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Recent advances in the determination of elemental impurities in pharmaceuticals and drugs: Status, challenges and moving frontiers

Elemental impurities have been regulated for many decades not only in environmental materials and food products, but also in pharmaceutical and drug products. Metal impurities such as As, Cd, Cu, Pb, Hg, V and Pt in pharmaceuticals and drugs may originate from several sources such as raw materials, catalysts, metal reagents and even manufacturing equipments. An account of the recent changes in the European Pharmacopoeia (EP), the United States Pharmacopoeia (USP) and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) regulations for inorganic impurities and new strategies to be adopted for heavy metals analyses will be presented. This presentation will also describe the need and scope of metallic impurity profiling and current trends in pharmaceutical research. Rapid screening methods in quality control operations, and a brief account of the classical spectrophotometry and the role of various instrumental methods such as atomic absorption spectrometry (AAS), X-ray fluorescence spectrometry (XRF), instrumental neutron activation analysis (INAA), inductively coupled plasma atomic emission spectrometry (ICP-AES) and the inductively coupled plasma mass spectrometry (ICP-MS) for the accurate determination of inorganic impurities in pharmaceutical samples will be presented. Further developments in ICP-MS have become very significant in the quality control of bulk drugs and pharmaceutical industry. Recent advances in sample preparation, speciation analysis, quality issues, and application of laser ablation ICP-MS and high-resolution ICP-MS in pharmaceutical analysis and possible future trends will also be discussed.

Biography

V Balaram received MSc (1974) and PhD degrees (1979) in Chemistry from the Andhra University, Visakhapatnam. He is currently Emeritus Scientist (Former Head & Chief Scientist of Geochemistry Division) at the CSIR-National Geophysical Research Institute, Hyderabad. His research areas include trace element geochemistry, environmental chemistry, spectroscopy, pharmaceutical sciences and reference materials. He is an expert of ICP-mass spectrometry (quadrupole, magnetic sector & time-of-flight) and their applications in different areas of earth, environmental and pharmaceutical sciences. He has >275 publications in international peer-reviewed journals, with ~2000 citations (h-index 23 & i10-index 52) and guided 4 PhD students, few postdoctoral and hundreds of PG students from different universities across the country. He is also recipient of several prestigious national and international awards such as "National Geoscience Award" from Government of India, New Delhi, "S Narayanaswamy Award" from Geological Society of India, Bangalore (for his contributions in economic geology); "Eminent Mass Spectrometrists Award" from Indian Society of Mass Spectrometry, Mumbai; "Mantripragada Gold Medal" from Indian Society of Applied Geochemists, Hyderabad and Lifetime Achievement Award for Excellence in Science and Technology from ISAS-Kerala (for his contributions in mass spectrometry & analytical chemistry). He was also the Leader of Regional Committee, Central Working Group for India for "International Geochemical Mapping Programme" (IGCP 360) during 1994-97. He has popularized science by delivering >350 lectures in >225 academic institutions across India and abroad (>30 countries in all 6 continents) during the last 28 years. He was a consulting scientist for making of educational TV programs for Indian TV-UGC-Country-wide Class Room and delivered a number of popular science talks on radio and TV. He is also mentor in ~50 DST INSPIRE Science Camps in 11 states in India.

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