Dissolution - A Quality Parameter for Testing of Pharmaceutical Dosage Form

Kusum Rajbhar[1]*, Yogita Jain[1], Varsha Barethiya[1], Shanu Sahu[1], Dr. Mrs. Gouri R. Dixit[2]
[1] Research scholar- Department of Pharmaceutics, Priyadarshini J.L. College of Pharmacy, Nagpur, India.
[2] Assistant Professor- Department of Pharmaceutics, Priyadarshini J.L. College of Pharmacy, Electronic zone building, Nagpur, Maharashtra, India.
*Corresponding author's E-mail: kusumrajbhar02@gmail.com

ABSTRACT

In the pharmaceutical industry, dissolution study is one of the vital tests for the evaluation of the pharmaceutical dosage form. Dissolution test is the most important tool for the testing of drug release profile of solid dosage form in the pharmaceutical preparation. Dissolution studies provide the knowledge about the efficacy of the dosage form. Dissolution tests are major for performing a various kind of investigations like drug degradation profiles, stability and shelf life studies, chemical stability and so on. Dissolution test can be easily performed in both the small and large scale with the proper techniques and it is also used for the comparison between the graph profile of the similar and different dosage form. Hence, it can be considered as the most qualitative and convenient test for the evaluation of the pharmaceutical solid dosage form.

Keywords: Dissolution, similarity factor, biopharmaceutical class, validation.

INTRODUCTION

Dissolution testing is a basic tool which is broadly used in the development of another pharmaceutical product. The test, in its most direct structure, consists of placing the formulation in a dissolution apparatus containing reasonable dissolution medium, allowing it to dissolve over a specified period of time and then assaying the resultant solution using appropriate analytical method to determine the measure of medication. Dissolution tests are significant for a variety of investigations like medication degradation profiles, stability and shelf life studies, physical and mechanical testing of dosage forms, upcoming QC testing on raw materials etc.

In-vitro dissolution testing serves as a significant tool for characterizing the biopharmaceutical quality of a product for additional turn of events and for evaluation of active ingredients/drug substances. In-vitro dissolution data are supportive in the evaluation and interpretation of potential risks, mainly in the case of controlled/modified-release dosage forms - for example as regards dose dumping, food impacts on bioavailability or interaction with other medications, which impact gastrointestinal environmental conditions. Biopharmaceutical aspects are as significant for stability concerns as they are for batch release after production, in-vitro dissolution being of high relevance in quality control and quality assurance. Last but not least, in-vitro dissolution information will be vital when assessing changes in production site, manufacturing procedure or formulation and assist in decisions concerning the requirement for bioavailability studies.

None of these purposes can be satisfied by an in-vitro test system without sufficient reliability. Reliability here would be characterized as the system being experimentally sound, yielding precise, accurate, repeatable outcomes and with adequate information on the in-vivo significance of the dissolution data obtained. Prerequisites for dissolution testing have been assessed in the literature. Since in-vitro dissolution is a physical test, characterized by convention and is of a destructive nature, proving reliability requires exceptional consideration. It therefore is within the scope of these Guidelines to characterize appropriate testing equipment and experimental design as well as to suggest the background for adequate physical and analytical validation, along with verification procedures according to the state of biopharmaceutical science. The Guidelines are primarily devoted to solid oral products. However, the general ideas may be adapted to in-vitro dissolution analysis of drug materials/powders, semisolid oral products, suppositories and, with distinctive limitations, to other non-oral products. [1-3]

History

The study of the dissolution procedure has been established since the end of the 19th century by physical chemists. Therefore, most of the important research in the field was not related to medications at all, and the basic laws for the depiction of the dissolution procedure were already available when interest in drug dissolution started to increase. In spite of the advances in vitro dissolution in chemical engineering sciences, in the pharmaceutical sciences the idea was not utilized broadly until the early 1950s. Until then the in vivo availability of the drug was thought to be determined exclusively by the disintegration of the tablet. For orally administered non-solution dosage forms, in vitro performance test procedures such as dissolution and disintegration are

used to i) guide drug development and select formulations for further in vivo studies, ii) evaluate comparability between products before and after changes in formulation and manufacturing; iii) serve as a surrogate for in vivo bioequivalence studies, with suitable in vitro/in vivo correlations and/or use of the Biopharmaceutics Classification System approach, and iv) ensure batch-to-batch uniformity for product performance. In pharmaceutical industry, in vitro dissolution test is achieved prompt in order to validate primary screening among probable formulations to detect the impact of critical manufacturing variables and to help in the choice of the candidate formulation. The use of dissolution test can speed up the formulation development, assisting a rapid identification of possible difficulties in drug release. In vitro release testing is also a very significant tool for batch to batch quality control. In vitro dissolution tests are significant in the development and eventually in the quality control (QC) of a solid dosage form. A dissolution test measures the rate of release of the medication. [3]

