Comparison of Dissolution Test for Metronidazole Tablets in International and American Pharmacopoeia

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Introduction

The tablets are commonly used dosage forms and as such are subject to tests to prove their quality. As inevitable here is the test that determine dissolution of active component from the tablet. Over the years the test suffered a series of improvements. At the end it become an official test in pharmacopoeias and mandatory testing for tablets quality. Depending on the properties of the active ingredient, pharmaceutical form and effect of the drug used specific standardized equipment, appropriate medium, and method of analysis is proscribed in pharmacopoeia monographs.

Goals

The purpose of this paper was to make a comparison of the tests for metronidazole tablets in official monographs in International Pharmacopoeia and US Pharmacopoeia in order to determine similarities and differences.

Results

Comparison of monographs in both pharmacopoeias was made in terms of apparatus used, the medium, the speed of rotation of the apparatus and the tolerances allowed when performing the test.

Although the dissolution test prescribed in general part of both pharmacopoeias is the same, in the individual monographs the visible differences exist in terms of the prescribed equipment, medium, speed and tolerance as shown in Table 1.

Table 1 – Dissolution testing for metronidazole tablets, comparison of monographs in International pharmacopoeia and US Pharmacopoeia

	International pharmacopoeia	US Pharmacopoeia
Apparatus	paddle	basket
Medium	500 ml buffer pH= 6,8	900 ml 0,1N HCl
Rotation speed	75 rpm	100 rpm
Sampling time	30 min	60 min
Tolerances	not less then 80% of labeled amount	not less then 85% of labeled amount

Materials and methods

Tests for metronidazole tablets in official monographs in International Pharmacopoeia and US Pharmacopoeia

Conclusions

It can be concluded that the dissolution test of active component in metronidazole tablets is an important parameter for testing the quality, despite the differences that exist in performing the test in various pharmacopoeias. Using the dissolution test in routine control of the production process proves compliance with the required quality of each batch produced. This is particularly important in terms of ensuring the quality of medicines and meeting the standards of good manufacturing practice.