | CAS # | Concentration | Volume | Matrix | Part # |
|-----------------------|----------|---------------|--------|--------------------|----------------|
| Chlorobenzene | 108-90-7 | 1,800 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S810-DMSO |
| Cyclohexane | 110-82-7 | 19,400 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S1015-DMSO |
| 1,4-Dioxane | 123-91-1 | 1,900 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S1715-DMSO |
| Ethylene glycol | 107-21-1 | 3,100 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S1952-DMSO |
| Methanol | 67-56-1 | 15,000 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S2380-DMSO |
| Nitromethane | 75-52-5 | 250 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S2722-DMSO |
| Tetrahydrofuran | 109-99-9 | 3,600 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S3460-DMSO |
| 1,1,1-Trichloroethane | 71-55-6 | 50,000 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S3605-DMSO |
| Trichloroethene | 79-01-6 | 400 µg/mL | 1 mL | Dimethyl sulfoxide | USP-S3615-DMSO |

ICH/Global Compliance Standards

The International Conference for Harmonization (ICH) has produced a concept paper proposing a new guideline intended to provide a global policy for qualitatively and quantitatively limiting metal impurities in drug ingredients and finished products. The new proposed guideline (Q3D) would provide clarification of the requirements for metals, which are included in the ICH inorganic impurities classification.

SPEX CertiPrep is proud to offer a line of analytical standards for the analysis of trace metals in pharmaceutical materials. These standards can be used as a calibration or check standard to verify all component or dosage limits.

Oral Elemental Impurities A

| Element | Concentration | Volume | Matrix | Part # |
|---------|---------------|--------|---------------------|----------|
| Arsenic | 1.5 mg/kg | 125 mL | 5% HNO ₃ | ICH-TXM2 |
| Cadmium | 25 mg/kg | | | |
| Lead | 5 mg/kg | | | |
| Mercury | 15 mg/kg | | | |

Analytical Standards for USP <232>, <233>, <467> and ICH/Global Compliance

| Precious Metal Impurities B (with Os) | | | | |
|---------------------------------------|---------------------------------|--------|---------|----------|
| Element | Concentration | Volume | Matrix | Part # |
| Iridium | 100 mg/kg for each component | 125 mL | 15% HCl | ICH-TXM3 |
| Osmium | | | | |
| Palladium | | | | |
| Platinum | | | | |
| Rhodium | | | | |
| Ruthenium | | | | |

| Precious Metal Impurities B (without Os) | | | | |
|--|---------------------------------|--------|---------|----------|
| Element | Concentration | Volume | Matrix | Part # |
| Iridium | 100 mg/kg for each component | 125 mL | 15% HCl | ICH-TXM4 |
| Palladium | | | | |
| Platinum | | | | |
| Rhodium | | | | |
| Ruthenium | | | | |

| Elemental Impurities E | | | | |
|------------------------|---------------|--------|---------------------|----------|
| Element | Concentration | Volume | Matrix | Part # |
| Chromium | 250 mg/kg | 125 mL | 5% HNO ₃ | ICH-TXM7 |
| Cobalt | 100 mg/kg | | | |
| Copper | 1,000 mg/kg | | | |
| Manganese | 2,500 mg/kg | | | |
| Molybdenum | 100 mg/kg | | | |
| Nickel | 250 mg/kg | | | |
| Vanadium | 100 mg/kg | | | |

| Elemental Impurities F | | | | |
|------------------------|------------------------------------|--------|---------------------|----------|
| Element | Concentration | Volume | Matrix | Part # |
| Iron | 13,000 mg/kg for each component | 125 mL | 5% HNO ₃ | ICH-TXM8 |
| Zinc | | | | |

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