ANALYTICAL EQUIPMENT

IDENTIFICATION OF **DRUGS** AND **MEDICINES**

STATE PHARMACOPOEIA. 12th edition

INTRODUCTION

At present, pharmacology, being an integral part of medical science, shows rapid development resulting in the discovery of ever growing number of new drugs and medicines. Hence, quality control and identification of drugs acquires vital importance as the number of counterfeited products inconsistent with Pharmacopoeia concurrently increases with the introduction of new numerous drugs. Identification of the drugs is necessary to reject the products that not only lack the required medicinal properties but might be hazardous to human health.

The IR spectroscopy techniques provide authentication of substances, identification 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 its unique transmission spectrum which allows for its precise identification.

MEASURING METHOD

Drugs and medicines are analyzed in a mixture with potassium bromide as pressed pellets or as an emulsion with immersion liquids (i.e., Nujol). If the analyzed product is in emulsified state (ointment), it is analyzed without pretreatment.

The prepared sample (pellet or emulsion) is placed, respectively, into a pellet holder or cell which are installed into the cell compartment. Then the IR spectrum of the analyzed sample is recorded.

EQUIPMENT AND REAGENTS

The following equipment and reagents are used:

- FTIR spectrometer InfraLUM® FT-08 (with software);
- Pellet holder or cell;
- Personal computer.

ADVANTAGES OF InfraLUM® FT-08 SPECTROMETERS

- Rapid analysis (one spectrum per minute)
- Some samples can be analyzed without pretreatment
- Complete line of compatible *PIKE Technologies* and *Specac* optical FTIR accessories can be used
- Reliability
- High selectivity
- Multi-component analysis
- The software versatility and efficiency are provided due to the integrated calibration module, the capability of the design of customized measuring procedures for the users' specific applications, and compliance with the GLP and 21 CFR Part 11 standard requirements.

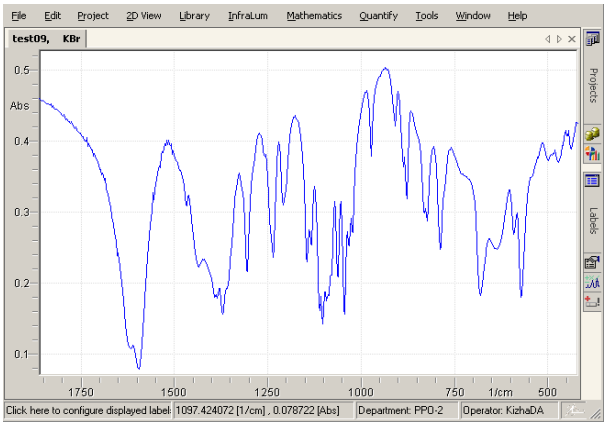
The software is easy to operate, logically designed and efficient; it allows for dedicated spectra libraries in the *JCamp* format to be plugged in and own user's libraries to be compiled. No special training and expertise are needed for the user to run the software.

EXAMPLE OF A REAL ANALYSIS

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

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

The authenticity of potassium gluconate sample is ascertained by the coincident transmission bands and their relative intensities that are prescribed in the pharmacopoeia article 42-3019-94.



The information in this leaflet is supplemental.

To get more specific information on this method, please contact the developer of this application Lumex Ltd.