REVIEW ON DISSOLUTION TESTING FOR PHARMACEUTICAL DOSAGE FORMS

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Abstract

In-vitro dissolution testing serves as an important tool for characterizing the biopharmaceutical quality of a product at different stages in its life cycle. In-vitro dissolution data are supported in the evaluation and interpretation of possible risks especially in the case controlled/modified-release dosage forms. Bio-pharmaceutical aspects are as important for stability concerns as they are for batch release after production, in-vitro dissolution being of high relevance in quality control and quality assurance. Present study was primarily dedicated to solid oral products. However, the general concepts may be adapted to in vitro dissolution testing of drug substances/powders, semi-solid oral products, suppositories and, with distinct restrictions, to other non-oral products.

Key words: Dissolution, Types of dissolution Apparatus, Modified release, Quality Assurance.

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INTRODUCTION

Tablets or capsules taken orally remain one of the most effective means of treatment available. The effectiveness of such dosage forms relies on the drug dissolving in the fluids of the gastrointestinal tract prior to absorption into the systemic circulation. The rate of dissolution of the tablet or capsule is therefore crucial. One of the problems facing the pharmaceutical industry is to optimise the amount of drug available to the body, i.e. its bioavailability. Inadequacies in bioavailability can mean that the treatment is ineffective and at worst potentially dangerous (toxic overdose). Drug release in the human body can be measured in-vivo by measuring the plasma or urine concentrations in the subject concerned. However, there are certain obvious impracticalities involved in employing such techniques on a routine basis. These difficulties have led to the introduction of official in-vitro tests which are now rigorously and comprehensively defined in the respective Pharmacopoeia. Tablet Dissolution is a standardised method for measuring the rate of drug release from a dosage form. The principle function of the dissolution test may be summarised as follows: [1]

a) Optimisation of therapeutic effectiveness during product development and stability assessment.

b) Routine assessment of production quality to ensure uniformity between production lots.

c) Assessment of ‘bioequivalence’, that is to say, production of the same biological availability from discrete batches of products from one or different manufacturers.

d) Prediction of in-vivo availability, i.e. bioavailability (where applicable).

Although initially developed for oral dosage forms, the role of the dissolution test has now been extended to drug release studies on various other forms such as topical and transdermal systems and suppositories.

Figure: 1. Dissolution Apparatus
DISSOLUTION TESTING

1. Concepts of Dissolution Testing:

In-vitro dissolution testing serves as an important tool for characterizing the biopharmaceutical quality of a product for further development and for evaluation of active ingredients/drug substances. In-vitro dissolution data are supportive in the evaluation and interpretation of possible risks, especially in the case of controlled/modified-release dosage forms - e.g. as regards dose dumping, food effects on bioavailability or interaction with other drugs, which influence gastrointestinal environmental conditions. Biopharmaceutical aspects are as important 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 data will be of great importance when assessing changes in production site, manufacturing process or formulation and assist in decisions concerning the need for bioavailability studies. None of these purposes can be fulfilled by an in-vitro test system without sufficient reliability. Reliability here would be defined as the system being experimentally sound, yielding precise, accurate, repeatable results and with sufficient knowledge of the in-vivo relevance of the dissolution data obtained. Requirements for dissolution testing have been reviewed in the literature [2 - 6]. Since in-vitro dissolution is a physical test, defined by convention and is of a destructive nature, proving reliability requires special attention. It therefore is within the scope of these Guidelines.
to define suitable testing equipment and experimental design as well as to suggest the background for adequate physical and analytical validation, together with verification procedures according to the state of biopharmaceutical science. The Guidelines are primarily dedicated to solid oral products. However, the general concepts may be adapted to in-vitro dissolution testing of drug substances/powders, semisolid oral products, suppositories and, with distinct restrictions, to other non-oral products.[2-6]

