

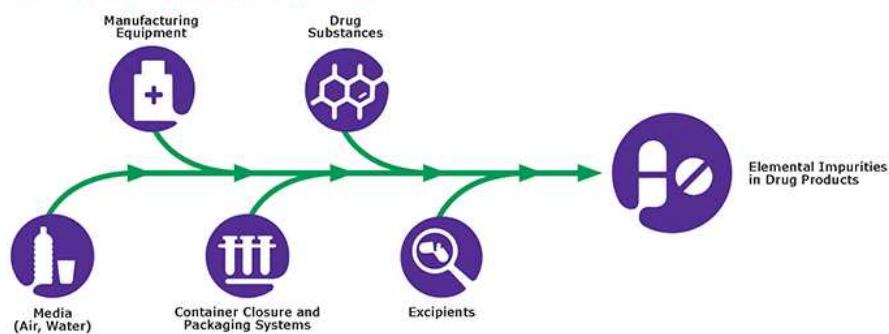
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Inorganic elemental impurity mixes according to ICH Q3D guidelines

Background

Metallic contamination in drug products, referred to as elemental impurities, may arise from several sources. They may be added intentionally in synthesis, or may be present as contaminants, (e.g., through interactions with processing equipment or by being present in components of the drug product) and are consequently detectable in the drug product. Because elemental impurities pose a risk to patient health, due to toxicological effects, their levels should be controlled within acceptable limits in the drug product.¹

Potential Sources of Elemental Impurities



The ICH Q3D guidelines

In 2009, the International Conference on Harmonization (ICH) proposed the development of a new harmonized guideline to provide a global policy for limiting metal impurities in drug products and ingredients. This approach provides clear regulatory guidance on specification limits for elemental impurities worldwide and logically should have an impact on the work of the national regulatory bodies in having transparent and comparable results.

The ICH categorized the various elemental impurities in four different classifications to facilitate decisions during the risk assessment process.

| Class | Descriptions | Elements |
|----------------|--|--|
| 1 | <ul style="list-style-type: none"> • Significantly toxic to humans • Limited or no use in the manufacture of pharmaceutical • Require evaluation during the risk assessment across all potential sources of the production process and routes of administration | Arsenic (As) Cadmium (Cd) Lead (Pb) Mercury (Hg) |
| 2a | <ul style="list-style-type: none"> • Considered as route-dependant human toxicants • Relatively high probability to occur in a drug product • Risk assessment required across all potential sources of the production process and routes of administration | Cobalt (Co) Nickel (Ni) Vanadium (V) |
| 2b | <ul style="list-style-type: none"> • Considered as route-dependant human toxicants • Reduced probability to occur in a drug product • Risk assessment required if they are intentionally added to a drug product, otherwise they may be excluded | Silver (Ag) Gold (Au) Iridium (Ir) Osmium (Os) Palladium (Pd) Platinum (Pt) Rhodium (Rh) Ruthenium (Ru) Selenium (Se) Thallium (Tl) |
| 3 | <ul style="list-style-type: none"> • Relatively low toxicity at oral administration • May require a risk assessment if applied via inhalation or parenteral routes | Barium (Ba) Chromium (Cr) Copper (Cu) Lithium (Li) Molybdenum (Mo) Antimony (Sb) Tin (Sn) |
| Other elements | <ul style="list-style-type: none"> • Permitted daily exposure limits (PDEs) have not yet been established due to their low toxicity • If present in a drug products, regional guidelines may apply | Aluminum (Al) Boron (B) Calcium (Ca) Iron (Fe) Potassium (K) Magnesium (Mg) Manganese (Mn) Sodium (Na) Tungsten (W) Zinc (Zn) |

The United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) Change

Starting January 1, 2018, the USP and the EP are adopting the ICH Q3D guidelines for elemental impurities limits in drug products, which results in a change of the analytical methods – from colorimetric determination of a metal sulfide precipitation (for USP) to analysis by ICP-OES or ICP-MS methods.

