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International Journal Of Pharma Professional's Research

Review Article

DISSOLUTION:- Life line of Pharmaceutics

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ISSN NO:0976-6723

Abstract

In this present review we studied the different dissolution parameters which are required for the dissolution. Different types of dissolution apparatus in detail with the help of diagram to understand it well. The validation procedures for the dissolution apparatus and its devices. we also study the different types of buffers which are used in dissolution their preparation methods are also included in it. From this study we concluded that anyone can go familiar with the dissolution, its apparatus and the buffers.

Keywords: - Dissolution, Dissolution Apparatus, Validation, Buffers.

Introduction

Dissolution testing is a requirement for all solid oral dosage forms and is used for drug product release and stability testing. The dissolution test is the most important analytical test for detecting physical changes in an API and in the formulation. The two commonly used dissolution apparatus are the basket (USP Apparatus 1) and the paddle (USP Apparatus 2).

Both apparatus have been widely accepted by the pharmaceutical community for measuring the rate of dissolution of an API from a given pharmaceutical solid dosage form. The setup of dissolution Apparatus 1 and 2 requires control over many variables as defined in USP <711> (*1)*, European Pharmacopoeia 2.9.3 (*2*), and Japanese Pharmacopoeia 15 (*3*). The variables in both of these apparatus are vessels, shaft dimensions, shaft wobble, rotation speed, shaft height from the bottom of the vessel, vessel centering and tilt, temperature, leveling of the dissolution apparatus at its base, vibration, and so forth. Many literature articles describe methods to control these variables (*4–20*). However, none of these address control of basket variability (refer to USP <711>).

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USP and FDA Requirements for Basket Apparatus

The basket apparatus consists of a wire-mesh basket that is attached to a rotation shaft, which is then immersed into a dissolution vessel for the duration of the dissolution test. Since the dosage unit is in direct contact with the basket, the physical dimensions and motion of the basket can have a dramatic effect on the dissolution rate of the solid dosage unit. Because of the critical nature of the basket, it is tightly controlled by several mechanisms. First, the dimensions of basket height, i.d. and o.d. of the basket opening, height of the open screen, and size of the mesh are specified in USP <711>. Next, the amount of wobble at the bottom of the basket while rotating is checked with a wobble meter at periodic intervals, anywhere from time of use to once a year, to ensure that it is within the 1-mm specification indicated in USP.Finally, a functional test using standardized performance-verification tablets is executed. The rate of release of the standardized calibrator tablet is measured and compared to the acceptance criteria. The performance verification tablets and acceptance criteria are designed so that if the apparatus is not set up in accordance with the tight USP specifications, it will not pass this final test.(21-23)

Dissolution Test

This test is designed to determine compliance with the dissolution requirements for solid dosage forms administered orally. The test is intended for a capsule or tablet. Use Apparatus 1 unless otherwise directed. All parts of the apparatus that may come into contact with the preparation under examination or with the dissolution medium are chemically inert and do not adsorb, react or interfere with the preparation under examination. All metal parts of the apparatus that may come into contact with the preparation or the dissolution medium must be made from