2. Apparatus:
Large numbers of different dissolution apparatuses are described in the literature but only some of them with stand critical methodological examination. The rotating basket and the paddle (apparatus 2, USP) devices are simple, robust and adequately standardised apparatuses which are used all around the world and thus are supported by the widest experience of experimental use. It is because of these advantages that the paddle and rotating basket apparatuses are recommended in various guidelines assists choice for the in-vitro dissolution testing of immediate as well as controlled/modified release preparations. However, because of the "single container" nature of the paddle/basket apparatus experimental difficulties may arise in terms of the need of a change in pH or of any other (partial) change in the test medium during an investigation. Furthermore, difficulties arise for a number of sparingly soluble drugs and for some dosage forms, particularly Europhilic multiple unit dosage forms that tend to float initially. Proposals have been made to increase solubility by addition of an appropriate amount of surfactant. With the flow-through cell (apparatus 4, USP) the specimen is placed in a small column which is continuously flushed with a stream of fluid, simultaneously providing the medium and the mechanical agitation for dissolution of the drug substance. It can be run as an open as well as a closed system. The open system design especially provides several advantages in some of the difficult cases mentioned above and was adopted first by the Deutscher Arzneimittelcodex (German Pharmaceutical Codex, DAC) in 1981. The flow-through apparatus is currently monographed in USP, Ph.Eur. And Ph.Jap. Description of the system is concordant worldwide. The paddle/basket system is described in USP, the European, the Japanese and many other Pharmacopoeias. Some minor discrepancies are still found in details of the respective monographs. Another system (apparatus 3) USP describes the reciprocating cylinder. With these four apparatuses, dissolution testing of most oral drug products should be possible on a reasonable basis. Neither too tight restrictions nor unnecessary proliferation of alternative dissolution apparatuses should be encouraged. If an
individual drug product cannot be accommodated by one of the apparatuses, described above, alternative models or appropriate modifications have to be developed. However, in such a case superiority of the alternative other modification has to be proven in comparison to the well established and standardised apparatuses. In the past, many papers intended to justify an alternative model by proving that in-vitro dissolution results were equivalent or similar to those obtained with e.g. the paddle method. According to the understanding of these Guidelines, the latter provides clear evidence that the paddle method should be used.[7]

Table 1. Apparatus used for solid dosage forms

<table>
<thead>
<tr>
<th>Apparatus</th>
<th>Name</th>
<th>Drug product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apparatus I</td>
<td>Rotating Basket</td>
<td>Tablets</td>
</tr>
<tr>
<td>Apparatus II</td>
<td>Paddle</td>
<td>Tablets, capsules modified drug products</td>
</tr>
<tr>
<td>Apparatus III</td>
<td>Reciprocating cylinder</td>
<td>cylinder Extended-release drug products</td>
</tr>
<tr>
<td>Apparatus IV</td>
<td>Flow cell</td>
<td>Drug products containing low-water-soluble drug</td>
</tr>
<tr>
<td>Apparatus V</td>
<td>Paddle Over Disc</td>
<td>Transdermal drug products</td>
</tr>
<tr>
<td>Apparatus VI</td>
<td>Cylinder</td>
<td>Transdermal drug products</td>
</tr>
<tr>
<td>Apparatus VII</td>
<td>Reciprocating disc</td>
<td>Extended-release drug products</td>
</tr>
<tr>
<td>Apparatus VIII</td>
<td>(Non-USP-NF)</td>
<td>Extended-release drug products (beads).</td>
</tr>
<tr>
<td>Apparatus IX</td>
<td>(Non-USP-NF)</td>
<td>Ointments, creams, suppository, transdermal drug products</td>
</tr>
</tbody>
</table>