The revised chapters are:

- Chapter USP <232>: Elemental impurities in Pharmaceutical Products – Limits
- Chapter USP <233>: Elemental impurities in Pharmaceutical Products – Procedures
- Chapter USP <2232>: Elemental contaminants in Dietary Supplements
- European Pharmacopoeia, 9th Edition, supplement 9.3., General Chapter 5.20 and 2.4.20

How to accurately test for elemental impurities

We offer different element mixes as certified reference material standard mixes with element ratios corresponding to the oral, parenteral and inhalation elemental concentrations limits of the ICH Q3D guideline. Their features are:

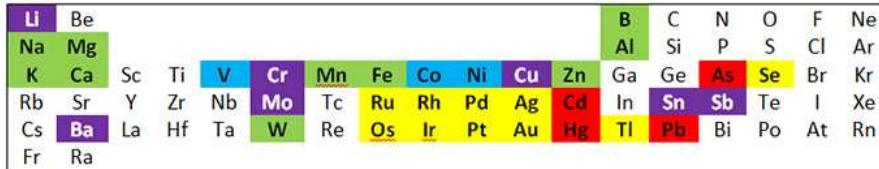
- Produced and analyzed under ISO 17025 and ISO 17034; values traceable to at least two independent references (NIST[®], BAM or SI unit kg)
- Unique level of accuracy and lot-specific value
- Sophisticated packaging and comprehensive documentation, including proper uncertainty calculation, expiry date and storage information.
- Packaged in special fluoropolymeric, opaque bottles and gas-tight aluminum foil bags for extended stability. Certificates are included in the packaging.
- Convenient 100 mL package size

For each classified and non-classified element, we offer single-element certified reference material solutions under the trademarks Certipur[®] and TraceCERT[®], NIST[®] SRM single-element solutions as well as various multi-element mixes for ICP-OES and ICP-MS application in multiple concentrations (10g/L, 1g/L, 10mg/L, 1mg/L). Please refer to the list of products at the end of this page.

Elemental impurity mixes according to ICH Q3D guidelines for USP<232>, USP <2232> and Ph.Eur. General Chapter 5.20

| Elemental impurities mixes according to ICHQ3D oral, parenteral and inhalational guidelines | | | | | | | | | | Mix for USP<2232> | |
|---|----------------------|---------|--------------------------------|----------------------------|---------|--------------------------------|----------------------------|---------|--------------------------------|-------------------------|--|
| Cat No | 19041 | 73108 | 69729 | 89118 | 89922 | 07368 | 92928 | 93696 | 93679 | 93676 | |
| | For oral application | | | For parenteral application | | | For inhalation application | | | For dietary supplements | |
| Matrix | 12% HNO ₃ | 10% HCl | 5% HNO ₃ + HF <0.5% | 12% HNO ₃ | 10% HCl | 5% HNO ₃ + HF <0.5% | 12% HNO ₃ | 10% HCl | 5% HNO ₃ + HF <0.5% | 12% HNO ₃ | |
| Element | Class | | | | | | | | | | |
| As | 1 | 15 | | 15 | | | 2 | | | 15 | |
| Cd | 1 | 5 | | 2 | | | 2 | | | 5 | |
| Hg | 1 | 30 | | 3 | | | 1 | | | 15 | |
| Pb | 1 | 5 | | 5 | | | 5 | | | 5 | |
| Co | 2a | 50 | | 5 | | | 3 | | | | |
| Ni | 2a | 200 | | 20 | | | 5 | | | | |
| V | 2a | 100 | | 10 | | | 1 | | | | |
| Ag | 2b | 150 | | 10 | | | 7 | | | | |
| 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 | | | | |
| Tl | 2b | 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 | | | |
| Al | No class | | | | | | | | | | |
| B | No class | | | | | | | | | | |
| Ca | No class | | | | | | | | | | |
| Fe | No class | | | | | | | | | | |
| K | No class | | | | | | | | | | |
| Mg | No class | | | | | | | | | | |
| Mn | | | | | | | | | | | |

| | |
|----|-------------|
| | No class |
| Na | No class |
| W | No class |
| Zn | No class |



Class 1 elements

Class 2a elements

Class 2b elements

Class 3 elements

Elements with no established PDE (permitted daily exposure) limits and no classification

- Ag
 - Al
 - As
 - Au
 - B
 - Ba
 - Ca
 - Cd
 - Co
 - Cr
 - Cu
 - Hg
 - Ir
 - K
 - Li
 - Mg
 - Mn
 - Mo
 - Na
 - Ni
 - Os
 - Pb
 - Pd
 - Pt
 - Rh
 - Ru
 - Si
 - Se
 - Sr
 - Ti
 - V
 - W
 - Zr

