

# Composition of amlodipine besylate tablets biology essay



**ASSIGN  
BUSTER**

(28) Karalis et al in 2008 discussed the issues in the conference involved physiological factors affecting drug absorption, the role of pre-systemic effects on bioavailability (BA), the impact of variability in bioequivalence (BE) studies, and a final closing panel session on unresolved issues in BA/BE regulations. Several important aspects of drug absorption were highlighted. It was presented how the complexity of gastrointestinal (GI) physiology and the site dependent absorption can impact on drug BA. Similarly, the effects of food and formulation were also studied. The second session focused on integrating the complexities of GI into modeling the inter-individual variability of absorption and the prediction of first-pass metabolism from in-vitro data. The necessity to measure metabolites, the value of Biopharmaceutical Classification System (BCS), and the more recently proposed Biopharmaceutical Drug Disposition Classification System (BDDCS) were assessed as well. This session closed with presentations of pharmacokinetic software delegates. In the second day of the conference, the problem of high intra-subject variability in BE studies was analyzed. Study design considerations, the use of multiple-dose studies and the role of statistics in BE were also highlighted. Finally, the current thinking of regulatory authorities (EMA and US-FDA) was presented. The conference closed with a last session on unresolved issues in the regulatory level.

## **EXPERIMENTAL**

Tablets are the most popular dosage forms of Pharmaceutical product. A typical tablet formulation consists of the Active Pharmaceutical ingredient(s), fillers, disintegrant, lubricant and other inactive ingredients (e. g. binder, glidant and colors) a formulation scientist must conduct a thorough both to

optimize a formulation so that it meets all specification and to ensure safety and efficacy. The specification for pharmaceutical tablets usually include appearance, weight, uniformity of content, diameter, Thickness, friability, dissolution, disintegration, Hardness, Assay, Organoleptic character & other product specific requirements. These specifications are established to ensure that the tablets will have sufficient mechanical strength to withstand packaging, shipping and handling and are physically and chemically stable to deliver the accurate amount of drug at the desired dissolution rate when consumed by the patient. Any changes in these characteristics may significantly affect the safety and efficacy of the product.

## **FORMULATION DEVELOPMENT OF AMLODIPINE BESYLATE BY DIRECT COMPRESSION METHOD**

Direct compression is a preferred manufacturing process for pharmaceutical tablets, according to survey conducted by Shangraw and Demarest. In this study Amlodipine besylate was directly compressed by using three different formulation i. e. with different diluent, binder, filler, disintegrant and lubricant. In this study we were not only study the biowaivers effect of different marketed brands and formulation of Amlodipine Besylate but also manufactured and developed three different formulation by reducing the cost and increased quality perspectives.

## **MATERIAL AND METHOD**

### **CHEMICALS.**

### **COMPOSITION OF AMLODIPINE BESYLATE TABLETS.**

#### **FORMULATION NO. 1**

#### **S. NO.**

#### **Material Name**

#### **Quantity per**

#### **Tablet (mg)**

#### **Percentage composition (%)**

#### **Quantity for 100 tablets (gm)**

**1**

#### **Amlodipine Besylate**

**5**

**5**

**0.5**

**2**

#### **Avecil 102**

**47**

**47**

**4.7**

**3**

**Starch Pregelatinized**

**47.75**

**47.75**

**4.775**

**4**

**Magnesium stearate**

**0.25**

**0.25**

**0.025**

**Target compression weight is 100mg containing 5 mg active**

**FORMULATION NO. 2**

**S. NO.**

**Material Name**

**Quantity per**

**Tablet (mg)**

**Percentage composition (%)**

**Quantity for 100 tablets (gm)**

**1**

**Amlodipine Besylate**

**5**

**5**

**0.5**

**2**

**Avecil 101**

**47**

**47**

**4.7**

**3**

**Avecil 102**

**47**

**47**

**4.7**

**4**

**Magnesium stearate**

**1**

**1**

**0.1**

**Target compression weight is 100mg containing 5 mg active**

**FORMULATION NO. 3**

**S. NO.**

**Material Name**

**Quanty per**

**Tablet (mg)**

**Percentage composition (%)**

**Quantity for 100 tablets (gm)**

**1**

**Amlodipine Besylate**

**5**

**5**

**0.5**

**2**

**Avecil 102**

**49**

**49**

**4.9**

**3**

**Dicalcium Phosphate Anhydrous**

**44**

**44**

**4.4**

**4**

**Sodium Starch Glycolate**

**4**

**4**

**0.4**

**5**

## **Magnesium stearate**

**1**

**1**

**0.1**

**Target compression weight is 100mg containing 5 mg active**

## **EQUIPMENTS**

Rotary press ( ZP19)

