# East Point College of Pharmacy

East Point Campus, Jnana Prabha, Virgo
Nagar PostBengaluru – 560049, Karnataka

**Approved**
***by***
**Pharmacy Council of India, New Delhi**

**Affiliated**
***to***
**Rajiv Gandhi University of Health Sciences**
**Karnataka**
**Bengaluru – 560041**
**India**

# *LAB MANUAL*

## PHARMACEUTICS PRACTICAL-I

## *M. PHARM 1st SEMESTER*

EAST POINT COLLEGE OF PHARMACY
East Point Campus, Jnana Prabha, Virgo Nagar Post,
Bengaluru – 560049, Karnataka

| M. Pharmacy (Pharmaceutics) | |
|---|---|
| **Programme Outcome (PO)** | |
| **PO1** | An ability to independently carry out research /investigation and development work. |
| **PO2** | An ability to write and present a substantial technical report/document |
| **PO3** | Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program |
| **PO4** | Graduates will demonstrate comprehensive knowledge and practical skills in advanced pharmaceutical development, encompassing drug analysis, drug formulation, and evaluation of novel drug delivery systems. |
| **PO5** | Students will acquire a deep understanding of regulatory processes and compliance, preparing dossiers for submission to regulatory agencies worldwide. They will navigate the intricacies of innovator and generic drug concepts, ensure adherence to global guidelines, and exhibit expertise in Biopharmaceutics& Pharmacokinetics. |
| **PO6** | Graduates will integrate technological advancements into pharmaceutical research and development, utilizing computational modelling, design of experiments, and prototype modelling. |

| Programme Specific Outcomes (PSO) | |
|---|---|
| **PSO1** | Apply appropriate tools and techniques for design and development of Pharmaceutical Dosage forms, cosmeceuticals and drug delivery systems |
| **PSO2** | Comprehend the pharmacokinetic parameters of drugs, dose calculations and biopharmaceutical approaches in problem solving |
| **PSO3** | Acquaint knowledge on investigational new drugs and regulatory submissions |

| Course Outcomes (CO's) | |
|---|---|
| **Code: MPH105P Pharmaceutics Practical-I** | |
| **CO 1** | Understand theory, principle and methodology of various formulations |
| **CO 2** | Prepare and analyze drug release profile |
| **CO 3** | Understand and perform various evaluation tests |

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EAST POINT COLLEGE OF PHARMACY
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## Experiment No: 01

# PREFORMULATION STUDIES OF TABLETS

**AIM**: To carry out Preformulation studies of tablets.

**Requirements**:

**Apparatus:** Measuring cylinder, Sieves, Funnel, Stop Watch, Digital Weighing Balance, etc.

**Principle:**

- **Bulk Density:**

  The bulk density may be defined as the mass of powder divided by bulk volume. Knowledge of particles i.e. particle size distribution, its surface area is important in pharmacy. They are related in significant ways to the physical, chemical, and pharmacological properties of a drug.

  The term "light'' means low bulk density or large bulk volume. Whereas "heavy" signifies a powder of high bulk density and small volume. Specific bulk volume is the reciprocal of bulk density referred to as bulkiness. It is an important consideration in packing powders in containers. (Unit – gm/ml).

$$\textbf{Db(Bulk Density)} = \frac{Mass\ or\ Weight\ of\ powder(m)}{Bulk\ Volume\ of\ Powder(Vb)}$$

- **Tapped Density**:

  It is the ratio of the total mass of powder to the tapped volume of the powder. Volume was measured by tapping the powder in the measuring cylinder for 100 times and tapped volume was noted. (Unit – gm/ml).

$$\textbf{Dt(Tapped Density)} = \frac{Mass\ or\ Weight\ of\ powder(m)}{Tapped\ Volume\ of\ Powder(Vt)}$$

- **Hausner's Ratio (H)**:

  This expresses the flow properties of the powder and is measured by the ratio of tap density (TD) to bulk density (BD), and it is calculated by,

$$\textbf{Hausner's Ratio} = \frac{\textbf{Dt(Tapped Density)}}{\textbf{Db(Bulk Density)}}$$

- **Carr's Index**;

  It indicates powder flow properties. It is expressed in percentage and given by,

$$\text{I (Carr's Index)} = \frac{\text{Dt(Tapped Density)} - \text{Db(Bulk Density)}}{\text{Dt(Tapped Density)}} \times 100$$

**Relationship between Carr's index and flow property**

| Carr's index | Type of flow |
|---|---|
| 5-15 | Excellent |
| 12-15 | Good |
| 15-22 | Fair |
| 23-30 | Poor |
| 33-38 | Very poor |
| >40 | Extremely poor |

- **Angle of repose**:

  Angle of repose has been defined as the maximum angle possible between the surface of the pile and the horizontal plane.

  The flow characteristics are measured by the angle of repose. Improper flow of powder is due to frictional forces between the particles.

$$\text{Tan } \theta = \frac{h}{r}$$

$$\Theta \text{ (Angle of repose)} = \tan^{-1} \frac{h}{r}$$

Where,

h = Height of pile

r = Radius of base of pile

**Relationship between Angle of reposes and flow property**

| Angle of repose(θ) | Type of flow |
|---|---|
| <25 | Excellent |
| 25-30 | Good |
| 30-40 | Passable |
| >40 | Very poor |

The lower the angle of repose, the better the flow property of granules. The rough and irregular surface of particles gives a higher angle of repose.

To improve the flow of characteristic materials, turn glides are frequently added to granules. Examples - Magnesium stearate, Talc, and Starch.

- **Flow Rate**:

  Flow rate has been defined as the maximum rate of flow of powder or granules. (Unit – gm/Sec).

**Procedure:**

1. **Determination of Bulk Density:**
   i. Take a clean, dry measuring cylinder of 50 ml capacity.
   ii. Weigh accurately 10gm of powdered granules and pour it into the measuring cylinder.
   iii. Note down the volume of granules in measuring cylinder.
   iv. The bulk density was calculated by using formula.
2. **Determination of Tapped Density:**
   i. Take a clean, dry measuring cylinder of 50 ml capacity.
   ii. Weigh accurately 10gm of powdered granules and pour it into the measuring cylinder.
   iii. Note down the volume of granules in the measuring cylinder.
   iv. Tap the measuring cylinder 100 times on the tapped density apparatus.
   v. Check the volume of granules in the measuring cylinder.
   vi. Calculate the tapped density by using a formula.
3. **Determination of Angle of repose:**
   i. Fix a glass funnel vertically on to clamp stand.
   ii. Place a clean dry paper below the funnel.
   iii. Weigh about 10 gm of given granules and pour them into the funnel while the orifice of the funnel is closed by a thumb.
   iv. Allow the granules to flow through the funnel and form a heap on the paper.
   v. Adjust the tip of the funnel so that it touches the tip of the heap.
   vi. Repeat the flow of granules through the funnel until the heap of funnel touches the tip of the heap itself.

vii. Finally note down the diameter of the circle formed by the heap and calculate its radius.

viii. Measure the height of the heap with the help of scale.

ix. Calculate the angle of repose using the formula.

