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Raman mapping-A powerful analytical tool for detection/quantification of API physical form and its form impurities as presented in solid samples to support R&D, QbD, license application and fighting against counterfeit medicine products and patent infringement

Jianping Wu and **Shahid Raza**
Pharmaterials, Ltd., UK

The regular analytical techniques for solid materials, such as XRPD, macro spectroscopy, thermal and/or gravimetric analyses, cannot provide 'micro-scale' information such as API crystal size, agglomeration, distribution, which could be vital for the initial formulation development, QbD, and final commercial product development. In addition, the aforementioned techniques generally have poor sensitivity to detect sub-percent (<1% w/w) API and/or its form impurities as presented in a solid sample. A technique with such capability could support QbD and license application for generic products to regulatory authorities. The identification of the patented physical form of API as presented in the tested solid sample, generally at a small amount, can provide solid evidence against counterfeit medicine products and patent infringement. Raman mapping is one of the most promising techniques to fulfil the aforementioned tasks. The importance of Raman mapping is largely due to the capability of simultaneously obtaining a great amount of Raman spectral and spatial information from a solid pharmaceutical or biopharmaceutical sample. However, there are some practical issues that hinder the application of Raman mapping to pharmaceutical and biopharmaceutical industry. In this presentation, the authors show the capability of Raman mapping through practical examples how to overcome these issues. This presentation presents its applications in developing single phase solid dispersion formulations; supporting license application with capability of detection/quantification of API and/or its form impurities at sub-percent (<1% w/w) in some potential commercial products and analyses of counterfeit products in a couple of legal casework.

Biography

Jianping Wu has completed his BSc and MEng in China and PhD in the UK. He started his career in pharmaceutical industry from Pfizer (Sandwich, UK) by using Raman microscope. He is now an expert with respect to pharmaceutical R&D from early stage API form selection and initial formulation developments for clinical studies to GMP manufacturing of commercial products. He acted as expert assistant and has taken part in more than 10 legal caseworks. He is now principal Scientist at Pharmaterials.

chesslw@yahoo.co.uk