Electronic Balance (Sartorius TE 214S)

Mixer ( polyethylene bag )

Sieve # 20

## **METHOD**

Three new formulation of Amlodipine Besylate were developed using three directly compressible agents i. e. microcrystalline cellulose (Avecil 101 and 102), starch pregelatinized and Dibasic Calcium Phosphate in order to check the multi purpose excipients. First active and all excipients were weighed accurately using Sartorius TE 214S, The weighed materials were screened through 20 mesh size sieve and then mixing of powders was performed by geometric dilution method in polythene bag. First active was mixed with diluents by tumbling action and then one by one other ingredients of formulation were mixed together. All the ingredients were thoroughly mixed to ensure uniform distribution of all the ingredients throughout the formulation.



## **Flow chart of manufacturing process**

Weighing of active and excipients

Sieving y 20 mesh size

Mixing of active and diluent

Addition of other ingredients

Addition of lubricant and mixing

Tableting

## **PHYSICAL TESTING OF TABLET**

Amlodipine Besylate tablets were evaluated for their physical and chemical properties by performing different pharmacopoeial test, i. e by official and unofficial tests including tablets weight variation, hardness, friability, disintegration, dissolution, Thickness, diameter and content uniformity and results were statistically analyzed and compared with marketed brands of Amlodipine Besylate named as test formulation # 1, test formulation # 2, test formulation # 3

## **TABLET THICKNESS AND DIAMETER**

The dimensional specifications of tablets are important for many reasons. The measurement of the thickness and the diameter of a tablet usually accomplished by the use of micrometer (Vernier) calipers. The value is initially employed as in process control during production.

## **UNIFORMITY OF THICKNESS**

### **EQUIPMENTS**

Vernier caliper

### **METHOD**

Tablet thickness is determined with a caliper or thickness gauge, which measures the thickness in millimeters. In this study, twenty tablets were taken and their thicknesses were determined using vernier caliper. Results were statistically analyzed using three sigma control chart.

### **LIMITS**

A plus or minus 5% standard deviation may be allowed, depending on the size of the tablet. Out of twenty tablets only two tablets will be allowed to exceed the limit.

## **UNIFORMITY OF DIAMETER OF TABLETS**

### **EQUIPMENT**

Vernier caliper

### **METHOD**

Twenty tablets were taken and their diameters were determined using vernier caliper. . Results were statistically analyzed using three sigma control chart.

### **LIMITS**

A deviation of  $\pm 5\%$  from the stated diameter is allowed except that for diameters exceeding 12.5mm the deviation allowed is  $\pm 3\%$ . Out of 20 tablets only 2 tablets will be allowed to exceed the limit.

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## **FRIABILITY TEST**

A certain weight of tablets , are subjected to a well defined level of agitation in a fixed geometry, closed container for a specific time. They are then again reweighed. The measure of abrasion resistance or “ FRIABILITY” is usually expressed as a percentage loss in weight.

## **EQUIPMENT**

Electronic Balance (Sartorius TE 214S)

Friabilator (Erweka Germany)

## **METHOD**

Preweight samples of 20tablets were taken and subjected to the combined effect of shock abrasion by utilizing the plastic chamber which revolved at 25rpm for 4minutes, dropped the tablet at a distance of 6 inches with each revolution. Then the tablets were removed, dedusted and reweighed.

## **LIMITS**

Values of friability of 0. 8 to 1. 0% are frequently quoted as the upper level of acceptability for pharmaceutical product. Generally the test is run once. If the results are doubtful for if weight loss is greater than 1% repeats the test twice and determines the mean of the three tests. A maximum weight of 1% of the weight of the tablets to be tested is considered to be acceptable for most products.

## **HARDNESS TEST**

This test is intended to determined under defined conditions, the resistance to crushing of tablets, measured by the forced needed to disturb them by

crushing apparatus. Probably the most widely used technique is testing of crushing strength precisely defined as that compressional force which, when applied diametrically to a tablet, just fractures it.

