

## **LOWERING THE LIMITS OF DETECTION OF PHARMACEUTICAL MATERIALS BY POWDER X-RAY DIFFRACTION**

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The detection of trace amounts of crystalline materials, like polymorphic impurities, is of significant interest to the pharmaceutical industry. Unfortunately, pharmaceutical materials are often more difficult to analyze due to sample quantity availability and the low atomic mass of the elements that make up these materials. In addition to these difficulties often the phase to be detected is a polymorph of the high concentration form and sometimes not significantly different with respect to its crystallographic structure. The presence of these polymorphs often results in overlapping peaks by X-ray diffraction that raises additional issues to address.

In this study pharmaceutical materials have been examined to elucidate the lowest limit of detection of polymorphs and/or impurities in different sample forms using current methodologies. Based on the analysis conducted these limits have been shown to be – in some cases - down to 0.05%.