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Review Article

A Review on In-Vitro Dissolution Apparatus

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ABSTRACT

Orally administered non-solution dosage forms are subjected to in vitro performance studies, similar to dissolution tests, for several reasons. This test is one of the routine quality control procedures for oral solid dosage forms. Since its inception as a branch of physical chemistry approximately a century ago, the study of dissolution has advanced significantly. In order to forecast the drug's in vivo bioavailability and to assure consistent product quality, dissolution testing is mostly utilized for biopharmaceutical characterization of the therapeutic product. It has now been used in other more recent dose forms, but it was first created for solid orals. The dissolving device calculates how quickly a medicine dissolves in a particular liquid. In pharmaceutical quality control, it is a crucial instrument. One of the elements influencing the safety and effectiveness of pharmaceuticals is their ability to achieve the required dissolution profiles, which is ensured by regulatory agencies utilizing the equipment. The pharmacopoeias of the United States and India outline uniform procedures and equipment for dissolve testing in order to guarantee consistent medication release and consequent bioavailability. Both IP and USP make reference to variables such the dissolving fluid volume, medium temperature, and rotational speed. Within the cylindrical basket of the basket equipment, the drug's dose form is inserted. Conversely, the Paddle apparatus functions by use of a revolving paddle that stirs the drug dissolving media.

INTRODUCTION

In -vitro dissolving equipment, the rate at which a medication dissolves in a solution that mimics its behaviour in the gastrointestinal tract from a dosage form like tablets or capsules may be measured. Indian Pharmacopoeia (IP) and United States Pharmacopoeia (USP) are two of the most significant international standards used in dissolution testing. Pharmacopeia uses dissolution testing to measure medication release from solid and semisolid dosage forms. Dissolution is crucial for assessing drug release in various dosage forms,

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including tablets, capsules, and aerosols. Physical chemists have been studying dissolution since the late 19th century, aiming to conduct performance tests for various USP dosage formulations.[1] Official dissolution equipment come under seven types. They are according to USP 30: United States Pharmacopoeia Apparatuses. These include: (Basket) Apparatus1, (Paddle) Apparatus 2, (Reciprocating) Apparatus 3, (Flow-Through Cell) Apparatus 4, (Paddle Over Disk) Apparatus 5, (Rotating Cylinder) Apparatus 6, (Reciprocating Holder) Apparatus 7. The Indian Pharmacopoeia uses two apparatuses, IP Paddle and Basket, while British, Japanese, and European Pharmacopoeia's apparatuses 1, 2, and 4 are official.[2] In-vitro dissolution testing is a crucial method in the pharmaceutical industry for determining the release speed of active ingredients from dosage forms, predicting their human body behavior.[3] The development of in-vitro dissolving equipment is motivated by the need for quality control in drug research and production. These tools assist in identifying drug releases. Features include testing the generic medications against their branded equivalents and guaranteeing consistency from batch to batch. USP dissolution tests, specified in monographs, evaluate product performance using specific apparatuses. USP training and services improve quality standards for regulatory compliance, using reciprocating cylinder, basket, paddle, and flow-through cell.[4]

1. Working Principle of Dissolution Test:

The role of dissolution testers, also known as a dissolution apparatus or dissolution testing equipment, would generally be to determine the rate and extent to which drugs are dissolved from solid dosages forms, for instance tablets or capsules, in a liquid medium under specified conditions. This dissolution tester was an important quality control tool in the drug development, optimization, and manufacturing process of the pharmaceutical tablets for reproducible and consistent release of the active pharmaceutical ingredient. Conventionally, a dissolution tester is made up of various vessels or cells containing the tablets or capsules and a mechanism for agitating the liquid medium most commonly water or a buffer solution to ensure uniform conditions in the dissolution test. The design of the dissolution tester should aim at replicating physiological conditions that are prevalent in the gastrointestinal tract in which the tablets or capsules must dissolve the API upon administration.[5]

Figure No 1: Dissolution apparatus

2. Functions Of Dissolution Tester:

1. **Standardized testing condition:** The dissolution tester provides a standard and controlled condition with regard to temperature, agitation speed, and PH for ensuring a performance of dissolution test.

