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A REVIEW ON DISSOLUTION TEST APPARATUS WITH THEIR DIFFERENT MODEL

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ABSTRACT

For orally administered non-solution dosage forms, in vitro performance test procedure such as dissolution test is performed for various purposes. It is widely used as the quality control tests for the oral solid dosage forms. The main uses of the dissolution testing include biopharmaceutical characterization of the drug product, as a tool to ensure consistent product quality and to predict in vivo drug bioavailability. Dissolution testing initially used for solid oral or orally non-solution dosage form, later on its use is widened to a variety of novel dosage forms. The research on dissolution from about 100 years ago as a field of physical chemistry. Apart from its importance in the field of pharmaceutical analysis it is also useful in pharmaceutical formulation technology and drug discovery. In this review paper we will focus on different mathematical aspects of dissolution process and different dissolution apparatuses are in use. The aim of review is detailed discussion on different types of dissolution apparatus.

KEYWORDS: Dissolution, Apparatus, Dissolution testing, Dissolution Theories, Compartment model, pharmaceutical Application.

INTRODUCTION

Dissolution in which the solid substance solubilises in a given solvent is called as “Dissolution”. Dissolution is the process by which a solid solute enters a solvent. In the pharmaceutical industry, Dissolution defined as the amount of drug that goes into solution per unit time under standardized conditions of liquid/solid interface, temperature and solvent composition. For the quality control test and for characterizing the quality of the product and also plays a major role in drug development drug dissolution testing plays important role.[1] Dissolution testing is an official test used by pharmacopeia’s for evaluating drug release of

solid and semisolid dosage forms dissolution tests were first developed to quantify the amount and extent of drug release from solid oral dosage forms including immediate/sustained release tablets and capsules.[2] More recently, dissolution has used in testing drug release of dosage forms such as, buccal and sublingual tablets, chewing gums, soft gelatine capsules, suppositories, transdermal patches, aerosols and semisolids the study of the dissolution process has been developing since the end of the 19th century by physical chemists. The aim is to have a fully functional set of USP performance tests for all kinds of dosage forms.[3] The study of the dissolution process has been developing since the end of the 19th century by physical chemists. So, most of the fundamental research in the field was not related to drugs at all, and the basic laws for the description of the dissolution process were already available when interest in drug dissolution started to rise. Despite the advances in in vitro dissolution in chemical engineering sciences, in the pharmaceutical sciences the concept was not used extensively until the early 1950s. Until then the in vivo availability of the drug was thought to be determined solely by the disintegration of the tablet, ignoring the dissolution process.[4]

The Application of dissolution test

1. The application of dissolution test can speed up the formulation development, enabling a prompt identification of potential problems in drug release.[5]
2. In vitro release testing is also a very important tool for batch to batch quality control.[6]
3. In vitro dissolution tests are important in the development and ultimately in the quality control (QC) of a solid dosage form.[7]

Based on absence or presence of sink conditions, there are three principal types of dissolution apparatus.[8]

1. Closed-compartment- non-sink conditions. e.g. App-I & II.
2. Open compartment- sink condition
3. Dialysis type system- maintenance of sink conditions would otherwise require large volume of dissolution fluid.

Theories of Dissolution

1. Diffusion layer model (Film Theory)
2. Danckwert's model
3. Interfacial Barrier Theory
4. Wagner Theory

5. Hixon-Crowel Model
6. Higuchi Model
7. Peppas Model
8. Weibull Model

1) Diffusion Layer Model / Theory

It is also known as 'Film theory'. This method is simplest and most common theory foe dissolution. Dissolution is the process of solid particles in a liquid, in the absence of reactive or chemical forces. This theory contain two steps, these are following.[21]

1. Firstly, drug enter into solution and forms a thin layer at the solid/ liquid interface called as 'stagnant film' or 'diffusion layer'. and saturated with drug. This is rapid step.

