DEVELOPMENT AND VALIDATION OF CEFTRIAXONE SPECTROPHOTOMETRIC PROCEDURE

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Introduction. Antibiotics are extremely important in medicine. Cephalosporins together with Penicillines belong to the most commonly used types of antibiotics. Ceftriaxone is a third-generation cephalosporin antibiotic with a broad spectrum of activity. The State Pharmacopoeia of Ukraine (SPhU) and British Pharmacopoeia provide HPLC for the cephalosporin determination, which surely is the best method but has a longtime preparation, expensive and complicated in performing. The intensive literature survey revealed many methods of Ceftriaxone quantitative determination. These include chromatography, spectrophotometry, voltammetry, spectrofluorimetry methods etc. The described methods have lack of accuracy, need heating or using of toxic reagents. The procedure of classical iodometric method depends on room temperature which is also a disadvantage. The kinetic-spectrophotometric methods belong to modern and prospective one. That is why the development and validation of new easy in performing, cheep and accurate procedures is of a great interest.

The aim of the proposed research is to develop and validate the procedure of the Ceftriaxone quantitative determination in pure substance and powder for injections by the method of spectrophometry in a kinetic variant using potassium caroate as analytical reagent.

Materials and methods. The pure substance and powder for injections of Ceftriaxone 1.00 g No. 10, «Zdorovye-Kharkov» that meets the requirement of the State Pharmacopeia of Ukraine were used. The potassium caroate was used as received as analytical reagent. A spectrophotometer SF-46 (LOMO) with 1 cm match quartz cells was used for spectral measurement. The statistic calculation were performed using Microsoft Excel 2016.

Results and discussion. It was determined experimentally that the reaction between Ceftriaxone and potassium caroate is basic medium is quantitative and stoichiometric: 1 mol of preparation goes for 2 mols of potassium caroate. The time of reaction does not exceed 20 min. During the conjugated reaction of S-oxidation and perhydrolysis a new product is formed – Sulfone of Ceftriaxone (Fig. 1). This product has a new wave compared to pure Ceftriaxone at λ_{max} = 295 nm. The optimal concentration of alkalin solution and potassium caroate as well as the order of mixing were determined. According to this data the procedure of Ceftriaxone quantitative determination was developed and validated for pure substance and medical preparation. The precision was calculated for pure substance (RSD=1.63-2.25%, δ= 0.33 ÷ 0.96%) and powder for injection (RSD=1.08-2.22%, δ= 0.13 ÷ 1.76 %). The procedure is linear in a wide range (60-160%).

Conclusions. The results of Ceftriaxone quantitative determination by the new procedure showed good agreement with Pharmacopeia HPLC method by the parameters of linearity, specificity, accuracy, precision, LOD and LOQ. So the developed procedure of Ceftriaxone spectrophotometric determination using potassium caroate as analytical reagent can be used as alternative to current pharmacopoeia methods with confidence.

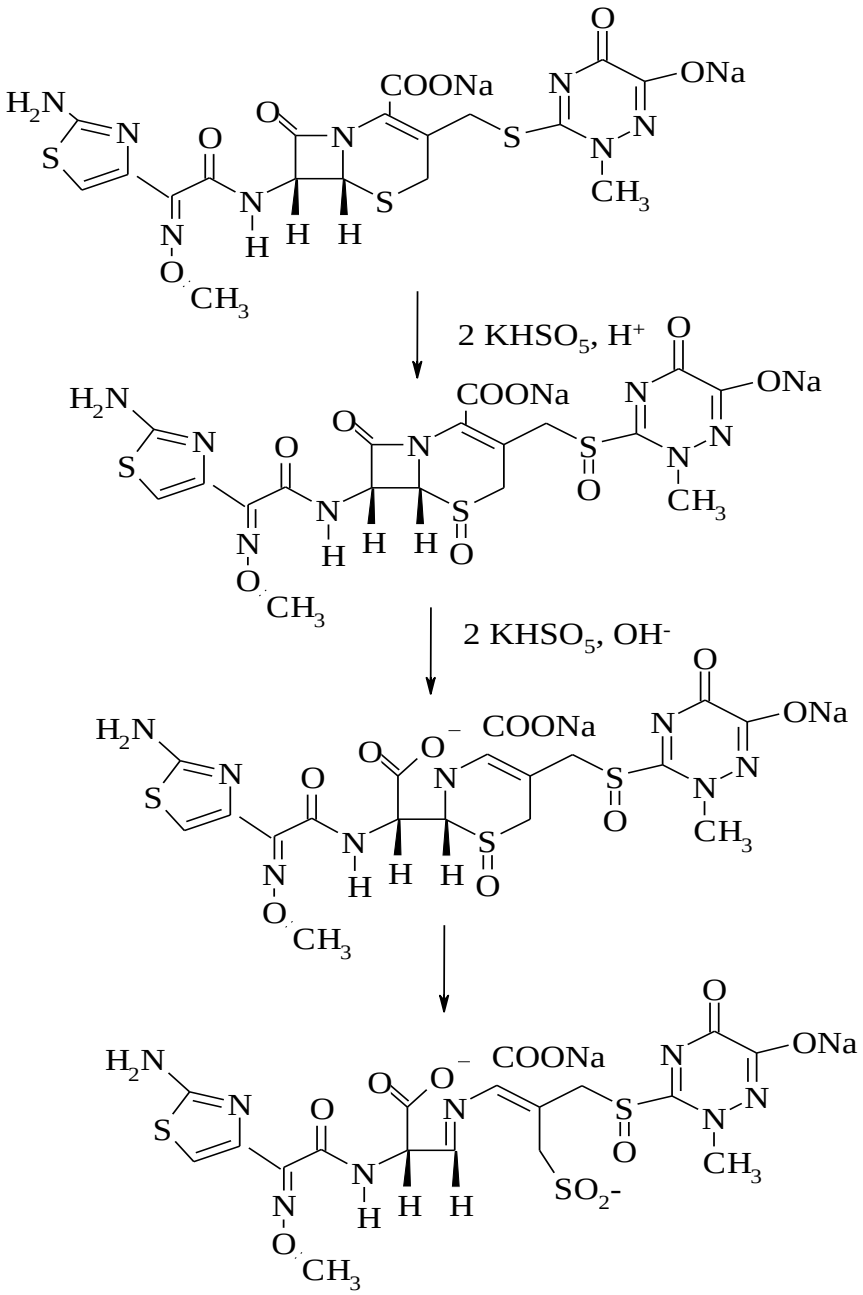

Fig.1. The scheme of Ceftriaxone transformation by means of potassium caroate.

DEVELOPMENT OF METHOD FOR DETERMINATION ACTIVE PHARMACEUTICAL INGREDIENTS IN THE MULTICOMPONENT MEDICAL FORM

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Introduction. Periodontitis and gingivitis are serious infections of the gums. They are caused by bacteria that have been allowed to accumulate on teeth and gums. As periodontitis progresses, bones and teeth can be damaged. However, if periodontitis is treated early and proper oral hygiene is maintained, the damage can be stopped. Nowadays there are so much medicines with ascorbic acid and peppermint, which widely used in medicine as an anti-inflammatory, antimicrobial and antioxidant against some gram-positive and gram-negative bacterial in the mouth. Some of them are prepared in chemists, and as