Dissolution

Dissolution is defined as the procedure by which a solid solute reaches the solution. In the pharmaceutical industry, it is defined as the amount of the drug substance that goes into solution per unit time under standardized circumstances of liquid/solid interface, temperature and dissolvable composition. Simply, it is amount of the drug get releases and distributed evenly to the site of action and providing the pharmacological effect of the drug. It works on the following principle:

Principle

1. Drug dissolution testing plays an important role as a routine quality control test, for characterizing the quality of the product and also plays a major role in drug development.

2. Dissolution testing is an approved test utilized by pharmacopeia's for assessing drug release of solid and semisolid dosage forms dissolution tests were first established to measure the amount and extent of drug release from solid oral dosage forms comprising immediate/sustained release tablets and capsules.

3. More recently, dissolution has become important in testing drug release of dosage forms, for example, buccal and sublingual tablets, chewing gums, soft gelatine capsules, suppositories, transdermal patches, aerosols and semisolids the investigation of the dissolution procedure has been evolving since the end of the 19th century by physical chemists.

4. The goal is to have a fully functional set of USP performance tests for all kinds of dosage forms. [4]

Different mathematical aspects of dissolution theory:

$$\frac{d_m}{d_t} = AD\frac{C_S - C}{h}$$

Where C is the prompt concentration of drug in the medium, A is the surface area accessible for dissolution, D is the diffusion coefficient of the molecule, Cs is its dissolvability in the dissolution medium and h is the thickness of the diffusion boundary layer adjacent the outside of the dissolving compound. From this simple mass balance equation one can assume that to improve the dissolution rate dm/dt it is possible to expand the total drug surface area A by micronization as well as by advance its wetting qualities, to advance perfect sink conditions (C→0), to lower the thickness of the boundary layer or by expanding the apparent drug solubility Cs. The parameter D is a factor of the diffusion coefficient of the solute molecules. Maximum dissolution rates are anticipated when C=0. Therefore, as C increase, the dissolution rate decreases. The parameter D is also dependent on Cs-C. Such conditions, where dissolution is followed by absorption of the drug, as in the in vivo condition, are described as sink condition.

Dissolution of mono-dispersed powder

Dissolution processes of multiparticulate systems where the particular surface area reduces during the dissolution, might be depicted by the Hixson and crowell cube root equation

$$W_o^{1/3} - W^{1/3} = Kt$$

W = the original mass of drug, W = amount of remaining drug at time t, and K = dissolution rate constant.

Dissolution of disintegrating tablets and capsules

Disintegration produces vast changes in surface area. Accordingly, the improvement of theories of dissolution from disintegrating down tablets and capsules becomes very difficult. Attempts have been made to develop models to describe dissolution rate from tablets using complex mathematical approaches.

Dissolution of non-disintegrating tablets

For systems where drug release includes the dissolution of a dissolvable drug at high concentrations from an insoluble matrix, the higuchi equation describes release rates
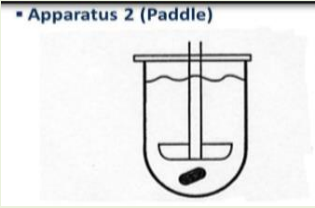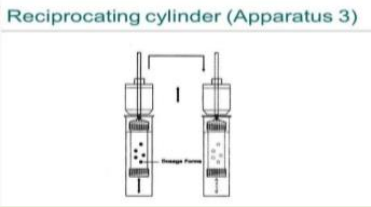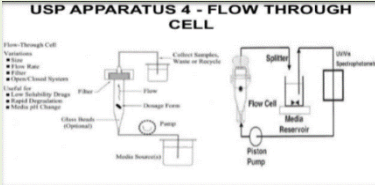
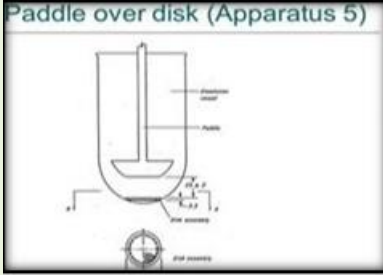$$\frac{W_r}{t_{1/2}} = 2W_0\frac{S}{V}(D/\pi\tau)^{1/2}$$