**4. Flow Rate:**

i. 10 gm of powder is allowed to flow through the glass funnel the powder granules flow through the orifice.

ii. the amount of powder passing through the orifice per sec is calculated. (Unit-gm/Sec)

**Report:**

The Preformulation parameters of the Powder/granules were found to be,

1. Bulk density:
2. Tapped density:
3. Hausner's ratio:
4. Carr's Compressibility Index:
5. Angle of repose:
6. Flow Rate:

# MATRIX TABLETS

## Introduction:

The goal of any DDS is to provide a therapeutic amount of drug to a proper site in the body to achieve and maintain the desired amount of drug concentration.

This can be achieved by sustained release formulation or controlled release formulation for the sustained release system. The oral route is given more attention because of the flexibility of dosage form then parental group because the acceptance for the oral route is quite high, relatively safe, and constraints on security requirements

are not present.

Sustained oral DDS are manufactured by

1. Diffusion system
2. System utilizing dissolution
3. Osmotic system
4. Pro-drug
5. Ion exchange resins

I. **Diffusion system**: In this, the release rate of the drug is determined by diffusion through a water-insoluble polymer

There are 2 types of diffusion system

1. **Matrix devices:** in this, the drug is dispersed uniformly throughout & inhert polymeric matrix.
2. **Reservoir devices**: the core of the drug is surrounded by a polymeric membrane, and the release of the drug is based on the following assumption,
   a. The dissolution of drug into the surrounding medium is the first step of drug release
   b. A pseudo study state is maintained during drug release, perfect sink condition are maintained. Drug particles are much smaller than the average distance of dissolution.
   c. Diffusion co-efficient.
   d. Interfacial part ion of drug molecule from polymer towards solution is related to its solubility in polymer.

$$K = \frac{CS}{Cd}$$

Where,

CS = concentration in solution.

Cd = concentration in polymer.

e. Major types of materials used in the matrix devices are insoluble plastic, hydrophobic polymer,& fatty compound .
   Plastic material ex: methyl acrylate, methyl acrylate
   Hydrophilic ex: methyl cellulose, hydroxyl propyl, methyl cellulose
   Fatty compounds ex: carbam wax, glyceryltri state etc.

f. The most common method used is to mix the drug with matrix material and then compressing the mixture into complex. It is necessary for the portion of the drug to be available as primary dose, loading dose & reminder to be release in sustained manner.

There are 2 general methods for preparing drug-polymer matrix

A. Congealing method.
B. Aqueous dispersion method.

A. **Congealing method:** the drug is mixed with polymer or wax material & either collected and screened or spray congealing.
B. **Aqueous dispersion method:** the drug-polymer mixture is simply sprayed & placed.

**Advantages:**

- Improve patient convenience.
- Complaint due to less frequent drug advices.
- Reduction in fluctuation in steady-state level & therefore better control of disease condition and reduce intensity of local or systemic side effects.
- Increase safety margin high potency of drug due to better control of plasma level.
- Maximum utilization of drug enabling reduction in the total amount of dose administered.
- Reduction in health care cost, improve therapy and shorter treatment period, lower frequency of dosing, reduction in personal to dispense & administered the drug.

- Controlled DDS can deliver the drug at pre-determined rate locally and systematically for specified period of time.

**Disadvantages:**

- Dose dumping.
- Need for addition patient education.
- Increase potential for first pass metabolism.
- Possible reduction in systemic availability.
- Increase variability among dosage unit.
- Delayed on set of action.
- Retrieval of drug is difficult.

## Experiment No: 02

# FORMULATION AND EVALUATION OF SUSTAIN RELEASE MATRIX TABLET

**AIM:** Formulation & evaluation of sustained release matrix tablet [Diclofenac matrix tablet]

**Requirements:**

**Apparatus:** UV- spectrophotometer, Tablet dissolution apparatus, beaker, Mortar and pestle, Tablet punching machine.

**Chemicals:** Diclofenac sodium, magnesium stearate, HPMC, lactose polymer, talc , phosphate buffer, acidic buffer, 90% alcohol etc.

**PRINCIPLE:**

Sustained release, Sustained action, Prolonged action, Controlled release, extended action, time release dosage forms are designed to achieve prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of single dose.

Matrix tablet of diclofenac was prepared by using hydrophilic polymer, HPMC (1c-1s) the drug release was sustained by using HPMC as a polymer, the rest of ingredients were used according to conventional tablets such as lactose as diluents, magnesium stearate & Talc as lubricant and glidants respectively, 90% Methanol as wetting agent.

**Official Formula:**

| Sl No. | Ingredients | Official Quantity (per tablet) | Working Quantity |
|---|---|---|---|
| 1. | Diclofenac sodium | 100 mg | |
| 2. | HPMC | 150 mg | |
| 3. | Lactose | 50 mg | |
| 4. | Magnesium stearate | 5.88 mg | |
| 5. | Talc | 2.95 mg | |
| 6. | 90% Methanol | QS | |

**Procedure:**

1. Weigh required quantity of drug substances, polymer lactose and half of disintegrating agent.
2. Mix all the compounds in clean mortar and prepare a damp mass by using 90% Methanol as wetting agent.
3. This damp mass is further passed through sieve no. 10 and dried at 60˚c for 15-20 min.
4. Dried granules are collected and passed through sieve no. 22, This is superimposed on sieve no. 44 and collect the granules, fines and weighed.
5. The required quantity of magnesium stearate and talc is added and compressed into the tablets.

**Evaluation parameters of granules:**

a. Bulk density
b. Tapped density
c. Hausnor's ratio
d. Carr's index
e. Angle of repose
f. Flow rate

**Evaluation of finished tablets:**

**1. Appearance:**

- Tablets from each formulation were randomly selected and organoleptic properties such as color, taste, and shape were evaluated.

**2. Thickness:**

- The thickness of tablets was determined using a Vernier caliper.
- Three tablets from each batch were used, and average values were calculated.

**3. Hardness test (Pfizer/ Monsanto apparatus):**

- The tablet hardness is defined as the force required to break a tablet in a diametric direction.
- A tablet (5 tablets) was placed between two anvils. Force was applied to anvils and the crushing strength that causes the tablet to break was recorded.
- The hardness was measured using the Pfizer/Monsanto hardness tester.