2. In this step, the diffusion of the drug from the stagnant layer into the bulk of solution or in blood. This is the slower step and it is the rate -determining step in the drug dissolution.[21]

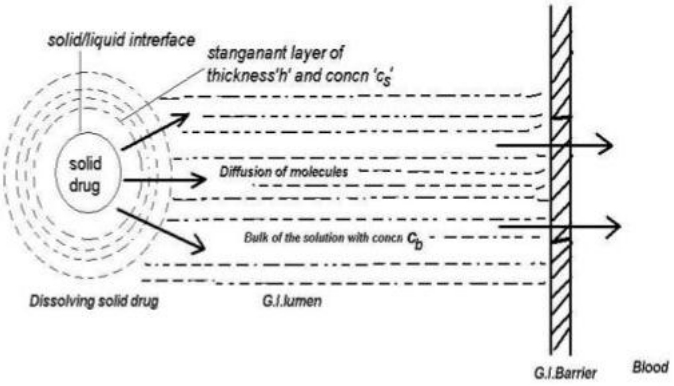

Fig. no. 1 Diffusion layer model.

The process of dissolution-controlled and involves no chemical reaction was given by 'Noyes and Whitney.' The equation is

$$\frac{dC}{dt} = k(C_s - C_b)$$

Where, dc/dt = dissolution rate of the drug

K= dissolution rate constant,

Cs= conc. of drug in the stagnant layer.

C_b = conc. Of drug in the bulk of the solution

The 'Nernst and Brunner' modified the Noyes-Whitney's equation.

$$\frac{dC}{dt} = \frac{DAK\underline{w}(c_s - c_b)}{Vh}$$

Where, D= diffusion coefficient of drug.

A= surface area of dissolving solid.

Kw/o= water/oil partition coefficient of drug.

V= volume of dissolution medium.

h= thickness of stagnant layer.

(Cs – Cb)= conc. gradient for diffusion of drug.[21]

2) Danckwert's Model

It is also known as the penetration or surface renewal theory. Danckwert's says that the stagnant layer is not present or exist, and suggest the turbulence in the dissolution medium exist at the solid/ liquid interface.

Result in agitated fluids consisting a packets reach at a solid/ liquid interface due to eddy current, absorb the solute or drug by diffusion and carry into a bulk of the solution.[21]

That solute or drug containing packets are continuously replaced by new packets of fresh solvent. The solvent packets are exposed to new solid surface each time therefore, theory is called as surface renewal theory.[21]

The Danckwert's model is represented by equation,

$$V\frac{dC}{dt} = \frac{dm}{dt} = A(C_s - C_b)\sqrt{\gamma D}$$

Where, m = mass of solid dissolved

Gamma (γ) = rate of surface renewal

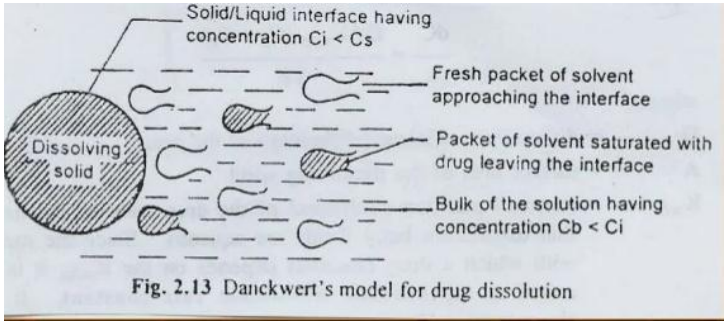

Fig. no. 2 Danckwert's model.

3) Interfacial Barrier Model

It is also known as the 'Double barrier' or Limited Solvation Theory. This model has two assumption.

1. The rate determine step control the dissolution is the mass transport.
2. Solid solution equilibrium achieved at the solid/ liquid interface

According to this model an intermediate concentration may exist at the interface as the result of solvation mechanism and is function of solubility.[21]

The equation is :-

$$G = K_i (C_s - C_b)$$

Where, G= dissolution rate per unit area.

K_i = Effective interfacial transport constant.

Dissolution research started from near about 100 years ago as a field of physical chemistry and since then important progress has been made (Table 1)