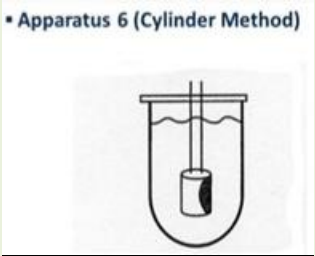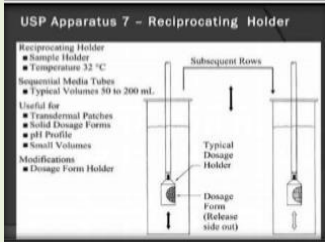Where, Wr = amount of drug dissolved in time t, W = dose of the drug, S = effective diffusional area, V = volume of the hydrated matrix, D = diffusion coefficient of the drug, τ = tortuosity of the matrix. [3]

Dissolution Apparatus Types [4-5]

There are various types of dissolution apparatus which are classified as per USP, IP or BP, so let us check it out all its types and their classification.

Table 1: Types of dissolution apparatus as per USP official.

Sr.no.	Dissolution apparatus types	Description	Diagram
I	Basket Type	Useful for: Capsules, Beads, Delayed release / Enteric Coated dosage forms, Floating dosage forms Standard volume: 900/1000 ml	
II	Paddle Type	Useful for: Tablets, Capsules, Beads, Delayed release, enteric coated dosage forms Standard volume: 900/1000 ml.	 **Figure 1:** Paddle
III	Reciprocating Cylinder	Useful for: Tablets, Beads, controlled release formulations. Standard volume: 200-250 ml/station.	 **Figure 2:** Reciprocating Cylinder
IV	Flow Through Cell	Useful for: Low solubility drugs, Micro particulates, Implants, Suppositories, Controlled release formulations Variations: (A) Open system & (B) Closed system	 **Figure 3:** Flow through Cell (USP)
V	Paddle Over Disc	Useful for: Transdermal patches Standard volume: 900 ml	 **Figure 4:** Paddle over Disk
VI	Rotating Cylinder	Use the vessel assembly from Apparatus 1 except to replace the basket and shaft with a stainless-steel cylinder stirring element and to maintain the temperature at 32 ± 0.5 during the test. Place the cylinder in the apparatus, and immediately rotate at the rate specified in the individual monograph.	 **Figure 5:** Cylinder Method
VII	Reciprocating Disc	The assembly consists of a set of volumetrically calibrated solution containers made of glass or other suitable inert material, a motor and drive assembly to reciprocate the system vertically and a set of suitable sample holders. The solution containers are partially immersed in a suitable water bath of any convenient size that permits maintaining the temperature, inside the containers at 32 ± 0.5.	 **Figure 6:** Reciprocating Holder

Table 2: Types of Dissolution apparatus as per IP, BP, USP Dissolution Apparatus (Non-Official).

Sr.no.	USP Dissolution Apparatus (Non-Official)	IP Dissolution Apparatus	BP Dissolution apparatus
1	Rotating Bottle Method	Paddle Type	Basket Type Apparatus
2	Diffusion Cell	Basket Type	Paddle Type Apparatus
3	Peristalsis Cell		Flow Through Cell
4	Intrinsic Dissolution Method		

Validated Method

The idea of validation was first proposed by two Food and Drug Administration (FDA) authorities, Ted Byers and Bud Loftus, in the mid 1970's so as to improve the nature of pharmaceuticals. The first validation exercises were focused on the procedures engaged with making these products, yet immediately spread to related procedures including environmental control, media fill and equipment sanitization and purified water production.