**Observations:**

| Tablet number/Brand Name | Trial No | | | | | Mean(kg/cm$^2$) |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**4. Friability test (Roche Friabilator):**

- Weigh 10 tablets.
- The friability of tablets was determined using Roche Friabilator. It is express in percentage (%).
- Ten or twenty tablets were initially weighed and revolved at 25 rpm for 4 min.
- The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.
- The % friability was then calculated by,

$$F_{(Friability)} = \frac{(W_{initial} - W_{fiinal})}{W_{initial}} \times 100$$

Acceptance criteria for % friability % weight loss should be less than 1%.

**Observations:**

| Tablet Number/Brand name | Initial Wt | Finial Wt | Loss in Wt | %Friability |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

**5. Weight variation test:**

- Twenty tablets are taken and weighed together.
- Average weight is calculated.
- Directly weigh each tablet and find out the deviation of each tablet from the average weight.
- Also calculate percentage deviation for the same.

**Observations:**

**Total Weight of 20 tablets- ……mg**

**Average Weight- ……mg**

| Sl. No | Individual weight (mg) | Deviation from average weight(n) | Percentage deviation from average weight |
|---|---|---|---|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| 7. | | | |
| 8. | | | |
| 9. | | | |
| 10. | | | |
| 11. | | | |
| 12. | | | |
| 13. | | | |
| 14. | | | |
| 15. | | | |
| 16. | | | |
| 17. | | | |
| 18. | | | |
| 19. | | | |
| 20. | | | |

**Percentage deviation = n /average weight ×100**

Where, **n**-difference between average weight and actual weight

**6. Disintegration test:**

- Place 6 tablets in the cylindrical test apparatus which is maintained at 37±2°C containing simulated gastric fluid (i.e 0.1N HCL) or medium specified in the monograph.
- Note down the time taken for the tablets to disintegrate or breakdown and passes through the mesh completely.

**Observations:**

| Tablet Number/ Brand name | Disintegration Time | | | | | Mean(mins) |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**7. *In Vitro* Dissolution Study:**

- The release rate of the medicaments from tablets was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus Type-II.
- The dissolution test was performed using 900 ml of specified dissolution medium (according to monograph), at 37ºC±0.5ºC and a specified rpm (according to monograph).
- A sample (10ml) of the solution was withdrawn from the dissolution apparatus at a specific time interval and the samples were replaced with fresh dissolution medium.
- The samples were filtered through a 0.45µ membrane filter.
- Absorbance of these solutions was measured at the absorption maxima of drug using a Thermospectronic-1 UV/V double-beam spectrophotometer.
- Cumulative percentage drug release was calculated using an equation obtained from a standard curve.

| Sl. No | Drug Name | $\lambda_{max}$ | Apparatus Type | RPM | Dissolution Medium |
|---|---|---|---|---|---|
| 1. | Paracetamol | 243 nm | USP II (Paddle) | 50 rpm | 5.8 pH phosphate buffer |
| 2. | Aspirin | 270 nm | USP II (Paddle) | 50 rpm | 4.5 pH phosphate buffer |
| 3. | Mebendazole | 234 nm | USP II (Paddle) | 50 rpm | 0.1 M HCl containing 1% SLS |

## Observations:

**Calibration Curve of Drug-**

| Sl. No | Concentration (µg/ml) | Absorbance (nm) | | | Mean± SD* |
|---|---|---|---|---|---|
| | | Trial 1 | Trial 2 | Trial 3 | |
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |
| 4. | | | | | |
| 5. | | | | | |
| 6. | | | | | |

*Standard Equation- **Y= mX ± c**

***In Vitro* dissolution-**

| Time (Mins /Hrs) | Abs (nm) | Conc in µg/ml [X= $\frac{Y \pm c}{m}$] | Conc in mg/ml [X′=X/1000] | Amt in 1 ml [X′ *100] | Amt in 10 ml (mg) | Amt in 900 ml (mg) | Cleared amt (mg) | CDR (mg) | % CDR |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | 0 | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
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## Report:

The Preformulation parameters of the granules were found to be,

1. Bulk density:
2. Tapped density:
3. Hausner's ratio:
4. Carr's Compressibility Index:
5. Angle of repose:
6. Flow Rate

The evaluation parameters of the tablet batch were found to be:

1. Appearance
2. Thickness
3. Hardness
4. Friability
5. % weight variation
6. Disintegration Time
7. % CDR

# HYRDODYNAMICALLY BALANCED TABLETS

## INTRODUCTION:

The primary aim of oral controlled drug delivery system is to achieve better bio-availability and release of drug from the system which should be predictable and reproducible but thus is difficult due to number of physiological problems such as fluctuation in gastric emptying process narrow absorption window and stability problem in GIT. This can be overcome by physiological state and designing the formulation by which gastric emptying process can be extended from few min to 12hrs.

The dosage form prepared prolonged gastric resident time enabling and extended absorption phase for the drug. Floating drug delivery system or hydrodynamically balanced system provide better bio-availability for the drug unstable in the environment

The three major requirements for floating drug delivery system are

1. It must form cohesive gel barrier.
2. It must maintain specific gravity lower than gastric contents [1.004-1.01g/ml]
3. It should swell slowly to serve as reservoir

**Classification of floating system:**

1. Single unit floating system
   A. Effervescent system
   B. Non- effervescent system
2. Multiple unit dosage form
   A. Effervescent
   B. Non-effervescent
   C. Hallow microsphere
3. Raft forming system

Effervescent floating drug delivery system thus reduce density of system remain buoyant in the stomach for a prolonged period of time and release the drug slowly at a desired level.

The main ingredients for swellable polymers such as chitosan, methyl cellulose. Effervescent like sodium bicarbonate and tartaric acid

The expandable tablets were prepared containing polymers and that swells rapidly in aqueous environment and thus stay in stomach over extended period of time in addition to this gas forming agent incorporated reduce the density of the system and tends to flow in the gastric environment.

