

Introduction. The researchers conducted on interactions between different drug substances combined in the same dosage form are fundamental to avoid the instability of the finished medicinal product. IR spectroscopy is one of the oldest physical methods, being one of the most suitable for obtaining absorption spectra, which are then applied to determine the compatibility by using electromagnetic radiation to interact with the substances and to investigate, therefore, certain characteristics of the sample depending on the wavelength.

Aim of the study. The bibliographic evaluation of IR techniques applied for the Exploring of compatibility of drug substances with excipients.

Materials and methods. 68 abstracts and articles from systematic research in the Cochrane Electronic Library, MEDLINE databases.

Results. Based on the absorption of infrared radiation by substances, IR spectroscopy provides sufficient information about the possible interactions between the active substances and excipients of a multicomponent dosage form. In all bibliographic sources, the Fourier Transformation Infrared Spectroscopy (FTIR) method is associated and complementary with other techniques for compatibility determination such as Differential Scanning Calorimetry (DSC), X-ray diffraction. The study of possible interactions between drug substances and excipients by using FTIR is performed by the KBr pellet method, where the IR spectra are first recorded individually, then in binary mixtures in the scanning range from 4000 to 500 cm⁻¹. The obtained spectra are indicative for the nature of chemical bonds in the sample test and for the mixtures of substances, that can be used to identify the chemical structures or composition of the investigated sample. Overlapping peaks of substances and excipients in mixtures are analyzed and compared to peaks of individual spectra.

Conclusions. It has been found that IR spectroscopy is a common, important and mandatory technique in assessing the compatibility of drug substances with excipients.

Key words: IR spectroscopy, compatibility, drug substances, excipients

378. COMPARISON OF FLUCONAZOL CAPSULES DISSOLUTION PROFILES

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Introduction. The dissolution test is the most used physico- chemical test in the evaluation of the quality of the medicinal product to assess the in vitro-in vivo correlation. In the development of drug formulation, is it used to select optimal composition, study of stability and physico-chemical parameters required in the technological process, and in quality control for verifying the reproducibility of in vitro release of series launched on the pharmaceutical market.

Aim of the study. is to investigate the dissolution profile of Fluconazole-RNP 50 mg capsules compared to another recognized manufacturer (Mycosyst 50 mg Gedeon Richter Ltd. (Hungary) capsules.

Materials and methods. "Shimadzu" HPLC Chromatograph with RID-10A Detector; electronic analytical balance; pH meter Consort C861; Fuconazole-RNP and Mycosyst Gedeon Richter capsules; acetonitrile; methanol.

Results. The dissolution test demonstrated the similarity of the dissolution profiles of the compared products.

Conclusions. All media used to compare the dissolution profiles of fluconazole capsules in the dissolution test show that the similarity factor (f₂) is at least 50, which demonstrates the similarity of the fluconazole-RNP bioavailability compared to Mycosyst.

Key words: dissolution test, bioavailability, fluconazole, Mycosyst, similarity.