Table 1: Major contributions and events in the development of dissolution testing.[4]

year	Contributor (s)	Major contribution
1987	Noyes AN and Whitney WR	Derived the first dissolution experiments and published an article entitled "the rate of solution of solid substances in their own solutions". Noyes-Whitney equation
1900	Brunner E and von Tolloczko S	Proved that the rate of dissolution depends on the exposed surface, the rate of stirring, temperature, structure of the surface and the arrangement of the apparatus.
1904	Nernst W and Brunner E	Nernst–Brunner equation depends on the diffusion layer concept and Fick's second law.
1931	Hixson AW and Crowell JH	reaction velocity depends upon surface and agitation. Hixson and Crowell stated that the Noyes–Whitney equation in its original form and without any details about the mechanism of the process had been sufficiently validated with a wide range of experiments, as used to the various mechanistic explanations that had appeared, none of which was entirely satisfactory
1951	Edwards LJ	First to appreciate that following the oral administration of solid dosage forms, if the absorption process of drug from the gastrointestinal tract is fast, then the rate of dissolution of that drug may be the step which controls its appearance in the

		body.
1957	Nelson E	First to explicitly relate the blood levels of orally administered drugs to their in vitro dissolution rates.
1961	Higuchi T	the interfacial barrier model proposed by Wilderman in 1909 and Danckwerts model (1951).
1962	Levich VG	modified the theoretical model of the dissolution experiment using rotating disks, taking into account the centrifugal force on diffusion.
1970		The basket-stirred-flask test (USP apparatus 1) was considered as an official dissolution test in 6 monographs of the United States Pharmacopeia (USP) and National Formulary (NF).
1978		selection of the paddle method (USP apparatus 2)
1981		The first guidelines for dissolution testing of solid dosage forms were broadcast as a joint report of the Section for Official Laboratories and Medicines Control Services and the Section of Industrial Pharmacist of the FIP.
1991		selection of the reciprocating cylinder (USP apparatus 3) for extended-release products.
1995		selection of the flow-through cell in (USP apparatus 4) for extended-release products.

Table no.1

The Difference between IP and USP is follow

According to IP: According to USP

1. Apparatus -I; Paddle apparatus 1. Apparatus -I; Basket apparatus

2. Appartus -II; Basket apparatus 2. Apparatus-II; Paddle apparatus

TYPES OF DISSOLUTION APPARATUS AS PER USP

Sr.no.	Official name	RPM	Application
1	USP Apparatus 1 (Basket apparatus)	50-120 rpm	Tablets, capsules, Floating dosage forms
2	USP Apparatus 2 (paddle apparatus)	25-50 rpm	Tablets, capsules, enteric forms
3	USP Apparatus 3 (Reciprocating cylinder)	6-35 rpm	Extended- release drug product
4	USP Apparatus 4 (Flow through cell)		Implants, powders, suspensions
5	USP Apparatus 5 (Paddle over disk)	25-50 rpm	TDDS, Ointments
6	USP Apparatus 6 (cylinder apparatus)		TDDS
7	USP Apparatus 7 (Reciprocating holder)	30 rpm	Extended- release drug product

Table no.2

1. BASKET TYPE APPARATUS

Pernarowski and his co-workers discovered basket method in 1968.[9] The methods is used for evaluating dissolution first appeared in the 13th edition of the U.S. Pharmacopeia in early

1970. The principle involved is "closed-system" methods because a fixed volume of dissolution medium is used.[10] The USP basket method is used for choice for dissolution testing of immediate release oral solid dosage forms.[11]

A basket is made up of borosilicate glass or any other suitable transparent material, with a hemispherical bottom. Having capacity of 500 to 1000 ml. The basket consists of two components. The top part attached to shaft. Another is the lower part made up of welded-steam cloth.[12] The shaft should position no more than 2mm at any point from the vertical axis of the vessel.[13]

Application: 1) Used for tablets, capsule, extended- release form,
2) Used for enteric coated and floating tablets etc.

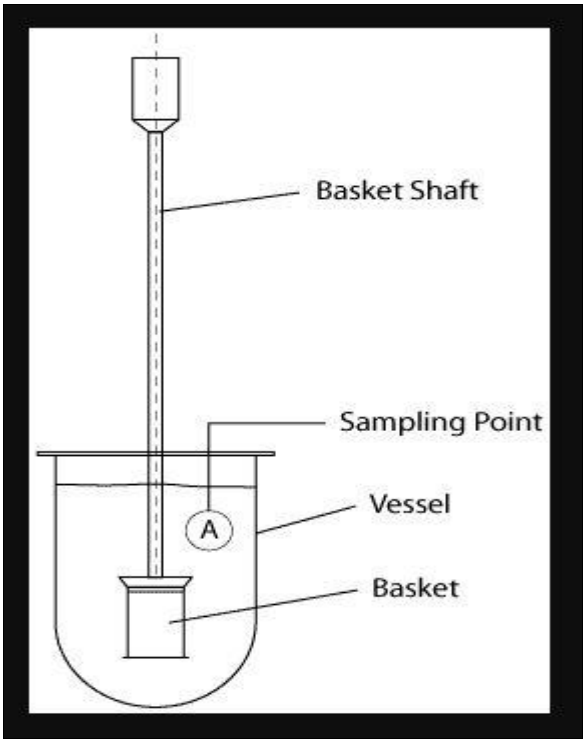

Fig. no. 3 Basket apparatus.