**ADVANTAGES:**

1. Floating dosage form such as tablet or capsule will remain the solution for prolonged period of time even in gastric pH.
2. Floating drug delivery system or advantageous for the drug meant for local action in the stomach.
   Ex: Antacids
3. Floating drug delivery system or advantageous in case of vigorous intestinal movement and in diarrhea to keep the drug floating condition and to get better response.
4. Acidic substances like aspirin causes irritation on the stomach wall when come in contact with it hence FDDS formulation may be useful for administration of aspirin and other similar drugs
5. FDDS are useful when drugs absorbed through stomach

**DISADVANTAGES:**

1. FDDS are not feasible for drugs that have solubility or stability problem in the GIT or gastric fluid.
2. FDDS are not applicable for the drugs that are irritant to gastric mucosa.
3. FDDS require a sufficiently high level of fluid in the stomach so that the dosage form floats and works efficiently.
4. This system also requires the presence of food to delay gastric emptying

## Experiment No: 03

# FOEMULATION AND EVALUATI0N OF FLOATING DRUG DELIVERY SYSTEM/ HYDRODYNAMICALLY BALANCED DRUG DELIVERY SYSTEM

**AIM:** Formulation and evaluation of floating drug delivery system / hydro-dynamically balanced drug delivery system.

**Requirements:**

**Apparatus**: Mortar and pestle, Beaker, volumetric flask, Dissolution test apparatus type-II

**Chemicals:** Ethyl cellulose, Metformin, HPMC, Sodium benzoate, Talc, Magnesium stearate, 0.1 N HCL buffer etc.

**PRINCIPLE:**

Floating drug delivery system acts locally in stomach. They are poorly soluble in alkaline pH and these drugs having narrow window of absorption. Floating drug delivery systems are expected to remain unbound to gastric mucosa and enhance the bioavailability of drugs. Floating drug delivery system has ability to float over the gastric fluid. So they have potency to provide a constant drug delivery without any affection on drug. It can achieve sustain therapeutic action. Metformin is anti-hyperglycaemic drug used for treating non - insulin dependent diabetes.

**Official Formula:**

| Sl No. | Ingredients | Official Quantity (per tablet) | Working Quantity |
|---|---|---|---|
| 1. | Metformin | 500 mg | |
| 2. | Ethyl cellulose | 375 mg | |
| 3. | HPMC | 375 mg | |
| 4. | Lactose | 50 mg | |
| 5. | Magnesium stearate | 5.88 mg | |
| 6. | Talc | 2.95 mg | |

## Procedure:

**Preparation of floating tablet:**

1. All ingredients except magnesium stearate and talc are weighed and mixed together.
2. After proper mixing add magnesium stearate and talc.
3. The prepared powder mixture is taken for direct compression.
4. Tablets are compressed by direct compression method.

## Evaluation parameters of powder:

a. Bulk density
b. Tapped density
c. Hausnor's ratio
d. Carr's index
e. Angle of repose
f. Flow rate

## Evaluation of finished tablets:

**Determination of floating time:**

- Take 100 ml of 0.1 N HCL.
- Tablet is placed on surface of buffer.
- Check the lag time and floating time of tablet.

**Dissolution study:**

1. The *in-vitro* dissolution study of the marketed formulation was carried out by using USP type II (paddle) apparatus.
2. 6 tablets were placed into different baskets containing 900 ml of dissolution media (HCL)
3. The temperature and RPM were set at 37˚c and 50 rpm respectively.
4. At predetermined time intervals, 5 ml of sample was withdrawn from all baskets[after each hr.] and analyzed spectrophotometrically after suitable dilutions.[at 234nm]
5. The % drug release was calculated based on equation and it was compared with specifications in official compendia.

## Observations:

**Calibration Curve of Drug-**

| Sl. No | Concentration (µg/ml) | Absorbance (nm) | | | Mean± SD* |
|---|---|---|---|---|---|
| | | Trial 1 | Trial 2 | Trial 3 | |
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |
| 4. | | | | | |
| 5. | | | | | |
| 6. | | | | | |

*Standard Equation- **Y= mX ± c**

***In Vitro* dissolution-**

| Time (Mins /Hrs) | Abs (nm) | Conc in µg/ml [X= $\frac{Y \pm c}{m}$] | Conc in mg/ml [X′=X/1000] | Amt in 1 ml [X′ *100] | Amt in 10 ml (mg) | Amt in 900 ml (mg) | Cleared amt (mg) | CDR (mg) | % CDR |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
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## Report:

The Preformulation parameters of the powder mixture were found to be,

1. Bulk density:
2. Tapped density:
3. Hausner's ratio:
4. Carr's Compressibility Index:
5. Angle of repose:
6. Flow Rate:

The evaluation parameters of the tablet batch were found to be:

1. Floating Time
2. % CDR

# MUCO ADHESIVE TABLETS

## INTRODUCTION:

- Adhesive may be defined simple as a process of fixing two surfaces to one another.
- Bio adhesion defined as the binding of natural or Synthetic polymer to a biological substrate when the substrate mucosal layer. The term is known as mucosal layeris known as muck adhesion.
- The rational beyond using bio adhesive system in the prolong retention time in the GIT resulting in maximum absorption and hence enhances bio availability

**Mechanism of Bio adhesion**

1. Physical or Mechanical bond
2. Chemical interaction

**1. Physical or mechanical bond:**

Physical bonds involve entanglement of Mucin glycoprotein with polymer chain in the polymer matrix.

**2. Chemical interaction:**

It includes Vanderwalls interaction or hydrogen bonds, Groups which form hydrogen bonds are Hydroxy Carboxyl Sulphates, amino acids etc.

The two main routes of administrations are:

- Sublingual delivery
- Buccal delivery

**Sublingual delivery:**

It refers to systemic administration of drug via membrane that lines floor of the mouth ventral surface of tongue.

**Advantages**:

- Rapid onset of action.
- Sublingual mucosa is thinner than buccal mucosa and hence comparatively high permeability to drugs.
- Quick termination of drug can be achieved.

**Disadvantages:**

- The two major salivary gland open the ducts in the Sublingual area to release saliva in this region because of which it is difficult to retain drug delivery system and maintain high concentration of drug in the Sublingual region.

**Buccal delivery:**

Administration of drug via the buccal mucosa (The linking of cheeks) to systemic circulation is defined as Buccal delivery

**Advantages:**

- Bypass first pass metabolism and dehydration in the stomach and intestine thereby greater bioavailability.
- Ease of administration.
- Termination of therapy is possible.
- It can be administered to unconscious patients.
- Significant reduction of dose can be achieved.
- Better patient compliance than rectal or nasal route
- Nausea and vomiting are avoided and very useful in patient with difficulty in swallowing.

**Disadvantages:**

- Drugs which irritate oral mucosa are have bitter taste cause allergic reaction anxious odour drug which causes discolour of teeth can't be formulated as buccal tablets.
- Drugs which are unstable at buccal Ph 6.6 can't be administrated by this route. Drugs in the swallowed saliva follows oral route and hence advantages of buccal route are lost.
- Excessive hydration may lead to formation of slippery surface and structural integrity of formulation may be lost.
- If the formulation contains antimicrobial agents, effect of natural microbial flora of mouth and buccal cavity may be affected.
- Bio adhesive tablets are immobilized drug delivery which consists of either monolithic partial coated or multilayer matrixes.
- The limitation of adhesive tablets includes small surface and their lack of flexibility.
- Permeability of oral mucosa is not greater compared to other mucosal membrane.