2. **API Release Measurement:** This dissolution tester plays a crucial role in determining the rate as well as the extent of release of APIs from a tablet or capsule into the dissolution medium over time.
3. **Dissolution profile generation:** The dissolution test gives dissolution profiles, whose graphical presentations with regard the rate and extent of drug dissolution in the tablets or capsules give results.
4. **Qualitative testing:** A dissolution tester is used like quality control tool in assessing the performance in tablets or capsules in order to ensure adherence to the required drug release characteristics**.**
5. **Documentation and reporting:** It makes it easier to document and report any dissolution test data, including dissolution profiles, sample analysis data, and deviation from acceptance criteria.[5]

3. **Key Components Of Ip And Usp Dissolution Apparatus:**

Dissolution apparatus is utilized in pharmaceutical testing to evaluate the rate and efficiency of an API's dissolution in a solution. Indian Pharmacopeia and United States Pharmacopeia have standardized guidelines for these instruments to make sure proper measurements are made across the pharmaceutical industry. The major parts of the IP and USP testers include:

- **Dissolution Vessels :** These are glass or plastic cylinders in the dosage form and liquid used in the dissolution process will be carried, either buffers or water. A normal amount would usually stand at 500, 900 or 1000 Millilitres. This can be controlled and maintained at around 37 ± 0.5°C.
- **Paddle or basket assembly:**

Apparatus 2-USP/IP Paddle Apparatus A paddle shall be balanced to be used for the pre - mixing of the dissolving agent.

Basket Apparatus (Apparatus 1 - USP/IP): A wire mesh basket is used as a vessel in which the dosage form is placed.

- **Rotation speed:** With respect to whatever form of dose, the paddle or basket will be rotating at some specified speed, usually between 50 to 100 revolutions per minute Shaft Rotation.
- **Sensor of Temperature:** Some recommendation is to have a thermostat or temperature sensor installed to control the medium temperature.
- **Probes used for sampling:** Allow dissolved samples to be withdrawn at an interval of time without stopping the apparatus. Samples are mainly filtered before analysis.
- **HPLC or a UV/Vis Spectrophotometer:** Collected samples are normally analysed for the presence of dissolved medication by utilizing either an High-Performance Liquid Chromatography or a UV/ Visible spectrophotometer**.** [6]

4. **Type Of Dissolution Apparatus :**

Table No 1 : Dissolution Apparatus

	IP	USP
Apparatus 1	Paddle apparatus	basket apparatus
Apparatus 2	basket apparatus	Paddle apparatus
Apparatus 3		Reciprocating cylinder apparatus
Apparatus 4		Flow-through cell apparatus
Apparatus 5		Paddle over disk type apparatus
Apparatus 6		Cylinder type apparatus
Apparatus 7		Reciprocating disk type apparatus

5.Indian Pharmacopoeia Dissolution Apparatus:

1. Paddle Type 1 Apparatus

A paddle type dissolving apparatus measures the rate at which drugs dissolve from tablets and capsules in liquid media, mimicking stomach mechanical agitation. The IP Type 1 and USP Apparatus 2 are commonly used in pharmaceutical testing to monitor dosage forms. The Indian Pharmacopoeia compendium requires two dissimilar apparatuses for dissolution tests.[7]

Procedures:

1. A tablet or capsule is placed in a bottle containing liquid media.
2. Perpendicular mounted within the vessel, with paddle secured on a rotating shaft.
3. The agitation of the dissolving liquid resembles digestive conditions for the gastrointestinal tract, as furnished by a paddle.
4. samples are collected at set time points, for example, 15, 30, and 45 minutes.
5. The dissolved active constituent is analyzed by UV spectroscopy or HPLC. [8]

Components:

1. Vessel: 1 L Glass or stainless steel vessel.
2. Paddle: The shaft is attached with a paddle of either titanium or stainless steel upon fixing it onto the shaft with the diameter of 4-5cm.
3. Speed of rotation: The paddle will rotate between 50 revolutions per minute to a hundred revolutions per minute.
4. Medium: A known quantity of water or buffer solution is added the dissolution medium.
5. Temperature: Device is a maintained at 37°C ± 0.5°C

ADVANTAGES:

1. straightforward and simple to use.
2. PH changes possible

DISADVANTAGES:

1. It might not replicate in vivo circumstances precisely.
2. The hydrodynamic circumstances might change based on the design of the paddle and vessel.

