



IDENTIFICATION OF DRUGS AND MEDICINES

EUROPEAN PHARMA COEIA 8.0

INTRODUCTION

Pharmacology, an integral part of medical science, shows rapid development resulting in the discovery of an ever-growing number of new drugs and medicines. Unfortunately, the number of counterfeited products inconsistent with Pharmacopoeia has also increased, underlining the importance of quality control and identification of drugs. These processes are necessary to prevent the circulation of products that not only lack the required medicinal properties, but might also be hazardous to human health.

The IR spectroscopy techniques provide authentication of substances, identification of active components, and rapid quality control of both source chemicals and ready-made drugs due to the fact that each chemical substance in the composition of a medicine has a unique, identifiable transmission spectrum.

MEASURING METHOD

Solid drugs and medicines are analyzed in a mixture with KBr as pressed pellets or as an emulsion with suitable liquid (mull). If the analyzed product is in an emulsified state (ointment), it is analyzed without any pretreatment. Liquid samples are injected in a cell of suitable path-length with windows made from KBr, CaF₂ or other materials transparent to infrared radiation in the region of interest.

The prepared sample (pellet, emulsion or liquid) is placed into a pellet holder or cell and then the IR spectrum of the analyzed sample is registered.

For measurements with the use of a diffuse reflectance accessory, a mixture of the substance with powdered and dried KBr or KCl is used and reflectance spectrum is measured in a sample cup.

For measurements with an ATR accessory the substance is placed on a crystal plate (ZnSe, Ge, etc) and pressed so that its ATR spectrum can be registered.

EQUIPMENT & REAGENTS

The following equipment and reagents are used:

- InfraLUM[®] FT-08 FTIR spectrometer (with software)
- Pellet holder or cells – for transmission or absorption spectra
- Diffuse reflection accessory – for reflectance spectra
- ATR accessory (with crystals for ATR and high-pressure clamp) – for ATR spectra
- Personal computer

ADVANTAGES & FEATURES OF InfraLUM[®] FT-08 FTIR SPECTROMETERS

- Excellent technical specifications
- Ergonomic design of the spectrometer
- Some samples can be analyzed without pretreatment
- Wide variety of accessories, including a complete line of IR spectroscopy accessories from PIKE Technologies
- Automatic validation system of the spectrometer and availability of IQ/OQ/PQ specifications
- Remote diagnostics of the spectrometer
- Comprehensible software with integrated calibration module
- Additional library search module with a connection to spectra libraries provided by S.T. Japan and the option for each user to create his/her own libraries. No special training and expertise are needed for the user to run the software.

EXAMPLE OF A REAL ANALYSIS

The screenshot shows a transmission spectrum of potassium gluconate pressed with KBr, scanned at 1 cm⁻¹ resolution and 60-s accumulation time.

The identification procedure of the analyzed sample is automated due to the capabilities of the dedicated SpectraLUM[®] software for InfraLUM[®] FT spectrometers. It allows for a quick search of the measured spectrum for matching the spectra of known drugs and substances compiled in a special spectral library.

The contents of this paper are subject to change without notice.