In a guideline, validation is demonstration of showing and documenting that any methodology, procedure, and action will reliably lead to the expected results. It contains the requirement of systems and equipment.The objective of the validation is to guarantee that quality is incorporated with the system at each progression, and not simply tried for toward the end, as such validation activities will generally include preparing for making material and operating procedures, training of individuals included and monitoring of the system whereas in production. In general, a whole process is validated and a specific object inside that process is confirmed. The guidelines also set out a desire that the various pieces of the production process are very much characterized and controlled, to such an extent that the results of that production won't significantly change over time. [6]
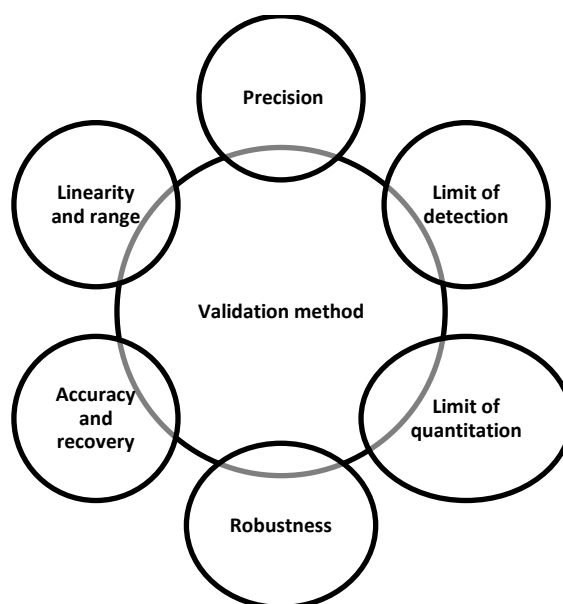
Validation is done to ensure that method or procedure achieves its intended purpose (USP 32-NF 27, 2009; ICH

rule, 2005). Dissolution testing fits into USP classification III, which are analytical procedures for the assurance of performance attributes. Since dissolution is a quantitative test, the entirety of the analytical performance attributes applies, except for the limit of detection.

Linearity and Range

Linearity is the capacity (inside a predefined range) to acquire test results which are related to the concentration of analyte in the example. The perspectives for linearity are testing over the range (at least 5 concentrations), to assess linearity by visual investigation of the plot and by statistical techniques; to calculate correlation coefficient, y-intercept and slope.

Range is characterized as a stretch among upper and lower concentration of the analyte in the example for which it has been exhibited that the method has a reasonable degree of precision, accuracy and linearity. Range can be characterized from linearity study and it relies upon the use of the technique for assay, dissolution test and content uniformity. Linearity and range are set up by getting ready arrangements of the drug, ranging in concentration from below the lowest probable concentration to above the highest concentration during not to surpass the linearity limits of the instrument. ICH recommends that for dissolution testing, linearity should be proved as ± 20% over the range of the dissolution test.

Figure 7: Method of validation

Accuracy and Recovery

Accuracy expresses the closeness of understanding between the qualities which are acknowledged either as a regular genuine value or an acknowledged reference value and the value found practically. Accuracy is estimated by (1) Use of reference standard with known purity and (2) Comparison with autonomous, well-characterized procedure. Accuracy and recuperation can be well-known by getting ready samples containing the drug and some other constituents present in the dosage form ranging in concentration from below the lowest expected concentration to above the maximum concentration during release. ICH suggests at least nine determinations over at least concentration, for example three concentrations, three imitates each. The measured recovery is ordinarily 95% to 105% of the sum included.

Precision

It is characterized as a closeness of agreement ('scatter') between a series of quantities acquired from various sampling of the same homogeneous example. The parts for precision are (1) Repeatability, (2) Intermediate precision and (3) Reproducibility. [7]

Precision – Repeatability

Repeatability communicates the Precision under the equivalent operating conditions over a short time period. Repeatability is additionally named intra- assay precision Repeatability is at time also termed within-run or within-day Precision.

Precision - Intermediate

Precision Intermediate precision expresses inside laboratories: variations days, various days, distinctive equipment and so on. The ISO definition utilized the expression "M-factor different intermediate precision", where the M-factor states the number of factors (administrator, equipment or time) that contrast between progressive determinations. Precision- Intermediate is now and again additionally called between-run, between-day or inter-assay precision.

Precision – Reproducibility

Reproducibility states the precision between laboratories (collaborative studies, generally applied to standardization of system). Reproducibility just must be studied, if a method should be used in various laboratories. Lamentably, a few authors likewise utilized the term reproducibility for inside laboratory studies at the degree of intermediate precision. This should, however, be avoided in order to prevent confusion. For dissolution method validation reason, precision is estimated more than two levels, repeatability and intermediate precision.

Repeatability refers to the use of the procedure inside one laboratory over a brief timeframe by one analyst utilizing one instrument.