## **EQUIPMENT**

Hardness tester (Pharma test)

## **METHOD**

Twenty tablets of every sample of brands and test formulation were taken and their hardness was determined using Pharma test hardness tester. In this type of tester load is applied at a constant rate by an electric motor. Results were statistically analyzed using three sigma control chart.

## **LIMITS**

Hardness will be measured in kg. Out of twenty tablets; only two tablets are allowed to exceed the limit.

## **DISINTEGRATION TEST FOR TABLETS**

Disintegration Test determines whether tablets or capsules disintegrate within the prescribed time when placed in the liquid medium in the experimental condition prescribed. For compressed uncoated tablets the testing fluid is usually water at 37 °C, but in some cases monographs direct that simulated gastric fluid TS be used.

This test is provided to determine whether tablets or capsules disintegrate within the prescribed time when placed in a liquid medium under the experimental conditions presented below.

For the purposes of this test, disintegration does not imply complete dissolution of the unit or even of its active constituent. Complete disintegration is defined as that

**“ State in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the discs, if used, is a soft mass having no palpably firm core.”**

Use apparatus A for tablets and capsules that are not greater than 18 mm long. For larger tablets or capsules use apparatus B.

## APPARATUS

The apparatus consists of a basket-rack assembly, a 1 liter, low-form beaker,  $149 \pm 11$  mm in height and having an inside diameter of  $106 \pm 9$  mm for the immersion fluid, a thermostatic arrangement for heating the fluid between  $35^\circ\text{C}$  and  $39^\circ\text{C}$ , and a device for raising and lowering the basket in the immersion fluid at a constant frequency rate between 29 and 32 cycles per minute, through a distance of  $55 \pm 2$  mm. The volume of the fluid in the vessel is such that at the highest point of the upward stroke the wire mesh remains at least 15 mm below the surface of the fluid, and descends to not less than 25 mm from the bottom of the vessel on the downward stroke. At no time should the top of the basket-rack assembly become submerged. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction is a smooth transition, rather than an abrupt reversal of motion. The basket-rack assembly moves vertically along its axis. There is no appreciable horizontal motion or movement of the axis from the vertical.

## **BASKET-RACK ASSEMBLY**

The basket-rack assembly consists of 6 open-ended transparent tubes, each  $77.5 \pm 2.5$  mm long and having an inside diameter of  $21.85 \pm 1.15$  mm and a wall  $1.9 \pm 0.9$  mm thick; the tubes are held in a vertical position by 2 plates, each  $90 \pm 2$  mm in diameter and  $6.75 \pm 1.75$  mm in thickness, with 6 holes, each  $24 \pm 2$  mm in diameter, equidistant from the centre of the plate and equally spaced from one another. Attached to the under surface of the lower plate is a woven stainless steel wire cloth, which has a plain square weave with  $2.0 \pm 0.2$  mm mesh apertures and with a wire diameter of  $0.615 \pm 0.045$  mm. The parts of the apparatus are assembled and rigidly held by means of 3 bolts passing through the 2 plates. A suitable means is provided to suspend the basket-rack assembly from the raising and lowering device using a point on its axis. The design of the basket-rack assembly may be varied somewhat provided the specifications for the glass tubes and the screen mesh size are maintained. The basket-rack assembly conforms to the dimensions.

**DISCS** The use of discs is permitted only where specified or allowed. Each tube is provided with a cylindrical disc  $9.5 \pm 0.15$  mm thick and  $20.7 \pm 0.15$  mm in diameter. The disc is made of a suitable, transparent plastic material having a specific gravity of 1.18-1.20. 5 parallel  $2 \pm 0.1$  mm holes extend between the ends of the cylinder. One of the holes is centered on the cylindrical axis. The other holes are centered  $6 \pm 0.2$  mm from the axis on imaginary lines perpendicular to the axis and parallel to each other. 4 identical trapezoidal-shaped planes are cut into the wall of the cylinder, nearly perpendicular to the ends of the cylinder. The trapezoidal shape is

symmetrical; its parallel sides coincide with the ends of the cylinder and are parallel to an imaginary line connecting the centres of 2 adjacent holes 6 mm from the cylindrical axis. The parallel side of the trapezoid on the bottom of the cylinder has a length of  $1.6 \pm 0.1$  mm and its bottom edges lie at a depth of  $1.6 \pm 0.1$  mm from the cylinder's circumference. The parallel side of the trapezoid on the top of the cylinder has a length of  $9.4 \pm 0.2$  mm and its centre lies at a depth of  $2.6 \pm 0.1$  mm from the cylinder's circumference. All surfaces of the disc are smooth.

