

A SYSTEMIC AND COMPLETE REVIEW ON DISSOLUTION TEST APPARATUS.

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ABSTRACT

Dissolution is an official test employed by pharmacopeia's for evaluating drug release of solid and semisolid dosage forms. The most applications of the dissolution testing include biopharmaceutical characterization of the drug product, as a tool to make sure consistent product quality and to predict in vivo drug bioavailability. Dissolution testing was developed initially for solid orals, soon its use is widened to a range of novel dosage forms. Because of complexities within the drug delivery of novel dosage forms there a necessity in developing modified dissolution testing methods so as to characterize the invitro release of those dosage forms. The article characterizes the current updates in dissolution testing approaches for predictable and novel pharmaceutical dosage forms and offers an insight to possible substitutions in drug dissolution testing design.

Keywords: Dissolution, Drug Release, Drug Product, Dissolution Testing.

INTRODUCTION

Dissolution is that the method by which a solid solute enters a solution. Within the pharmaceutical industry, it defined because the quantity of drug substance that goes into solution per unit time under standardized conditions of liquid or solid interface, temperature and solvent composition. Drug dissolution testing plays awful a very important role during a routine control test, for characterizing the standard of merchandise and plays a heavy role in drug development [1].

Dissolution testing is an official test utilised by pharmacopeia's for evaluating drug release of solid and semisolid dosage forms dissolution tests were first developed to quantify the quantity and extent of drug release from solid oral dosage forms like, immediate/sustained release tablets and capsules [2]. More recently, dissolution has become vital in testing drug release of dosage forms such as, buccal and sublingual tablets, chewing gums, soft gelatine capsules, suppositories, transdermal patches, aerosols and semisolid of the dissolution technique has been emerging since the tip of the 19th century done by physical druggists. The goal is to possess a completely functional set of USP performance tests for every kind of dosage forms [3].

List of the Official Dissolution Apparatus along with its uses

1. USP Apparatus 1 Basket Type: capsules, Floating dosage forms - 50-120 rpm
2. USP Apparatus 2 Paddle Type: capsules, enteric forms- 25-50 rpm
3. USP Apparatus 3 Reciprocating cylinder: Extended-release drug product- 6-35 rpm
4. USP Apparatus 4 Flow through cell Implants: powders and suspensions.
5. USP Apparatus 5 Paddle over disk TDDS: Ointments- 25-50 rpm
6. USP Apparatus 6 Cylinder 6 TDDS
7. USP Apparatus 7 Reciprocating disk: Extended-release drug product- 30 rpm

1) Apparatus 1: Basket Apparatus: [USP]

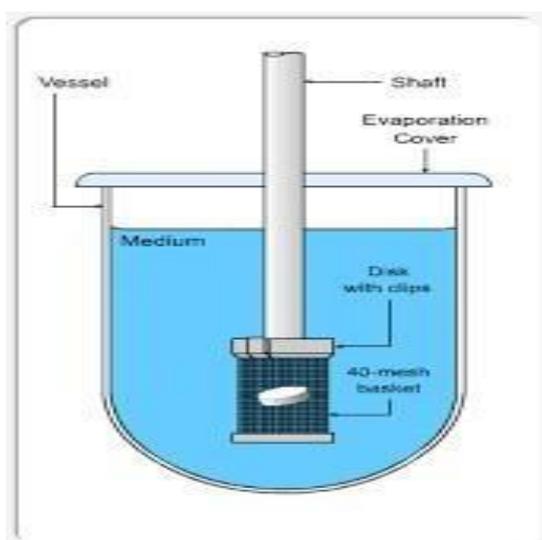


Fig:(1)

The basket procedure was first defined in 1968 by Parmakoski and his co-workers. [4] The leading normally used methods for assessing dissolution first appeared within the 13th edition of the U.S. Pharmacopeia in early 1970. These methods are spoken because the USP basket (method I) and paddle (method II) methods and are spoken as “closed-system” methods because a difficult and fast volume of dissolution medium is utilised. [5]

2)Appratus 2: Paddle Appratus. [USP]