## Experiment No: 04

# FORMULATION AND EVALUATION OF MUCOADHESIVE TABLETS

**AIM:** Formulate and evaluate of mucoadhesive tablets.

**Reference:** International Journal of Pharmacy and Pharmaceutical science.

**Requirements:**

**Apparatus:** USP type II dissolution apparatus, beaker, petri dish, UV spectrophotometer, tablet punching machine, UV-Spectrophotometer.

**Chemicals**: Simulated salivary solution (6.75 pH), diclofenac drug, carbopol, HPMC, alcohol etc.

**PRINCIPLE:**

In short, bio-adhesive describes adhesion of polymer to a biological membranes and if adhesion is restricted to the mucus layer lining of the mucosal surface, it is termed as 'muco-adhesion'. Mucoadhesive drug delivery systems utilize the property of bio-adhesion of certain water soluble polymers which becomes adhesive on hydration.

Development of bond between a polymer and biological membrane occurs due to:

a) Initial contact between two surfaces,

b) Formation of secondary bonds due to non-covalent interactions.

Mechanistically bio- adhesion involves the formation of hydrogen andelectrostatic bonding at the mucus polymer interface. Immobilization of drug at the mucosal surface would result in prolonged residence time. Localization of drug which ultimately results in better absorption and better bioavailability.

**Buccal Delivery**:

Buccal delivery is a potential alternative to the conventional therapy especially for the drugs that undergo degradation due to acidic environment anddrugs that undergo extensive first pass metabolism and also drugs that have poor bioavailability when given by oral route.

**Drug Selection Criteria**:

1. Drugs should have high pharmacological activity at low dose requirements.
2. Site of dosage form should not exceed 12cm 2 for buccal application or 3cm 2 for sublingual or gingival application.
3. Drug with daily requirements of 25mg or less would make a good criterion.
4. Limited solubility or absorption through gastro intestinal membrane.
5. Drug susceptible to degradation and first pass metabolism.
6. The Half-life should be 2-8hrs.

**Official Formula:**

| Sl No. | Ingredients | Official Quantity (per tablet) | Working Quantity |
|---|---|---|---|
| 1. | Diclofenac sodium | 100 mg | |
| 2. | PVP | 10% | |
| 3. | Sodium Alginate | 150 mg | |
| 4. | Lactose | 50 mg | |
| 5. | Magnesium stearate | 5.88 mg | |
| 6. | Talc | 2.95 mg | |

**Procedure:**

1. Accurately weighed quantity of Diclofenac sodium was mixed with weighed quantity of sodium alginate.
2. PVP was used as granulating agent (10% w/v in alcohol)
3. The coherent mass was passed through sieve no:10/12.
4. The granules were dried for $40^0$ C for 15 min and collected and regranulated with the sieve no:22/44.
5. The percentage of fine were collected and 10% of fines were used the granules are weighed and calculate amount of magnesium stearate and talc were added and blended.
6. Theoretical weight of tablet was determined and compress in suitable punch.

**Evaluation parameters of powder:**

a. Bulk density
b. Tapped density
c. Hausnor's ratio
d. Carr's index
e. Angle of repose
f. Flow rate

## Evaluation of mucoadhesive tablets:

**Weight uniformity:**

- 10 tablets were taken and weighed individually.
- Average weight was calculated and std. deviation was computed.

**Hardness test**:

- Hardness or crushing strength of tablet was measured using Pfizer hardness tester. (expressed in kg/cm2)

**Thickness**:

- The tablet thickness was measured by Vernier calibre. It is expressed in mm.

**Friability**:

- % friability was determined by using Roche friabilator.

**Swelling studies**:

- The degree of swelling of muoadhesive polymer is an important factor affecting adhesion.
- For this test tablets weighed individually and immersed in petri dish containing simulated salivary solution. At predetermined time intervals viz 0.25,0.5,1,2,4,8 hrs.
- one tablet was removed and excess water content was removed by filter paper.
- The tablet weight was determined and percentage swelling was calculated by,

$$\% \text{ swelling} = \frac{(w2 - w1)}{w2} \times 100$$

**Surface pH**:

- It is necessary to investigate possibility of any side effects of mucoadhesive tablet on buccal mucosa.
- Tablets are allowed to swell in distilled water and pH was found by placing a electrode of pH meter just in contact with the surface of tablets,
- average of 3 readings are computed.

**Drug content uniformity:**

- 20 tablets were weighed and triturated.
- The powder mass equivalent to 100 mg of drug was weighed accurately and transferred to 100ml volumetric flask small quantity of ethanol was placed into volumetric flask and drug was allowed to dissolve.

- The final volume was made up to the mark with ethanol. The resulted solution was filtered and diluted suitably.
- Absorbance was determined at 262nm.

**Determination of *in vitro* mucoadhesion strength:**

- This is done by using tissue of mucosa of goat chick placed in a beaker containing simulated saliva solution of pH 6.75. membrane was placed over the surface of lower poly propylene cylinder and secure.
- Then assembly was placed into beaker containing simulated saliva solution of pH 6.75 at 37±2˚c , and tablet was stuck to the lower surface of polypropylene cylinder with the standard cyanoacrylate adhesive.
- The exposed part of the tablet was wetted with a drop of simulated saliva solution and then a weight of 10 gm was placed above the expanded cap.
- Wait for 10 min to bind tablet with mucin and take the weight.

**Report:**

The Preformulation parameters of the powder mixture were found to be,

1. Bulk density:
2. Tapped density:
3. Hausner's ratio:
4. Carr's Compressibility Index:
5. Angle of repose:
6. Flow Rate:

The evaluation parameters of the tablet batch were found to be:

1. Weight uniformity:
2. Hardness test:
3. Thickness:
4. Friability:
5. Swelling:
6. Surface pH:
7. Drug content uniformity:
8. *in vitro* mucoadhesion strength:

## Experiment No: 05

# TO PERFORM *IN-VITRO* DISSOLUTION PROFILE OF SR/CR MARKETED FORMULATION

**AIM**: To perform *in-vitro* dissolution profile of SR/CR marketed formulation.

**Requirement:**

**Apparatus**: USP TYPE-I dissolution apparatus, beaker, pipette, UV spectrophotometer.

**Chemicals:** Dissolution Medium-pH 7.4 phosphate buffer

Marketed Formulation-Diclofenac gastro-resistant tablet IP INAC 50

Company Name: XYZ.