If the use of discs is specified, add a disc to each tube and operate the apparatus as directed under Procedure. The discs conform to the dimensions. The use of automatic detection employing modified discs is permitted where the use of discs is specified or allowed. Such discs must comply with the requirements of density and dimension.

## **PROCEDURE**

Place 1 dosage unit in each of the 6 tubes of the basket and, if prescribed, add a disc. Operate the apparatus using the specified medium, maintained at  $37 \pm 2$  °C, as the immersion fluid. At the end of the specified time, lift the basket from the fluid and observe the dosage units: all of the dosage units have disintegrated completely. If 1 or 2 dosage units fail to disintegrate, repeat the test on 12 additional dosage units. The requirements of the test are met if not less than 16 of the 18 dosage units tested have disintegrated.

## **EQUIPMENT**

Disintegrating Apparatus (Pharma Test)

## **METHOD**

Test 6 tablets or capsules either by using 2 basket-rack assemblies in parallel or by repeating the procedure. In each of the 3 tubes, place 1 tablet or capsule and, if prescribed, add a disc; suspend the assembly in the beaker containing the specified liquid. Operate the apparatus for the prescribed period, withdraw the assembly and examine the state of the tablets or capsules. To pass the test, all 6 of the tablets or capsules must have disintegrated.

## **LIMITS**

All tablets must disintegrate completely, if one or two tablets fails to disintegrate, the test is to be repeated using 12 tablets. Out of the 18 tablets then tested, 16 must have disintegrated within the given period of time. The condition of the test are varied somewhat for coated tablets, buccal tablets and sublingual tablets. Disintegration time are included in the individual tablet monograph. For most uncoated tablets the period is less than 15 minutes although the time for some uncoated tablets varied greatly from this.

## **WEIGHT VARIATION**

Most pharmacopoeias include a simple weight test on a specified number of tablet(N) which are weight individually and the arithmetic mean weight calculated. Limitations on the number of test tablets that may lie outside certain limits are than specified. However, in the USP the results of the assay are used to convert these weights into active ingredients content.



## EQUIPMENTS

Electronic Balance (Sartorius TE 214S)

## METHOD

Twenty tablets of every samples were taken randomly and eight individually, and then average weight was determined.

## LIMITS

According to USP not more than two of the tablets must not differ by more than the percentage listed below, no tablet differs by more than double that percentage. Tablets that are coated are exempt from these requirements but must conform to the test for content uniformity if it is applicable. The USP has provided tolerance for the average weight of uncoated compressed tablets. These are applicable when the tablets contain 50mg or more of the drug substances or when the matter comprises 50% or more, by weight, of the dosage form.

Average Weight

%age Difference

130mg or less

10

€<sup>3</sup>/<sub>4</sub>130mg to 324 mg

7. 5

More than 324mg

5

**ASSAY:****AMLODIPINE BESYLATE****REAGENTS**

0. 1N Sodium Hydroxide in Methanol

Dimethyl formamide (DMF)

**STANDARD SOLUTION**

50mcg/ml of Amlodipine Besylate in DMF.

**SAMPLESOLUTION**

Extract appropriate quantity of powdered sample with DMF to get concentration of 50mcg/ml.

**PROEDURE**

To 2ml each of sample and standard solution, add 0. 2ml of Sodium hydroxide solution and dilute to 10ml with DMF and measure the absorption of orange chromato-gen at 450nm against reagent blank. Calculate the contents of amlodipine by comparison.(237)

**AMLODIPINE BESYLATE**

The tablets comply with the requirement stated under tablet and with the following requirement.

