

RAMANRXN3™ PhAT Analyzer



The **RAMANRXN3™ PhAT** analyzer uses **PhAT** technology to allow quantitative monitoring and control of solid formulations during unit operations. The advent of **PhAT** technology has redefined the standard for simplicity and reliability for Raman spectroscopic analysis of solid samples. The use of **PhAT** technology is opening up new areas to Raman analysis both *in situ* and at-line including solid-state chemistries applications and with the pharmaceutical, catalysts, polymers, and specialty chemicals industries.

The **RAMANRXN3™ PhAT** analyzer is a powerful process analytical technology (PAT) analyzer based on Raman spectroscopy. Raman data generated is high in information content.

The sharp Raman peaks can often be interpreted in terms of individual chemical moieties, thus providing a fundamental insight into the critical quality variations and attributes of the process and yielding an increase in process understanding. Kaiser's staff of experts are focused on providing solutions for our users.

PhAT technology has revolutionized solid sampling by eliminating sample irreproducibility and focusing, by measuring a representative volume of sample, and by offering the benefits of non-destructive sampling using laser powers below the ANSI exposure limit for skin.

The **RAMANRXN3™ PhAT** analyzer incorporates the most advanced self-



Applications

- Analyze powders, slurries, flakes, plaques, gels, or liquids
- PAT - R&D, primary, secondary or QA/QC
- API polymorphic form and stability
- API hydrate, solvate, or salt formation
- API co-crystal formation
- Unit operations; blending, granulation, milling, and drying
- Process induced transformations during unit operations
- Tablet coating and thickness
- Tablet API form, content, and stability
- Low dosage tablets (polymorph and degradants)
- Lyophilization
- Hot melt-extrusion
- PAC - polymers and catalysts

calibration and self-diagnostics to ensure the validity of each analysis. The analyzer's precision allows both advanced chemometric analyses and traditional univariate methods to be used.

The **RAMANRXN3™ PhAT** analyzer operates in classified environments and is housed in a stainless steel IP 66 enclosure. This analyzer is equally well-suited for formulations development in the lab, or process control in a manufacturing environment. The analyzer's enclosure package allows the analyzer to be washed down between batches meeting the clean-ability requirements of the pharmaceutical industry. As standard the analyzer is mounted to a trolley so it can be moved between unit operations. Alternatively, the analyzer can be mounted permanently to a wall.

Sampling versatility to various unit operations and a variety of manufacturing equipment is accomplished using a fiber-optically coupled [PhAT probe head](#). Both insertion and non-contact sampling options are available for the [PhAT probe head](#) to enhance sampling flexibility. A special probe interface is available for *in situ* tablet coating applications.

PhAT Technology

In situ Raman Measurement of Solids



Unit Operations

- Formulations Development
- Raw Materials ID
- Blending
- Granulation
- Drying
- Tablets / Gelcaps
- QA / QC

On-Line or At-line

- API Low Dosage
- Amorphous Content
- Form Confirmation
- Coating Quality
- Quantitation Demonstrated to 0.05%



Revolutionary New Raman PAT Tool

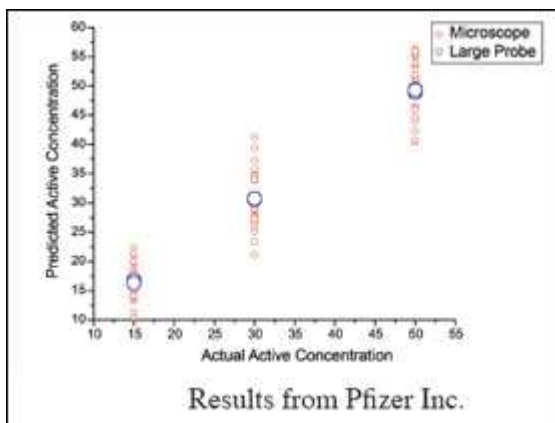


**KAISER
OPTICAL SYSTEMS, INC.**
A ROCKWELL COLLINS COMPANY

WWW.KOSI.COM

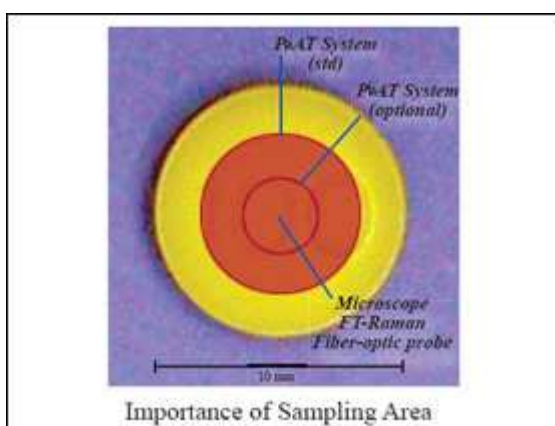
Analyzer Features

- Easy sampling of solids and slurries
- Representative mm scale measurement
- Reproducible sampling
- "Focus free" alignment
- Non-contact or insertion sampling
- Non-destructive measurement
- 21 CFR Part 11 compatible software option
- IP 66, stainless steel enclosure
- Purge for classified environments
- Modular design for easy maintenance
- Advanced self calibration protocols



Why Raman?

- Fast measurements
- Sharp spectral peaks for qualitative and quantitative analysis
- Univariate or multivariate prediction mode



Select Customer Publications

"Raman Spectroscopy: A PAT Tool for Quantitative Assessment of Tablet Potency", J. Johansson, J. Eriksson, S. Folestad, and B. Lagerholm, FACSS, 50S, Oct (2004) - AstraZeneca

"Raman Spectroscopy for Quantitative Monitoring of Solid Dosage Manufacturing Process", S-Y. Chang, A. El-Hagrasy, W. Earlv, H. Guo, D. Li, S. Kotliari, S. Paruchuri, and V. Nesarikar, IFPAC, 1-142, Jan 13 (2005) - BMS

"Comparison of Techniques for In-line Monitoring using Raman Spectroscopy.", H Wikstrom, I.R. Lewis and L.S. Taylor, Appl. Spectrosc., 59, 934-941 (2005) - Purdue University

"Raman Spectroscopy for Quantitative Monitoring of Tablet Coating", S-Y. Chang, A. El-Hagrasy, S. Paruchini, S. Kothari, D. Desai, and S. Kiang, FACSS, 92, Oct (2005) - BMS

"Quantitation of Polymorphs in Drug Products by Raman Spectroscopy", F. LaPlant and X. Zhang, Am.Pharm.Rev., 8, 88-95 (2005) - Pfizer