2. PADDLE TYPE APPARATUS

An apparatus derived by Levy and Hayes may be considered the forerunner of the beaker method.[14] A cylinder is made up of borosilicate glass or any other suitable transparent material, with a hemispherical bottom. Having capacity of 1000 ml and inner diameter of 98-106 mm.[12] In the Apparatus 2, a paddle replaces the basket as the source of agitation. As

with the basket apparatus, the shaft should position no more than 2mm at any point from the vertical axis of the vessel and rotate without significant wobble.[13]

The capacity of a 400 ml beaker and a three-blade, centrally placed polyethylene stirrer (5 cm diameter) rotated at 59 rpm in 250 ml of dissolution fluid (0.1N HCl). The sample was placed down the side of the beaker and samples were removed periodically.[13] The principle involved in this apparatus is "closed-system". Standard volume: 900/1000 ml.

Application: 1) used for tablets, capsules and suspensions.
2) used for monodisperse and polydisperse (encapsulated beads)

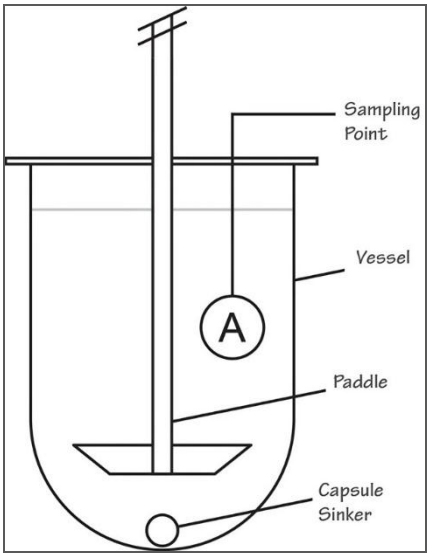

Fig. no. 4 Paddle apparatus.

3**) RECIPROCATING CYLINDER APPARATUS (USP APPARATUS 3)**

The construction of apparatus is a set of cylindrical, flat-bottomed glass vessels; a set of glass reciprocating cylinders; stainless steel fittings (type 316 or equivalent) and screens (for e.g. 20 mesh to 100 mesh) that are made of suitable non-absorbing and nonreactive material and that are designed to fit the tops and bottoms of the reciprocating cylinders and a motor and drive assembly to reciprocate the cylinders vertically inwardly the vessels.[12]

Principal involves programming the agitation rate, in rpm, of the up and down for the inner tube inside the outer tube. On the up stroke, the bottom mesh in the inner tube moves upper side to contact the product and on the down stroke the product leaves the mesh and floats freely within the inner tube. The action produced carries the product being tested through a moving medium.[15]

The working of apparatus a Reciprocating Cylinder, dips a transparent cylinder containing the dosage form at a rate determined by operator. Mesh present at base and allow the medium to drain into a sampling reservoir as the tube moves up and down, thus creating convective forces for dissolution. A second part is design is the rotating bottle apparatus, which also allow for changing of medium to simulate a pH gradient or fed and fasted conditions.[10] Allow to start automated testing for up to six days and the manufacturers advocate its use in the testing of extendedrelease dosage forms. It become official in USP 22 as Apparatus 3 and is prescribed for the testing of extended-release articles.[16]

Standard volume: 200-250 ml/station.

Temperature is 37 ± 0.5 during the test.