Mfg. date – 01/20XX

Exp. date- 12/20XX

**PRINCIPLE:**

The therapeutic efficacy of any formulation is dependent on many factors. *In-vitro* dissolution of the drug from its dosage form is one of the most important factors. The desired therapeutic efficacy of formulation can be observed only when its dissolution pattern complies with its specification specified in official compendia like IP, BP & USP, etc.

*In-vitro* dissolution is a prerequisite for the absorption of drugs into systemic circulation. In this context present practical aims to study the in-vitro dissolution profile of the diclofenac gastro-resistant tablet and determine whether it complies or not complies with specification in official compendia.

**Procedure:**

**Development of calibration curve of diclofenac sodium:**

1. Accurately weighed 10 mg of diclofenac sodium was transferred into 100 ml of volumetric flask.
2. A small quantity of pH 7.4 phosphate buffer was added into volumetric flask and shaken to dissolve the drug completely.
3. The volume was made up to the mark by diluting with pH 7.4 phosphate buffer. This is regarded as stock solution.
4. Aliquots of stock solutions were taken and further diluted with the buffer to get test solutions of various concentrations viz 2, 4, 6, 8 and 10 µg/ml.

5. The absorbance of these prepared concentrations was measured at previously determined $\lambda_{max}$ of the drug i.e. 257nm.
6. Based on the concentrations and corresponding absorbance values of solutions, calibrations curve was plotted and equations and regression coefficient ($r^2$) of obtained line was calculated.

**Observations:**

**Calibration Curve of Drug-**

| Sl. No | Concentration (µg/ml) | Absorbance (nm) | | | Mean± SD* |
|---|---|---|---|---|---|
| | | Trial 1 | Trial 2 | Trial 3 | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |

***Standard Equation- Y= mX ± c**

**Dissolution study:**

1. The *in-vitro* dissolution study of the marketed formulation was carried out by using USP type II (paddle) apparatus.
2. 6 tablets were placed into different baskets containing 900 ml of dissolution media (pH7.4 phosphate buffer).
3. The temperature and RPM were set at 37˚c and 50 rpm respectively.
4. At predetermined time intervals, 5 ml of sample was withdrawn from all baskets and analyzed spectrophotometrically after suitable dilutions.
5. The % drug release was calculated based on equation and it was compared with specifications in official compendia.

## Observations:

***In Vitro* dissolution-**

| Time (Mins /Hrs) | Abs (nm) | Conc in µg/ml [X= $\frac{Y \pm c}{m}$] | Conc in mg/ml [X′=X/1000] | Amt in 1 ml [X′ *100] | Amt in 10 ml (mg) | Amt in 900 ml (mg) | Cleared amt (mg) | CDR (mg) | % CDR |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | 0 | | |
| | | | | | | | | | |
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## Report:

The evaluation parameters of the SR/CR marketed formulation were found to be:

1. CDR:
2. % CDR:

## Experiment No: 06

# FORMULATION AND EVALUATION OF TRANSDERMAL PATCHES

**AIM**: To prepare and evaluate the transdermal patches of Diclofenac sodium.

**Requirements:**

**Apparatus**: Beaker, Petridish, Aluminium foil, Magnetic stirrer and Oven.

**Chemicals:** Diclofenac sodium, Methyl cellulose, Phosphate buffer of pH 7.4.

**PRINCIPLE:**

Diclofenac – 100mg.

Ethyl cellulose : PVP – 900mg (7:3)

Toulene : Ethanol - 20ml (8:2)

Polyethylene glycol 400 – 0.3ml

**BASIC COMPONENTS OF TRANSDERMAL PATCH:**

**1) POLYMER MATRIX:**

Polymer matrix controls the release of the drug from device. The polymer should be;

1. An inert drug carrier .Does not decompose on storage.

2 .Allow the diffusion of drug at desirable rate.

3. The most widely used polymers in the preparation of transdermal patch are polypropylene, poly vinyl carbonate, cellulose acetate nitrate, poly acrylonitrate, ethylene vinyl acetate copolymer, hydroxyl propyl cellulose, polyethylene tetrapthalate and polyesters.

**2) DRUG:**

1. Molecular weight of the drug should be less than 1000 daltons.

2. Affinity to both hydrophilic and lipophilic phases.

3. The drug should have low melting point i.e.,<200ºc.

4. The half life of the drug should be short.

5. The drug should not induce cutaneous irritation/allergic response.

**3) PERMEATION ENHANCERS:**

Permeation enhancers promote skin permeability by altering the behaviour of skin as a barrier to the flux of a desired product.

a) Solvents : They enhance the swelling of polar pathway or by fludising lipids.

Eg: Methanol, ethanol.

b) Surfactants : They enhance the poor pathway especially hydrophilic drugs.

c) Binary systems : Binary systems open up the heterogenous multilaminate pathway as well as continuous pathways.

Eg: propylene glycol, oleic acid.

d) Backing membrane :

This provides good bond to the drug reservoir prevent drug release from the top of the patch.

**TYPES OF TRANSDERMAL SYSTEMS :**

1. Reservoir devices.
2.Adhesive dispersion system.
3. Matrix dispersion system.
4.Micro reservoir system.

**ADVANTAGES:**

1Trandermal medication delivers a steady infusion of a drug over an extended period of time.

2. Adverse or therapeutic failures frequently associated with intermittent dosing can also be avoided.

3. Avoid hepatic or first pass metabolism.

4. Patient compliance.

5.Reduced dosage frequency.

**LIMITATIONS:**

If the drug dosage required for therapeutic value is more than 10mg/day the transdermal delivery will be very difficult if not impossible. The dose of less than 5mg/day are preferred.

**Procedure:**

1. Standard calibration curve of diclofenac sodium.
2. Stock solution was prepared by dissolving 100 ml of 7.4 pH buffer solution.
3. Concentrations of 2, 4, 6, 8, & 10 mg /ml were prepared by withdrawing 2, 4, 6, 8, and 10 ml from stock solution.
4. Diluted up to 100ml. measure the absorbance at 275 nm.

I. **Preparation of transdermal film-**

1. Methyl cellulose is dissolved in sufficient quantity of water and kept on magnetic stirrer for 15min.
2. The weighed quantity of Diclofenac sodium was added to the polymeric solution and mixed vigorously.
3. Propylene glycol, Span 80, Methyl Paraben was added to above solution in appropriate quantity.
4. Appropriate volume was made by adding water to get proper viscosity and spreadability.
5. The resulting dispersion was poured in petridish in which aluminium foil was spread and allowed to dry in oven .
6. **Determination of drug content:**

- 7ml formulation was placed in petri dish.
  - Internal diameter=7cm
  - Radius=3.5 cm
  - Area of petridish =3.14 X (3.5)2
    = 38.465 cm2

In the above manner obtain the area and by dissolving 1cm2 patch in 7.4 pH buffer 100ml and the calibration curve obtained drug content in 1cm2patch.

