

## Raman Spectroscopy as PAT Tool for Tablet Analysis

- PAT in the Pharmaceutical Industry
- Fast and reproducible sampling for quantitative analysis of solids and tablets
- P<sup>h</sup>AT System for Tablet Analysis

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(Dia 1) Raman Spectroscopy as PAT Tool for Tablet analysis

(Dia 2) Using Raman as analytical tool to continually build knowledge avoids the need to trial other techniques. As a non-destructive and fiber optic coupled method, Raman can follow a new product throughout its lifecycle. Knowledge gained at each development step can be made directly available to the next department/development team.

(Dia 3) Solid, oral dosage forms comprise the largest class of pharmaceutical formulations. The aim of this work was to explore the applicability of Raman spectroscopy to the analysis of tablet dosage forms

(Dia 4) Due to a large sampling volume (6x2 mm!!) the P<sup>h</sup>AT System solves some major limitations and fits the needs for fast, quantitative in-line tablet analysis

(Dia 5) The P<sup>h</sup>AT System has been designed to address the limitations of traditional Raman system for direct, quantitative analyses of solid state chemistry. Inhomogeneity, present in most solid mixtures, becomes negligible due to the large sampling area of 6mm.

(Dia 6) Compared to a Raman Microscope the P<sup>h</sup>AT Systems allows faster acquisition of solids with an enhanced reproducibility and repeatability. Stable and reliable calibration models can easily be established and used for on-line and in-line applications.

(Dia 7) The PhAT System is the preferred Raman approach for analyzing both, static solid-state samples and solid masses during DP unit operations. For granulation of Theophylline, Raman has shown to be capable of following Process-Induced Transform (PIT) in situ and real time

(Dia 9) In this application PIT leads to hydration of the API (Nitrofurantoin ) – changing its crystal structure. This process can be followed and controlled by in-line Raman spectroscopy via the P<sup>h</sup>AT System.

(Dia 8) As a PAT tool, the P<sup>h</sup>AT Ramanspektrometer can be used to monitor dynamic processes (granulation, drying, tablet pressing, powder mixing) and ensure that the appropriate form is manufactured.

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