International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

A Review of Different Dissolution Method

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Abstract
Pharmacopoeias have approved the test of dissolution for evaluating the drug arrival of solid and semisolid measurement structures. Dissolution testing is mostly used in the biopharmaceutical description of pharmaceutical products as a tool to ensure consistent product quality and forecast drug bioavailability in vivo. Dissolve testing was first developed for solid orals, but its application was later expanded to include a variety of innovative dose forms. To characterize the in-vitro arrival of these measurement structures, new dissolving testing procedures must be developed due to the complexities involved in the medicine conveyance of unique dose structures. The article provides information on possible options for drug dissolving and discusses the continuous improvements in dissolution testing methodologies for both conventional and unique drug measuring structures

Introduction -
Since the late 1800s, physical chemists have been studying how substances dissolve. Because of this, most basic research in this field is not directly related to pharmaceuticals. In addition, by the time the field of interesting drug dissolution began to take shape, essential laws describing the dissolving process had already been established

1. The dissolution profile test is among the most beneficial tests. Drug development, stability studies, compatibility assessments, routine scales, and modifications after approval and quality control are only a few of the techniques applied at various phases of the drug product lifecycle. S test is suitable for a range of dosage forms, such as injections and internal usage for suppositories, gums, chewable tablets, powders, vaginal inserts, implants, transdermal absorbers, suspensions, etc
2. The gastrointestinal tract (GIT) fluid's medication dissolution and intestinal permeability affect the absorption of drugs taken orally. A cycle that produces solids with only acceptable dissolving properties leads to the configuration.

Objective of dissolution –
When developing solution carriers for medications that are not easily soluble, common techniques used are as follows:

1. Inducing drug solubility by increasing the volumetric or eliminating aqueous sinks medication.
2. Co-solvent for drugs Anionic and non-anionic surfactants can be dissolved and added up to 40% for post-micelle concentration.
3. Adjust the pH to increase the solubility of a pharmaceutical molecule that is insoluble. Surfactant solutions are often advised as solutions for drugs with low water solubility. Such a surfactant's

aqueous solutions more closely approximate the physiological environment than sorbents, hydro alcohols, or other aliphatic method.

History of Dissolution-

The literature discusses the initial dissolving research. Thanks to Noyes and Whitney, they found out in 1897 how lead chloride and benzoic acid, two compounds that dissolve sparingly, do so. In 1951, he made the decision to adopt rate restriction for aspirin absorption into the bloodstream. Nelson, referring to blood levels, was the first scientist to deliberately provide theophylline orally for its disintegration in 1957. However, in the middle of the 1960s, the therapeutic efficacy of taking these medications orally started to fade. In 1971, a seven-fold difference in serum digoxin levels was observed.

Table : List of the official Dissolution Apparatus and their uses

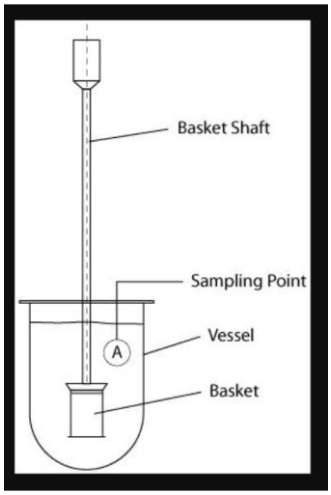
s.no	Official Name	Main features of the apparetus	uses	Rot.speed
1	USP Apparatus 1	Basket	Tablets, Capsules, floating dosage forms	50-120 rpm
2	USP Apparatus 2	Paddle	Tablets, Capsules, enteric forms	25-50 rpm
3	USP Apparatus 3	Reciprocating cylinder	Extended relase drug product	6-35 rpm
4	USP Apparatus 4	Flow through cell	Implant, powders, Suspentions	N/A
5	USP Apparatus 5	Paddle over disk	TDDS, Ointments	25-50 rpm
6	USP Apparatus 6	Cylinder 6	TDDS	N/A
7	USP Apparatus 7	Reciprocating Disk	Extendedrelease drug product	30 rpm

CONDITION (for all in general):

1. Temp.- 37+/- 0.5
2. PH - +/- 0.05 unit in specified monograph
3. Capacity – 1000ml
4. Distance between inside bottom of vessel and paddle/ basket is maintained at 25+/-mm .
5. For enteric coated dosage form it is first dissolved in 0.1 N HCL & then in buffer of ph 6.8 to measure drug release. (Limit – NMT 10% of drug should dissolve in the acid after 2 hr. and about 75% of it should dissolve in the buffer after 45 min.

