Comparison of the Dissolution test for solid dosage forms in different pharmacopoeia

Biljana Gjorgjeska, Sofija Petkovska

Department of Pharmacy, Faculty of Medical Sciences, University Goce Delcev,

str. "Krste Misirkov" no.10-A, 2000 Schtip, Republic of Macedonia

+389 75 499 912, biljana.gorgeska@ugd.edu.mk

Dissolution testing for solid dosage form is a standard officinal test prescribed in pharmacopoeias, which is very important for assessing the quality of these products. This test which is strictly controlled allows monitoring the quality of products from series to series and reduces errors during production.

The aim of this study was to compare dissolution testing in International Pharmacopoeia and US Pharmacopoeia monographs for tablets that were selected randomly and to notice similarities and differences in the individual monographs in terms of apparatus that is used, the medium, the speed of rotation in the apparatus and the tolerance allowed when performing the test.

The comparison was made with descriptive method by using monographs for Acyclovir tablets, Albendazole tablets, Isoniazid tablets, Doxycycline tablets and Metronidazole tablets in International Pharmacopoeia and US Pharmacopoeia, respectively.

The differences between the individual monographs for the same tablets were observed in different pharmacopoeia. As we have noticed the difference in the medium used, speed, and tolerance occurred. In the latter case of metronidazole tablets the test has to be performed with different apparatus in different pharmacopoeia monographs.

It can be concluded that the dissolution testing is an important parameter for testing the quality of tablets despite the differences that exist in the implementation of the various pharmacopoeias. Using this test according to particular pharmacopoeia monograph in routine control of the production process proves compliance with the required quality of each batch produced. This is particularly important in terms of quality assurance and meeting the standards of good manufacturing practice.

Keywords: apparatus, dissolution test, International Pharmacopoeia, European Pharmacopoeia, US Pharmacopoeia