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DEVELOPMENT OF SECNIDAZOLE QUANTIFICATION PROCEDURE BY THE METHOD OF UV-SPECTROPHOTOMETRY

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Actuality. 5-nitroimidazoles are the group of antiprotozoal medicines widely used for treatment of infectious diseases caused by Trichomonas, Lamblia, Leishmania, etc. The action mechanism of nitroimidazoles consists in biochemical reduction of 5-nitrogroup by intracellular transport proteins of anaerobes and protozoa. Reduced nitroimidazoles interact with DNA of microorganism cells and inhibit synthesis of their nucleic acids that leads to microorganism death. Secnidazole is one of the medicine from the group of 5-nitroimidazoles, it is characterized by a prolonged serum half-life. Chemically, secnidazole is 1-(2-methyl-5-nitroimidazol-1-yl)propan-2-ol.

For secnidazole determination the method of high-performance liquid chromatography is widely used, it ensures high selectivity and sensitivity of analysis. Secnidazole is applied in high concentration; single oral dose is 1 – 2 g. Thus, we may use for determination of the medicine less sensitive methods of analysis such as spectrophotometry.

Aim: to develop UV-spectrophotometric procedure of secnidazole quantification using 0.1 M hydrochloric acid solution as a solvent and carry out step-by-step validation of the developed procedure in the variants of the method of calibration curve (MCC) and method of standard (MS) to choose the optimal variant for further application.

Materials and methods. Secnidazole was of pharmacopoeial purity. All reagents were of analytical grade. All spectrophotometric measurements were carried out using a single beam UV/VIS spectrophotometer SPEKOL®1500 (Analytik Jena AG, Germany).

The stock solutions 1 and 2 (250 μg/mL) were prepared by dissolving 50.0 mg of secnidazole in 0.1 M hydrochloric acid solution and the solutions were diluted to 200.0 mL with the same solvent. The reference solution (20 μg/mL) was prepared by diluting 4.00 mL of the stock solution 1 to 50.0 mL with 0.1 M hydrochloric acid solution. The stock solution 2 was diluted with 0.1 M hydrochloric acid solution to prepare the model solutions 1 – 7 having concentrations of 5; 10; 15; 20; 25; 30 and 35 μg/mL respectively.

The absorbance of the model solutions 1 – 7 was measured 3 times with randomization of cell position. 0.1 M hydrochloric acid solution was used as a compensation solution.

Results and discussion. UV-spectrum of the secnidazole solution in 0.1 M hydrochloric acid solution has the absorption maximum at λ_{max} = 277 nm. The value of specific absorbance have been calculated for the concentration range of 5 – 35 μg/mL and $A_{1cm}^{1\%}$ = 321.

Validation of the developed procedures has been carried out by model solutions in the variants of MCC and MS. Such validation parameters as in process stability, linearity/calibration model, accuracy and precision (repeatability) have been estimated by model solutions.

In process stability of secnidazole in the model solution was verified in the way of measuring the absorbance for the reference solution immediately and in 1, 12, 24 and 48 hours after its preparation. It is satisfied the acceptability criteria for all periods of time.

The total results of validation allow to point to the conclusion about acceptable linearity, accuracy and precision of UV-spectrophotometric procedure of secnidazole quantitative determination in the variant of the MCC and MS for all ranges of the method application.

Conclusions. A new procedure of secnidazole quantitative determination by the method of UV-spectrophotometry have been developed using 0,1 M hydrochloric acid solution as a solvent (wavelengths λ_{max} is 277 nm). Its validation by such parameters as stability, linearity, accuracy and precision in the variants of the method of calibration curve and method of standard has been carried out and acceptability for application has been shown.