Using portable x-ray diffraction (XRD) with pseudo-thin-film type analysis for API verification and counterfeit formulation investigations.

All medication formulations have a unique fingerprint of both active and inactive ingredients that identifies the efficacy and brand of each drug. Incorrect formulations containing foreign or substitute ingredients can jeopardize a patient's well-being. Additionally, when incorrect or counterfeit formulations are distributed under a brand name, the reputation of the manufacturer is at risk.

Pharmaceutical manufacturers must protect their business interests by ensuring that the correct formulations of their products are being distributed. This will ensure that patients are receiving the correct API and dosage, and that their branding isn't compromised by counterfeiters. Just as important, they also need to ensure that they have documented fingerprint records of all their drug and formulation steps. X-ray diffraction (XRD) offers a non-destructive fingerprinting method for drug formulations. This is essential for pharmaceutical manufacturers. It offers factual support for patent and other legal records as well as retention of the original powder material if needed.

Olympus offers a unique and viable portable XRD system, meaning it can travel to a site where it is needed rather than having to bring specimens to it. It traces its lineage back to the NASA XRD developed for the current and ongoing Mars mission. The same scientists that invented that configuration also developed the commercial version which Olympus sells today.

Olympus XRD systems employ a technology without moving parts. Essentially, Olympus uses a pseudo-thin-film type analysis, we suspend a very small amount of sample (<15mg) inside two mylar windows, and then apply a frequency to it. This has the effect of convecting a powdered material, and rotating it on its axes, this is commonly referred to as Powder liquefaction.

Due to this type of configuration, we guarantee that within one minute of analysis, every single particle within the windows will at some point cross the x-ray beam in every possible orientation, thereby allowing for 100% randomization. With XRD, the better you randomize your crystallites, the better off your analysis is going to be.

It has been long theorized that if one had a way to do transmittance XRD such as Olympus does, it would be a much better way to achieve diffraction events. Essentially, the pseudo-thin-film transmittance technique avoids the peak broadening issues from which most traditional systems suffer.

Supporting data will presented from both prescription medications, and over-the-counter formulations. Olympus will rely on the user to supply specimens for proof of concept, these can be either from legitimate sources or from counterfeit.

Author:
Jose Brum
XRD Scientist
Analytical Instruments
Olympus Scientific Solutions Americas