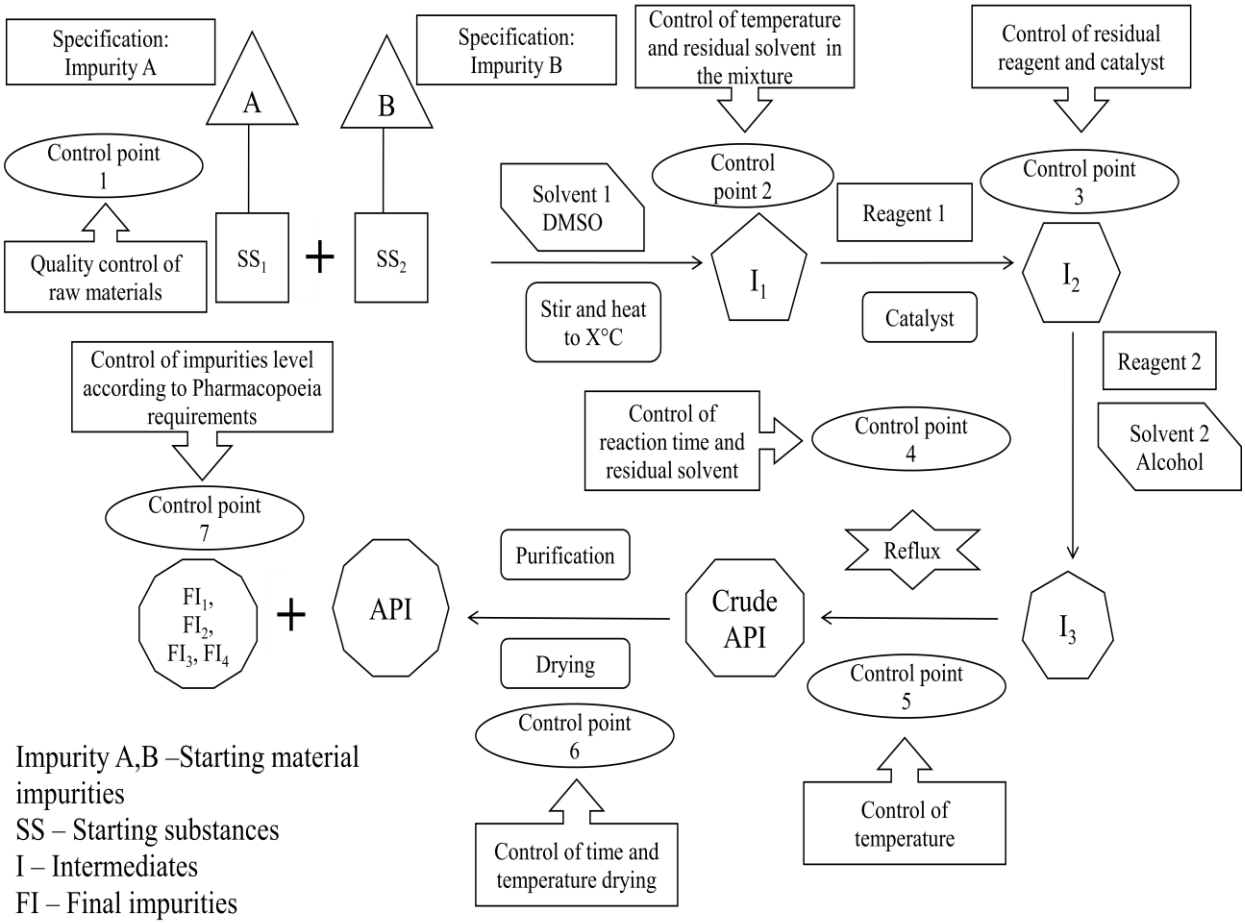

Pic. 1 Process analytical technology of produce active pharmaceutical ingredient (hypothetical)

product and process that include understanding that ensures process performance and product quality. Also set of controls should include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications and the associated methods and frequency of monitoring and control.

Conclusions. This work outlines the development of technology that can help to prevent contamination of API or medicine by impurities. Overall control strategy is based on knowledge of the types impurities and their potential source of emergence. The control of related substances by PAT has benefits for all members of pharmaceutical market. For patients: they get product of high quality. For regulators: a clear control strategy from the manufacturers provides transparency and added assurance that risk of impurity has been controlled. For pharmaceutical companies: a clear control strategy is identified which ultimately facilitates successful production of medicines.