3. Experimental Testing Conditions:

For all applications, in-vitro dissolution data should at least allow some interpretation with regard to in-vivo biopharmaceutical performance. In order to increase their predictive value, attempts have been made to adjust in-vitro test conditions [8 - 11] as close as possible to physiologic conditions. Nevertheless, several examples demonstrate that such conditions can also lead to misinterpretations and are not able to guarantee in-vitro results routinely relevant to the in vivo situation [12]. In general, an aqueous medium should be used. It is not recommended to
attempt to strictly mimic the physiologic gastrointestinal environment (e.g. composition of gastric or intestinal fluid) but to choose the testing conditions as far as is reasonable, based on the physicochemical characteristics of drug substance, within the range which a drug or dosage form could experience after oral administration. These following ranges were established based on several conferences and recommendations [e.g. 13 - 15]. There might be specific products for which no dissolution test can be established without exceeding the recommended ranges of testing conditions. In these cases, it should be clearly demonstrated that dissolution results obtained with other, more extreme testing conditions (e.g. pH > 8.0) allow for appropriate biopharmaceutical interpretation. For basket/paddle methods the volume should be 500 to 1000 ml. 900 ml had been introduced historically; 1000 ml should be easier to handle in a metric system, this volume being practicable with all equipment commercially available today. 1000 ml therefore should be considered for new drug products or in case of a revision of existing test procedures. This recommendation does not mean that 1000 ml should be adopted to all existing test procedures and specifications. Although larger vessels, such as up to 4,000 ml, could be advantageous for poorly soluble drugs, they are not described in compendia, and thus are not as well standardised and therefore should be regarded as modification of a compendia method (see section 2.) The pH of the test medium should be set within pH 1 and 6.8. A higher pH needs to be justified on a case-by-case basis and in general should not exceed pH 8. For low pH in the acidic range HCl should be used (0.1N HCl for pH 1). If, in a certain case, artificial gastric juice without enzymes (pH 1.2) is advantageous, this should be demonstrated. The use of simulated gastric juice (with pepsin) may be appropriate for gelatine capsules. In the pH-range of 4.5 to 8.0 USP buffer solutions are recommended. A change of pH of dissolution medium during the test or a pH gradient may be appropriate for gastroresistent formulations and products for which dissolution testing at one pH-level or at different pH-levels in parallel does not give biopharmaceutically relevant results. The use of water as dissolution medium bears the disadvantage that test condition details, such as pH and surface tension, can vary depending on the source of water and may be changed during the dissolution test itself, due to the influence of the drug product and to the(re)absorption of carbon dioxide from air. Water therefore is recommended as dissolution medium only when it is proven, that the variations mentioned do not have influence on the dissolution characteristics. Further additives e.g. enzymes, salts or surfactants, could be considered in specific cases. Their use should be justified as regards nature and concentration of additive [16]. Addition of organic solvents should be avoided. Agitation typically should be
obtained in the basket/paddle apparatus by stirring at 50 to 100 rpm and in general should not exceed 150 rpm. Although maximum discriminatory power should be obtained with lowest stirring rate, in many cases experience with 75 rpm was felt to represent a reliable agitation for paddle equipment [17]. Regarding media temperature, 37 ± 0.5°C should generally be used for oral dosage forms. Slightly increased test temperatures (e.g., 38 ± 0.5°C) are under consideration for special applications e.g., for rectal dosage forms, lower temperatures (e.g., 32 ± 0.5°C) for transdermal systems. Relevant parameters to be considered for the definition of test conditions are solubility and deaeration. In former Guidelines [1], "sink" conditions were requested. "Sink" was defined indifferent ways e.g., as 10 to 20% [1] or approximately 30% [18] of solubility concentration to assure that dissolution is not significantly influenced by solubility characteristics. Since "sink" conditions per se do not guarantee in vivo-in vitro associations and since reliable and predictive in-vitro profiles in certain cases can be obtained by violating "sink" conditions, solubility and drug substance concentrations during the test should be matter of verification studies to demonstrate that a chosen in vitro test method yields bio-pharmaceutically relevant results.[9-18]

**DISSOLUTION APPARATUS TYPES**

There are many 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.

Types of Dissolution Apparatus as per USP (Official):

1. Basket Type
2. Paddle Type
3. Reciprocating Cylinder
4. Flow Through Cell
5. Paddle Over Disc
6. Rotating Cylinder
7. Reciprocating Disc
8. Apparatus VIII (Non-USP-NF)
9. Apparatus IX (Non-USP-NF)
USP Dissolution Apparatus (Non-Official):

1. Rotating Bottle Method
2. Diffusion Cell
3. Peristalsis Cell
4. Intrinsic Dissolution Method

IP Dissolution Apparatus:

1. Paddle Type
2. Basket Type

BP Dissolution apparatus:

1. Basket Type Apparatus
2. Paddle Type Apparatus
3. Flow Through Cell

**Apparatus Dissolution 1 - Rotating Basket:**
The assembly consists of the following: a covered vessel made of glass or other inert, transparent materials motor; a metallic drive shaft; and a cylindrical basket. The vessel is partially immersed in a suitable water bath of any convenient size or placed in a heating jacket. The water bath or heating jacket permits holding the temperature inside the vessel at 37 ± 0.5 during the test and keeping the bath fluid in constant, smooth motion. No part of the assembly, including the environment in which the assembly is placed, contributes significant motion, agitation, or vibration beyond that due to the smoothly rotating stirring element. Apparatus that permits observation of the specimen and stirring element during the test is preferable. The vessel is cylindrical, with a hemispherical bottom and with one of the following dimensions and capacities: for a nominal capacity of 1 L, the height is 160 mm to 210 mm and its inside diameter is 98 mm to 106 mm; for a nominal capacity of 2 L, the height is 280 mm to 300 mm and its inside diameter is 98 mm to 106 mm; and for a nominal capacity of 4 L, the height is 280 mm to 300 mm and its inside diameter is 145 mm to 155 mm. Its sides are flanged at the top. A fitted cover may be used to retard evaporation. The shaft is positioned so that its axis is not more than 2 mm at any point from the vertical axis of the vessel and rotates smoothly and without significant wobble. A speed-regulating device is used that allows the shaft rotation speed to be
selected and maintained at the rate specified in the individual monograph, within ±4%. Shaft and basket components of the stirring element are fabricated of stainless steel, type 316 or equivalent, to the specifications shown in below figure. Unless otherwise specified in the individual monograph, use 40-mesh cloth. A basket having a gold coating 0.0001 inch (2.5 µm) thick may be used. The dosage unit is placed in a dry basket at the beginning of each test. The distance between the inside bottom of the vessel and the basket is maintained at 25 ± 2 mm during the test. [27]

Drug Dissolution Apparatus II USP (Paddle):
The paddle apparatus (Apparatus II) consists of a special, coated paddle that minimizes turbulence due to stirring. The paddle is attached vertically to a variable-speed motor that rotates at a controlled speed. The shaft is positioned so that its axis is not more than 2 mm at any point from the vertical axis of the vessel and rotates smoothly without significant wobble. The vertical center line of the blade passes through the axis of the shaft so that the bottom of the blade is flush with the bottom of the shaft. The paddle conforms to the specifications shown in below figure.
The distance of $25 \pm 2$ mm between the blade and the inside bottom of the vessel is maintained during the test. The metallic or suitably inert, rigid blade and shaft comprise a single entity. A suitable two-part detachable design may be used provided the assembly remains firmly engaged during the test. The paddle blade and shaft may be coated with a suitable inert coating. The dosage unit is allowed to sink to the bottom of the vessel before rotation of the blade is started. A small, loose piece of nonreactive material such as not more than a few turns of wire helix may be attached to dosage units that would otherwise float. Other validated sinker devices may be used. [19-21][27][28]

**Dissolution Apparatus III Reciprocating Type:**

The reciprocating cylinder was proposed by Beckett and coworkers41. and its incorporation into the USP followed in1991. The idea to generate a new test method came from a presentation at the International Pharmaceutical Federation (FIP) Conference in 1980 (U.S. Pharmacopeial Convention). In this presentation, problems with the dissolution results from USP Apparatuses I and II, which may be affected physical factors like shaft wobble, location, cantering, deformation of the baskets and paddles, presence of the bubbles in the dissolution medium, etc. were enumerated. It was agreed at the conference that major problems could arise in the acceptance of
pharmaceutical products in international trade due to the resultant variations in the dissolution data. A team of scientists working under Beckett’s direction in London, UK, subsequently developed the reciprocating cylinder, which is often referred to as the “Bio-Dis”.

Although primarily designed for the release testing of extended-release products, USP apparatus 3 may be additionally be used for the dissolution testing of IR products of poorly soluble drugs. In terms of design, the apparatus is essentially a modification of the USP/NF disintegration tester. [22][27]

**Dissolution Apparatus IV Flow through Cell:**

The flow-through-cell apparatus (Apparatus I consists of a reservoir for the dissolution medium and a pump that force dissolution medium through the cell holding the test sample. Flow rate ranges from 4 to 16 ml/min. six samples are tested during the dissolution testing. And the medium is maintained at 37°C. Apparatus I may be used for modified-release dosage forms that contain active ingredients having very limited solubility. There are many variations of this method. Essentially, the sample is held in a fixed position while the dissolution medium is pumped through the sample holder. Thus dissolving the drug, Laminar flow of the medium is achieved by using a pulse less pump. Peristaltic or centrifugal pumps are not recommended. The flow rate is usually maintained between 10 and 100 ml/min. The dissolution medium may be
fresh or recalculated. In the case of fresh medium, the dissolution rate at any moment may be obtained, whereas in the official paddle or basket method, cumulative dissolution rates are monitored. A major advantage of the flow-through method is the easy maintenance of a sink condition for dissolution. A large volume of dissolution medium may also be used, and the mode of operation is easily adapted to automated equipment. [23][24][27]

