VERIFICATION OF DISSOLUTION TEST FOR DOXYCYCLINE HYCLATE IN CAPSULES

Dobrova A., Golovchenko O.
Scientific supervisor: Doctor of Pharmacy, professor Georgiyants V. A.
National University of Pharmacy, Kharkiv, Ukraine
anna.dobrova08@gmail.com

Introduction. "Dissolution" test is recommended by the State Pharmacopoeia of Ukraine to determine the capsules kinetics of dissolution and their compliance with the requirements. According to the State Pharmacopoeia of Ukraine and the international pharmacopoeias recommendations, before being used in the laboratory, pharmacopeia method or test should be verified. This is necessary to confirm, that this laboratory is able to reproduce chosen method.

The **aim** of study was to verify the "Dissolution" test analytical method for doxycycline hyclate capsules, recommended by the US Pharmacopoeia.

Materials and methods. Getting the experimental data was performed simultaneously by a standardized procedure. Total uncertainty, linearity, accuracy, precision and specificity of model mixtures of a series samples with the known amounts of active substances were defining. For those 9 points within the investigated range of method 55-135% with 10% increment was studied. This was carried out in parallel on three measurements for each concentration. The results were treated statistically accordance with SPU.

Results and discussion. Carried out forecast showed that the total uncertainty of the methodic results is 1.04% and doesn’t exceed a critical value (3.0%). To determine the specificity investigated the effects of placebo. Our calculation showed that the overall effect of placebo on the total drug absorption is insignificant. The method is linear for all range of concentrations. Results systematic error satisfies the recommended criteria. Analysis of doxycycline hyclate model mixtures study showed that the investigated procedure is correct.

Conclusions. During the experiment the verification of the test "Dissolution" analytical method of doxycycline hyclate capsules was held. Characteristics of validation were determining using eligibility criteria. Researched validation characteristics confirm linearity, precision (convergence), the accuracy and specificity of the chosen method. Forecast total uncertainty of the proposed methodic meets the eligibility criteria. This method can be used in the future to study the solubility profile of doxycycline hyclate capsules.