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PHARMACEUTICAL SCIENCES

VALIDATION OF KINETIC SPECTROPHOTOMETRIC PROCEDURE OF CEFAZOLINE DETERMINATION BY MEANS OF CARO ACID

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Introductions. Antibiotics are one of the most important in medicine. Cephalosporins belong to one of the most widely used types of antibiotics. There are a lot of methods proposed for Cefazoline quantitative determination but still they have some disadvantages. The methods are divided on chromatography, titrimetry, voltammetry, spectrophotometry, spectrofluorimetry and other. The State Pharmacopeia of Ukraine, British and Europian Phaermacopeia recommend HPLC for the cephalosporins quantitative determination, which surely is the most accurate method but has some disadvantages such as a longtime preparation, complicity in performing and expensive reagents. Spectrophotometry in a kinetic variant is a prospective method easy in performance and sensitive enough to solve the question of quantitative determination. Validation of such procedure can be of a great interest while its introduction into routine pharmaceutical analysis on pharmaceutical factories. Caro acid, used in the investigation, is a powder commercially available as analytical reagent and stable in the form of solution. So, the development and validation of a new procedure of Cefazoline quantitative determination using Caro acid in the kinetic spectrophotometric variant is of a great importance.

Aim to validate a kinetic spectrophotometric procedure of Cefazoline quantitative determination using Caro acid.

Materials and Methods. The triple potassium salt of Caro acid was used as oxidizing agent, $2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$ (commercial name «Oxon®» DuPont production). The active substance is potassium hydrogenperoxomonosulfate, $KHSO_5$. The choice of the reagent was determined by its rather high oxidative activity, E_0 = 1.84 V, availability, and satisfactory solubility in water.

All the reagents were of analytical grade.

A spectrophotometer SF-46 (LOMO) with 1 cm match quartz cells were used for spectral measurement.

Procedure of S-oxidation reaction kinetics study. 10.0 mL of 0.02 mol L^{-1} potassium caroate solution was transferred using the into 100 mL volumetric flask, 10.0 mL of 0.01 mol L^{-1} Cefazoline solution was added and a stop watch was switched on. 10.0 mL of 0.091 solution of NaOH was added and shaked vigorously. The volume was brought to the mark and mixed. After 10 mL of the obtained solution were transferred using the pipette into quartz cell 1 cm^2, and the density was measured every 1 minute.

The calibration graph were plot and the tangent of inclination of a straight line showed the dependence on concetraion of Cefazoline.

The proposed method was validated according to the SPhU. The range of analytical procedure is the interval between 80% and 120% as recommended in SPhU.

Results and discussions. The linear dependence was studied by determination of five working solutions on the whole range of determination (80%; 90%; 100%; 110%; 120%) using the procedure given above. Each of the solution was investigated three times. The obtained data were analyzed by the least square method for the straight linear dependence: $Y = b \cdot X + a$. the linear dependence can be demonstrated in the normalized coordinates. Linearity is significant on the whole range of analyzed concentrations (80-120%). The linear equation generated from the calibration curve was Y = (1.0098x-0.378)X with a correlation coefficient r=0.9998 (Figure 1.). From this equation the content of Cefazoline in the sample was calculated. Precision and accuracy of the developed procedure was studied by measuring five concentrations.

Each of them was measured three times. Metrological characteristics are given in the Table 1.

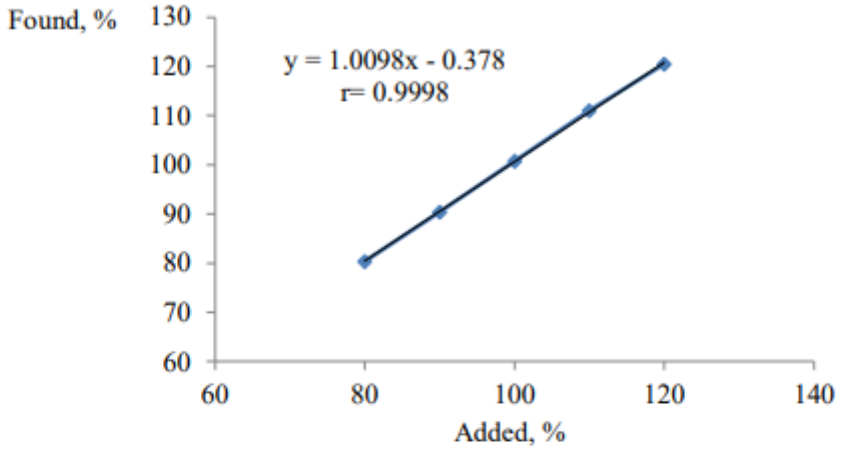

Figure 1. Straight linear dependence of Cefazoline concentration in normalized coordinates

Table 1

Characteristics of linear dependence Y = b·X + a

Parameter	Value	Standard deviation (SD)	Statistical uncertainty criterion (≤ 1.21·SD)	Practical acceptability criterion	Conclution
a	1.0098	S_a = 1.118	|a| ≤2.25		corresponds
b	0.378	S_b = 0.050	|b-1| ≤0.146		corresponds
S_{rest}	0.442			≤0.48	corresponds
R	0.99984			≥0.99965	corresponds
LD	5.22%				
LOQ	17.24%				

The obtained data meet the requirements of the SPhU. All the parameters correspond to those that are obligatory to evaluate while validation of spectrophotometric methods.

The detection limit (LD) and the limit of quantification (LOQ) are less than 32% and do not influence quantitative determination.

Conclusions. The Linearity, accuracy, and precision were found to be acceptable over the concentration range of 80-120% with correlation coefficient 0.999. The proposed method was validated statistically and through recovery studies.

The advantages of the proposed method are ability of analytical determination of Cefazoline 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 as in HPLC method are the advantages of the procedure. It is simple and rapid in application.