Dissolution Apparatus

**V Padle Over Disc:**
Use and vessel assembly from Apparatus 2 as described under Dissolution 711, with the addition the paddle of a stainless steel disk assembly designed for holding the transdermal system at the bottom of the vessel. Other appropriate devices may be used provided they do not sorb, react with, or interference with the specimen being tested. The temperature is maintained at 32 ± 0.5. A distance of 25 ± 2 mm between the paddle blade and the surface of the disk assembly is maintained during the test. The vessel may be covered during the test to minimize evaporation. The disk assembly for holding the transdermal system is designed to minimize any “dead” volume between the disk assembly and the bottom of the vessel. The assembly holds the system flat and is positioned such that the release surface is parallel with the bottom of the paddle blade. [25][27]
Dissolution Apparatus VI Rotating Cylinder:

Use the vessel assembly from Apparatus 1 as described under Dissolution 711, 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. The shaft and cylinder components of the stirring element are fabricated of stainless steel to the specifications shown in Figure 2. The dosage unit is placed on the cylinder at the beginning of each test. The distance between the inside bottom of the vessel and the cylinder is maintained at 25 ± 2 mm during the test. [25][27]
Dissolution Apparatus VII Reciprocating Disc:
The assembly consists of a set of volumetrically calibrated or tarred solution containers made of glass or other suitable inert material, a vertically and to index the system horizontally to a different row of vessels automatically if desired, and a set of suitable sample holders containers are partially immersed in a suitable water bath of any convenient size that permits maintaining the temperature, T, inside the containers at 32 ± 0.5 or within the allowable range, as specified in the individual monograph, during the test. No part of the assembly environment in which the assembly is placed, contributes significant motion, agitation, or vibration beyond that due to the smooth, vertically reciprocating sample holder. Apparatus that permits observation of the system and holder during and sample holder as specified in the individual monograph. [26][27]

Dissolution apparatus VIII (Non-USP-NF) Extended-release drug products (beads).
Vertical Diffusion Cell Method:
The vertical diffusion cell (VDC) system is a simple, reliable, and reproducible means of measuring drug release from semisolid dosage forms. A thick layer of the test semisolid is placed in contact with a reservoir. Diffusive communication between the delivery system and the reservoir takes place through an inert, highly permeable support membrane. The membrane keeps the product and the receptor medium separate and distinct. Membranes are chosen to offer the least possible diffusional resistance and not to be rate controlling.
Samples are withdrawn from the reservoir at various times. In most cases, a five- to six-hour time period is all that is needed to characterize drug release from a semisolid, and when this is
the case samples usually are withdrawn hourly. After a short lag period, release of drug from the semisolid dosage form in the VDC system is kinetically describable by diffusion of a chemical out of a semi-infinite medium into a sink. The momentary release rate tracks the depth of penetration of the forming gradient within the semisolid. Beginning at the moment when the receding boundary layer’s diffusional resistance assumes dominance of the kinetics of release, the amount of the drug released, \( M \), becomes proportional to \( t \) (where \( t = \text{time} \)) for solution, suspension, or emulsion semisolid systems alike. The momentary rate of release, \( dM/dt \), becomes proportional to \( 1/t \), which reflects the slowing of drug release with the passage of time. The reservoir is kept large so that the drug is released into a medium that remains highly dilute over the entire course of the experiment relative to the concentration of drug dissolved in the semisolid. In this circumstance, drug release is said to take place into diffusional sink. [28]

**Dissolution apparatus IX (Non-USP-NF) ointments, creams, suppository, transdermal drug products:**

Dissolution testing is often required for suppositories to test for hardening and polymorphic transitions of active ingredients and suppository bases. However, unlike for tablets and capsule dosage forms, there are not enough dissolution testing methods or validations for suppositories. This can be partly attributable to the immiscibility of some of the suppository vehicles in water. If the drug is immiscible in an aqueous dissolution fluid then it may require a partitioning step; unfortunately this involves extra time, which alters the dissolution rate calculation. If a filtration step is involved in dissolution testing, the filtration membrane may introduce an erroneous result between actual and obtained results as it may clog. Variations in density between the suppository and the receiving fluid must also be considered. Dissolution testing methods include the paddle method, basket method, and membrane diffusion method/dialysis method, and the continuous flow/bead method. The equipments for these various methods are shown in Figures. The application of the paddle, basket, and flow-through dissolution methods was studied by Gjellan and Graffner for seven different rectal compositions of hydrophilic and lipophilic-type suppositories.

