



## USP 232 Elemental Impurities Standards

Limits for the amounts of elemental impurities in drug products are specified by the United States Pharmacopeia (USP) and the International Council for Harmonisation (ICH). These limits are detailed in USP General Chapter 232 and ICH Guideline for Elemental Impurities Q3D. Standards based on oral permitted daily exposures along with an internal standard are provided, as well as high and low level multi-element calibration standards, which allow for quantitative analysis through custom applications. Additional custom standards are available and may be requested through our Inorganic Technical Service Department.

### USP 232 Oral Impurities Mix 1

**USP-232-01-1** **100 mL**  
At stated conc. ( $\mu\text{g/mL}$ ) 4 comps.  
2-5%  $\text{HNO}_3$

Arsenic (As)	15
Cadmium (Cd)	5
Lead (Pb)	5
Mercury (Hg)	30

### USP 232 Oral Impurities Mix 3

**USP-232-03-1** **100 mL**  
100  $\mu\text{g/mL}$  each in 10%  $\text{HCl}$  7 comps.

Gold (Au)
Iridium (Ir)
Osmium (Os)
Palladium (Pd)
Platinum (Pt)
Rhodium (Rh)
Ruthenium (Ru)

### USP 232 Internal Standard

**USP-232-05-1** **100 mL**  
At stated conc. ( $\mu\text{g/mL}$ ) 6 comps.  
2-5%  $\text{HNO}_3$  tr.  $\text{HCl}$  tr.  $\text{HF}$

Bismuth (Bi)	5
Germanium (Ge)	5
Indium (In)	5
Lutetium (Lu)	5
Scandium (Sc)	10
Tellurium (Te)	25

### USP 232 Oral Impurities Mix 2

**USP-232-02-1** **100 mL**  
At stated conc. ( $\mu\text{g/mL}$ ) 6 comps.  
2-5%  $\text{HNO}_3$

Cobalt (Co)	50
Nickel (Ni)	200
Selenium (Se)	150
Silver (Ag)	150
Thallium (Tl)	8
Vanadium (V)	100

### USP 232 Oral Impurities Mix 4

**USP-232-04-1** **100 mL**  
At stated conc. ( $\mu\text{g/mL}$ ) 7 comps.  
2-5%  $\text{HNO}_3$  tr.  $\text{HF}$ .

Antimony (Sb)	120
Barium (Ba)	140
Chromium (Cr)	1100
Copper (Cu)	300
Lithium (Li)	55
Molybdenum (Mo)	300
Tin (Sn)	600



UPDATED

### USP 232 High Level Calibration Standard A

**USP-232-CAL-HIGH-A-1** **100 mL**  
100  $\mu\text{g/mL}$  each in 5% Nitric acid, tr  $\text{HF}$  16 comps.

Antimony (Sb)	Lithium (Li)
Arsenic (As)	Molybdenum (Mo)
Barium (Ba)	Nickel (Ni)
Cadmium (Cd)	Selenium (Se)
Chromium (Cr)	Silver (Ag)
Cobalt (Co)	Tin (Sn)
Copper (Cu)	Thallium (Tl)
Lead (Pb)	Vanadium (V)

### USP 232 Low Level Calibration Standard A

**USP-232-CAL-LOW-A-1** **100 mL**  
10  $\mu\text{g/mL}$  each in 5% Nitric acid, tr  $\text{HF}$  16 comps.

Antimony (Sb)	Lithium (Li)
Arsenic (As)	Molybdenum (Mo)
Barium (Ba)	Nickel (Ni)
Cadmium (Cd)	Selenium (Se)
Chromium (Cr)	Silver (Ag)
Cobalt (Co)	Tin (Sn)
Copper (Cu)	Thallium (Tl)
Lead (Pb)	Vanadium (V)

### USP 232 High Level Calibration Standard B

**USP-232-CAL-HIGH-B-1** **100 mL**  
100  $\mu\text{g/mL}$  each in 10% Hydrochloric acid 7 comps.

Gold (Au)	Platinum (Pt)
Iridium (Ir)	Rhodium (Rh)
Osmium (Os)	Ruthenium (Ru)
Palladium (Pd)	

### USP 232 Low Level Calibration Standard B

**USP-232-CAL-LOW-B-1** **100 mL**  
10  $\mu\text{g/mL}$  each in 10% Hydrochloric acid 7 comps.

Gold (Au)	Platinum (Pt)
Iridium (Ir)	Rhodium (Rh)
Osmium (Os)	Ruthenium (Ru)
Palladium (Pd)	

### USP 232 High Level Calibration Standard C

**USP-232-CAL-HIGH-C-1** **100 mL**  
100  $\mu\text{g/mL}$  in 5% Nitric acid

Mercury (Hg)
--------------

### USP 232 Low Level Calibration Standard C

**USP-232-CAL-LOW-C-1** **100 mL**  
10  $\mu\text{g/mL}$  in 5% Nitric acid

Mercury (Hg)
--------------