Iodometric determination of metoclopramide hydrochloride in tablets using potassium hydrogen peroxymonosulfate

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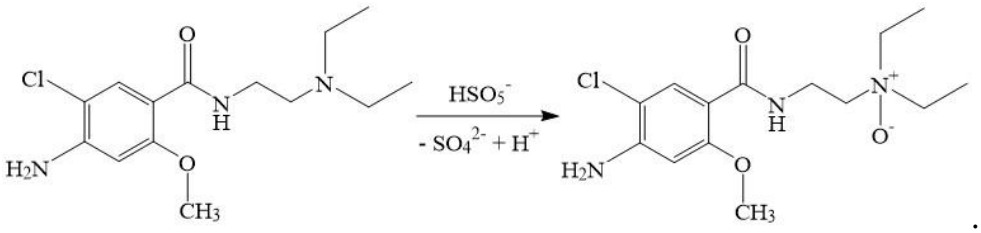
Metoclopramide Hydrochloride (MH) is the hydrochloride salt of the substituted benzamide metoclopramide, a para-aminobenzoic acid derivative that is structurally related to procainamide, with gastroprokinetic and antiemetic activities. It is commonly used to treat and prevent nausea and vomiting, to help with emptying of the stomach in people with delayed stomach emptying, and to help with gastroesophageal reflux disease. It is also used to treat migraine headaches. Its application in therapy requires methods for the determination in pharmaceutical dosage forms.

The oxidation of Metoclopramide Hydrochloride to its corresponding *N*-oxide by means of potassium hydrogen peroxymonosulfate was used to develop a new method for oxidimetric determination of the drug.

Materials and methods. As a reagent we used the triple salt $2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$ (known by the tradename Oxone) is a form with higher stability. Kinetic of Metoclopramide Hydrochloride oxidation by potassium hydrogen peroxymonosulfate ($KHSO_5$) was studied in aqueous buffer solutions of pH 8.6; 9.3; and 9.9 under second-order conditions at the temperature 293 K by iodometric titration method.

Results and discussion. Concenrtation versus time plot of potassium hydrogen peroxymonosulfate during the oxidation of Metoclopramide are shown in Fig 1. According to the results of the study of the reaction kinetics, it was found that at pH 8.6-9.9 the interaction between MH and $KHSO_5$ occurs quantitatively and stoichiometrically for 10-15 min: 1 mole of MH consumes 1 mole of $KHSO_5$ (Fig.).:



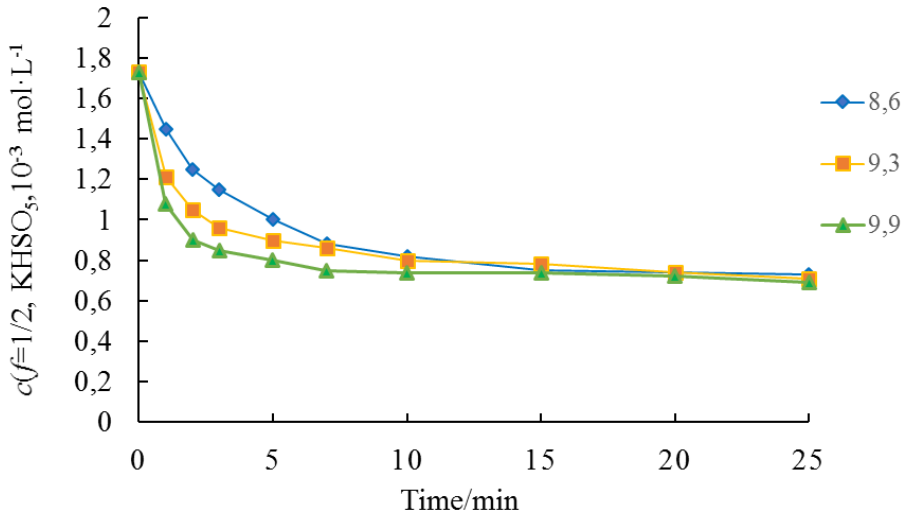


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Fig. 1 Concenrtation versus time plot of potassium hydrogen peroxymonosulfate during the oxidation of Metoclopramide. pH: 8,6; 9,3 and 9,9;. *c*(f=1/2,$KHSO_5$) =$1.73 \cdot 10^{-3}$ mol·L^{-1}; *c*(Metoclopramide)=$1 \cdot 10^{-3}$ mol·L^{-1}.

Metoclopramide Hydrochloride was determined by indirect titration with potassium hydrogen peroxymonosulfate. The required amount of Metoclopramide Hydrochloride was dissolved in water, pH 9.9 buffer solution and potassium hydrogen peroxymonosulfate solution was added. After 10 min, the solution was acidified. The excess potassium hydrogen peroxymonosulfate was iodometry titrated applying either visual end-point detection. The advantages of the applied analytical techniques in the determination of Metoclopramide Hydrochloride in tablets «Metoclopramide 10 mg» was presented. The recovery of this analyte in preparation sample ranged from 99.15 to 101.05%. A paired *t*-test showed that all results obtained for bulk drug and in tablets «Metoclopramide 10 mg», using the proposed procedure and the official procedure respectively, agreed at the 95% confidence level.

Conclusions. Potassium hydrogen peroxomonosulfate in the form of Oxone was proposed as an analytical reagent for Metoclopramide. A new method has been developed and the possibility of quantitative determination of metoclopramide hydrochloride in Metoclopramide 10 mg tablets has been demonstrated. The results are in good agreement with the findings of the study of Metoclopramide Hydrochloride tablets in accordance with the recommendations of the European Pharmacopoeia.