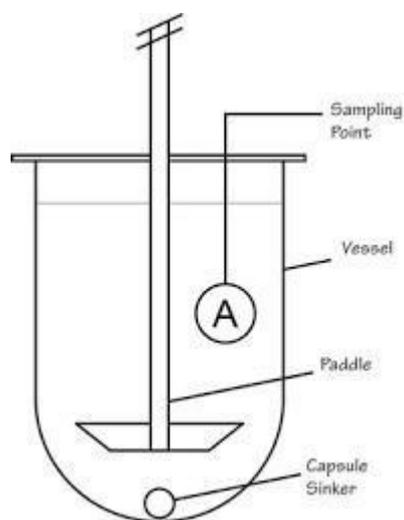


Fig:(2)

An apparatus designated by Levy and Hayes [6] is additionally considered the indication of the beaker process. It consists of a 300 ml beaker and a three-blade; place at centrally polyethylene agitator (5 cm diameter) rotate at 59 rpm in 250 ml of dissolution liquid (0.1N HCl). The tablet was place down the side of the beaker and samples were removed occasionally. Within the Apparatus 2, (the paddle apparatus method) a paddle substitutes the basket because the source of agitation. Just Alike the basket apparatus, the shaft should spot no quite 2mm at any point from the upright axis of the vessel and rotate without important shake. [7]

The apparatus is helpful for tablets, capsules and suspensions. Like USP Apparatus 1 solids (mostly floating), monodisperse (tablets) and polydisperse (encapsulated beads) drug products are tested by using USP Apparatus 2. But floating dosage forms require sinker which may well be considered as a drawback disadvantage of the apparatus. Moreover, cone formation and positioning of tablet during the test is usually hard to take care of. [8]

Both the USP Apparatus 1 and 2 share some advantages and disadvantages. Advantages include: I) widely accepted apparatus for the dissolution test, ii) apparatus of first choice for solid oral dosage forms, iii) standardized, iv) easy to use v) robust vi) broad experience. Disadvantages include: I) limited volume of the dissolution media, ii) stimulation of the gastrointestinal transit is not possible and iii) hydrodynamic conditions are not known. Dissolution results obtained with the USP Apparatuses 1 and 2 may be significantly affect by shaft wobble, location, cantering, and coning [8].

3)Appratus 3: Reciprocating Cylinder [USP]

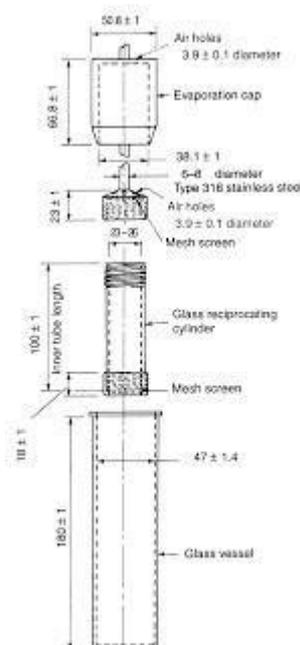


Fig:(3)

The design of USP apparatus 3 is depend on the disintegration tester. Operation involves programming the agitation rate, in dpmo, of the up and down for the internal tube inside the outer tube. On the up stroke, the bottom of mesh in the inner tube moves to upward to contact the product and on the down stroke the product leaves the mesh and floats free within the inner tube. Thus, the action produced carries the product being tested through a moving medium. [8]

It became official in USP 22 as Apparatus 3 and a used for the testing of extended-release articles. [9] This apparatus is originally utilised for extended-release products, bead type modified release dosage form, [10] particularly beads in capsules. It is useful for solids which are mostly no disintegrating.

USP Apparatus 3 offers advantages some I) programmed for dissolution in various media for different time, ii) the media can be changed so easily iii) It may start at pH 1 and then pH 4.5 and then at pH 6.8 iv) It attempts to mirror pH changes and transit times in the GI tract. But it has got disadvantages too, i.e., I) disintegrating dosage forms show too low results, ii) surfactants cause foaming iii) volume of dissolution media is too much small.