Application: 1) Used for extended -release form, tablet

2) Used for bead type modified release dosage form.[11]

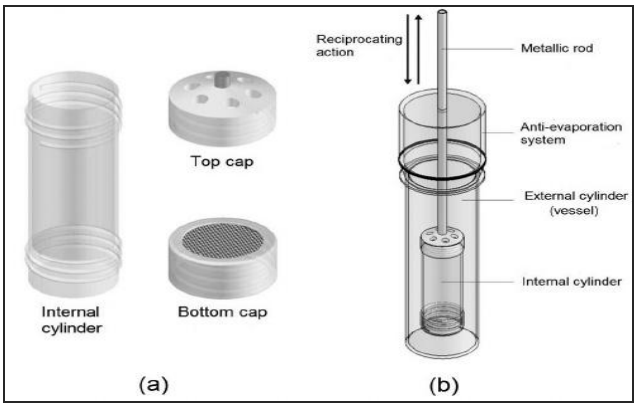

Fig no. 5 Reciprocating cylinder.

4) FLOW THROUGH CELL (APPARATUS 4)

The construction of apparatus, a reservoir and a pump for the Dissolution Medium; a flowthrough cell; a water bath that maintains the Dissolution Medium at 37 ± 0.5. The cell size is set out in the individual monograph.[12] The study on flow through is started from 1950. The first attempt of the flow-cell method was probably made in the laboratories of the U.S. Food and Drug Administration in 1957.[17]

It can operate under different conditions such as open or closed system mode, different flow rates and temperatures.

The working of apparatus, the pump forces the Dissolution Medium upwards through the flow-through cell. The pump has range between 240 and 960 per hour with standard flow

rates of 4.8 and 16 ml per minute. Put the glass beads into the cell specified in the monograph, put 1 dosage unit on top of the beads or, if specified in the monograph, on a wire carrier and then assemble the filter head, and join the parts together by means of a suitable clamping device. Introducing the pump into Dissolution Medium warmed to 37 ± 0.5 through the bottom of the cell to obtain the flow rate specified in the individual monograph. Assemble the elute by fractions at each of the times stated, Perform the analysis as conducted in the individual monograph.[12]

Application: 1) used for Low solubility drugs, Micro particulates.

2) used for Implants, Suppositories.

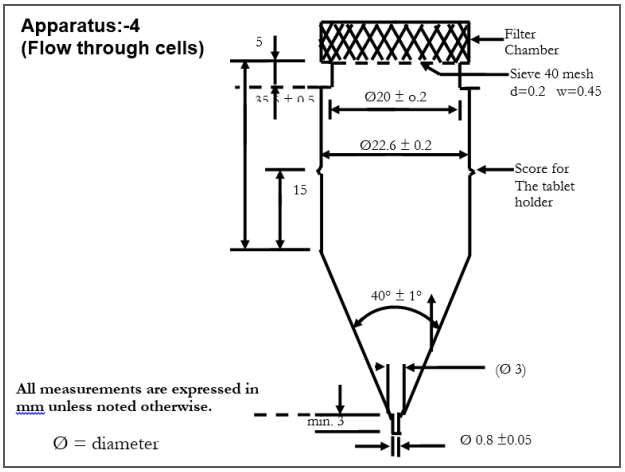

Fig no. 6 Flow through cell.

5) PADDLE-OVER-DISK (USP APPARATUS 5)

The construction is same USP apparatus 2, in addition of a stainless -steel disk assembly designed for holding the transdermal system at the bottom of the vessel. Devices used for, provided they react with, or interfere with the specimen being checked. The disk used for griping the transdermal system is used to reduce the any "dead" volume between the disk assembly and the bottom of the vessel. The disk control the system flat and in a position such that the release surface is parallel with the bottom of the paddle blade.[18]

The temperature is maintaining at 32°C ± 0.5°C.

Standard volume: 900 ml.

Application: 1) Used for transdermal patches.[6]

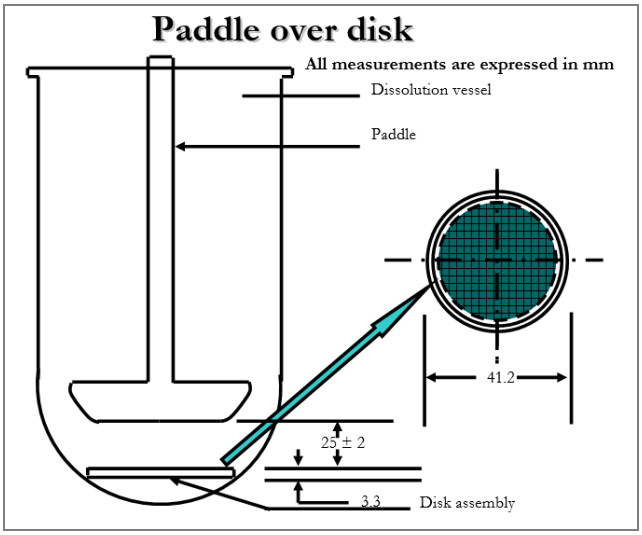

Fig. no.7 Paddle over disk apparatus.