Ag

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|----------|-----------------------|-------------------|----------------------|------------------|------------|
| NIST3151 | HNO ₃ 14% | Ag metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 91543 | HNO ₃ 5% | Ag metal | 10,000 | 100 mL | TraceCERT® |
| 1.70352 | HNO ₃ 2-3% | AgNO ₃ | 1,000 | 100 mL | Certipur® |
| 12818 | HNO ₃ 2% | Ag metal | 1,000 | 100 mL | TraceCERT® |
| 69389 | HNO ₃ 2% | Ag metal | 1 | 100 mL | TraceCERT® |

AI

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|--|-----------------------------|------------------|------------|
| NIST3101A | HNO ₃ 10% | Al metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 1.70371 | HNO ₃ 2-3% | Al(NO ₃) ₃ | 10,000 | 100 mL | Certipur® |
| 41377 | HNO ₃ 5% | Al(NO ₃) ₃ .9H ₂ O | 10,000 | 100 mL | TraceCERT® |
| 1.70301 | HNO ₃ 2-3% | Al(NO ₃) ₃ | 1,000 | 100 mL | Certipur® |
| 61935 | HNO ₃ 2% | Al(NO ₃) ₃ .9H ₂ O | 1,000 | 100 mL | TraceCERT® |
| 05674 | HNO ₃ 2% | Al(NO ₃) ₃ .9H ₂ O | 1 | 100 mL | TraceCERT® |

As

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|---------------------------------|-----------------------------|------------------|------------|
| NIST3103A | HNO ₃ 10% | As ₂ O ₃ | 10 mg/g | 5x10 mL ampoules | NIST |
| 67904 | HNO ₃ 5% | As ₂ O ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70303 | HNO ₃ 2-3% | H ₂ AsO ₄ | 1,000 | 100 mL | Certipur® |
| 01969 | HNO ₃ 2% | As ₂ O ₃ | 1,000 | 100 mL | TraceCERT® |
| 72718 | HCl 2% | As ₂ O ₃ | 1,000 | 100 mL | TraceCERT® |
| 76686 | H ₂ O | As ₂ O ₅ | 1,000 | 100 mL | TraceCERT® |
| 75016 | HNO ₃ 2% | As ₂ O ₃ | 1 | 100 mL | TraceCERT® |

Au

Cat. no. **Matrix** **Size**

| | | Starting material | Concentration (mg/L) | | |
|-----------------|-------------------------------------|--------------------------|-----------------------------|------------------|------------|
| NIST3121 | HCl 10% | Au metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 1.70321 | HCl 7% HCl 5% + | H(AuCl ₄) | 1,000 | 100 mL | Certipur® |
| 38168 | HNO ₃ Traces HCl 5% + | Au metal | 1,000 | 100 mL | TraceCERT® |
| 67363 | HNO ₃ Traces | Au metal | 1 | 100 mL | TraceCERT® |

B

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|--|--------------------------------|-----------------------------|-------------|------------|
| NIST3107 | H ₂ O H ₂ O + | H ₃ BO ₃ | 5 mg/g | 50 mL | NIST |
| 18822 | NH ₄ OH <0.5% | H ₃ BO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70307 | H ₂ O | H ₃ BO ₃ | 1,000 | 100 mL | Certipur® |
| 01932 | H ₂ O | H ₃ BO ₃ | 1,000 | 100 mL | TraceCERT® |
| 41511 | H ₂ O | H ₃ BO ₃ | 1 | 100 mL | TraceCERT® |

Ba

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|-------------|------------|
| 75187 | HNO ₃ 5% | BaCO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70304 | HNO ₃ 2-3% | Ba(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 59943 | HNO ₃ 2% | BaCO ₃ | 1,000 | 100 mL | TraceCERT® |
| 75017 | HNO ₃ 2% | BaCO ₃ | 1 | 100 mL | TraceCERT® |

Ca

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3109A | HNO ₃ 10% | CaCO ₃ | 10mg/g | 5x10 mL ampoules | NIST |
| 1.70373 | HNO ₃ 2-3% | Ca(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 94458 | HNO ₃ 5% | CaCO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70308 | HNO ₃ 2-3% | Ca(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 19051 | HNO ₃ 2% | CaCO ₃ | 1,000 | 100 mL | TraceCERT® |
| 41559 | HNO ₃ 2% | CaCO ₃ | 1 | 100 mL | TraceCERT® |