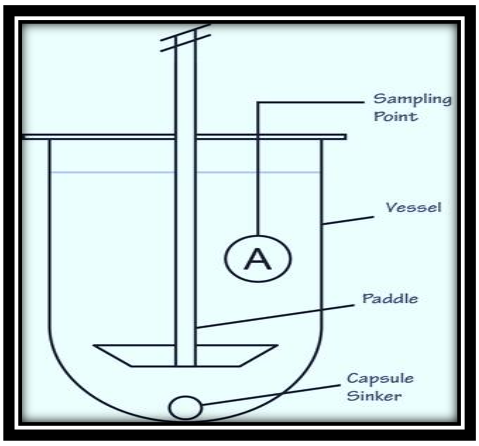

Figure No 2 : Paddle Apparatus

2. Basket Type 2 Apparatus

It closely looks like Apparatus 1. However, the paddle, which is the stirring elements, is replaced with a basket. There is much slick rotation in the metal shaft. The top end of the basket a fitted for a three spring clips. The bottom detachable portion is composed of welded steam cloth that has 0.381mm apparatus, which has been formed into a cylinder.[7] The basket assembly includes a woven basket with a rotating metallic shaft, a dissolution medium with a PH range of 0.05 units, and a sample withdrawn at predetermined intervals. The basket must be gold-coated and 2.5 µm thick, with a space between the basket and vessel's bottom

between 23 and 27 mm. The mesh integrity should be examined using a microscope. A water bath or heating apparatus can maintain the medium's temperature. Conventional tablet dissolution approval requirements are listed in Table 1.2.[8]

Table No 2 : IP Acceptance criteria for dissolution test

S_1	6 tablets	At least D+ 5 percent
S_2	6 tablets	12 units (s1 + s2) above D on average, and no unit < D -15 percent
S_3	12 tablets	AV 24 units ≥ D NMT 2 units less than D – 15 percents and non < 25

Procedures:

1. Put the dose container inside the basket.
2. Fill the container with 900 milliliters of the dissolving solution.
3. To simulate circumstances in the digestive tract, heat and stir the mixture.
4. Take Samples and Examine Them at Suitable Times .[8]

ADVANTAGES:

1. Fundamental and manageable
2. Not very prone to clogging
3. The most substantial types of medication

DISADVANTAGES:

1. It might not accurately resemble processes that occur in real time.
2. The design and dimensions of the basket are not very flexible.[9]

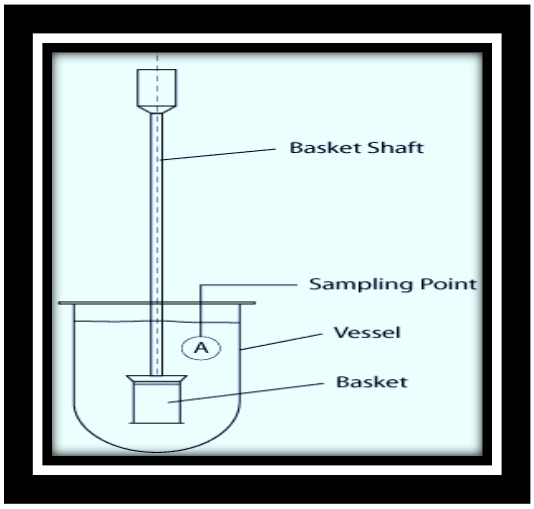

Figure No 3 : Basket Apparatus

5. United States Pharmacopoeia Dissolution Apparatus

The USP dissolution apparatus measures the speed of a medicine's dissolution in liquid media, ensuring consistent drug performance and bioavailability. Different types of devices are developed for different drug formulations or release mechanisms.[10]

USP Dissoluttion Apparatus:

Table No 3 : USP Dissolution Apparatus

Apparatus	Type	Rotation speed (RPM)	Dosage form
Apparatus 1	Basket Apparatus	50-120	Conventional tablets, Chewable tablets, Controlled release
Apparatus 2	Paddle Apparatus	25-50	Orally disintegrating tablets, Chewable tablets, Controlled release, Suspension

Apparatus 3	Reciprocating Cylinder	6-35	Controlled release, Chewable tablets
Apparatus 4	Flow through cell apparatus	N/A	Extended release, poorly soluble API tablets, Granules, Microparticle, Implants
Apparatus 5	Paddle Over Disk	25-50	Transdermal
Apparatus 6	Rotating Cylinder	N/A	Transdermal
Apparatus 7	Reciprocating Holder	30	CR (non disintegrating oral and transdermal)

7.1 Basket Type 1 Appratus

The basket method, created in 1968 by Parmakoski and colleagues, is a closed-system procedure used for determining dissolution of drugs with significant water solubilities, utilizing minimal agitation and examining various medications. Examples of medications examined using this method include: – [11]

Tablets : Lithium carbonate tablets USP
Phenylbutazone tablets USP

Capsules : Extended phenytoin sodium capsules USP Methaqualone hydrochlorides capsules.

