



ELEMENTAL IMPURITIES

A Pharmaceutical Development Company.

INDUSTRY UPDATE

LET IRVINE HELP IDENTIFY THE LEVELS OF METAL IMPURITIES IN YOUR DRUG PRODUCTS.

USP has proposed two new general chapters: Elemental Impurities - Limits <232> and Elemental Impurities - Procedures <233> [PF 36(1), Jan-Feb 2010]. These chapters are proposed to replace Heavy Metals <231>.

Irvine leads the industry as an active participant in collaborative studies to develop methodologies to support the determination and control of elemental impurities. Irvine has the technical expertise and state-of-the-art resources to provide complete solutions for meeting these new requirements as they become effective.

Timely Analysis with Modern, Precise Instrumentation:

- ICP-OES
- ICP-MS
- Graphite AA
- Flame AA
- Cold Vapor AA

We invite you to visit us, audit our laboratories, discover our insight, and learn more about our passionate commitment to partnering excellence. To learn more, please visit www.irvinepharma.com or call 877-445-6554.

Irvine leads the way as the contract industry expert.

- ✓ Elemental Impurities – Limits <232>
- ✓ Elemental Impurities – Procedures <233>

Trust the industry leader to detect and control the proposed limits of Class 1 and Class 2 impurities:

Element	Oral Component Limit (µg/g) per 10-g Dose	Oral Daily Dose PDE (µg/day)	Parenteral Component Limit (µg/g) per 10-g Dose	Parenteral Daily Dose PDE (µg/day)
Arsenic	1.5	15	0.15	1.5
Cadmium	0.5	5	0.05	0.5
Lead	1	10	0.1	1
Mercury	1.5	15	0.15	1.5
Chromium	25	250	2.5	25
Copper	250	2500	25	250
Manganese	250	2500	25	250
Molybdenum	25	250	2.5	25
Nickel	25	250	2.5	25
Palladium	10	100	1.0	10
Platinum	10	100	1.0	10
Vanadium	25	250	2.5	25
Osmium	10 (Combination not to exceed)	100 (Combination not to exceed)	1.0 (Combination not to exceed)	10 (Combination not to exceed)
Rhodium				
Ruthenium				
Iridium				



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