

# Applications of near-infrared spectroscopy in the pharma and biopharma industries

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## Abstract

Near-Infrared spectroscopy is used in the synthesis and purification of APIs (active pharmaceutical ingredients) and biopharmaceutical fermentations. The technology is ideal because it has been designed to analyze complex mixtures. The speed of the technology allows rapid measurements of rapid synthetic reactions (of API) and has the computational power to follow multiple ingredients in a bio-process: often up to a dozen nutrients and by-products, simultaneously. The talk will briefly cover the types of equipment used, some basic theory, and numerous examples of applications in both the Pharma and BioPharma industries. Absorption spectroscopy is an important analytical chemistry technique used in pharmaceutical analysis. The United States Pharmacopeia (USP) defines absorption spectroscopy as "the measurement of an interaction between electromagnetic radiation and the chemicals, or atoms, of a chemical substance." To ensure the safety, quality and efficacy of compounds being produced, USP has developed standards and guidelines that must be observed by the pharmaceutical industry. FTIR spectroscopy relies on measurements taken in the infrared and near-infrared wavelengths of the light spectrum of a liquid, solid or gas. This process collects data from a wide spectral range. Raw ingredients can be analyzed taking absorption measurements across the infrared spectrum. The resulting curve is compared to a known, pure compound. Differences in the observed spectrum indicate impurity in the sample. UV/Vis spectroscopy can be used in the manufacturing process to identify contaminants within a substance or measure the kinetics of a reaction. Identifying contaminants: Many organic compounds will absorb light in a particular region of the UV spectrum and contaminants can easily be detected and quantified with a single measurement. Kinetics of a reaction: Small molecule pharmaceuticals can be modified by adding chemicals to a solution containing the drug in order to change the absorbance properties of the compound. For example, diazepam can easily be quantified through the addition of small amounts of sulfuric acid. The change in absorbance at 284 nm is proportional to the amount of diazepam in solution. Thus, simple and cost-effective assays can be designed for quantitative analysis of compounds. Biologics, genetically engineered proteins from human genes, have opened a new avenue for UV/Vis spectrometers in the pharmaceutical industry. These compounds are purified from a complex cellular solution using HPLC by separating a complex solution into individual components. Each component elutes from a chromatography column at a different rate based on its

chemical properties. UV/Vis spectrometers can detect and identify the unique footprint of the desired biologic, which allows laboratory personnel to obtain a purified compound. Our discussion delineates the advantages and the pharmaceutical applications of FTIR and UV/Vis spectroscopy techniques. Growing research in the pharmaceutical industry and the issue of compliance will compel manufacturers to create innovative instruments that echo the demands of increased efficiency and accuracy in spectroscopy instruments. It can be used for qualitative as well as quantitative analysis with the assistance of chemometrics. Current pharmaceutical applications cover a broad range from discovery to manufacturing of drugs in the pharmaceutical industry like identifying polymorphs, monitoring real-time processes, detection of counterfeit and adulterated pharmaceutical products and imaging solid dosage formulations. Raman imaging combines spectral and spatial information and generates chemical image of a twodimensional area of a sample. By adopting NIR spectroscopy for QC purposes, pharmaceutical companies can now make significant time and cost savings in raw materials characterization. This article will explore how and provide a review of Abiogen Pharma S.p.A and its use of NIR spectroscopy for raw material analysis. In compliance with GMP guidelines the identification of the starting raw materials must be executed on each API and excipient. As most pharmaceutical manufacturing laboratories often receive a huge amount of raw materials, this can be a difficult job in terms of time and cost. Scientists are often required to spend time away from the laboratory in order to carry out raw material analysis, resulting in decreased productivity, and the administrative burdens of carrying out several tests on each batch of raw material can significantly increase laboratory workloads. Pharmaceutical companies have the option to comply with traditional Pharmacopoeia methods for raw material identification. Prior to the European Pharmacopoeia 5th edition (2002), there was no universal method recommended by pharmaceutical guidelines relating to the analysis of raw materials. For the characterization of raw materials, the technique has been found to have some unique benefits. NIR spectroscopy enables analysis of the starting material in the original packaging, without the need to open the main container, thus reducing the risk of cross-contamination and abolishing the need to conduct the analysis within a designated sampling area. This leads to a significant decrease in the time involved for each analysis. For example, the time required for identification of one container of raw material using IR spectroscopy is approximately 15 minutes, using color reaction and viscosity is approximately 45 minutes, while identification of the same amount using NIR spectroscopy takes approximately two minutes.

## Conclusion

In addition to helping laboratory and manufacturing workers to improve productivity by reducing analysis time, using NIR spectroscopy can also aid regulatory compliance. In recent years NIR spectroscopy has been recommended as a valuable tool for raw material analysis by a range of pharmaceutical guidelines, including the Pharmaceutical Analytics Science Group's guidelines for the developments and validation of NIR spectroscopic methods, and the European Agency for the Evaluation of Medical Products note for guidance on the use of NIR spectroscopy by the pharmaceutical industry. It is also possible to see by looking at the practical example of Abiogen, that using NIR spectroscopy for raw material analysis can save a significant amount of time in the laboratory, as well as improving productivity, and reducing operating costs.

Emil W. Ciurczak holds advanced degrees in chemistry from Rutgers and Seton Hall Universities and worked in the Pharma industry since 1970. In 1983, he introduced NIRS for pharmaceutical qualitative applications at Sandoz. He consults for numerous instruments and manufacturing companies, has published over 70 articles, over 400 magazine columns, has 14 patents, and presented over 300 technical papers. He is a Contributing Editor for Pharmaceutical Manufacturing and Contract Pharma, has written and edited numerous texts ("Molecular Spectroscopy Workbench", "Handbook of NIR Analysis", 4th Ed in process, "NIR in Pharmaceutical and Medical Applications", 2nd Ed.) teaches courses in Chemistry, Physics, and Process Analysis, was on the PAT sub-committee (Validation) for the US-FDA (2002) and a member of the PAT Expert Committee (Spectroscopy) for the USP; (co-author of the USP chapter 1119).