The formulations were

1. Lipophilic, melting–Witepsol,
2. Lipophilic, melting–Witepsol with 2% Tween 85,
3. Lipophilic melting–Novata,

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(4) Hydrophilic dissolving–polyethylene glycol (PEG) 3350 + 1500,
(5) Hydrophilic dissolving–PEG 3350 + 1500 with 2% Myrj 51,
(6) Hydrophilic dissolving–gelatin capsule, and
(7) Lipophilic melting–gelatin capsule with a surfactant. [29]

**Table 2: Conventional Tablets**

<table>
<thead>
<tr>
<th>S.NO</th>
<th>DRUG NAME</th>
<th>DOSAGE FORM</th>
<th>USP FORM</th>
<th>USP APPARATUS</th>
<th>SPEED (RPMs)</th>
<th>MEDIUM</th>
<th>VOLUME (ML)</th>
<th>RECOMMENDED SAMPLING TIMES (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Abacavir Sulfate</td>
<td>Tablet</td>
<td>II (Paddle)</td>
<td>75</td>
<td>0.1 N HCl</td>
<td>900</td>
<td>5, 10, 15, and 30</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Abacavir Sulfate/Lamivudine</td>
<td>Tablet</td>
<td>II (Paddle)</td>
<td>75</td>
<td>0.1 N HCl</td>
<td>900</td>
<td>10, 20, 30, and 45</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Abiraterone Acetate</td>
<td>Tablet</td>
<td>II (Paddle)</td>
<td>50</td>
<td>0.25% SLS in 56.5 mM phosphate buffer, pH 4.5</td>
<td>900</td>
<td>10, 20, 30, 45 and 60</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3: ODT tablets**

<table>
<thead>
<tr>
<th>S.NO</th>
<th>DRUG NAME</th>
<th>DOSAGE FORM</th>
<th>USP FORM</th>
<th>USP APPARATUS</th>
<th>SPEED (RPMs)</th>
<th>MEDIUM</th>
<th>VOLUME (ML)</th>
<th>RECOMMENDED SAMPLING TIMES (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amlodipine besylate</td>
<td>Tablet(ODT)</td>
<td>II (Paddle)</td>
<td>50</td>
<td>0.1M HCL</td>
<td>500</td>
<td>5, 10,15 and 20</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Aripiprazole</td>
<td>Tablet(ODT)</td>
<td>II (Paddle)</td>
<td>75</td>
<td>Acetate buffer, pH 4.0</td>
<td>1000</td>
<td>10,20,30 and 45</td>
<td></td>
</tr>
</tbody>
</table>
Table 4: Extended Release Tablets

<table>
<thead>
<tr>
<th>S.NO</th>
<th>DRUG NAME</th>
<th>DOSAGE FORM</th>
<th>USP APPARATUS</th>
<th>SPEED (RPMs)</th>
<th>MEDIUM</th>
<th>VOLUME (ML)</th>
<th>RECOMMENDED SAMPLING TIMES (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Albuterol Sulfate Tablet</td>
<td>II (Paddle)</td>
<td></td>
<td>50</td>
<td>0.1 N HCl</td>
<td>900</td>
<td>1, 2, 4, 6, 9 and 12 hours</td>
</tr>
<tr>
<td>2</td>
<td>Alfuzosin HCL Tablet</td>
<td>II (Paddle)</td>
<td></td>
<td>100</td>
<td>0.01 N HCL</td>
<td>900</td>
<td>1,2,12,20 hours</td>
</tr>
<tr>
<td>3</td>
<td>Alprazolam Tablet</td>
<td>I (Basket)</td>
<td></td>
<td>100</td>
<td>1% phosphate buffer, pH 6.0</td>
<td>500</td>
<td>1,4,8,12 and 16 hours</td>
</tr>
<tr>
<td>4</td>
<td>Bupropion hydrobromide</td>
<td>I (Basket)</td>
<td></td>
<td>75</td>
<td>0.1 N HCL</td>
<td>900</td>
<td>1,2,4,6,8 and 10 hours</td>
</tr>
</tbody>
</table>