Repeatability is dictated by duplicate measurements of standard or potentially sample solution. It tends to be measured by calculating the RSD of the numerous HPLC injections or spectrophotometer readings for every standard solution. Repeatability can likewise be measured from similar samples utilized in the accuracy, recovery and linearity experiments. Intermediate precision is assessed to determine the impacts of random events on the precision of the analytical procedure. This assessment is typically done later in the improvement of the drug product.

Limit of Detection

It is characterized as a most minimal measure of an analyte in a sample which can be identified but not really quantitated. Detection method like visual estimation, signal-to-noise ratio (3:1) and standard deviation (SD) of response and slope (DL=3.3xSD/S).

Limit of Quantitation

It is characterized as a most minimal measure of an analyte in a sample which can be quantitatively determined with a reasonable precision and accuracy. Quantitation methods like visual assessment, signal to-noise ratio (10:1) and standard deviation (SD) of response and slope (DL=10xSD/S).

Robustness

The robustness of an analytical process is the proportion of its ability to stay unaffected by small conscious variations in parameters internal to the procedure (USP 32-NF 27, 2009; ICH guideline, 2005). For dissolution testing, boundary to be varied incorporates medium composition, pH, volume, agitation rate and temperature. These boundaries would be examined in addition to those commonly assessed during validation of assay method, either spectrophotometric or HPLC.

System Suitability Test

The test requires a set of parameters and criteria thereof to ensure the system is working properly. It depends on type of test. For chromatographic techniques: tailing factor, relative retention times, resolution factor, relative standard deviation and number of theoretical plates should be calculated. The number of theoretical plates to be tested before start of run and to be verified afterwards. The suitable test is also described in Pharmacopoeias. [8-9]

Dissolution Development Guide

Each significant parameter of a dissolution test is separated into individual section to permit simple identification. The procedure itself was made around wellbeing authority guidances or guidelines. This guide presents parts of dissolution method advancement for at last making a method suitable to regulatory agencies.

Critical dissolution parameters							
Solubility	Apparatus	Spindle speed	Media and buffers	Medium volume	Sampling time points	Sinkers	Filtration and endpoint analysis

Figure 8: Critical dissolution parameters

Solubility Based on BCS

The most significant data collection for dissolution method advancement is the solubility-pH profile. The solubility profile will show whether the compound is considered as a greatly soluble compound dependent on the BCS. If the most elevated proposed strength dosage dissolves in 250 mL of media over the pH range 1–6.8 as indicated by the EMA guidance or pH 1–7.5 as per the United States FDA guidance, at that point it is considered as a highly soluble compound. In the event that the compound is highly soluble, dissolution profiles ought to be established utilizing 900 mL of 0.1 N HCL, pH 4.5, and pH 6.8 media, with commonly USP Apparatus 2 (paddles) at 50 rpm. The medium that produces the slowest dissolution rate with a standard spindle speed ought to be chosen for the method. A more slow dissolution rate will improve the probability that the method may have the option to discriminate formulation composition, producing process varieties, or pharmacokinetics execution. If the compound has low solubility over the pH range, at that point the initial objective is to develop a dissolution method that dissolves down in any event 85% by 30–60 min.

Apparatus

For rapid release solid oral dosage forms, USP Apparatus 1 (Basket) or Apparatus 2 (paddle) are ordinarily utilized. The other USP dissolution apparatus are ordinarily utilized for controlled release or non-oral preparations. The paddle apparatus ought to be picked if the foreseen commercial dosage form will be a non- floating dosage form, except if there are uncontrollable conditions. The expected issue with baskets for breaking down formulations is that the hydrodynamic condition below a basket is not too mixed as that of the paddle, which may lead to a more challenging interpretation of the dissolution data.

Spindle Speed

With the paddle apparatus, a 50-rpm spindle speed ought to be utilized as the initial stage dependent on regulatory directions from FDA, the European Medicines Agency (EMA), and the Japanese Pharmaceutical and Food Safety Bureau (PFSB). If there are issues with coning (the piling of non-dissolving excipients under the paddle that limits media penetration into the pile), the use of paddles with a 75-rpm spindle speed should be investigated. The FDA & PFSB recommend a 75-rpm paddle as an option. The increased paddle speed may disperse excipients better, mimicking in vivo dispersion, and allow unhampered dissolution. A 100-rpm paddle technique might be utilized with adequate support, for example, taking out or reducing surfactant concentration. With the basket apparatus, a shaft speed of 100 rpm ought to be examined at first. A good diagnostic tool for advancement is an "infinity spin" added to the furthest limit of a dissolution method to attempt to persuasively break apart granules and dissolve any undissolved active pharmaceutical ingredient (API). After the last ordinary sampling time point, the shaft speed is expanded to 150–250 rpm for 15–30 min, and an extra example is taken. This can give a speedy check on dosage form strength and guarantee that the dissolution is not solubility restricted or that a low dissolution is not because of low potency. Any way for batch release testing, the additional estimation of an infinity spin is restricted.

