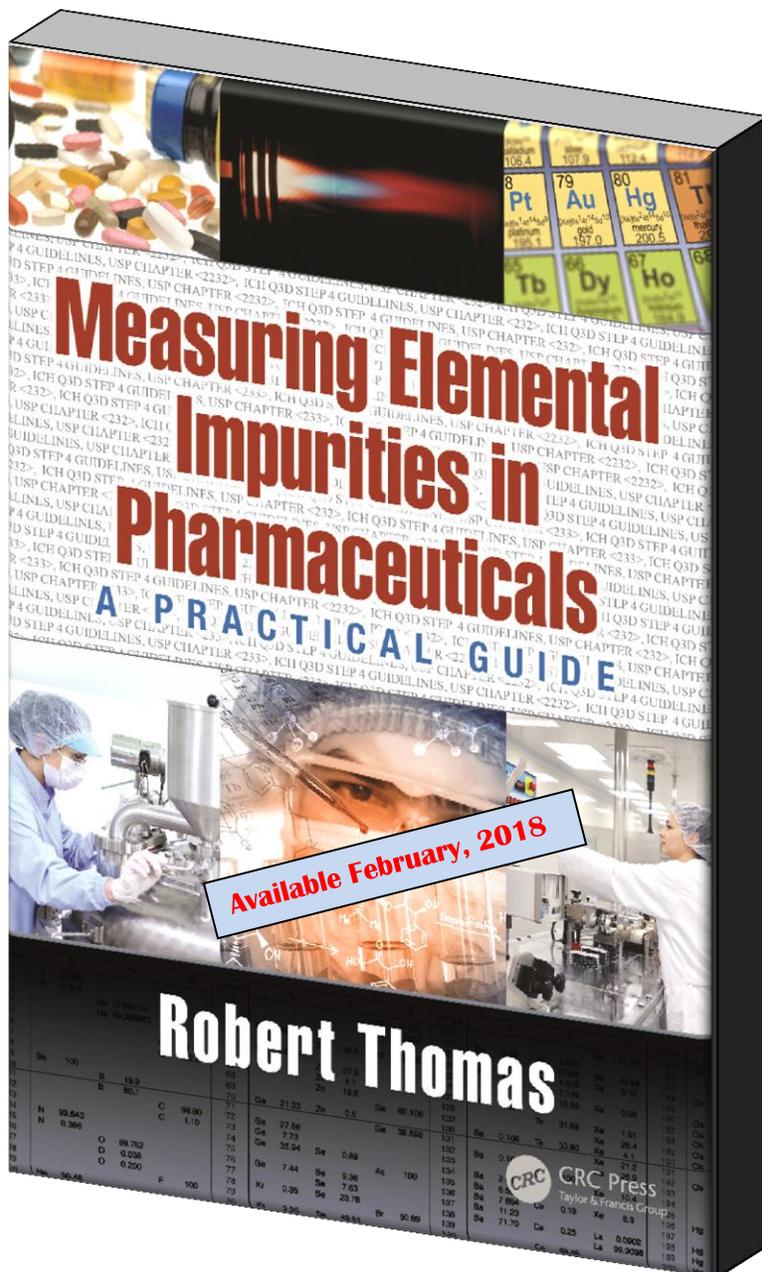


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Robert J. Thomas, CSci, CChem, FRSC  
Principal Consultant  
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- Offers guidelines about the optimum strategy for risk assessment.
- Provides tips on how best to prepare and present your data for regulatory inspection.

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## Measuring Elemental Impurities in Pharmaceuticals: A Practical Guide

Robert. J. Thomas

Recent regulations on heavy metal testing have required the pharmaceutical industry to monitor a suite of elemental impurities in pharmaceutical raw materials, drug products and dietary supplements. These new directives are described in the new United States Pharmacopeia (USP) Chapters <232>, <233>, and <2232>, together with Q3D, Step 4 guidelines for elemental impurities, drafted by the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use), a consortium of global pharmaceutical associations, including the European Pharmacopeia (Ph.Eur.), the Japanese Pharmacopeia (JP) and the USP. This book provides a complete guide to the analytical methodology, instrumental techniques and sample preparation procedures used for measuring elemental impurities in pharmaceutical and nutraceutical materials.

It offers readers the tools to better understand plasma spectrochemistry to optimize detection capability for the full suite of elemental PDE (Permitted Daily Exposure) levels in the various drug delivery categories. Other relevant information covered in the book includes:

- Coverage of heavy metals testing in the pharmaceutical industry from a historical perspective.
- Overview of current status of USP Chapters <232> <233>, <2232> and ICH Q3D Step 4 guidelines.
- An explanation of the strict validation protocols required to meet data quality objectives, including how real-world J-values are calculated.
- Guidelines on the optimum strategy for risk assessment.
- Insight on how best to prepare and present your data for regulatory inspection.

An indispensable resource, the fundamental principles and practical benefits of ICP-OES and ICP-MS are covered in a reader-friendly format that a novice, who is carrying out elemental impurities testing in the pharmaceutical and nutraceutical communities, will find easy to understand.

**Robert J. Thomas** has worked in the field of trace element analysis for over 40 years, including 24 years for an ICP-MS manufacturer and 15 years as a principal of his own consulting company. He has served on the ACS (American Chemical Society) Reagent Chemical Committee for the past 17 years as leader of the elemental impurities task force where he has worked closely with the USP to align heavy metal testing procedures in analytical reagents with those of pharmaceutical materials. He has authored almost 100 publications on trace element analysis and written three textbooks on ICP-MS and related topics, including this new book, which focuses on the new global directives on elemental impurities in pharmaceutical materials and dietary supplements. He is currently editor and frequent contributor to the Atomic Perspectives Column in Spectroscopy Magazine. He has a graduate degree in Analytical Chemistry from the University of Wales in the UK and is a Fellow of the Royal Society of Chemistry (FRSC, and a Chartered Chemist (CChem).

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