1. APPARATUS 1- Basket Apparatus :

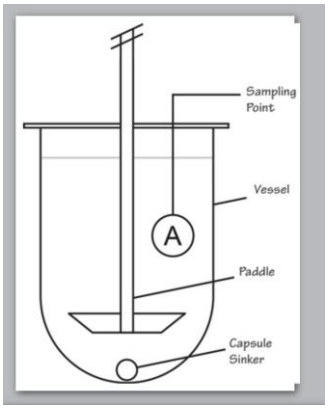
- Unless otherwise specified in the individual monograph, use 40- mesh cloth.
- Useful for: Capsules, Beads, Delayed relayed / Enteric Coated dosage forms, Floating dosage forms
- Standard volume: 900/1000 ml



2. Apparatus-II - Paddle Apparatus:

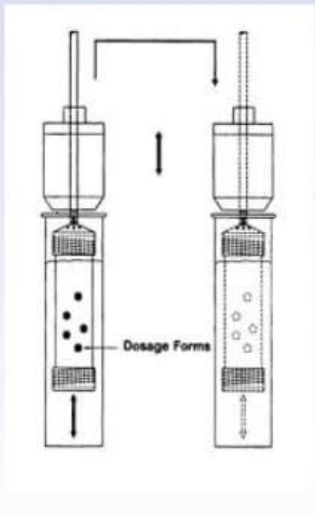
First-choice method Before the blade begins to rotate, the dose unit is allowed to sink to the bottom of the jar. Dosage units that float can have a small, loose piece of non-reactive material connected to them like a few twists of wire helix. You may use other sinker devices that have been validated

- Useful for: Tablets, Capsules, Beads, Delayed release, enteric coated dosage forms
- Standard volume: 900/1000 ml.



3. Apparatus 3- Reciprocating cylinder:

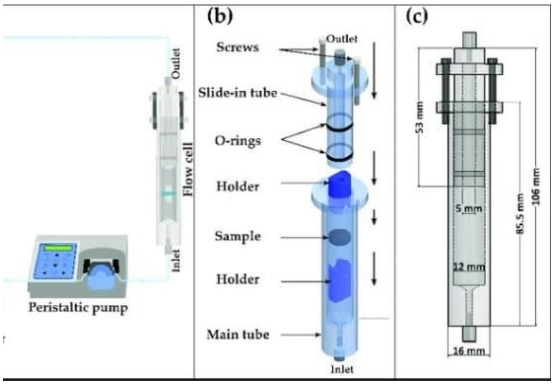
The assembly is made up of several glass vessels with flat bottoms that are cylindrical in shape, several glass reciprocating cylinders, and stainless steel fittings (type 316 or equivalent); screens that fit the tops and bottoms of the reciprocating cylinders; and a motor and drive assembly to reciprocate the cylinders vertically inside the vessels. The screens and fittings should be composed of appropriate nonsorbing and nonreactive material (polypropelene). During the test, the vessels are partially submerged in an appropriate water bath of any practical size that allows the temperature to be maintained at 37 ± 0.5. The dose unit is inserted into a reciprocating cylinder, which is continuously permitted to move both upward and downward. Drug release into the solvent inside the cylinder is measured. Benefits: Beads, tablets, and formulations with controlled release. Standard volume: 200– 250 ml/station.



4. Apparatus 4 - flow through cell:

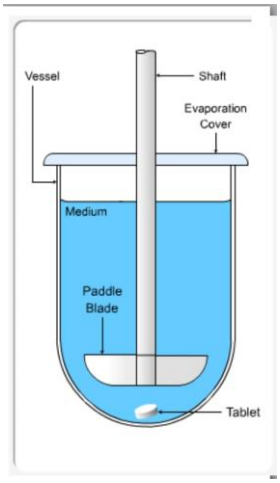
The assembly is made up of a water bath that keeps the dissolution medium at 37 ± 0.5, a flowthrough cell, a reservoir, and a pump. The individual monograph specifies the cell size. The Dissolution Medium is forced upward through the flow-through cell by the pump. After inserting the glass beads into the monograph-specified cell and placing one dosage unit atop the beads or, if indicated in the literature, on a wire carrier, assemble the filter head and secure the components with an appropriate clamping device. In order to achieve the flow rate mentioned in each particular monograph, the pump was introduced and the Dissolution Medium warmed to 37 ± 0.5 through the bottom of the cell.

As instructed in the individual monograph, collect the elute by fractions at each of the designated times and carry out the analysis. Beneficial for: Implants, controlled release formulations, microparticles, low solubility medications, and suppositories Changes: Two types of systems: open and closed.



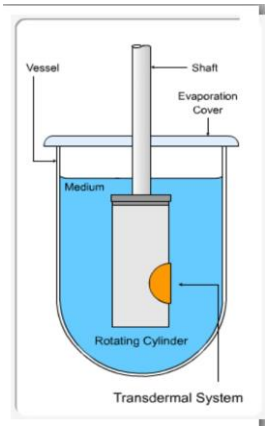
5. Apparatus V: Paddle over-Disk:

Utilize the paddle and vessel assembly from Apparatus plus an additional disk assembly made of stainless steel that is intended to hold the transdermal system at the vessel's bottom. If the other devices don't absorb, react with, or obstruct the specimen being evaluated, then they can be used instead. The transdermal system's disk assembly is made to minimize any "dead" volume that may exist between it and the vessel's bottom. It keeps the system flat and is positioned so that the release surface is parallel to the paddle blade's bottom. If necessary, the vessel may be covered during the test to reduce evaporation. Ideal for: Transdermal patches; standard capacity: 900 milliliters.



