



## USP 232 Oral Impurities Standards

Limits for the amounts of elemental impurities in drug products are specified by The United States Pharmacopeia (USP) and the International Conference on Harmonization (ICH). The following standards are based off these limits as detailed in USP General Chapter 232 and ICH Guideline for Elemental Impurities Q3D. Standards based on oral permitted daily exposures are provided along with an internal standard. High and low level multi-element calibration standards that allow quantitative analysis through custom applications will be available soon.



### USP 232 Oral Impurities Mix 1

<b>USP-232-01-1</b>	<b>100 mL</b>
<i>At stated conc. (<math>\mu\text{g/mL}</math>) 2-5% <math>\text{HNO}_3</math></i>	
	4 comps.
Arsenic (As)	15
Cadmium (Cd)	5
Lead (Pb)	5
Mercury (Hg)	30

### USP 232 Oral Impurities Mix 2

<b>USP-232-02-1</b>	<b>100 mL</b>
<i>At stated conc. (<math>\mu\text{g/mL}</math>) 2-5% <math>\text{HNO}_3</math></i>	
	6 comps.
Cobalt (Co)	50
Nickel (Ni)	200
Selenium (Se)	150
Silver (Ag)	150
Thallium (Tl)	8
Vanadium (V)	100

### USP 232 Oral Impurities Mix 3

<b>USP-232-03-1</b>	<b>100 mL</b>
<i>100 <math>\mu\text{g/mL}</math> each in 10% <math>\text{HCl}</math></i>	
	7 comps.
Gold (Ag)	
Iridium (Ir)	
Osmium (Os)	
Palladium (Pd)	
Platinum (Pt)	
Rhodium (Rh)	
Ruthenium (Ru)	

### USP 232 Oral Impurities Mix 4

<b>USP-232-04-1</b>	<b>100 mL</b>
<i>At stated conc. (<math>\mu\text{g/mL}</math>) 2-5% <math>\text{HNO}_3</math> tr. <math>\text{HF}</math></i>	
	7 comps.
Antimony (Sb)	120
Barium (Ba)	140
Chromium (Cr)	1100
Copper (Cu)	300
Lithium (Li)	55
Molybdenum (Mo)	300
Tin (Sn)	600

### USP 232 Internal Standard

<b>USP-232-05-1</b>	<b>100 mL</b>
<i>At stated conc. (<math>\mu\text{g/mL}</math>) 2-5% <math>\text{HNO}_3</math> tr. <math>\text{HCl}</math> tr. <math>\text{HF}</math></i>	
	6 comps.
Bismuth (Bi)	5
Germanium (Ge)	5
Indium (In)	5
Lutetium (Lu)	5
Scandium (Sc)	10
Tellurium (Te)	25