The equipment consists of a generator, rotating shafts, cylindrical baskets, and a glass vessel, maintained at 37°0.5°C. The bath liquid is stirred in a rotating basket technique, easy to standardize and reliable. The USP container method is preferred for assessing oral solid dosage forms with instantaneous release.[12]

Procedures:

1. Put everything together, making sure the basket is in its proper location.
2. Fill the vessel with the dissolving medium.
3. Put the dosage form in the basket; it could be a tablet, capsule, or pellet.
4. Sample dilution (often 10–20 ml) at predetermined intervals of 15, 30, 45, and 60 minutes.
5. Use an appropriate analytical technique (such as UV spectroscopy or HPLC) to perform analytical characterisation of the samples.

ADVANTAGES:

1. The solid material dosage form is submerged in the reducing solvent in a little volume
2. It also has an advantage over capsules because it floats on top, minimizing the exposed area's interaction with the dissolving fluid.[2]

DISADVANTAGES:

1. Up to 40 mesh screens may be clogged by granulation.
2. When hydrochloric acid is present, the stainless- steel screen corrodes quickly.[2]

Applications:

1. The manufacturing of drugs remains constant from batch to batch.
2. Studying how pharmacological drugs evaporate from dose forms.
3. To compare different formulations dissolving properties.[13]

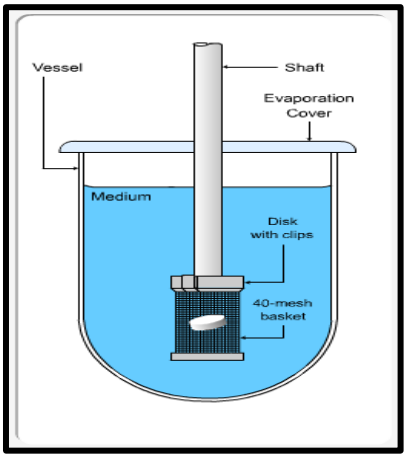

Figure No 4: Basket Apparatus

7.2 Paddle Type 2 Appratus

Levy and Hayes' device may have been regarded as the forerunner of the beaker technique.[14] A cylinder is a cylindrical object made of optically clear materials, with an inside diameter of 98-106 mm and a capacity of 1000 ml.[15] The apparatus from Apparatus 1 is used for stirring, except for a paddle with a blade fixed on a shaft. The shaft should rotate smoothly and cross through the axis to ensure flush bottoms. The paddle and drive shaft are one unit, and a two-piece removable structure can be used if securely engaged.[16] Drugs that are poorly soluble in water are generally advised to use Equipment 2. More challenging circumstances are given by this device to yield faster outcomes. It takes a lengthy time for instruments 1 to finish the test for these medications. The medications that this kind of testing looks at are – [11]

- Tolbutamide tablets USP
- Methaqualone tablets USP
- Danazol capsules

Procedures:

1. Equipment: the device holds 900 milliliters of dissolving medium.
2. The form of administration is inserted into the device.
3. paddle's height from the apparatus's bottom can be changed from 25 to 40 mm.
4. Next, the paddle's rotation rate is adjusted between 50 and 100 rpm.
5. The temperature range is maintained at 37 ± 0.5°C.
6. The solution used for dissolution is stirred at specified intervals, such as 30 minutes.
7. Samples are taken at prearranged intervals of 15, 30, and 45 minutes.[11]

ADVANTAGES:

1. A pH shift is possible.
2. Easily adaptable to equipment. [2]

DISADVANTAGES:

1. Buoyancy type dosage forms need sinker.

2. The configuration of the paddle is important, else the results vary. [2]

APPLICATIONS:

