DEVELOPMENT OF QUANTIFICATION METHODS FOR PROCAINE HYDROCHLORIDE IN COMBINE EXTEMPORANEOUS OINTMENT

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Introduction. Currently compounding pharmacy drug production is wide enough. At the same time, the quality requirements for medicines are also significantly higher. However, the quality control of factory medicines and pharmaceutical manufacturing is still different. This is due to the fact that in pharmacies, often, there is no expensive equipment and production volumes are much less.

To expand the pharmacological action of drugs in pharmacy conditions, individual selection of components is possible. Therefore, the development of rapid, accurate and reproducible methods of drug quality control in pharmacy conditions is very relevant in our time.

The **aim** of our work was the development of methods for the identification and quantification of procaine hydrochloride in the following ointment:

Rp.: Streptocidi 1,0
Novocaini 0,5
Sulfuris 0,5
Ung. Tetracyclini 3% - 15,0
M. D. S.

Materials and methods. Analytical studies were performed at spectrophotometer Evolution 60S. For operation were used measuring glassware of class A and excipients met the requirements of the State Pharmacopoeia of Ukraine.

Results and discussion. Since studied ointment is a multicomponent, we propose to carry out separation of the components during the sample preparation for their identification.

A weighed sample of the ointment was dissolved in hexane R and then were extracted the water soluble components. The aqueous layer was separated and carried out the identification of procaine hydrochloride by the reactions: bleaching of potassium permanganate (1 g/l) solution, the formation of Schiff's bases and formation of azo dye. The reactions of identification the chlorides are also made.

This multicomponent ointment is very difficult from the point of view of the analyst. Using the most appropriate titration methods for the pharmacy is impossible because each of the components will interfere with the definition of the other. Thus, when titrating the procaine hydrochloride, the sulfanilamide, which also contains the

primary aromatic amino group, will be titrate by nitritometry. If we titrate procaine hydrochloride by related hydrochloric acid alkalimetrically or argentometrically, along with it will be titrated tetracycline hydrochloride.

Therefore, we decided to develop a physico-chemical method for the quantitative determination of procaine hydrochloride in our ointment.

At the first stage of development, we studied the literature data, from which we found out that procaine hydrochloride is able to form ion associates. To confirm this, we tested the ability of procaine hydrochloride to form associates with various indicators. Proceeding from the experimental data obtained, it is proposed to use methyl orange as the reagent for the development of the quantitative determination method.

In the second stage, our task was to develop an optimal method of sample preparation. For this purpose, a model solution of procaine hydrochloride was prepared with a concentration close to that prescribed in the ointment. To create a specific pH medium, use a saturated solution of sodium bicarbonate.

To avoid the influence of tetracycline hydrochloride on the absorption of this associate, it is proposed to convert the indicator into an acid form by changing the pH of the resulting solution.

For the ointment preparation we propose the next method: the exact sample of the ointment is dissolved in chloroform, placed in a separation funnel; saturated sodium bicarbonate solution is added to create the pH of the medium and a solution of methyl orange is added also. Extraction is carried out, the chloroform layer placing into a volumetric flask.

Absorbance is measured at 522 nm wavelength. The quantitative content is calculated according to the standard method, using as a standard SPS of procaine hydrochloride.

One of the main requirements, which allow using spectrophotometric methods for substance assaying, is the subordination to Bouger-Lambert-Beer law. To check the submission of substance solution light absorption to the Bouger-Lambert-Beer law, we need to draw graph dependence of the absorbance on the solution concentration. Solutions light absorption obeys Bouger-Lambert-Beer law within concentration, in which the constructed calibration graph appears as a straight line.

To study this dependence, solutions of different concentrations were prepared. After series of experimental studies we established that the procaine hydrocloride solution obeys this law within concentrations from 0,02 to 0,5 mg/ml.

Conclusions. The developed methods for identification and quantitative determination of procaine hydrochloride in combine extemporaneous ointment will be used in the further development of technological instructions for this dosage form and in the stability studies.