VALIDATION OF CEFUROXIME IODOMETRIC ASSAY USING POTASSIUM CAROATE

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Introduction. Cephalosporins are a large group of antibiotics derived from the mold Acremonium, which are widely used in the pharmacotherapy of many diseases. Cefuroxime (Cefuroxim), is a derivate of 7-ADCC and belongs to semisynthetic cephalosporin β -lactam antibiotics of the II generation. EPh and BPh recommend to determine cefuroxime using the method of HPLC.

Aim. The aim of the proposed research is to validate the procedure of the quantitative Cefuroxime determination in pure substance and powder for injection preparation by oxidimetric method using potassium caroate as analytical reagent (KHSO₅).

Materials and methods. The preparation Cefuroxime, powder for injection preparation 0.75 No1, «Lekchim-Kharkov» production, serial number 10712230412 was used. As analytical reagent the triple potassium salt of Caro's acid, 2KHSO₅ · KHSO₄ · K₂SO₄ (Acros Organics) was used. Its active substance is potassium hydrogen salt of peroxomonosulfuric acid, KHSO₅. The method was validated according to the State Pharmacopoeia of Ukraine and the guidelines of the International Conference on Harmonization. The statistic calculation were performed using Microsoft Excel 2016. The Precision and Accuracy on these procedures were investigated with respect to repeatability and determined by performing five repeated analysis of the samples on the same day, under the same experimental conditions. The Linearity was determined for a wide range of concentration. The calibration curve was obtained, each research comprises 7 experimental points. LOD and LOQ were calculated from regression equation as 3.3 S₀/b and 10 S₀/b respectively, where S₀ and b are standard deviation slope of the calibration curve.

Results and discussion. The proposed method is based on the S-oxidation reaction of Cefuroxime by potassium caroate in acidic medium to the formation of corresponding S-oxide. The recovery percent ranged from $0.57 \div 0.97$ %, $\delta = 0.3 \div 0.91$ %). The Limit of Quantification (LOQ) is 0.05 mg mL⁻¹.

Conclusions. The proposed reaction of Cefuroxime S-oxidation using potassium caroate can be applied into analytical analysis. The obtained results have good agreement with those in SPhU. The obtained data shows that the proposed method can be applied for the determination of Cefuroxime in pure substance and medical preparation and can be used as alternative to current pharmacopoeia methods with confidence.