Media and Buffers

Dissolution testing with biorelevant media might be valuable for internal decision-making purposes during formulation advancement; be that as it may, the QC test could utilize a totally discrete test method. Biorelevant media are intended to imitate the complexity of human GI tract solutions and are much of the time utilized during improvement to well understand a compound's potential in vivo solubility and stability and for formulation screening. USP characterizes sink condition as "the volume of medium at any rate three times that required so as to form a saturated solution of drug substance." The solubility versus-pH profile offers the greatest helpful data in medium selection for primary assessment. The general pH range of dissolution media is from 1.1 - 6.8. The pH can be higher if necessary, for solubility reasons. In general, the pH ought not surpass 8.0. A medium is chosen based on the desired pH, for example, hydrochloric acid for pH 1.0–3.0, glycine for pH 2.0–3.0, citrate for pH 2.5–3.5, acetate for pH 4.0–5.5, and phosphate pH 6.0–8.0. These expressed buffer pH ranges are in no limits. A distinctive dissolution buffer has a 0.05 molar concentration. Unbuffered water is not an ideal medium because of potential variability in pH relying upon the source.

Medium Volume

The standard dissolution medium volumes used in the industry and acknowledged by regulatory activities are 500 mL and 900 mL. These volumes are chosen to give sink conditions to the compound and don't express the volumes of liquid experienced by the product in vivo. In depth reviews of the human gastrointestinal physiology are documented by McConnell and Mudie. Smaller dissolution medium volumes can be utilized during advancement to decrease API flexibly necessities, and

larger volumes up to 4 L might be utilized whenever required for sink–solubility reasons. In either case, an appropriate apparatus is required. Also, utilization of a similar method across dosage strengths qualities may give chances to bracket-testing of just the high and low strengths in specific conditions.

Sampling Time Points

During improvement of IR products, sample time points usually range from 5 min to in excess of 60 min. The 5-min time point might be utilized for suspensions or other fast dissolving formulations where the variety isn't high. Normal time points are 15, 30, 45, and 60 min. However, the time points are based on the product's profile and on the method's ability of tracking main aspects of the formulation. If there is a desire to better understand or track the disintegration effect, a 5- or 10-min time point would be needed. (For fast-dissolving products, a fiberoptic dissolution system could check additional time points to get a better characterized dissolution profile). If there is a critical risk of easing back on stability, a period point might be added past 60 min to guarantee that at least 85% dissolved average values are accomplished. It is helpful to make some sampling time point at 15 min, particularly if the compound is dissolved at any rate 85% within that timeframe. If this is accomplished in 0.1 N HCL, the FDA thinks about that the dosage "acts like a solution and for the most part ought not have any bioavailability problems". It is additionally the predefined time point and determination for a potential BCS 3 biowaiver. At long last, in comparing degeneration profiles, a f_2 computation, which is a logarithmic change of the sum squared error changes between the dissolution curves, isn't required for similarity justification within any event 85% dissolved or more prominent than 85% dissolved in 15 min.

Sinkers

As mentioned previously, sinkers can be utilized on capsules to allow use of the USP 2 Apparatus. Sinkers may also aid in other conditions, such as sticky tablets or slowly disintegrating tablets. Tablets sticking to vessels may result in high variability in dissolution profiles because they may stick at various off-centre locations in the vessels. The non-cantered tablets are exposed to a different hydrodynamic environment than those that are centered. Slowly disintegrating tablets may need fluid flowing around the tablets to produce more consistent dissolution profiles. Placing the dosage forms in sinkers may resolve these concerns, allowing the use of the paddle apparatus. Various sinker configurations and models should be tested to find one that gives the desired results. Finally, the sinker arrangement or model ought to be specified in the method because of the potential impacts that distinctive sinker models may have on the hydrodynamics surrounding the dosage form.