6) CYLINDER APPARATUS (USP APPARATUS 6)

The construction is same as USP Apparatus 1except, the basket and shaft replace with a stainless- steel cylinder stirring element.[18] The working of apparatus is the sample is placed on the cylinder at the beginning of each test, to the exterior of the cylinder such that the long axis of the system fits around the circumference of the cylinder & removed trapped air bubbles. Put the cylinder in a apparatus, and immediately rotate at the rate specified in the individual monograph.

The temperature at 32 ± 0.5 during the test.

Application: 1) Used for transdermal patches.[6]

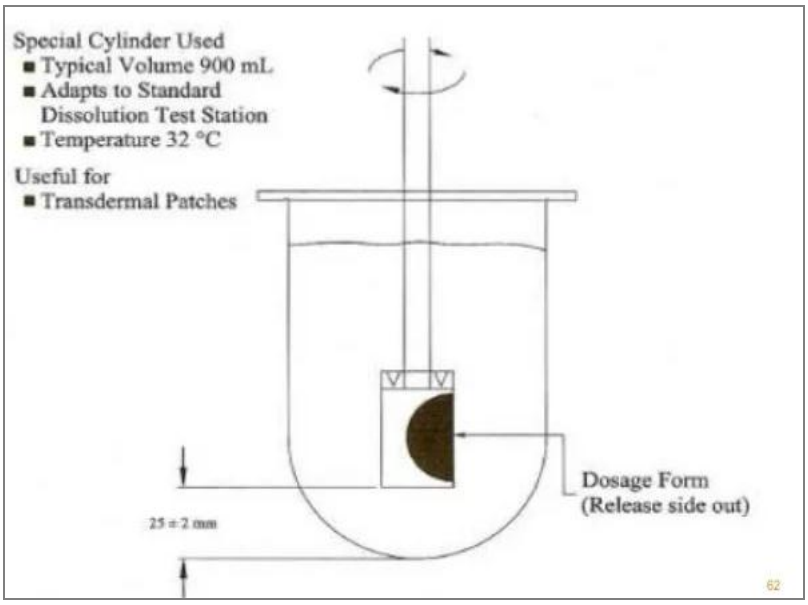

Fig.no. 8 Cylinder apparatus.

7) RECIPROCATING HOLDER APPARATUS (USP APPARATUS 7)

This apparatus is introduced by USP for small-volume option for small transdermal patches. The reciprocating disk apparatus was later renamed the reciprocating holder apparatus.[19] The construction of apparatus is a set of volumetrically calibrated sample containers made of glass or other suitable inert material, a motor and drive reciprocate to the system vertically and a set of suitable sample holders.

The working is the sample containers are partially immersed in a suitable water bath of any convenient size. For Coated tablet drug delivery system connect each system to be tested to a suitable sample holder. Temperature at 32 during test.

The temperature is maintaining at 32 ± 0.5

Standard volume is 50 to 200 ml.

Application: 1) used for transdermal patches[6]

2) used for solid dosage form

3) used for pH profile.

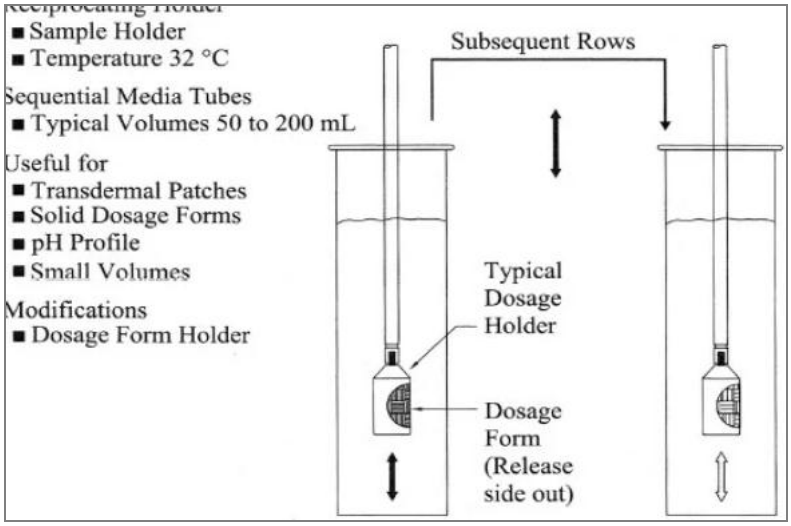

Fig. no. 9 Reciprocating holder apparatus.

