

Solid Analysis Techniques to Monitor Metals in Plastic Packaging for Pharmaceuticals

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In order to ensure the quality of a pharmaceutical product and the safety of individuals administered the product, the safety and quality of the packaging that contains the pharmaceutical must be established. Metals may be present in plastic packaging as a result of the purposeful introduction of metals during the manufacturing process and/or as contaminants found in the materials and equipment used. These metals may leach or transfer from the packaging into the pharmaceutical posing health concerns to the patient if these metals are toxic (for example, As, Cd, Hg, and Pb) and potential negative effects on the quality of the pharmaceutical product. The current recommended method of analysis requires digestion of plastic packaging in acid and analysis of the extract by ICP-AES or ICP-MS. This extraction method may not reflect the conditions that a pharmaceutical package may realistically ever encounter. As an alternative to this extraction method, several solid analysis techniques, including X-ray fluorescence spectroscopy (XRF), laser-induced breakdown spectroscopy (LIBS), and laser ablation - ICP-MS (LA-ICP-MS), will be evaluated for metals analysis of plastic packaging and components used in pharmaceuticals. An array of plastic packaging materials will be submitted to various sample storage and handling situations commonly used in the pharmaceutical industry and then analyzed for metal content using these solid analysis techniques.