Cd

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3108 | HNO ₃ 8% | Cd metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 90006 | HNO ₃ 5% | Cd metal | 10,000 | 100 mL | TraceCERT® |
| 1.70309 | HNO ₃ 2-3% | Cd(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 36379 | HNO ₃ 2% | Cd metal | 1,000 | 100 mL | TraceCERT® |
| 12313 | HNO ₃ 2% | Cd metal | 1 | 100 mL | TraceCERT® |

Co

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3113 | HNO ₃ 10% | Co metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 01488 | HNO ₃ 5% | Co metal | 10,000 | 100 mL | TraceCERT® |
| 1.70313 | HNO ₃ 2-3% | Co(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 30329 | HNO ₃ 2% | Co metal | 1,000 | 100 mL | TraceCERT® |
| 41798 | HNO ₃ 2% | Co metal | 1 | 100 mL | TraceCERT® |

Cr

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|--|-----------------------------|------------------|-----------|
| NIST3112A | HNO ₃ 10% | N.N. | 10 mg/g | 5x10 mL ampoules | NIST |
| 1.70374 | HNO ₃ 2-3% | Cr(NO ₃) ₃ .9H ₂ O | 10,000 | 100 mL | Certipur® |

| | | | | | |
|----------------|-----------------------|--|--------|--------|------------|
| 93104 | HNO ₃ 5% | Cr(NO ₃) ₃ .9H ₂ O | 10,000 | 100 mL | TraceCERT® |
| 1.70312 | HNO ₃ 2-3% | Cr(NO ₃) ₃ .9H ₂ O | 1,000 | 100 mL | Certipur® |
| 74582 | HNO ₃ 2% | Cr(NO ₃) ₃ .9H ₂ O | 1,000 | 100 mL | TraceCERT® |
| 68131 | HNO ₃ 2% | (NH ₄) ₂ Cr ₂ O ₇ | 1,000 | 100 mL | TraceCERT® |
| 92966 | HNO ₃ 2% | Cr(NO ₃) ₃ .9H ₂ O | 1,000 | 100 mL | TraceCERT® |
| 19036 | H ₂ O | (NH ₄) ₂ Cr ₂ O ₇ | 1,000 | 100 mL | TraceCERT® |
| 72995 | HNO ₃ 2% | Cr(NO ₃) ₃ .9H ₂ O | 1 | 100 mL | TraceCERT® |

Cu

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|-------------|------------|
| NIST3114 | HNO ₃ 10% | Co metal | 10 mg/g | 50 mL | NIST |
| 1.70378 | HNO ₃ 2-3% | Cu(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 94459 | HNO ₃ 5% | Cu metal | 10,000 | 100 mL | TraceCERT® |
| 1.70314 | HNO ₃ 2-3% | Cu(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 68921 | HNO ₃ 2% | Cu metal | 1,000 | 100 mL | TraceCERT® |
| 41621 | HNO ₃ 2% | Cu metal | 1 | 100 mL | TraceCERT® |

Hg

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3133 | HNO ₃ 10% | Hg metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 1.70384 | HNO ₃ 10% | Hg(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 75111 | HNO ₃ 12% | Hg metal | 10,000 | 100 mL | TraceCERT® |
| 1.70333 | HNO ₃ 10% | Hg(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 28941 | HNO ₃ 12% | Hg metal | 1,000 | 100 mL | TraceCERT® |
| 1.08623 | HNO ₃ 2-3% | Hg(NO ₃) ₂ | 10 | 100 mL | Certipur® |

Ir

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|---------------|--------------------------|-----------------------------|-------------|-----------|
| 1.70325 | HCl 7% | IrCl ₃ | 1,000 | 100 mL | Certipur® |

K

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|--------------------------|-----------------------------|------------------|------------|
| NIST3141A | HNO ₃ 1% | KCl | 10 mg/g | 5x10 mL ampoules | NIST |
| 1.70377 | HNO ₃ 2-3% | KNO ₃ | 10,000 | 100 mL | Certipur® |
| 68371 | HNO ₃ 5% | KNO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70342 | HNO ₃ 2-3% | KNO ₃ | 1,000 | 100 mL | Certipur® |
| 06335 | HNO ₃ 2% | KNO ₃ | 1,000 | 100 mL | TraceCERT® |
| 30937 | HNO ₃ 2% | KNO ₃ | 1 | 100 mL | TraceCERT® |