Dissolution study of paracetamol

Preparation of solutions for Calibration curve:

Stock solution 1: Stock solution of sample drug (1mg/ml) is prepared by dissolving 100 mg of drug in 100 ml solution of methanol and phosphate buffer pH 6.8 in a ratio of 1:3 in 100 ml volumetric flask (to get 1000 µg/ml drug solutions) with vigorous shaking and further sonicated for about 10 minutes.

Stock solution 2: 10 ml of this (stock solution 1) is diluted to 100ml with phosphate buffer pH 6.8 to get a stock solution containing 100 µg/ml of sample drug. The stock solution was filtered by Whatmann filter paper No.41.

Dilutions: Take the respective samples (0.2ml, 0.4ml, 0.6ml, 0.8ml, 1ml, 1.2ml, 1.4ml, 1.6ml, 1.8ml, 2ml, 2.2ml, 2.4ml) in each test tube, add phosphate buffer pH 6.8 to make total volume of 10 ml to produce (2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24µg/ml) respectively.

Determination of absorption maxima: By using UV- visible spectrometer the UV absorption maximum was determined using the scanning 10 µg/ml solution of paracetamol in phosphate buffer 6.8, in between 200-400 nm. The representative spectrum was drawn of paracetamol in phosphate buffer pH 6.8.

Preparation of Calibration curve

The standard solutions for the sample drug having concentration 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 24µg/ml was prepared with phosphate buffer ph 6.8 from the stock solution. The absorbance of solutions of pure paracetamol sample drug were measured at 243 λ max and a calibration curve is plotted between absorbance v/s concentration to get the linearity and regression equation.

Phosphate buffer preparation: Phosphate buffer: Place 50ml of 0.2 M Potassium di-hydrogen phosphate in a 200ml volumetric flask. Add the specified volume of 0.2 M sodium hydroxide and add distilled water to make up the volume 200ml.

Preparation of 0.2 M Potassium di-hydrogen phosphate solution: Dissolve 27.218g of potassium di-hydrogen phosphate in sufficient distilled water containing in the 1000ml volumetric flask and make up the volume upto 1000ml. Preparation of ‘x’ M sodium hydroxide: Solution of any molarity ‘x’ Molar may be prepared by dissolving 40*x gm of sodium hydroxide in a distilled water containing in the 1000ml volumetric flask and make up to the volume 1000ml.

Dissolution study procedure

1. Turn on the heater of the dissolution device on and manage the temperature to reach 37°C.
2. Wash the vessel of dissolution apparatus using water and soap then put 900 ml of medium (phosphate buffer pH 6.8) in each.
3. make the paddle at 25±2 mm from the bottom of the vessel.

4. Work on the paddle on a rotation speed equals to 50 rpm.

5. Add one 500 mg tablet in one vessel and at once start timing.

6. After specified time intervals (5, 10, 15, 20, 25, 30, 45 and 60 min) Withdraw 1 ml using the volumetric pipette from each filtrated sample (filtrate) and put it in 10 ml volumetric flask, then complete the volume up to 10 ml by the medium (phosphate buffer at pH=6.8).

7. Take the same volume into dissolution vessel by another volumetric pipette.

8. study the absorbance of the diluted sample solutions at λ=243 nm using the buffer as a blank.

9. Draw the graph between Time intervals on x-axis vs % of drug release on y-axis.

10. Determine the slope, concentration, amount of drug release, percentage of drug release and report it.

Fig no. 10 USP apparatus 2.