**Evaluation of transdermal patches:**

1. **Weight variation:**

i. The transdermal patches were cut in circular shape in such a way that each patch will be having 1cm diameter.

ii. The 6 patches were weighed individually and their average weight and std. deviation was calculated.

2. **Thickness:**

i. The thickness of 6 randomly selected patches was determined by vernier caliper
ii. and their mean was calculated.

3. **Folding endurance:**

i. This was determined by repeatedly folding one film at the same place till it broke.
ii. The number of times the film could be folded at the same place without breaking or cracking gave the value of folding endurance.

**4. Drug content:**

i. The patches were placed in phosphate buffer of pH 7.4 and drug was extracted in it.
ii. The drug content was determined by using previously developed and validated calibration curve.

**5. *In vitro* drugdiffusion study:**

i. The *in vitro* study was carried out by using locally fabricated franz diffusion cell 125 ml capacity. It is consisting of donor and receptor compartment.
ii. The receptor compartment was filled with phosphate buffer of pH 7.4.
iii. Previously soaked cellophane membrane was placed in between donor and receptor compartment.
iv. Taking care that no any bubble will be formed below membrane.
v. The transdermal patch was placed in donor compartment in a such a way that the drug dispersion was facing the membrane.
vi. The temp.of receptor compartment was maintained at 37˚ by thermostat.
vii. The assembly was kept on magnetic stirrer and continuously stirred.
viii. The sample were taken out from sampling port at predetermined time interval and analysed for their drug content by photo spectroscopy.

**Report:**

The evaluation parameters of the transdermal patches formulation were found to be:

1. Weight variation:
2. Thickness:
3. Folding endurance:
4. Drug content:
5. *In vitro* drug diffusion study:

## Experiment No: 07

# EFFECT OF PARTICLE SIZE ON DISSOLUTION OF TABLETS

**AIM**: To study the effect of particle size on dissolution of tablets.

**Requirements**: Diclofenac sodium, Xanthan , Magnesium stearate , Talc , Alcohol , Micro crystalline cellulose, Dissolution test apparatus- USP type II

**PRINCIPLE:**

The effect of particle size on bioavailability of drug their absorption in the gastrointestinal tract is very important while producing medicinal products. The particle size of the drug substances may have significant effect on final drug product performance i.e dissolution bioavailability, content uniformity , stability.

Dissolution testing is a required test currently used to demonstrate the performance of all solid oral dosage form in which absorption of a drug is necessary for the product to exert a therapeutical effect. Dissolution is defined as the process by which a known amount of drug substances goes into solution at a given time. Under standardized condition effect of particle size on the degree of dissolution depends on physical chemical characteristic of the drug pharmaceutical form and degree of active ingredient depends on physiological conditions of GI tract.

Dissolution of pure substances follow the noye's whitney equation,

$$dc/dt = ks (Cs – Ct)$$

where,

dc/dt = Rate of dissolution

k = Dissolution rate constant

s = Active surface area of the dissolved solid.

Cs = Conc. of drug in diffusion layer

Ct = Conc. of drug in media

**Procedure:**

1. Weigh required quantity of all ingredients and mix thoroughly in a clean and dry mortar and prepare a dump mass by using alcohol 90 % as a solvent or wetting agent.
2. This prepared dump mass is passed through sieve no 10 and allow to dry 15 -20 min in an oven at temperature 60˚.
3. Then collect the granules and pass through sieve no 22 which is superimposed on sieve no 44.

4. Collect the granules and fines separately and note down the weight .mix lubricant and 10% fines with it. Mix thoroughly and compress on a tablet compression machine.

**Dissolution Study:**

1. The dissolution study of the compressed tablet was carried out by using USP type II (paddle) apparatus.
2. 6 tablets( 3 tablets(A) of sieve no.22 & 3 tablets(B) of sieve no 44) were placed into different baskets containing 900 ml of dissolution media (pH7.4 phosphate buffer).
3. The temperature and RPM were set at 37˚c and 50 rpm respectively.
4. At predetermined time intervals, 5 ml of sample was withdrawn from all baskets and analysed spectrophotometrically after suitable dilutions.
5. The % drug release of both tablets was calculated.

## Observations:

***In Vitro* dissolution-**

| Tablet Batch | Time (Mins/ Hrs) | Abs (nm) | Conc in µg/ml [X= $\frac{Y \pm c}{m}$] | Conc in mg/ml [X′=X/1000] | Amt in 1 ml [X′ *100] | Amt in 900 ml (mg) | Cleared amt (mg) | CDR (mg) | % CDR |
|---|---|---|---|---|---|---|---|---|---|
| A | | | | | | | | | |
| A | | | | | | | | | |
| A | | | | | | | | | |
| B | | | | | | | | | |
| B | | | | | | | | | |
| B | | | | | | | | | |

## Report:

The specific surface area increased with decreasing particle size of the drug, resulting in an increase in dissolution rate.

## Experiment No: 08

# EFFECT OF BINDERS ON DISSOLUTION OF TABLET

**AIM**: To study the effect of binder on dissolution of tablet.

**Requirement**:

**Chemicals**: Diclofenac sodium, Xanthan gum, Starch paste, PVP, Micro-crystalline cellulose, Magnesium stearate, Talc, Methanol etc

**Apparatus & glassware**: Test tube, Beaker, oven, Mortar & Pestle, Dissolution test apparatus

**PRINCIPLE:**

Bioavailability is the most important property of a dosage form. It is availability of dosage form to deliver the active ingredient to its site of action in an amount sufficient to the desired pharmacological response. It is affected by a number of factors related to the drug dosage form and patient. It is known that the drug bio-availability and efficacy are severely limited by its poor aqueous solubility and dissolution rate. The drug in a solid dosage form must undergo dissolution before it is available for absorption in the gastrointestinal track. Dissolution forms the rate limiting step in the absorption of drug from solid dosage form especially when the drug is poorly soluble.

**Procedure:**

1. Weigh required quantity of the excipients polymer and different binders.
2. Mix all weighed ingredient in a clean and dry mortar pestle and prepare a damp mass by using 90% methanol as a wetting agent. Different formulation of a tablets are prepared by using different binder like Acacia, Starch Paste, Sucrose, Methyl Cellulose, PVP K30, & HPMC etc.
3. A damp mass is prepared and passed through sieve no-10 and dried in an oven for 10-20 min.
4. Dried granules were collected and passed through sieve no-22 which is superimposed on sieve no-44 and collect and weigh granules and fines separately.
5. Required quantity of magnesium stearate and talc is added to the granules and 10% of fines is also added and mixed well.
6. After proper mixing granules were compressed by using tablet compression method.

