

THE USE OF FIELD-PORTABLE pXRD FOR THE RAPID IDENTIFICATION OF COUNTERFEIT PHARMACEUTICAL PRODUCTS AND SUBSEQUENT EXCIPIENT IDENTIFICATION AND QUANTIFICATION

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Counterfeit pharmaceuticals are an ever increasing problem, with the World Health Organization estimating that more than 10% of all pharmaceutical products are not genuine.¹ Furthermore, the fake products may contain materials that are themselves hazardous. Efforts to thwart counterfeits include enhanced product packaging security and field detection of genuine vs. counterfeit via spectroscopic techniques. While Infrared and Raman spectroscopy are quite capable of identifying counterfeits in the field, they are less able to either quantify the active ingredient (e.g., when insufficient active ingredient is present), or to identify the counterfeit substance(s).

Powder X-ray diffraction (pXRD) has long been the technique of choice for the identification and quantification of both the active ingredients and excipient fillers found in pharmaceutical products. Phase identification and quantification by pXRD utilizes standard databases containing nearly 500,000 XRD patterns, enabling the rapid identification of all crystalline and many amorphous materials. A variety of methods exists for quantitative analysis with or without the use of standards.

Following the development by NASA of “CheMin”, a miniature X-ray diffraction/X-ray fluorescence instrument intended for flight on the Mars Science Laboratory (MSL ’11) mission,² a self-contained, field-portable instrument “Terra” was developed for terrestrial applications. We will describe this new technology as well as present the results of pXRD analysis of several real and counterfeit pharmaceuticals.

References: [1]. World Health Organization, Geneva. Counterfeit medicines. Revised February, 2006; Fact sheet No. 275. [2]. <http://mssl-scicorner.jpl.nasa.gov/Instruments/CheMin/>