

# Tablet Dissolution Test Apparatus

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Use apparatus A for tablets and capsules that are not greater than 18 mm long. For larger tablets or capsules use apparatus B. TEST A - TABLETS AND CAPSULES OF NORMAL SIZE Apparatus. The main part of the apparatus (Figure 2.9.1.-1) is a rigid basket-rack assembly supporting 6 cylindrical transparent tubes  $77.5 \pm 2.5$  mm long,  $21.5$  mm internal

### 2.9.3. DISSOLUTION TEST FOR SOLID DOSAGE FORMS

apparatus and cover the latter with a glass plate to maintain appropriate conditions of humidity. Examine the state of the samples after the period prescribed in the monograph. To pass the test all the samples must have disintegrated. A. glass plate D. water B. vaginal tablet E. dish, beaker C. water surface Figure 2.9.2.-2. 01/2008:20903 2.9.3.

## Reflection paper on the dissolution specification for ...

2.1. Dissolution test method ... • The selection of the dissolution apparatus is up to the applicant and should be sufficiently justified. ... tablet sticking). However, it is known that methods with increased stirring speeds may be less discriminatory. Increasing the stirring speed at the expense of the discriminatory power simply to

## **Guidance for Industry - Food and Drug Administration**

C. Dissolution Testing Case A: Dissolution of Q = 85% in 15 minutes in 900 milliliters (mL) of 0.1N hydrochloride (HCl), using the United States Pharmacopeia (USP) Apparatus 1 at 100 revolutions

## **Guideline on quality of oral modified release products**

Level A IVIVC the dissolution test can be used only as a quality control method. ... disintegrating tablet/capsule containing multiple-units of pellets, etc. ... (media, pH (normally pH range 1- 7.5; in cases where it is considered necessary up to pH 8), apparatus, agitation, etc.). Testing conditions, including sampling time points and ...

## Generic Drugs and Bioequivalents - Food and Drug ...

Parameter Test Reference Ratio 90% C.I. ... - Apparatus - Media - Volume - Speed ... Dissolution Profile of Tablet X.  $f_2 = 62.3$ . Additional Information

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