DEVELOPMENT AND VALIDATION OF CEFUROXIME QUANTITATIVE DETERMINATION USING TITRIMETRIC METHOD

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Introduction. *Cefuroxime* (Cefuroxim), (6R,7R)-3-{[(aminocarbonyl)oxy] methyl}-7-({(2E)-2-furan-2-yl-2-[(methyloxy)imino]acetyl}amino)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, is a derivate of 7-ADCC and belongs to semisynthetic cephalosporin *β*-lactam antibiotics of the II generation. It is used to treat bacterial infections. It is produced in the form of powder for injections, 0.75 g.

Aim. The aim of the proposed research is to develop and validate a new procedure of quantitative Cefuroxime determination in pure by titrimetric method using potassium hydrogenperoxomonosulfate as analytical reagent.

Materials and methods. The triple potassium salt of Caro acid was used as oxidizing agent, $2KHSO_5 \bullet KHSO_4 \bullet K_2SO_4$ (commercial name «Oxon®» DuPont production). The active substance is potassium hydrogenperoxomonosulfate. The choice of the reagent was determined by its rather high oxidative activity, E_0 = 1.84 V, availability, and satisfactory solubility in water. The preparation «Cefuroxime-Darnitsa», Kiev, powder for injection 0.75 №1, was used in the research. All the materials were of an analytical reagent grade, and the solutions were prepared with double-distilled water. The procedure was validated according to the State Pharmacopoeia of Ukraine. The statistics was calculated using Microsoft Excel 2016.

Results and discussion. The proposed peroxiacidic procedure is based on the reaction of Cefuroxime oxidation by the excess of $KHSO_5$ with quantity formation of corresponding S-oxide. The $KHSO_5$ excess was determined by the method of iodometric tirtation. It was determined that oxidant-redundant reaction between Cefuroxime and potassium hydrogenperoxomonosulfate is quantitative and stoichiometric: 1 mol of preparation goes for 1 mol of $KHSO_5$.

The time of sulphur atom oxidation does not exceed 1 min which was determined by the method of iodometric titration. The scheme of Cefuroxime S-oxidation reaction using hydrogenperoxomonosulfate is given on the Fig. 1.

The results of accuracy and precision show good agreement with the results obtained in the reference method. For pure substance RSD = 0.87-1.17 %, δ = 0.32-0.80 %. The linearity was studied in a wide range (80-120%) with LOD = 0.35 μg/mL, LOQ = 1.2 μg/mL.

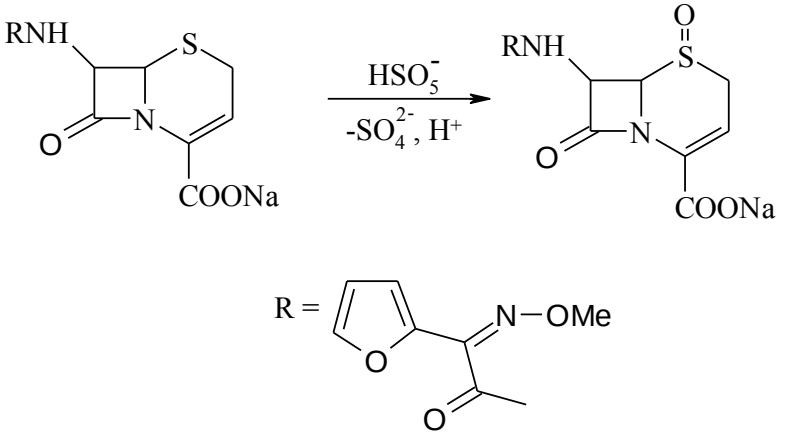

Fig. 1. The scheme of Cefuroxime S-oxidation reaction using hydrogenperoxomonosulfate as analytical reagent

Conclusions. The advantages of the proposed procedure are ability of analytical determination of Cefuroxime by the biologically active part of the molecule, mainly alicycle Sulphur, good precision and accuracy. The absence of expensive device, toxic solvents and special facilities. It is simple and rapid in application.

DETERMINATION OF EXTRACTS IN THE SEDATIVE PREPARATION BY THIN LAYER CHROMATOGRAPHY

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Introduction. The main task of modern phytotherapy is the introduction in medical practice of a maximum number of standardized phytopharmaceuticals (including those with sedative effect) with proven action and dosage, as well as narrowing the sphere of placebo phytopharmaceuticals, or so-called illusory products. According to experts from WHO and EU, despite the success of synthetic chemistry, it is considered advisable to implement programs for the development and production of standardized effective and safe drugs based on the accumulated experience of world traditional and folk medicine.The composition includes only natural components: Rhizomes with valerian roots, Leonurus urticifolius, peppermint leaves, Melissa leaves standardized for the amount of active substance, which together have a calming effect. Valerian extract, in addition to sedative effect associated with reducing the excitability of CNS, has antispasmodic properties, regulates heart activity, improves coronary blood circulation, and increases the secretion of gastrointestinal glands and bile secretion. Extract of Leonurus urticifolius reduces the excitability of the CNS, enhances the processes of inhibition, cardiovascular neuroses, vascular dystonia, increased nervous excitability. Melissa extract is characterized by antipruritic, antihypertensive, antispasmodic, antiarrhythmic action. In addition, it has a mild choleretic effect, helps restore the saprophyte flora of the intestine and the secretion of the gastrointestinal tract, improves drainage function of the airway shimmering epithelium, sputum viscosity; has antipyretic effect, helps to normalize the function of the glands, eliminate the mild forms of dysmenorrhea, menopause, toxicosis of pregnant women, shows antihypoxic activity, cardio, neuro, nephro and immunoprotective properties.

Peppermint extract (peppermint leaf extract) - has antianginal, choleretic, analgesic, antiseptic, sedative and anti-emetic action, prevents the development of hypoxia. The most studied component of peppermint is essential oil (about 60% of essential oil is menthol), but peppermint extract contains other active components, including flavonoids, tannins, bitterness, isovalerian acid esters, cineol, citric acid and tannins. Menthol stimulates the synthesis and release of endogenous biologically active substances by stimulating cold receptors in the oral mucosa. Under the influence of menthol noted reflex dilation of coronary and cerebral vessels, as well as lung vessels.

Aim. Our work is to identify dry extracts of valerian, leonurus, melissa and pepper mint by confirming the presence of the standard method of thin layer chromatography in the preparation "Sedarem".

Materials and methods. For determining dry extract of Valeriana TLH the aim of the method is to identify dry valeriana extract by confirming the presence of isovalerian acids by a thin layer chromatography method in film-coated tablets. Preparation of a solution of a reference standard sample: approx. 5 mg accurate suspension of acetyovalerian acid, identification standard dissolved in 20 ml of methanol. Hydroalcoholic dry extract of valeriana extract: weigh 250 mg of