

TXRF TRACE ELEMENT ANALYSIS APPLIED TO AUTHENTICITY AND PURITY CONTROL OF PHARMACEUTICAL SAMPLES

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The characterization of brand drugs and their generics is a very important task in pharmaceutical analysis. For this, several analytical techniques with regard to the determination of grain size distribution, morphology and phase distribution are available. Currently, the determination of chemical drug composition has not turned out satisfactorily. Additionally, the elemental composition of raw materials and end products must be analyzed regularly to comply with public and internal regulations.

The applicability of common X-ray fluorescence (XRF) techniques for these analytical tasks is limited due to the high demand on sensitivity, the oftentimes small sample amount available and the lack of suitable calibration standards. The use of other methods for trace element analysis, like atomic absorption spectroscopy (AAS) or inductively coupled plasma optical emission spectroscopy (ICP-OES), is often restricted by sample quantity, the necessity for sample digestion and matrix-related difficulties.

With total reflection X-ray fluorescence spectroscopy (TXRF), sample quantities below milligram amounts can be analyzed for their trace element content. As this method is based on internal standardization, no standards for external calibration are needed.

The topic of this presentation is the application of TXRF spectroscopy for authenticity analysis of pharmaceutical samples. Different commercially available acetylsalicylic acid based drugs were tested by qualitative and quantitative TXRF analysis. Significant differences in trace element composition allowed accurate differentiation of the origin.

Additionally, the results of TXRF measurements regarding the analysis of Pd and other trace elements in drugs and raw materials will be presented.