Li

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|---------------------------------|-----------------------------|------------------|------------|
| NIST3129A | HNO ₃ 1% | Li ₂ CO ₃ | 10 mg/g | 5x10 mL ampoules | NIST |
| 90766 | HNO ₃ 5% | Li ₂ CO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70329 | HNO ₃ 2-3% | LiNO ₃ | 1,000 | 100 mL | Certipur® |
| 12292 | HNO ₃ 2% | Li ₂ CO ₃ | 1,000 | 100 mL | TraceCERT® |
| 39185 | HNO ₃ 2% | Li ₂ CO ₃ | 1 | 100 mL | TraceCERT® |

Mg

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3131a | HNO ₃ 10% | Mg metal | 10mg/g | 5x10 mL ampoules | NIST |
| 1.70379 | HNO ₃ 2-3% | Mg(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 80759 | HNO ₃ 5% | Mg(NO ₃) ₂ | 10,000 | 100 mL | TraceCERT® |
| 1.70331 | HNO ₃ 2-3% | Mg(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 30083 | HNO ₃ 2% | Mg(NO ₃) ₂ | 1,000 | 100 mL | TraceCERT® |
| 53906 | HNO ₃ 2% | Mg(NO ₃) ₂ | 1 | 100 mL | TraceCERT® |

Mn

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|--|-----------------------------|------------------|------------|
| NIST3132 | HNO ₃ 10% | N.N. | 10 mg/g | 5x10 mL-ampoules | NIST |
| 1.7038 | HNO ₃ 2-3% | Mn(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 42071 | HNO ₃ 5% | Mn(NO ₃) ₂ ·4H ₂ O | 10,000 | 100 mL | TraceCERT® |
| 1.70332 | HNO ₃ 2-3% | Mn(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 74128 | HNO ₃ 2% | Mn metal | 1,000 | 100 mL | TraceCERT® |
| 42058 | HNO ₃ 2% | Mn metal | 1 | 100 mL | TraceCERT® |

Mo

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|---------------------------------------|---|-----------------------------|------------------|------------|
| NIST3134 | HCl 10% | Mo metal | 10 mg/g | 5x10 mL-ampoules | NIST |
| 39891 | HNO ₃ 5% + <0.5% HF | Mo metal | 10,000 | 100 mL | TraceCERT® |
| 1.70334 | H ₂ O | (NH ₄) ₆ Mo ₇ O ₂₄ | 1,000 | 100 mL | Certipur® |
| | HCl 10% + | | | | |
| 68780 | HNO ₃ Traces | Mo metal | 1,000 | 100 mL | TraceCERT® |
| 04488 | NH ₄ OH + H ₂ O | (NH ₄) ₆ Mo ₇ O ₂₄ | 1 | 100 mL | TraceCERT® |

Na

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|--------------------------|-----------------------------|-------------|------------|
| NIST3152A | HNO ₃ 1% | NaCl | 10mg/g | 50 mL | NIST |
| 1.70381 | HNO ₃ 2-3% | NaNO ₃ | 10,000 | 100 mL | Certipur® |
| 39924 | HNO ₃ 5% | NaNO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70353 | HNO ₃ 2-3% | NaNO ₃ | 1,000 | 100 mL | Certipur® |
| 00462 | HNO ₃ 2% | NaNO ₃ | 1,000 | 100 mL | TraceCERT® |
| 80831 | HNO ₃ 2% | NaNO ₃ | 1 | 100 mL | TraceCERT® |

Ni

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST986 | HNO ₃ 8% | Ni metal | 10 mg/g | 5x10 mL-ampoules | NIST |
| 1.70382 | HNO ₃ 2-3% | Ni(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 19013 | HNO ₃ 5% | Ni metal | 10,000 | 100 mL | TraceCERT® |
| 1.70336 | HNO ₃ 2-3% | Ni(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 28944 | HNO ₃ 2% | Ni metal | 1,000 | 100 mL | TraceCERT® |
| 72631 | HNO ₃ 2% | Ni metal | 1 | 100 mL | TraceCERT® |

Os

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|---------------|---|-----------------------------|-------------|-----------|
| 1.70338 | HCl 7% | (NH ₄) ₂ OsCl ₆ | 1,000 | 100 mL | Certipur® |

