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Development and Validation of the Iodometric Method for the Quantitative Determination of Mezlocillin in Pure Substance and Medical Preparation

Svitlana Karpova*, Sergiy Kolisnyk, Igor Bylov, Oleg Kryskiv

National University of Pharmacy, Kharkiv, Ukraine
**za9594506@gmail.com*

Introduction. Mezlocillin (Mezl) is a 4th generation penicillin antibiotic which kills certain bacteria that cause infection, or stops their growth. It treats many kinds of infections including those of the skin, blood, CNS, respiratory tract, sinuses. This drug is discontinued in the US. Mezl has in vitro activity against gram-positiv and gram-negative aerobic and anaerobic bacteria. The bactericidal activity of mezlocillin results from the inhibition of cell wall synthesis and is mediated through mezlocillin binding to penicillin binding proteins (PBPs). Mezl is stable against hydrolysis by a variety of beta-lactamases, including penicillinases, and cephalosporinases and extended spectrum beta-lactamases.

Materials and methods. Baypen® – powder Mezl sodium monohydrate in flacons for preparation of solution for injections (Mezl 1,0 g). A new iodometric method for quantitative determination of sodium monohydrate Mezl in Baypen® preparation using potassium hydrogenperoxomonosulfate ($KHSO_5$) as analytical reagent was proposed. Peroxomonosulfate acid as triple potassium salt $2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$ (Oxone®) of «extra pure» qualification was used as oxidant. At pH 1-4 for 1 mole of penicillin, 1 mole of $KHSO_5$ is consumed, the quantitative interaction is achieved within a time of more than 1 minute (observation time). Classical iodometry of hydrolysis products is determined to be a basic method of penicillin summary quantitative determination. Its disadvantage is duration at least 40 min, and the necessity in standard samples and in rigid conditions standardization, as iodine interaction with hydrolysis products of penicillin reaction doesn't proceed strictly stoichiometrically: iodine expense, and also the quantity of substance that is equivalent to 1.00 ml 0.005 mol/L (f=1/2, I_2) of iodine, depend on the reaction medium temperature. By the method of back iodometric titration of $KHSO_5$ residue was determined that 1 mol of $KHSO_5$ is used per 1 mol of penicillin. The reaction finishes during 1 min and stays for 30 min (observation time at pH 1-4).

Results and discussion. The results were obtained by the recommended procedure for seven replicate titrations of mixtures containing the three species at various concentrations. RSD=1.8%, δ=+0.7%. It can be seen that piperacillin can be determined successively with good accuracy and reproducibility. The new procedure was developed and ability of quantitative determination of penicillin in pharmaceutical preparation Baypen® by iodometric method using potassium hydrogenperoxomonosulfate ($KHSO_5$) as analytical reagent was shown.

Conclusions. The developed methods of quantitative determination of Mezlocillin can be used to develop analytical regulatory documentation for medicinal products, as well as in the practice of state laboratories for quality control of medicinal products and central factory laboratories of pharmaceutical enterprises. The proposed methods of performing the analysis do not require the use of expensive devices, as well as toxic chemical reagents. In terms of sensitivity, speed of execution and selectivity, the developed methods of analysis are more perfect and economically profitable than the existing ones.

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