1. Quality assurance and control.
2. Research on bioequivalence .[13]

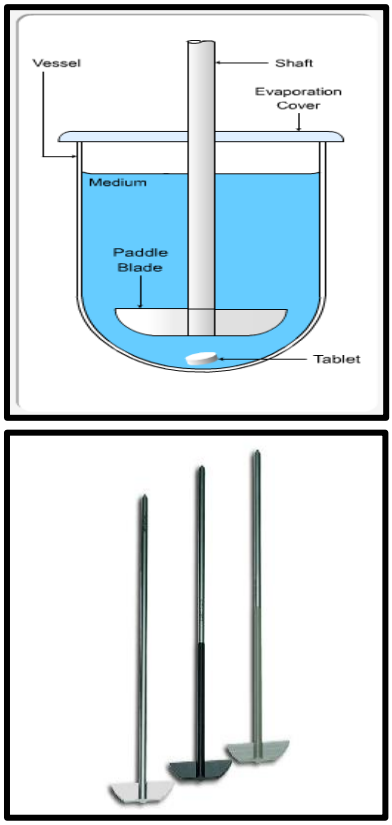

Figure No 5 : Paddle Apparatus

7.3 Reciprocating Cylinder Type 3 Apparatus

The release of drugs studies from delayed let go quick release, and beaded formulations is the objective of Apparatus 3. It works well with chewable tablets as well. This can be particularly helpful when the procedure for testing calls for a number of PH/buffer adjustments. Another name for it is "Bio-Disc."[11] The equipment includes glass vessels with smooth, cylinder-shaped bottoms, reciprocating cylindrical objects, metallic parts (type 316 or similar), suitable displays, an electric motor, and an assembly that rotates the cylinders upwards.[16] At a predetermined time, each cylinder can also be automatically switched to another medium. The next concept is the revolving container devices, which allows for media exchange to create feeding and fasting situations or a pH gradient.[17] The company encourages its usage in testing extended-release amount mixtures and enables automated evaluation for up to six days. It is suggested for the assessment of extended-release products that is apparatus 3 in USP 22.[18]

Procedures:

1. Fill every container with the disintegrating media at the specified volume.
2. The dissolving solution reaches 37 ± 0.5°C.
3. Fill each of the 6 revolving chambers with a single dose component.
4. Turn the assembly on.
5. The rotating cylinder moves 9.9 to 10.1 cm in total throughout its vertical and horizontal cycle.
6. As time goes by, remove a part of the experimental liquid about each vessel at a point that is as close to halfway above the disintegration medium's bottom and its free surfaces as feasible.

7. Follow the instructions in the person's datasheet for carrying out the evaluation.[11]

ADVANTAGES:

1. Hydrodynamics can also be directly altered in the process by varying the dip rate
2. Physical aspects such as the centering of the site, wobbling of the shaft.[2]

DISADVANTAGES:

1. Low volume (max. 250ml)
2. Data restricted [2]

Applications:

1. Used for chewable and extended-release forms
2. For prolonged released dosage formulations depending on the bead type.[14]

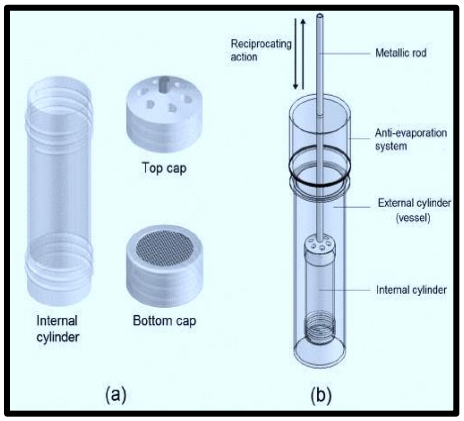

Figure No 6 : Reciprocating cylinder

7.4 Flow Through Cell Type 4 Apparatus

The dissolution efficiency of the capsules and coated in sugar tablets is measured using apparatus 4. Patches, soft gelatin with water capsule-like structures, semi-solids, powdered materials, pellets, and injections are additional alterations.[11] Place the crystal beads in the monograph's appropriate compartment. Install the filter head after putting a single administration dose on front of each of the pellets or, if specified in the publication, on a metallic carrier. Then, use a suitable fastening mechanism to hold the components together.[19] The finite placements of the proportion investors, that also reduce as the quantity of sample material to be collected rises, further restrict the amount time periods that can be assembled.[20]

Proceduures:

1. Insert the crystal pellets inside the container as the datasheet explains.
2. Put the filtration system unit up and fix the components with a suitable fastening method.
3. Fill bottom of the container into the heated dissolution medium-sized, that was successfully heated to 37 ± 0.5°C by the pump.
4. At each of the specified times, gather the results of assessment by fractions. Complete the evaluation as specified in the respective volume.[11]