4)Appratus 4: Flow through cell [USP]

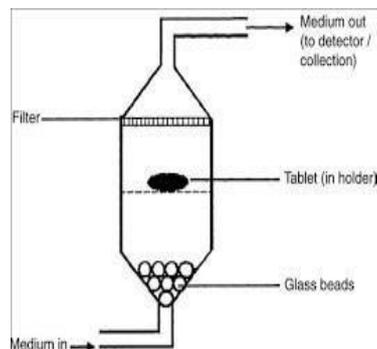


Fig:(4)

The method was involved in various pharmacopoeias. [11] USP Apparatus 4 can be operated under various conditions such as the open or closed system mode, different flow rates and temperatures. The diversity of available cell types allows the application of this apparatus for testing of the wide range of dosage forms including tablets, powders, suppositories or hard and soft gelatine capsules. It is process of choice for extended release and poorly soluble products. [12,13]

More commonly a dual sampling rack has been designed to permit samples to be collected during at the same time diluting, if it is mandatory, and injecting into either an HPLC system or the UV spectrophotometer. [15]

Drug products like some solids (tablets, capsules, implants, powder, and granules), semisolids (suppositories, soft gelatine capsules, ointments) and liquids (suspensions) are mostly tested using this apparatus.

Advantages of the apparatus include some I) no limitation regarding the volume of media utilised for the dissolution test, ii) suitable for the low soluble drugs, iii) gentle hydrodynamic conditions, iii) stimulation of the gastrointestinal transit and iv) suitable for the special dosage forms such as a powder and granules, implants.

5)Appratus 5: Paddle Over Disk [USP]

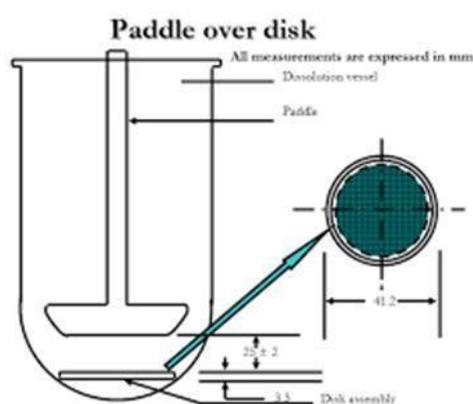


Fig:(5)

In Paddle-over-Disk technique the paddle and vessel assembly from Apparatus 2 with the adding of a stainless-steel disk assembly designed for holding the transcutaneous system at the lowermost of the vessel. The temperature is kept at $32^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. The disk assembly holds the system even and is situated such that

the release surface is parallel with the bottom of the paddle blade. [14] The apparatus is used to test transdermal patches. [1]

6)Appratus 6: Cylinder Appratus [USP]

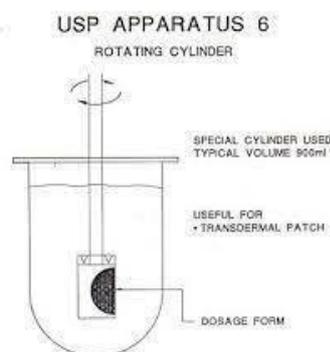


Fig:(6)

This is a modified process of the basket apparatus (USP Apparatus 1). It uses a vessel assembly from Apparatus 1 except to replace the basket and shaft with a stainless-steel cylinder stirring element. [14] The apparatus is use to test transdermal patches. [1]

7)Appratus 7: Reciprocating Holder Appratus [USP]



Originally introduced in the USP a small-volume option for the small transdermic patches, the reciprocating disk apparatus process was later named the reciprocating container apparatus with an adoption of four added holders for the transdermal systems, osmotic pumps, other low dose delivery systems. [16] The apparatus is for to test transdermal patches.

CONCLUSION

Dissolution research start to progress in 1897 when Noyes and Whitney originate their comparison in the sequence of their dissolution educations on benzoic acid and lead chloride. Thus, dissolution started as the topic in physical chemistry, and is still a significant subject of research in various sections of physical sciences. The goal of dissolution testing is to ensure the pharmaceutical quality of the product which includes not only ability to manufacture the product reproducibility and the drugs to maintain its release properly

during its self-life but also that the product's biopharmaceutical characteristics, such as rate and level of absorption, can be relied on. It would, be desirable to develop dissolution tests that can derive the capability of the dosage form to release the drug completely and to concurrently indicate how the product will designed in vivo.

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