Table 5: Capsules

<table>
<thead>
<tr>
<th>S.NO</th>
<th>DRUG NAME</th>
<th>DOSAGE FORM</th>
<th>USP APPARATUS</th>
<th>SPEED (RPMs)</th>
<th>MEDIUM</th>
<th>VOLUME (ML)</th>
<th>RECOMMENDED SAMPLING TIMES (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acrivastine/Pseudoephedrine HCl</td>
<td>Capsule</td>
<td>II (Paddle)</td>
<td>50</td>
<td>0.01 N HCl</td>
<td>900</td>
<td>5, 10, 15 and 30</td>
</tr>
<tr>
<td>2</td>
<td>Alvimopan Capsule</td>
<td>II (Paddle)</td>
<td></td>
<td>50</td>
<td>0.1 N HCl</td>
<td>900</td>
<td>5, 10, 15, 20, 30 and 45</td>
</tr>
</tbody>
</table>
### Table 6: Extended Release capsules

<table>
<thead>
<tr>
<th>S.NO</th>
<th>DRUG NAME</th>
<th>DOSAGE FORM</th>
<th>USP APPARATUS</th>
<th>SPEED (RPMs)</th>
<th>MEDIUM</th>
<th>VOLUME (ML)</th>
<th>RECOMMENDED SAMPLING TIMES (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acetazolamide</td>
<td>Capsule</td>
<td>II (Paddle)</td>
<td>75</td>
<td>Acetate buffer, pH 4.5 with 2.2% tween 20</td>
<td>900</td>
<td>1,2,5,7,9,12 and 14 hours</td>
</tr>
<tr>
<td>2</td>
<td>Carbamazepine</td>
<td>Capsule</td>
<td>II (Paddle)</td>
<td>75</td>
<td>First 4 hours: dilute acid, pH1.1. After 4 hours: phosphate buffer, pH7.5 with 0.1%SLS</td>
<td>First 4 h: 900, After 4 h: 900</td>
<td>1,2,4,6,8,10 and 12 hours:</td>
</tr>
</tbody>
</table>

### Table 7: Specifications

<table>
<thead>
<tr>
<th>Category</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STIRRER</strong></td>
<td></td>
</tr>
<tr>
<td>Speed</td>
<td>25-200 RPM ± 1 RPM</td>
</tr>
<tr>
<td>Resolution</td>
<td>1 RPM</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>± 1 RPM</td>
</tr>
<tr>
<td><strong>Depth Adjustment</strong></td>
<td>25 mm to 40 mm</td>
</tr>
<tr>
<td><strong>TEMPERATURE</strong></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>10 - 50 °C</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>± 1 °C</td>
</tr>
<tr>
<td><strong>Temperature Control</strong></td>
<td>Thermostat 0-85°C</td>
</tr>
<tr>
<td><strong>SAMPLING</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Reaction Vessel</strong></td>
<td>1000 ml jar with stirrer pedal and basket</td>
</tr>
<tr>
<td><strong>Heater</strong></td>
<td>1 KW</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>230 V ± 10% AC, 50 Hz</td>
</tr>
<tr>
<td><strong>Dimension</strong></td>
<td>(L x B x H): 320 x 320 x 375 mm (Approx.)</td>
</tr>
</tbody>
</table>

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Weight | 9 Kg. (Approx.)
---|---
Accessories | 1) Main Unit with acrylic tank and rectangular cover platey
2) Reaction vessel - capacity 1000 ml
3) Round acrylic cover plate with hole and a large slit
4) Stirrer motor with tightening knob
5) S.S. paddle, stirrer shaft and clamp, stainless steel wire mesh basket, glad thermometer, s.s. support rod fitted with acrylic block
6) Instruction Manual-1 No., Dust Cover-1 No.

CONCLUSION

At the conclusion of acceptable installation and operational qualifications, the dissolution apparatus is considered validated and acceptable for use to perform dissolution testing. The system suitability tests should be performed after any significant equipment change (e.g. change from a basket apparatus to a paddle apparatus, unless multiple apparatus are qualified at the time of validation) or relocation of the dissolution apparatus (e.g., to another laboratory). Barring any significant change, the system suitability tests should be conducted at least twice a year as part of a robust preventive maintenance.

REFERENCES:

21. http://www.pharmacopeia.cn/v29240/usp29nf24s0_c711.html#usp29nf24s0_c711