USE OF THE REACTIONS WITH THE HEAVY METAL SALTS FOR IDENTIFICATION OF OMEPRAZOLE IN PALLETS

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Introduction. Omeprazole is one of the most prescribed drugs from the proton pump inhibitors group that is used in therapy of passionately-destructive diseases of the digestive system. Omeprazole decreases the level of the stimulated and basale secretion of hydrochloric acid (dose-dependently), reduces secretion of pepsin and general volume of gastric secretion, it has also the expressed antihelicobacter effect. This medical drug is included into the standard chart of gastric and duodenum ulcer treatment.

The State Pharmacopoeia of Ukraine does not have a monograph to regulate the order of quality control of medical forms with the omeprazole. So it is necessary to develop and introduce it, because the medical forms with omeprazole are often prescribed and they require the presence of normative documents for their quality control.

Not all laboratories of drugs quality control have the proper hardware-based equipment and other, so the issue of the development and introduction of the chemical methods of quality control, which would be specific but at the same time economical enough and easily recreated, are urgent issues nowadays.

The chemical structure of omeprazole (the presence of acid center of the nitrogen atom of pyrrole core) determines the possibility of motion of the identification reactions for omeprazole with the heavy metal salts, such as copper sulfate, cobalt chloride, iron (III) chloride et al – with formation of complex salts with the characteristic colouring by the principle of sulfanilamides.

Aim. The aim of our research was checking the possibility of interaction between omeprazole and heavy metal salts and defining the most characteristic among themfor this drug.

Materials and methods. On the pharmaceutical market of Ukraine the substance of omeprazole is supplied as pallets, because it is unsteady and hydroscopic. Therefore the possibility of influence of auxiliary substances should be taken into account during the development of the possible identification reactions.

With regard to physical and chemical properties of omeprazole pallets (bad solubility in water and mineral acids solutions) for the improvement of solubility pallets were preliminary grounded in the mortar. The weight amount of pallets powder was dissolved in a 0.1M sodium hydroxide solution and in the future result solution was used as the investigated solution. Control experiments were carried out

in the same conditions without adding any weight amount of testing samples, to make sure that observed analytical effects are not hydroxides of the corresponding metals.

All reagents that conform to the State Pharmacopoeia of Ukraine which are harmonized with the European ones were used in the study.

Results and discussion. After adding the cobalt chloride solution to the test solution with the omeprazole in drops, light blue coloured precipitate was formed, unlike the control experiment, where precipitate had dark blue-green colour.

During the interaction between the test solution and the iron (III) chloride solution, we observed formation of the light brown precipitate that differed from the characteristic darkly-brown precipitate of control experiment.

With the copper sulfate solution in the test solution, we observed formation of blue-green color precipitate; at the same time in the control experiment we observed formation of brightly-blue precipitate.

For the interaction between the omeprazole solution and the silver nitrate solution conditions of slightly alkaline environment to prevent the formation of silver oxide precipitate, which would mask other analytical effects, were created previously. For this propose, omeprazole was dissolved in the 0.1 M sodium hydroxide solution, the result solution was neutralized to the slightly alkaline reaction of the environment, using phenolphthalein as an indicator. Upon adding silver nitrate solution to the test solution in drops, we observed formation of yellow-white volumate precipitate. Formation of white amorphous precipitate was observed in the control experiment. The formed precipitates of silver salt of omeprazole and silver oxide differ in structure and colour, which is well noticeable, while viewing of them on a black background.

After adding the lead acetate solution in drops to the omeprazole solution, which was neutralized to the slightly alkaline reaction of the environment, using phenolphthalein as an indicator. Formation of white lamellar precipitate was observed. In the control experiment without addition of the omeprazole weight amount after adding the lead acetate solution visual changes were not observed.

Conclusions. Thus, based on the obtained results, it is possible to make the conclusion that coloured reactions with heavy metal salts solutions can be used for identification of omeprazole in pallets. The optimal conditions for the reaction between silver nitrate and lead acetate are previous neutralization of alkaline omeprazole solutions to the slightly alkaline reaction of the environment, using phenolphthalein as an indicator. With solutions of cobalt chloride, iron (III) chloride, iron sulfate and lead acetate, analytical effects are observed very clearly which differ from the control tests. Analytical effect of interaction between omeprazole and silver nitrate is well noticeable in comparing to the control test, while viewing of them on a black background.