Modelling of Particle Size, Shape and Size Distribution in Pharmaceutical Suspensions and the Effects on Visible/Near Infrared (vis-NIR) Spectra

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For many types of pharmaceutical products, there are a number of “equivalent” products by different manufacturers (both branded and generic) available. These equivalent products contain the same chemical characteristics (composition) of active pharmaceutical ingredients (API). However, there can be variations by the manufacturers in the physical characteristics (particle size/shape) of the particulate ingredients, as well as the chemical characteristics of the supplementary ingredients. Impact of these variations includes the stability of the product and the dissolution behaviour which in turn can affect the efficacy of the product. Another issue that is encountered is the counterfeiting of popular pharmaceutical products; the counterfeit product can have variations in both the physical and chemical characteristics of the ingredients from the authentic product.

Optical measurements can be a relatively simple and effective way to identify the differences in the products since the differences in the physical and chemical characteristics of pharmaceutical products will manifest as differences in their optical (scattering and absorption) properties. Most research to-date has focussed on the use of multivariate statistical modelling approach. We have developed demonstrated the use of spatially and angularly-resolved diffuse reflectance (SARDR) spectroscopy in combination with light propagation theory to obtain bulk optical properties in various suspension systems. The bulk optical properties are extracted from the SARDR spectra by solving radiative transport equation to simultaneously decouple the physical (particle size/shape) and chemical (composition) characteristics. The effect of the particle size/shape and their distribution has not yet been explored fully for the purpose of providing critical product-related information for pharmaceutical suspensions.

Aim and Objectives
The project investigates insight of the optical scattering properties obtained from the novel SARDR measurements in vis-NIR region. The aim is to establish a methodology to provide particle size/shape distribution information for pharmaceutical suspensions.