## **CONTENT OF AMLODIPINE BESYLATE**

**C<sub>20</sub>H<sub>25</sub>CIN<sub>2</sub>O<sub>5</sub>, C<sub>6</sub>H<sub>6</sub>O<sub>3</sub>S 97. 0% to 102. 0% (Anhydrous substance)**

### **CHEMICALS**

Sodium hydroxide pellets

Methanol

N-N Dimethyl Formamide

### **EQUIPMENT AND GLASS WARES**

Electronic Balance (Sartorius TE 214S)

UV-VIS spectrophotometer (Double beam Shimadzu 1650PC )

Volumetric Flask (100ml, Pyrex England)

Volumetric Flask (10ml, Pyrex England)

Pipettes (10ml Pyrex England)

Pipettes (2ml Pyrex England)

Conical Flasks (Pyrex England)

Beaker (Pyrex England)

Filter paper (Whatman #42)

## **METHOD**

Weigh and powder 20tablets of amlodipine Besylate 5mg (DC). Take quantity of the powder containing 5mg of amlodipine Besylate (average weight) in a 100ml volumetric flask and add N-N Dimethyl Formamide into it and mix thoroughly with the help of magnetic stirrer and then make up the volume up to 100ml. Then take 2ml from first dilution into a 10ml volumetric flask, add 0. 2l of 0. 1N Sodium hydroxide solution in 10ml volumetric flask then make up volume with N-N Dimethyl Formamide. Then take the absorbance at 450nm on spectrophotometer and calculate the content of amlodipine Besylate.

## **CALCULATION**

**(AMLODIPINE BESYLATE mgtablet)**

$$\% \text{ ASSAY} = \text{Abs of sp} \times \frac{100}{\text{Abs of STD}}$$

**Abs of STD**

## **UNIFORMITY OF CONTENT**

The test for uniformity of content of single-dose preparations is based on the assay of the individual contents of active substance(s) of a number of single-dose units to determine whether the individual contents are within limits set with reference to the average content of the sample. Tablets containing highly potent medicaments present in milligram or microgram does may be subject to a large inter tablet variation. This may be due to failure to achieve a homogenous mix of active ingredient and exciient during manufacture.

The test is not required for multivitamin and trace-element preparations and in other justified and authorized circumstances.

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Method Using a suitable analytical method determines the individual contents of active substance(s) of 10 dosage units taken at random.

Apply the criteria of test A, test B or test C as specified in the monograph for the dosage form in question.

### **Test A**

**Tablets, powders for parenteral use, ophthalmic inserts, suspensions for injection**

### **Test B**

**Capsules, powders other than for parenteral use, granules, suppositories, pessaries**

### **Test C**

**Transdermal patches**

### **Test A**

Tablets, powders for parenteral use, ophthalmic inserts, suspensions for injection The preparation complies with the test if each individual content is between 85 per cent and 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside the limits of 75 percent to 125 percent of the average content.

If one individual content is outside the limits of 85 percent to 115 percent but within the limits of 75 percent to 125 percent, determine the individual contents of another 20 dosage units taken at random. The preparation complies with the test if not more than one of the individual contents of the

30 units is outside 85 percent to 115 percent of the average content and none is outside the limits of 75 percent to 125 per cent of the average content.

## **CONTENT UNIFORMITY**

**C.  $U = \frac{\text{Abs of Sample}}{\text{wt of std}} \times 100 \times 100$**

**$\frac{\text{Abs of STD}}{\text{LC}} \times 100 \times 100$**

**\* LC = Label claim**

## **DISSOLUTION**

This test is provided to determine compliance with the dissolution requirements for solid dosage forms administered orally.

Apparatus 1 (Basket apparatus) the assembly consists of the following: a vessel, which may be covered, made of glass or other inert, transparent material a motor; a drive shaft; and a cylindrical basket (stirring element). The vessel is partially immersed in a suitable water-bath of any convenient size or heated by a suitable device such as a heating jacket. The water-bath or heating device permits maintaining the temperature inside the vessel at  $37 \pm 0.5$  °C during the test and keeping the dissolution medium 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 preparation and stirring element during the test is preferable. The vessel is cylindrical, with a hemispherical bottom and a capacity of 1 litre. Its height is 160-210 mm and its inside diameter is 98-106 mm. Its sides are flanged at the top. A fitted cover may be used to retard

evaporation. 2 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 that could affect the results. A speed-regulating device is used that allows the shaft rotation speed to be selected and maintained at a specified rate, within  $\pm 4$  per cent.

Shaft and basket components of the stirring element are fabricated of stainless steel, type 316 or equivalent, to the specifications shown in Figure 2. 9. 3.-1.

A basket having a gold coating of about 2. 5  $\mu\text{m}$  (0. 0001 inch) 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 bottom of the basket is maintained at  $25 \pm 2$  mm during the test.