ADVANTAGES:

1. The state of the sink
2. Potential pH character [2]

DISADVANTAGES:

1. Deareation must be done
2. Extensive labor.

Applications:

1. Used with microparticles and low solubility medications.
2. For implants and suppositories.[13]

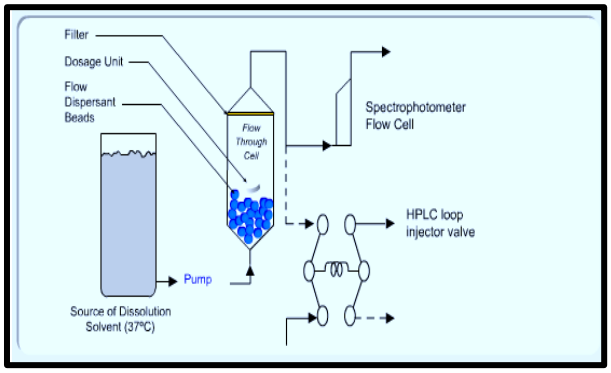

Figure No 7: Flow through cell

7.5 **Paddle Over Disk Type 5 Apparatus**

The exception of an aluminium plate structure at the bottom inside the container for storing the epidermal structure, the design is identical to that of USP apparatus 2. Pretesting equipment, if they interfere with or interact with the sample being tested. The purpose of this plate assemblage is to decrease the quantity of "deceased" space above the storage device arrangement and the container's bottom. The mechanism is round and oriented so that its opening area was equal to the paddles cutting bottom caused by the disk's shape.[13]

Procedures:

1. Determined the chamber's Mixing fluid proportion Put the apparatus together minus the platter components. Set the medium's operating ph to 32 ± 0.5°C.
2. Using the hard drive structure for the capillary technique.
3. Location a appropriate solution can be used to adhere the structure to the disk.
4. The opening area of the plate component must be located near the bottom for the container, running level to the sides of the dissolving substance and paddles edge.
5. The equipment will be operated. A sample must be obtained from a region that is not less than 1 cm below the exterior of the vessel and halfway above the leading edge of the cutting edge and the dissolution media area during any given time interval.
6. Evaluate each sample's portion in conformity to paddle.[11]

ADVANTAGES:

1. The condition of the sink is maintained.
2. There is very little membrane impact.[2]

DISADVANTAGES:

1. The patch's size is restricted by the disk assembly.

Applications:

1. To be used as patches for transdermal use. [13]

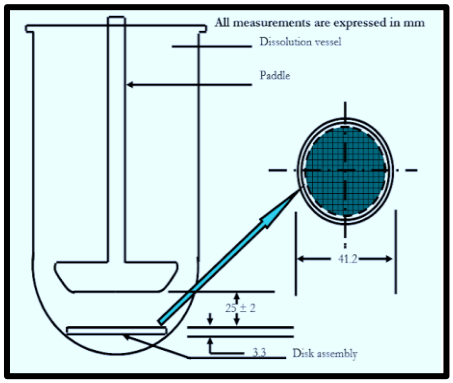

Figure No 8 : Paddle Over Disk

7.6 Rotating Cylinder Type 6 Apparatus

The exception of the use of a stainless steel cylinder mixing component placed on top of the basket and shaft, and the construction is identical as that of USP Instrument 1. The apparatus's purpose is to load the material being tested into the cylinder at the starting point of each test, to ensure the long direction of the system fit within the cylinders's diameter or takes away air trapped in molecules. After inserting the chamber into the device, rotate it at the speed recommended by this particular monographs.[13]

Procedures:

1. Complete the chamber with the required quantity of the dissolve the media.
2. A pre-equilibrated dissolving substances at 32°C ± 0.5°C
3. After removing the system's protective lining, insert the surface with adhesive onto an area of cuprophan.
4. Position of a cuprophan coated sideways on a spotless appear, and then cover the open cuprophan edge with an appropriate glue. Give it a minute to dry.
5. To eliminate air spaces, lightly press the cuprophan lid.
6. Insert the cylinder into the device and rotate it right away at the specified rate.
7. Complete the decision in accordance with the specific monograph's recommendations.[11]

ADVANTAGES:

1. A higher reactivity to modifications in formulations.
2. Hydrodynamic Regulation Parameters.

DISADVANGES:

1. Large volume of medium: This is required, and the medication is diluted, making analysis difficult**.**

Applications:

1. Used for transdermal patches.[13]

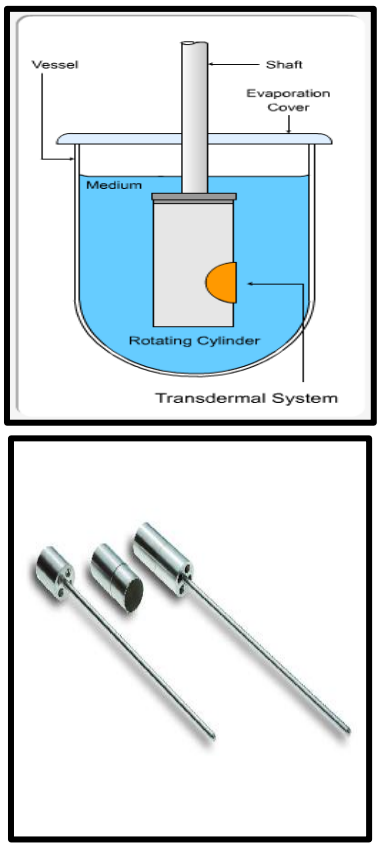

Figure No 9 : Rotating cylinder

7.7 Reciprocating Holder (USP 7 Apparatus)

After USP offered the smaller-volume option of small patches that were transdermal, the reciprocating disk instruments was renamed the reciprocating holder apparatus. A set of glass or another appropriate inert material measured corrected sampling containers as well, a motor and drives that rotate vertical to the system, along with a pair of proper sample containers make up the equipment. appropriate water bath of any practical size is used to partially submerge the sample containers. Attach all the systems to be examined to an appropriate sample container for the covered tablets that delivers the medication. 32 degrees Celsius throughout the test.[21]

Procedures:

1. Volumetrically calibrated liquid vessels make up the assembly.
2. A rotating device and driving component that allows the entire structure to rotate vertical.
3. An appropriate collection of sampling containers.
4. Appropriate vessels are partially immersed in a water bath, with the solution temperature between them ranging from 32°C to 0.5°C. [12]

ADVANTAGES:

1. It is a convenient method for volume selection of the medium.
2. A more sensitive technique .[2]

DISADVANTAGES:

1. Heavy capital cost as its design is not a standard equipment already an industry has in stock.

Applications:

1. A transdermal patch procedure.
2. A solid dosage form procedure.[13]

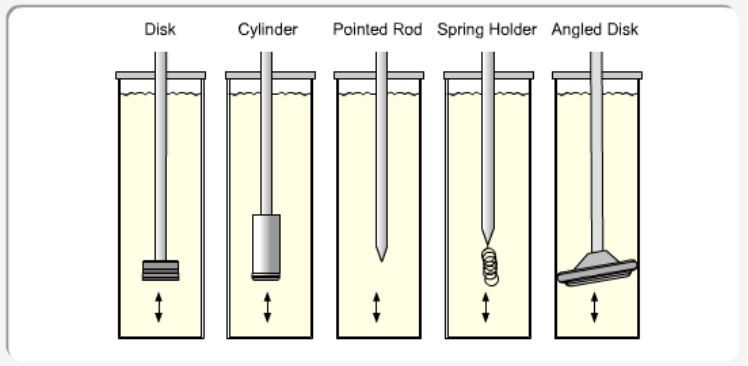

Figure No:10 Reciprocating Holder

CONCLUSION:

Dissolution testing aims to ensure the pharmaceutical stability of the product, involving not only its capacity to be developed continuously and the drug's ability to preserve its release correctly throughout the duration of its self-life, but also the dependability of the product's biopharmaceutical characteristics, including its rate and degree of absorption. Therefore, it would be ideal to create dissolving assays that can analyze a dosage form's ability of dissolving the substance adequately while also estimating the product's performance in vivo. In order to guarantee the effectiveness and quality of pharmaceutical dosage forms, the dissolution instruments utilized in the USP and Indian Pharmacopoeia (IP) is essential. By simulating in vitro settings, these devices enable the assessment of how medications release their active constituents over a period of While the types and specifications of IP and USP devices vary to meet local regulations, both are standardized to produce accurate and repeatable findings. Comprehending these approaches is crucial for the creation and quality assurance of reliable, secure, and efficient pharmaceuticals across the globe.

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