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

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Introduction

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.

Goals

The aim of this study was to compare dissolution testing conditions 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 and the tolerance allowed when performing the test.

Results

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. For example in the case of Isoniazid and Metronidazole tablets, the test has to be performed with different apparatus in different pharmacopoeia monographs.

The tables below shows comparison of dissolution methods included in the monographs for Isoniasid and Acyclovir tablets in International pharmacopoeia and US Pharmacopoeia. It can be seen that the method conditions for Isoniazid tablets are different between the two pharmacopoeia monographs unlike to the Acyclovir tablets.

Isoniazid tablets		
	Internacional pharmacopoeia	US Pharmacopoeia
Apparatus	paddle	basket
Medium	Buffer pH = 6.8; 500ml	0.01 N hydrochloric acid; 900ml
rpm	75	100
Time	30 min	45 min
Tolerances	80%	80%

Acyclovir tablets		
	Internacional pharmacopoeia	US Pharmacopoeia
Apparatus	paddle	paddle
Medium	hydrochloric acid 4g/l; 900ml	0.1 N hydrochloric acid; 900ml
rpm	75	50
Time	45 min	45 min
Tolerances	75%	80%

Materials and methods

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 comparative method was used.

Conclusions

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 conditions and implementation in various pharmacopoeias for the same product. 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.