**Report:**

The order of increasing dissolution rate (K1) observed with various binders was acacia = C3 > starch paste > sucrose> methyl cellulose > PVP K30 > HPMC.

## Experiment No: 09

# EFFECT OF COMPRESSIONAL FORCE ON DISINTEGRATION TIME

**AIM:** To study the effect of Compressional force on tablet disintegration time

**Requirement**:

**Chemicals:** Diclofenac sodium, Xanthan gum, MCC, Magnesium stearate, Talc, Methanol etc

**Apparatus & glassware:** Tablet punching machine, Oven, Mortar & Pestle

**PRINCIPLE:**

For tablets containing sparingly water soluble drugs, start of dissolution is often delayed by the poor wettability of the tablet surface and slow liquid penetration into tablet matrix. This property causes increased disintegration time and slow drug release that can be overcome by the adding of disintegrating agent. The disintegration time is also affected by compression force. Higher compression force makes tablet more intact and strong which results in the higher disintegration time. Thus formulation scientist has to balance the compression force in such a way that, tablet should have required strength and disintegration time and at the same time they should pass the friability test.

**Procedure:**

1. Weight required quantity of all the ingredients and half of disintegration agent and mix it properly in a clean and dry mortar.
2. Prepare a damp mass using 90% methanol and pass through sieve no.10.
3. Then granules are allowed to dry at 600c for 15-20min in an oven.
4. The dried granules are collected and passed through sieve no -22 which is superimposed on sieve no. 44 and granules and fine collected separate.
5. Then granules collected when mixed with 10%fine extra granular disintegrant.
6. Tablets were compressed with different compressional force viz hardness of 4, 5, 6, 7 and 8 the disintegration time studies were carried out.

**Report:**

Increasing the compression force resulted in an increase in both disintegration time and hardness in a quite linear relationship

## Experiment No: 10

## HECKAL PLOT, HIGUCHI AND PEPPAS PLOT AND DETERMINE SIMILARITY FACTORS

**AIM:** To plot heckal plot, higuchi and peppas plot and determine similarity factors

**PRINCIPLE:**

It is graphical representation (in the terms of concentration v/s time) of the complete release of drug from a dosage form in an appropriate selected dissolution medium that is in short it is the measure of the release of A.P.I. from a dosage form with respect to time

I. **Higuchi model**- Higuchi published the probability most famous and most often used mathematical equation to describe drug release from matrix system this is often applicable to the different geometric processes system

The basic equation of higuchi model is

$$C = [D (2qt – Cst] T/2$$

Where,

c=total no.of drug release per unit area

D=diffusion coefficient for the drug in matrix (cm2/hr.)

Qt=total volume of drug in unit volume

Cs=dimensional solubility of drug in polymer matrix(mg/cm3)

T=time (hr.)

Data obtained where plotted by the cumulative percentage of the drug release

**Application**-By using this model dissolution of drug form several modified release dosage form like some transdermal patches and matrix system with water soluble drug

II. **Peppas model** –korsmeyer et al (198)derived a simple relationship which describe the release of the drug from a polymeric system to illustrate the mechanism of the drug release first 60% of the drug release date was filled in korsmeyerpeppas model

$$Ct/Co=KTn$$

Where,

ct/co-faction of drug releases at time t

k-rate constant

n=release exponent

**Application-**

This model describe the release of the drug from several modified release dosage form

III. **Heckal plot-** Heckal plot estimates the force porosity relationship in the production of tablet Heckal equation assumes that the pores (in the mass)are considered as relationship is treated as a first order reaction

$$\textbf{Log 1/e = kyp +kr}$$

Where,

ky-constant depends on the material

Kr-constant related to the initial packaging stage

## Experiment No: 11

## DETERMINATION OF PARTICLE SIZE OF GIVEN POWDER SAMPLE

**AIM**: To determine the particle size of given powder sample and study particle size distribution by using optical microscopic method

**Apparatus:** Optical microscope, Stage micrometer, Ocular micrometer, Slides etc.

**Reference**: Text book of physical pharmacy and pharmaceutical science

**PRINCIPLE:**

The science and techniques used in the study of small particle is used is called micrometrics. The powder properties are divided into fundamental properties such as particle size ,particle size distribution ,number of partials, shape and surface area weight derived properties ,flow properties, bulk volume, granular volume, density, bulkiness, compactness. when powder contains particle of uniform size if is said to be mono-dispersed since all powder are polydispersed.it is important that characterize the particle size techniques employed to determine particle size and particle size distribution are image analysis, sedimentation method and conductivity method

**Optical microscopy**-The method is used to analysis particle within the range of 0.5µm to 100µm the power is directly sprinkled on the standard slide in dispersed form in suspension which is mounted on the slide the eyepiece is fitted with micrometer scale which is calibrated with stage micrometer particle size is measured by the counting number of division occupied by particle on ocular micrometer to obtain reproducible result at least 500 particle should be measured the limitation of the method are that only two dimension that is length and breadth can be measured which leads to error in particle size determination.

**Advantage:**

1. Accurate and simple method.
2. Particle are easily observed.

**Disadvantage:**

1. Time consuming method since large number of particle are to be measured.
2. Some particle may be observed repeatedly.
3. Not suitable for the very fine particle

**Procedure:**

1. Take a clean microscope and adjust for maximum light intensity.
2. Mount the stage micrometer on and focus eyepiece micrometer.
3. Replace eyepiece with eyepiece micrometer.
4. Calibrate ocular micrometre with stage micrometer (determine the value of 1 division of ocular micrometer)
5. Remove stage micrometer and replace with slide containing particle sprinkled on it.
6. Focus particle on ocular micro scale and determine particle size.

**Report**:

# Vision and Mission of the Institution

## Vision

The East Point College of Pharmacy aspires to be a globally acclaimed institution, **recognized** for **excellence in** pharmaceutical education, research and nurturing students for **holistic development.**

## Mission

| | |
|---|---|
| **M1** | Create pharmacy graduates through **quality education** |
| **M2** | Promote innovation, **creativity**, and excellence **in teaching**, learning, and **research** |
| **M3** | **Inspire** integrity, teamwork, critical thinking**, personal** development, and ethics in **students** and lay **the** foundation for lifelong learning |
| **M4** | **Serve** the **healthcare, technological, scientific**, and **economic** needs of then **society**. |