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NEW TECHNIQUES FOR PHARMACOPOEIA QUALITY CONTROL OF MANGIFERIN SUBSTANCE

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BACKGROUND

Mangiferin is naturally occurring glucosylxanthone with many pharmacological activities: antioxidant, anti-inflammatory, anti-virus, anti-tumor, anti-radiation, antibacterial, hypoglycemic, lowering blood uric acid, protecting the liver and choleretic, immune regulation (Naraki et al., 2020). Mangiferin has a wide range of plant sources, but its poor solubility and bioavailability limit its clinical use (Acosta et al., 2016). According to recent research five polymorphs of anhydrous and hydrate mangiferin with different biopharmaceutical properties had been screened and prepared. One of them (amorphous form V) is obtained by mechanical milling and presents the dominant polymorph for the development of innovative pharmaceuticals (Yang et al., 2020). Worldwide mangiferin is only used as a component in several traditional Chinese medicines to treat respiratory diseases, but in Russia this substance is registered in the public register of drugs to treat herpes viral infections. So, there is no article on this substance in the world's leading pharmacopoeias. The existing regulatory methods for quality control of mangiferin in Russia do not include assessment of polymorphism or optical activity and in whole are limited by the low solubility of the substance in water.

Purpose of the Study:

To assess the quality of sample of mangiferin substance in accordance with the requirements of the company's pharmacopoeial monograph (All-Russian Scientific Research Institute of Medicinal and Aromatic Plants), as well as to investigate new characteristics of this compound as potentially new pharmacopoeial criteria for its quality control.

MATERIALS AND METHODS

A Zetasizer Nano ZSP (Malvern, UK) based on dynamic light scattering was used to measure the size of particles in the aqueous solutions of mangiferin from 0.1 nm to 10.000 nm. UV spectra were recorded using an Agilent Cary 60 Spectrometer, USA. IR spectra in transmission mode were obtained with FTIR spectrophotometer Agilent Cary 630 (USA), range 4000 – 750 cm^{-1}. NIR spectra were recorded using MPA FT NIR Analyzer (Bruker, Germany). Measurement of the angle of rotation of plane polarized light (λ=589 nm) was carried out with an automatic polarimeter Atago POL-1/2 (Japan). The Agilent Cary Eclipse fluorescence spectrophotometer was used to record fluorescence spectra of mangiferin solution.

RESULTS

As a result of the study, the identity of mangiferin substance was proved by IR and UV spectroscopy. The IR spectrum completely coincided in the position of the absorption bands with the spectrum presented in the monograph of the enterprise. Spectral characteristics in the middle (Fig. 1) and near infrared region of the initial substance and mangiferin after recrystallization from a water-acetone mixture showed no significant difference. In the UV spectrum (0.0008%, acetone-water mixture 1:1) the minimum and maximum absorption were found at 339 and 369 nm, respectively. For the first time the absorbance (Fig. 2) and fluorescence spectra for 0.002% mangiferin aqueous solution were obtained. Excitation at 406 nm led to the appearance of maximum at 550 nm, and excitation at 350 nm led to fluorescent peak at 700 nm (Fig. 3). The specific rotation of a 0.5% solution of the substance in a mixture of water-acetone 1:1 turned out to be 30.33±0.75 (n=5).

CONCLUSIONS

The work presents results of the analysis of a sample of mangiferin substance in accordance with pharmacopoeial standards: the solubility in an acetone-water mixture and in water was assessed; identification was carried out using the method of IR and UV spectrometry and Shinoda test. New characteristics of mangiferin that can serve as criteria for the identity of a substance have been firstly investigated — the value of specific rotation (0.5% solution in water-acetone mixture 1:1) was established, absorption and fluorescence spectra for aqueous solution of substance were obtained.

Keywords:
mangiferin, quality control, polarimetry, spectral analysis.

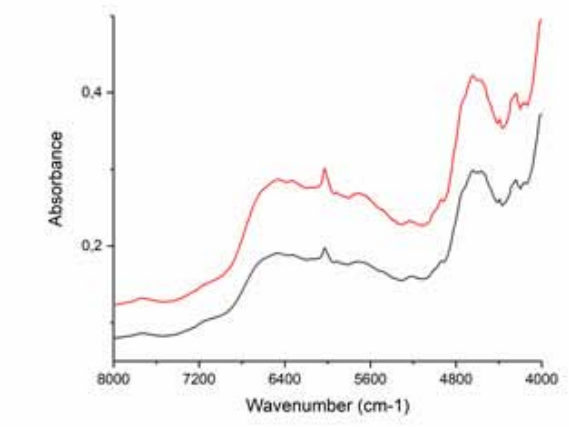

Fig. 1. *Near infrared absorption spectrum of mangiferin substance (black - initial substance, red - after recrystallization)*

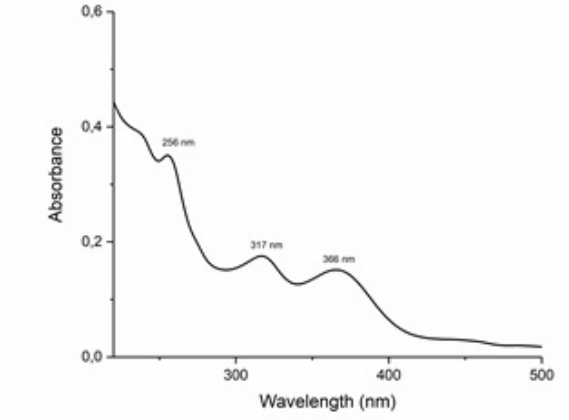

Fig. 2. *Absorption spectrum of an aqueous solution of mangiferin (0.002%) in the ultraviolet region*

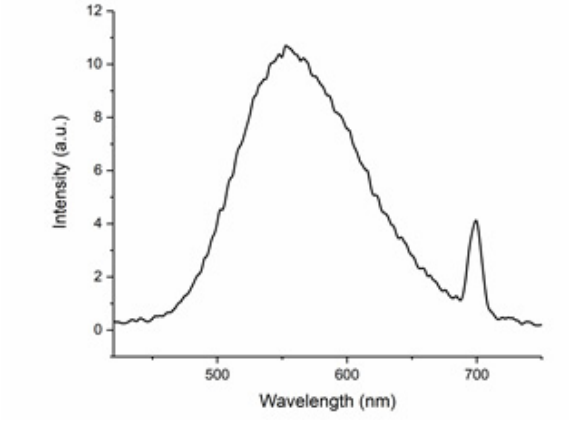

Fig. 3. *Fluorescence spectrum of an aqueous solution of mangiferin (0.002%), with excitation at 350 nm*