413. DETERMINATION OF METRONIDAZOLE AND MICONAZOLE NITRATE IN A MIXTURE BY SPECTROPHOTOMETRIC METHOD

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Introduction. Metronidazole and miconazole nitrate are substances with antiprotozoal, antifungal and antibacterial contents. For quality control of these drugs, in particular, quantitative determination, the European Pharmacopoeia recommends the HPLC method.
Aim of the study. Development of an express method for the quantitative determination of a mixture of metronidazole and miconazal nitrate based on the spectrophotometric method.
Materials and methods. In the work was used an Agilent 8453 single-beam spectrophotometer from Hewlett Packard, USA. As standard (control) substances, the pharmaceutical substances metronidazole and miconazole were used, the content of the main substance in which was not lower than 98%.
Results. The dependence of the absorption intensity in the ultraviolet (200-400 nm) and visible (400-760 nm) spectral regions in various solvents was studied.
Conclusions. The obtained spectra demonstrated the possibility of analysis of the studied substances in the joint presence.
Key words: Metronidazole, miconazole nitrate, spectrophotometer.

DEPARTMENT OF DRUGS TECHNOLOGY

414. THE LEGAL SUPPORT OF QUALITY OF TECHNOLOGICAL PROCESSES IN THE PHARMACEUTICAL INDUSTRY OF THE REPUBLIC OF MOLDOVA

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Introduction. Of particular importance in ensuring the quality of technological processes and medicinal products is the legal support - all the legal acts and norms adopted in the vision of promoting and ensuring quality at all stages of production and distribution. According to ISO, quality requires all the performances and characteristics of a product or a care service determined by the ability to have a direct or implicit consumer satisfaction. The legal regulation of the quality of the technological processes in the pharmaceutical companies ensures the correspondence of the composition indicated on the label with the real one, by observing all the legal norms in force regarding: a. creation of the internal management system (ISO 9001); b. optimization of drug manufacturing (GMP); c. creation of the pharmaceutical quality system (ICH Q).
Aim of the study. The aim is to raise awareness of the correct understanding of the concept of quality, to support the implementation of the quality management systems of technological processes.
Materials and methods. As bibliographic sources served the Internet, the official data presented by amed.md. The research methodology used: analytical, statistical, comparison, etc.