

## **EDXRD PROBE FOR PHAMACEUTICAL VERIFICATION**

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Verification of materials is an increasingly important part of pharmaceutical processes. Both the quality and authenticity of materials before, during and after manufacture are important for brand name protection, control in product lines, as well as, identification of counterfeit items. No single technology can accomplish all of these tasks alone. To perform these tasks adequately, manufacturers, distributors, etc. need to apply a number of technologies.

XStream Systems, Inc has developed an Energy Dispersive X-ray Diffraction (EDXRD) system which can fit into a number of places in the development and distribution cycle of pharmaceuticals. As an x-ray diffraction technique, the instrument is sensitive to crystalline materials. Materials may be in solid or powder form, and the technique is non-destructive. Unlike Angular X-ray Diffraction (AXRD), a “white” x-ray beam is used. This energetic beam can penetrate through relatively thick materials, diffracting from crystallites within the sample. These materials can be observed even when they are located within opaque, sealed containers. That is, for many cases the drugs can be examined in sealed, packaged vials without any sample preparation.

The table top unit uses a confocal geometry to maximize the x-ray intensity from a relatively low-powered, air-cooled 80 kV x-ray source. The beam is collimated by a circular slit assembly before the sample. A similar slit assembly after the sample collimates the diffracted beam. A single, state-of-the-art, CdTe solid-state detector with a multichannel analyzer is used to process the diffracted signal. This collimation system allows us to interrogate a doughnut-shaped volume within the sample under test.

One of the design goals was to develop a unit that is capable of performing quick verification or detection of complex materials and mixtures at a number of points along the manufacturing and distribution paths, yet can be operated by personnel with minimal scientific knowledge. Rapid identification of unknowns is possible using neural network search algorithms or pattern matching techniques. The Material Recognition Software Engine (MRSE) utilizes a localized SQL database to store and process the raw spectra data. The MRSE takes the sample data and determines if it matches any known patterns within its database. This engine has demonstrated that it can verify a number of drugs within 30 sec with better than 97 percent accuracy.