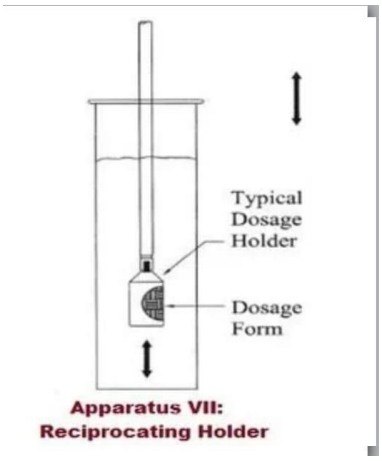
6. Apparatus VI– cylinder:

Employ the same vessel assembly as Apparatus 1, but swap out the basket and shaft for a stainless steel cylinder stirring element. Throughout the test, keep the temperature at 32 ± 0.5. At the start of every test, the dosage unit is attached to the outside of the cylinder so that the system's long axis fits around the cylinder's circumference and releases trapped air bubbles. After inserting the cylinder inside the device, start rotating it at the pace mentioned in the respective monograph.



7. Apparatus VII: Reciprocating Holder:

This assembly is composed of a motor and drive assembly to reciprocate the system vertically, a set of appropriate sample holders, and a set of glass or other acceptable inert material solution containers that have been volumetrically calibrated. The solution containers are submerged to some extent in an appropriate water bath of any practical size that allows the temperature inside the containers to be maintained at 32 ± 0.5. In order to test a coated tablet drug delivery system, attach each system to be tested to an appropriate sample holder (for example, by attaching the system's edge with 2-cyano acrylate glue to the end of a plastic rod, or by putting the system inside a metal coil attattachment or a small nylon net bag at the end of a plastic rod).



- **Dissolution Mechanism:**

1. First mechanical lag
2. Moistening dosage containers
3. The dissolving media infiltration
4. Decline
5. Disintegration
6. Breakdown
7. Some particles becoming occluded 2.

- **Theories of dissolution:**

Diffusion layer model [Film theory]
Danckwert' s model [Penetration or surfac renewal theory]
cial barrier model [Double barrier OR Limited solvation theory] Diffusion layermode/Film theory.
Fick' s second law of dispersion Nernst and Brunner integrate Fick' s most memorable law of dissemination and adjusted the Noyes-Whitney' s condition to:
dc/dt = DAKw / O{Cs – Cb}/ vh
Where,
D = Diffusion coefficient of medication.
A = Surface area of dissolving solid.
Kw /o = Water / oil segment coefficient of
medication
V = volume of dissolution medium.
h = thickness of a stagnant layer.
{Cs – Cb} = Concentration gradient for diffusion

- **Danckwert's Model / Surface Renewal or Penetration Theory:**

According to this theory, mass vehicles are steadily approaching the disintegration process and solid solution balance is achieved at the connecting point. The model can be thought of as an extreme film with a concentration Ci that is not as high as immersion because it is continuously exposed to new fluid surfaces with a concentration much lower than Ci. According to the model, the unsettled liquid is made up of a mass of eddies or bundles that are continually exposed to new, strong surfaces before being returned to the majority of liquid. The condition conveys the Danckwert's model: dm/dt = A (Cs-Cb) = dC/dt. $\sqrt{(\gamma.D)}$ where m is the mass of dissolved solid and γ is the rate of surface renewal

- **Double Barrier, Interfacial Barrier Model, or Limited Solvation Theory:**

Both the Dankwert's model and the dispersion layer model relied on two theories:

1. The mass vehicle tcis the rate-determining step that governs disintegration.
2. At the point of interaction between solid and fluid, strong arrangement equilibrium is achieved. The solvation instrument at the point of interaction can result in a transitory concentration, which is a component of dissolvability rather than diffusion, according to the interfacial boundary model. When taking into account that the valuable crystal's disintegration will have a different interfacial blockage caused by the subsequent condition: G is equal to Ki (Cs-Cb). G is for disintegration per unit area. Ki is the interfacial transport constant that is viable.

Conclusion:

In 1897, Noyes and Whitney conducted dissolve tests on lead chloride and benzoic acid, which led to the deduction of their condition and the official start of the dissolution research. Thus, dissolving was initially examined as a subject in physical chemistry and is still a vital field of research for other physical scientific specialties. Dissolution testing serves the dual purposes of verifying the drug nature of the product—that is, if it can consistently create the item and maintain its distribution over the course of its self-life—and the dependability of the product's biopharmaceutical properties, including rate and degree of absorption. Thus, it would be desirable to support dissolving studies that assess how well the dose form distributes the medication.

A standard procedure for verifying the quality of oral solid dosage forms, such as tablets and capsules, is dissolution testing. It is also essential for transdermal drug delivery systems. Research on dissolution testing is produced continuously. Global logical testing has led to advancements in invention that have streamlined the procedure and made it dependable, simple, and fast. It is a vital instrument for doing medical research .

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