MODELING OF DISSOLUTION KINETICS OF ANTIBIOTICS WITH MINERAL WATERS

Bondareva A. Yu., Dobrova A. O., Golovchenko O. S.
Scientific supervisor: prof. Georgiyants V. A.
National University of Pharmacy, Kharkiv, Ukraine
anna.dobrova08@gmail.com

Introduction. In the face of an increasing number of medicines, the problem of their rational use is acute. This is relevant both for over-the-counter and prescription groups of drugs, since the wrong reception of the latter, even if properly prescribed by a doctor, can lead to serious consequences. Currently, the concept is adopted that all medicines must be washed down with water. However, there are a number

of mineral waters in which metals of various types are contained in a rather large amount. At the same time, many antibiotics contain in their composition carboxyl and hydroxyl groups, which can enter a complexation reaction with metal cations.

Aim. Study how complexation can affect the release kinetics of amoxicillin from tablets.

Materials and methods. At the first stage of our study, we conducted an assessment of the mineral water market and selected those that contain the largest amount of minerals in their composition. After preliminary analysis of the content specified by the manufacturer, we selected the following trademarks: “Karpatska Dzherelna”, “Truskavetska”, “Essentuki №17”, “Polyana kvasova”, “Borjomi". At the next stage, is necessary to carry out a quantitative analysis of water hardness by complexometric titration to calculate the exact content of calcium and magnesium cations in a sample. After that it is necessary to select the test conditions.

To carry out the dissolution test, we chose to use a State Pharmacopoeia of Ukraine monograph for amoxicillin tablets, making some changes: the medium of dissolution – 0.1 M HCl, whose pH is near to the pH of the stomach, the rotation speed is 150 rmp, time of analysis – 45 min, number of samples – 6. The volume of medium is 900ml of 0.1 HCl with addition 100 ml of mineral water.

Results and discussion. The results showed that the calcium content is greatest in such waters as “Karpatska Dzherelna”, “Truskavetska” and “Essentuki №17” the content in all waters is close to the average value of the concentration range specified by the manufacturer. The magnesium content in all investigated waters is minor but in total with calcium it also can make some influence.

Conclusions. With the help of this technique, the dissolution kinetics profile of amoxicillin tablets in a medium of 0.1 M HCl solution with addition of a portion of mineral waters presented on the Ukrainian market can be investigated. Similarity factors should be calculated to equivalence estimates.

COMPARATIVE ESTIMATION OF THE METHODS OF ASSAY OF ESTRADIOL VALERATE IN TABLETS

Can Abdurrahman
Scientific supervisor: assoc. prof. Taran K. A.
National University of Pharmacy, Kharkiv, Ukraine
kate.taran@gmail.com

Introduction. Pharmaceutical preparations containing estradiol valerate are among the most popular and prescribed in gynecology estrogen-containing medications for the correction of hormonal balance in women’s organism. The assay of estradiol valerate substance by Europeian Pharmacopoeia is carried out by the method of UV-spectrophotometry.

Aim. The purpose of our research is to carry out quantitative estimation of estradiol valerate content in tablets using various techniques of UV-spectrophotometry method and different solvents for quantitative determination, to make a conclusion about possibilities of the tested techniques in quantification of medication.

Materials and methods. We used the analytical balance Axis ANG-200 and the measuring glass wear of class A. For the spectrophotometric investigations we used the spectrophotometer Evolution 60S. The statistical studies were carried out by the common procedure.

Results and discussion. For our investigations tablets of estradiol valerate 2 mg of Bayer producer and estradiol valerate certified reference standard were taken. The electron absorption spectra of estradiol valerate certified reference standard in water and ethanol were studied. It was found that its spectra in water and ethanol have the absorption maximum at 278 nm and 280 nm respectively. Estradiol valerate was extracted from the powder of grinded tablets by ethanol and UV-spectrum was obtained. As the spectrophotometric quantification of estradiol valerate can be carried out by the methods of specific absorbance, calculations by the graph and the method of standard, the corresponding procedures were developed. The validation characteristics that prove the possibility of the methods of specific absorbance and the method of standard usage for the assay of estradiol valerate in tablets were obtained.

Conclusions. The most preferable technique for quantification of estradiol valerate in the composition of tablets by UV-spectrophotometry is the method of standard. The simple UV