Pb

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3128 | HNO ₃ 10% | Pb metal | 10 mg/g | 5x10 mL-ampoules | NIST |
| 1.70372 | HNO ₃ 2-3% | Pb(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 39082 | HNO ₃ 5% | Pb(NO ₃) ₂ | 10,000 | 100 mL | TraceCERT® |
| 1.70328 | HNO ₃ 2-3% | Pb(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 41318 | HNO ₃ 2% | Pb(NO ₃) ₂ | 1,000 | 100 mL | TraceCERT® |
| 75015 | HNO ₃ 2% | Pb(NO ₃) ₂ | 1 | 100 mL | TraceCERT® |

Pd

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|---------------|--------------------------|-----------------------------|------------------|------------|
| NIST3138 | HCl 10% | Pd metal | 10 mg/g | 5x10 mL-ampoules | NIST |
| 50719 | HCl 10% + | Pd metal | 10,000 | 100 mL | TraceCERT® |

HNO₃ Traces

| | | | | | |
|----------------|-------------------------------------|-----------------------------------|-------|--------|------------|
| 1.70339 | HNO ₃ 2-3% HCl 5% + | Pd(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 77091 | HNO ₃ Traces | Pd metal | 1,000 | 100 mL | TraceCERT® |
| 42396 | HNO ₃ 2% + HCl Traces | Pd metal | 1 | 100 mL | TraceCERT® |

Pt

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-------------------------------------|----------------------------------|-----------------------------|------------------|------------|
| NIST3140 | HCl 10% | Pt metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 74554 | HCl 10% | Pt metal | 10,000 | 100 mL | TraceCERT® |
| 1.70341 | HCl 7% HCl 5% + | H ₂ PtCl ₆ | 1,000 | 100 mL | Certipur® |
| 19078 | HNO ₃ Traces HCl 5% + | Pt metal | 1,000 | 100 mL | TraceCERT® |
| 49763 | HNO ₃ Traces | Pt metal | 1 | 100 mL | TraceCERT® |

Rh

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|----------------------------|---|-----------------------------|------------------|------------|
| NIST3144 | HCl 10% | (NH ₄) ₃ RhCl ₆ | 1 mg/g | 5x10 mL ampoules | NIST |
| 1.70345 | HNO ₃ 2-3% | Rh(NO ₃) ₃ | 1,000 | 100 mL | Certipur® |
| 04736 | HCl 5% | RhCl ₃ | 1,000 | 100 mL | TraceCERT® |
| 1.08525 | HNO ₃ 0.5 mol/l | Rh(NO ₃) ₃ | 10 | 100 mL | Certipur® |
| 04026 | HNO ₃ 0.5 mol/l | Rh(NO ₃) ₃ | 10 | 100 mL | TraceCERT® |

Ru

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|---------------|--------------------------|-----------------------------|-------------|-----------|
| 1.70347 | HCl 7% | RuCl ₃ | 1,000 | 100 mL | Certipur® |

Sb

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|------------------------------------|--------------------------------|-----------------------------|-------------|------------|
| 91482 | HNO ₃ 5% + HF <0.5% | Sb metal | 10,000 | 100 mL | TraceCERT® |
| 1.70302 | HCl 7% | Sb ₂ O ₃ | 1,000 | 100 mL | Certipur® |
| 73495 | HNO ₃ 2% + HF Traces | Sb metal | 1,000 | 100 mL | TraceCERT® |
| 89519 | HNO ₃ 2% + HF <0.1% | Sb metal | 1 | 100 mL | TraceCERT® |

Se

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|--------------------------|-----------------------------|------------------|------------|
| NIST3149 | HNO ₃ 10% | Se semi metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 98838 | HNO ₃ 5% | Se semi metal | 10,000 | 100 mL | TraceCERT® |
| 1.7035 | HNO ₃ 2-3% | SeO ₂ | 1,000 | 100 mL | Certipur® |
| 50002 | HNO ₃ 2% | Se semi metal | 1,000 | 100 mL | TraceCERT® |
| 56544 | HNO ₃ 2% | Se semi metal | 1 | 100 mL | TraceCERT® |

Sn

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------------------|--------------------------|-----------------------------|-------------|------------|
| 42991 | HNO ₃ 5% + HF <0.5% | Sn metal | 10,000 | 100 mL | TraceCERT® |
| 1.70362 | HCl 7% | SnCl ₄ | 1,000 | 100 mL | TraceCERT® |

| | | | | | |
|--------------|--------------------------------|----------|-------|--------|------------|
| 92615 | HCl 10% | Sn metal | 1,000 | 100 mL | TraceCERT® |
| 63564 | HNO ₃ 2% + HF <0.1% | Sn metal | 1 | 100 mL | TraceCERT® |