UV Spectrum of Paracetamol

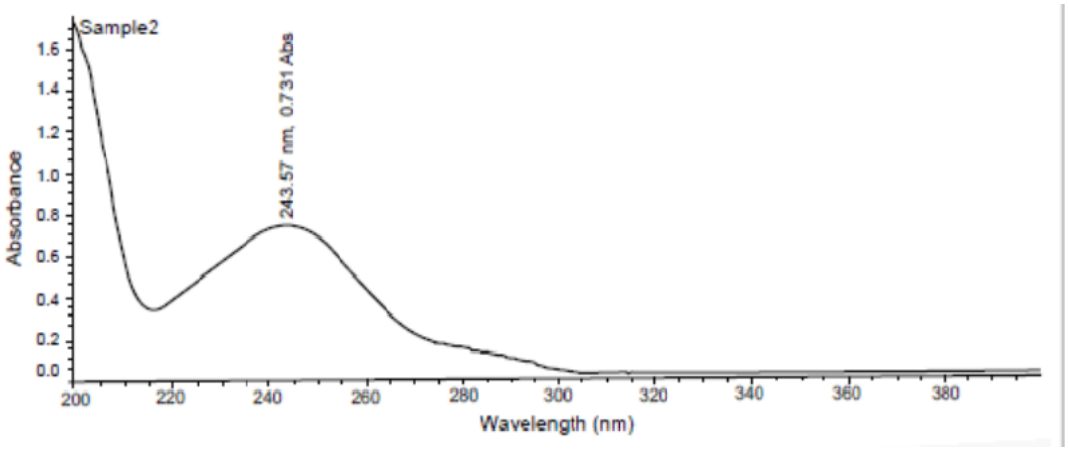

Fig no. 11 UV spectrum of paracetamol in standard solution.

Dissolution Test for Capsule

The procedure dissolution testing depends upon the product of formulation. The solubility of active ingredient (s) and the dispersion fill into the dissolution media by the given formula. For example in formulation a lipid-soluble active ingredient with hydrophobic excipients and a melting point in excess of 37° will likely not release the active ingredient into solution in aqueous media in a specified period that is consistent with the expectations for immediate-release dosage forms. A freely water-miscible active ingredient dissolved or dispersed in a water-soluble or water-dispersible put formula at room temperature will be released into solution very soon after the shell ruptures and the dosage form releases the put material into the media. Soft gelatine capsules can be made up of either hydrophilic or hydrophobic components. In the case of hydrophilic capsules dissolution tests can be performed quite easily using USP apparatus 2 but this becomes more difficult for hydrophobic medication. It is speculated that exposure of the gelatine shell to such media may induce physical or chemical changes of the drug, arising either through complex formation or crosslinking reactions.

When the lipid phase reaches the triangular area top of the left side cell, it stays there, the dissolution medium continuously extracts the drug from the lipid layer like as flows through the cell. The dissolved drug sample determined using a conventional fraction collector and be analyzed in the medium. The results of their study showed that, after 6 hrs of dissolution, most of the viscous oily vehicle still remained entrapped within the basket, so failure to release drug into the aqueous phase. It appears that the standard dissolution basket pores (40 meshes) and due to lack of appropriate hydrodynamic conditions within the basket had a significant limiting effect on drug release from the oleaginous formulation. The study proved that the most reproducible results can be obtained when the paddle is positioned in aqueous medium.[20]

CONCLUSION

The study on dissolution started to develop in 1897 when Noyes and Whitney derived their equation in the course of their dissolution studies on benzoic acid and lead chloride. Dissolution in which the solid substance solubilises in a given solvent is called as “Dissolution”. For the quality control test and for characterizing the quality of the product and also plays a major role in drug development drug dissolution testing plays important role. Dissolution has used in testing drug release of dosage forms such as, buccal and sublingual

tablets, chewing gums, soft gelatine capsules, suppositories, transdermal patches, aerosols and semisolids the study of the dissolution process has been developing from the end of the 19th century by physical chemists. As per the USP there are seven types of apparatus as follow, 1) Basket apparatus, 2) Paddle apparatus, 3) Reciprocating cylinder apparatus. 4) Flow through cell apparatus, 5) Paddle over disk apparatus, 6) Cylinder apparatus, 7) Reciprocating holder apparatus. The difference between IP & USP is change in first apparatus in USP first apparatus is basket and in IP first apparatus is paddle apparatus.

On the basis of presence or absence sink condition, there are three type of principal. 1) close compartment, 2) open compartment 3) Dialysis type system. There are so many theory available for study of dissolution such as film theory, Danckwert's model, interfacial barrier model, Peppas model, etc.

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