Filtration and Endpoint Analysis

Filtration of dissolution samples should wipe out post-sampling dissolution of API particles and decrease the potential that excipient particles may make backpressure/stopping up issues in the analytical instrumentation. Typical filter pore sizes go from 0.45 to 70 μm. For micronized drug substance, the analyst ought to endeavor to use the filter with the smallest possible pore size. The analytical technique will rely upon the dosage form, measure of compound, and compound UV absorptivity. UV analyst utilizing a fiber-optic or online instrument is the most effective technique accessible for dissolution sample analysis, when appropriate. Likewise, online UV or fiber-optic analysis will give the dissolution results toward the finish of the dissolution test for quick turnaround time. A deviation of ±0.05 pH units ought to have no huge effect on the dissolution rate. If there is, a different pH should be chosen for robustness reasons. [10]

Statistical Considerations

In 1996, Moore and Flanner proposed two indices, or fit factors, to compare dissolution profiles in a pairwise fashion. These indices are known as the difference factor (f_1) and the similarity factor (f_2).

Dissolution efficiency (D.E.), the region under a dissolution curve among described time points, as well as the fit factors (f_1 and f_2) have been studied for the depiction of dissolution profiles, utilizing information from three sets of a product in nine distinct packs put away under two conditions. The factors f_1 and f_2 offer ease of calculation and a simple measure of similarity between pairs of dissolution profiles.To accurately compare two profiles using these fit factors, the dissolution results should be obtained at a sufficient number of time points to adequately characterize the shape of the dissolution profiles. Because the mean dissolution profiles are compared using these fit factors, the variability associated with the dissolution results of the individual dosage forms at each time point must also meet certain regulatory criteria.

Difference factor

The f_1 factor calculates the percent difference between the two dissolution profiles at each time point and is a measurement of the relative error between the two profiles:

$$f_1 = \left\{ \frac{\left\{ \sum_{t=1}^{n} |R_t - T_t| \right\}}{\sum_{t=1}^{n} R_t} \right\} \times 100$$

where n is the number of time points, R_t is the mean dissolution value for the reference product at time t, and T_t is the mean dissolution value for the test product at that same time point. The f_1 value is equivalent to zero when the test and reference profiles are indistinguishable and increments as the two profiles become less comparative.

Similarity factor

The similarity factor (*f*₂) is a logarithmic reciprocal square root change of the sum of squared error and is an estimation of the similarity in the percent (%) dissolution between the two curves. It can be defined as a measurement of the similarity in the percent dissolution between the two profiles:

Marketed Available Dissolution Apparatus

Figure 9: Electronics India Elec_1918 Microprocessor Dissolution Test Apparatus, 8 Station Model by Electronics India

Figure 10: Tablet Dissolution Apparatus Model- Sigma 135

Figure 11: Rectangular Prolab India Tablet Dissolution Test Apparatus, Capacity: 8 Channel, Model Name/Number: Disso 8000 & Disso 6000

Figure 12: Biobase Bk-RC8 Dissolution Test

$$f2 = 50 \times \log \left[\left\{ 1 + \frac{1}{n} \sum_{r=1}^{n} wt(Rt - Tt) \right\}^{-0.5} \times 100 \right]$$

The *f*₂ value is equal to 100 when the test and reference profiles are identical and exponentially decreases as the two profiles become less similar. [11]

Figure 13: Microcontroller based dissolution test optical dissolution apparatus model: vda-8d

Figure 14: [Tianjin] RC-3 intelligent optical dissolution tester tablet capsule pharmaceutical RC-3D

Figure 15: RC-6 Tablet Dissolution Test Apparatus Tester

Figure 16: Tablet Dissolution Tester Model TrustE-8 Basic

CONCLUSION

For knowing the drug release profile of the pharmaceutical dosage form specially of the solid dosage forms such as tablets, films, transdermal patches, solid dispersions, co-crystals and etc., dissolution test study plays an important role. Over the other evaluation tests, it provides an accurate and précised result of the formulated preparations. Validations of the dissolution test are performed by performing the test multiple times to get an accurate result of the optimized batch. In the market, several types of the dissolution apparatus are available fulfilling the requirement for the particular dosage form. A dissolution study provides the details about the drug release kinetics, stability of the product and its shelf life. A similarity and difference factor helps to compare the release profile of the products at the multiple points and helps to select the best one. Hence, it was concluded dissolution studies is the significant tool of the pharmaceutical industry required for the evaluation of the solid dosage form providing the qualitative results.

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