T

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|--------------------------|-----------------------------|------------------|------------|
| NIST3158 | HNO ₃ 10% | Tl metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 5295 | HNO ₃ 5% | TINO ₃ | 10,000 | 100 mL | TraceCERT® |
| 1.70359 | HNO ₃ 2-3% | TINO ₃ | 1,000 | 100 mL | Certipur® |
| 51873 | HNO ₃ 2% | TINO ₃ | 1,000 | 100 mL | TraceCERT® |

V

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------|---------------------------------|-----------------------------|-------------|------------|
| 1.70388 | HNO ₃ 15% | NH ₄ VO ₃ | 10,000 | 100 mL | Certipur® |
| 44712 | HNO ₃ 5% | V metal | 10,000 | 100 mL | TraceCERT® |
| 1.70366 | HNO ₃ 2-3% | NH ₄ VO ₃ | 1,000 | 100 mL | Certipur® |
| 18399 | HNO ₃ 2% | V metal | 1,000 | 100 mL | TraceCERT® |
| 75593 | HNO ₃ 2% | V metal | 1 | 100 mL | TraceCERT® |

W

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|-----------------|-----------------------------|---|-----------------------------|-------------|------------|
| 50938 | HNO ₃ 5% + HF 2% | W metal | 10,000 | 100 mL | TraceCERT® |
| 1.70364 | H ₂ O | (NH ₄) ₂ WO ₄ | 1,000 | 100 mL | Certipur® |
| 50334 | HNO ₃ 5% + HF 2% | W metal | 1,000 | 100 mL | TraceCERT® |

Zn

| Cat. no. | Matrix | Starting material | Concentration (mg/L) | Size | |
|------------------|-----------------------|-----------------------------------|-----------------------------|------------------|------------|
| NIST3168A | HNO ₃ 10% | Zn metal | 10 mg/g | 5x10 mL ampoules | NIST |
| 1.70389 | HNO ₃ 2-3% | Zn(NO ₃) ₂ | 10,000 | 100 mL | Certipur® |
| 68961 | HNO ₃ 5% | Zn metal | 10,000 | 100 mL | TraceCERT® |
| 1.70369 | HNO ₃ 2-3% | Zn(NO ₃) ₂ | 1,000 | 100 mL | Certipur® |
| 18562 | HNO ₃ 2% | Zn metal | 1,000 | 100 mL | TraceCERT® |
| 75594 | HNO ₃ 2% | Zn metal | 1 | 100 mL | TraceCERT® |

Materials

| Product # | Image | Description | Add to Cart |
|------------------|--------------|---|-------------------------|
| 73108 | | Elemental Impurities according to ICH Q3D oral, Standard 2 TraceCERT®, (in 10% hydrochloric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 92928 | | Elemental Impurities according to ICH Q3D inhalation, Standard 1 TraceCERT®, (in 12% nitric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 93696 | | Elemental Impurities according to ICH Q3D inhalation, Standard 2 TraceCERT®, (in 10% hydrochloric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 93679 | | Elemental Impurities according to ICH Q3D inhalation, Standard 3 TraceCERT®, in nitric acid and hydrofluoric acid (5% nitric acid and <0.5% hydrofluoric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 19041 | | Elemental Impurities according to ICH Q3D oral, Standard 1 TraceCERT®, (in 12% nitric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 69729 | | Elemental Impurities according to ICH Q3D oral, Standard 3 TraceCERT®, in nitric acid and hydrofluoric acid (5% nitric acid and <0.5% hydrofluoric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 89118 | | Elemental Impurities according to ICH Q3D parenteral, Standard 1 TraceCERT®, (in 12% nitric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 89922 | | Elemental Impurities according to ICH Q3D parenteral, Standard 2 TraceCERT®, (in 10% hydrochloric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |
| 07368 | | Elemental Impurities according to ICH Q3D parenteral, Standard 3 TraceCERT®, in nitric acid and hydrofluoric acid (5% nitric acid and <0.5% hydrofluoric acid), applicable for testing acc. to USP<232>, Ph.Eur. Gen. Chapter 5.20 | pricing |