Apparatus 2 (Paddle apparatus) Use the assembly from Apparatus 1, except that a paddle formed from a blade and a shaft is used as the stirring element. The shaft is positioned so that its axis is not more than 2 mm from the vertical axis of the vessel, at any point, and rotates smoothly without significant wobble that could affect the results. 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 Figure 2. 9. 3.-2. The distance of  $25 \pm 2$  mm between the bottom of 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 coating so as to make them inert. 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 non-reactive material, such as not more than a few turns of wire helix, may be attached to dosage units that would otherwise float. An alternative sinker device is shown in Figure 2. 9. 3.-3. Other validated sinker devices may be used.

## **DISSOLUTION MEDIUM**

### **1. 2 pH BUFFER DISSOLUTION MEDIA**

#### **REAGENTS USED**

Hydrochloric Acid (Merck grade)

Distilled and deionized water

#### **PREPARATION**

0. 1N HCl was used as 1. 2pH buffer media.

### **4. 5 pH BUFFER DISSOLUTION MEDIA**

#### **REAGENTS USED**

Potassium Dihydrogen Phosphate (Merck, Germany)

Distilled and deionized water

#### **PREPARATION**

6. 8gm of Potassium Dihydrogen Phosphate in 1000ml DI water and adjust pH with Phosphoric acid.



## **6. 8 pH BUFFER DISSOLUTION MEDIA**

### **REAGENTS USED**

0. 2M Potassium Dihydrogen phosphate

0. 1M Sodium hydroxide

Distilled and deionized water

### **PREPARATION**

0. 2M KH<sub>2</sub>PO<sub>4</sub> 13. 61gm of Potassium Dihydrogen phosphate in 500ml DI water.

0. 1MNaOH 4gm in 500ml DI water.

6. 8pH Buffer 250ml of 0. 2M KH<sub>2</sub>PO<sub>4</sub> and 112ml of 0. 1MNaOH to make 1000ml with DI water.

### **CALCULATION**

**% age drug release = Abs of sp X100**

**Abs of STD**

### **SAMPLING SCHEDULE**

Sample were drawn at 5min then

After 10min

After 15min

After 20min

After 30min

After 45min

After 60min

After 120min

## **EXPERIMENTAL CONDITIONS**

Usual experimental conditions are e. g.:

Apparatus: paddle/basket

€ Volume of dissolution medium: 900 ml

€ Temperature of the dissolution medium:  $37\text{ }^{\circ}\text{C}\pm 1^{\circ}\text{C}$

€ Agitation: paddle apparatus – usually 50 rpm, basket apparatus – usually 100 rpm

€ Sampling schedule: e. g. 5, 10, 15, 20, 30, 45, 60, and 120 min

€ Buffer: pH 1.2 (0.1 N HCl or SGF without enzymes), pH 4.5, and pH 6.8 (or SIF without enzymes); (pH should be ensured throughout the experiment; Ph. Eur. buffers recommended)

## **CHEMICALS**

Buffer 1.2 pH (0.1 N HCl)

Buffer 4.5 pH

Buffer 6.8 pH

## **EQUIPMENT AND GLASS WARES**

Dissolution paddle apparatus

Distillation plant

Electronic Balance (Sartorius TE 214S)

UV-VIS spectrophotometer (Double beam Shimadzu 1650PC )

Volumetric Flask (100ml, Pyrex England)

Pipettes (10ml Pyrex England)

Pipettes graduated(2ml Pyrex England)

Conical Flasks (Pyrex England)

Beaker (Pyrex England)

Filter paper (Whatman #42)

## **PREPARATION OF STANDERD**

Accurately weight the standard and poured it into 100ml volumetric flask.

The volume was made with the respective buffer and mixed, the stock solution was obtained.

Then pipet out 1. 1ml from the stock solution into another volumetric flask again made the volume with the respective buffer solution . Mixed it properly by shaking that was the first dilution and the required strength of standard was achieved to analyse.

## **PREPARATION OF SAMPLE**

Placed the tablets of each brand into the vessel of paddle dissolution having 900ml of resoeptive dissolution media.

Switch on the apparatus and collect the sample according to the respective sampling interval that is 5min, 10min, 15min, 20min, 30min, 45min, 60min, and 120min.

Every time the withdrawn media was replaced by the freh media.