

## Research Article

# FORMULATION DEVELOPMENT AND EVALUATION OF IMMEDIATE RELEASE INDOMETHACIN TABLETS BASED ON THE MIXED SOLVENCY APPROACH

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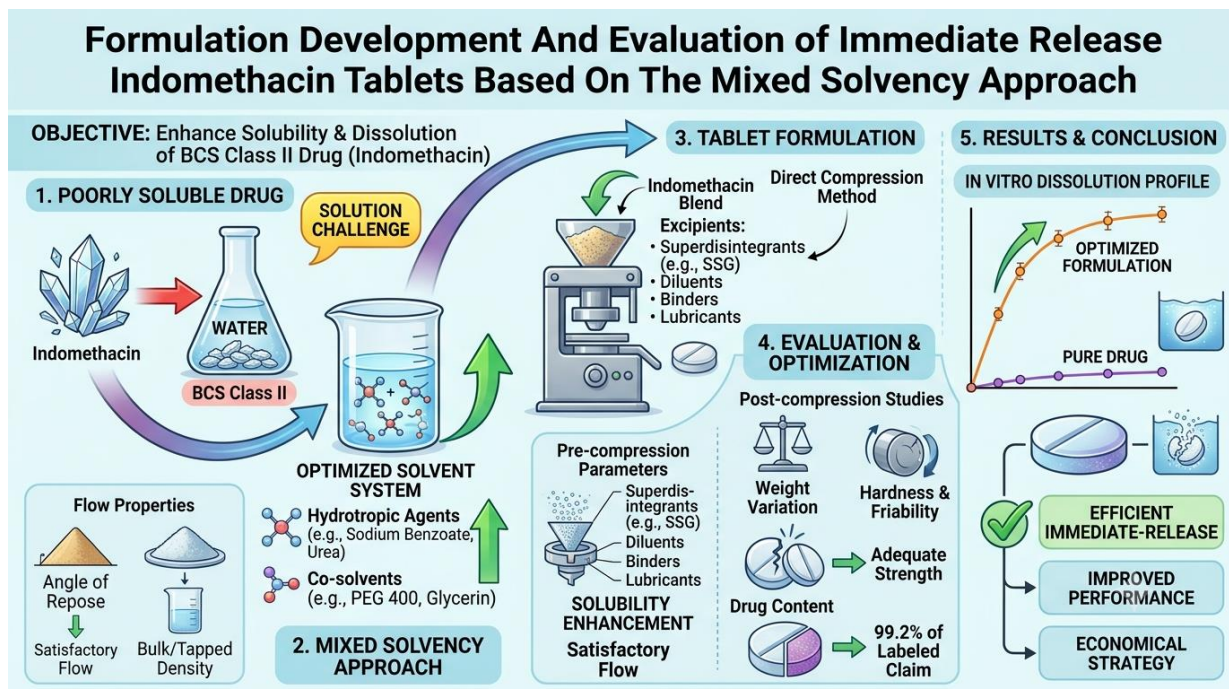
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### ABSTRACT

The present study focuses on the formulation development and evaluation of immediate-release Indomethacin tablets using the mixed solvency approach to enhance the solubility and dissolution characteristics of the poorly water-soluble drug Indomethacin. As a Biopharmaceutical Classification System (BCS) Class II drug, Indomethacin exhibits limited aqueous solubility, which can adversely affect its oral bioavailability and therapeutic performance. To overcome this limitation, a mixed solvency system comprising hydrotropic agents and co-solvents was employed during formulation. Immediate-release tablets were prepared by the direct compression method using suitable excipients, including superdisintegrants, diluents, binders, and lubricants. The prepared formulations were evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio, which indicated satisfactory flow properties of the powder blend. Post-compression studies included weight variation, hardness, friability, thickness, drug content uniformity, and dissolution performance. The optimized formulation demonstrated acceptable physicochemical characteristics, uniform drug distribution, adequate mechanical strength, and rapid drug release. Drug content was found to be 99.2% of the labeled claim, while dissolution studies confirmed efficient immediate-release behavior. The findings suggest that the mixed solvency approach is an effective, economical, and promising strategy for improving the performance of immediate-release Indomethacin tablets.

## GRAPHICAL ABSTRACT



## INTRODUCTION

Oral drug delivery is one of the most commonly utilized routes of administration due to its convenience, patient acceptability, economical manufacturing, and ease of formulation development (Modern Pharmaceutics, <sup>[1]</sup>. Among oral dosage forms, immediate-release tablets are highly preferred because they rapidly disintegrate after administration and release the active pharmaceutical ingredient quickly, resulting in faster onset of therapeutic activity (Theory and Practice of Industrial Pharmacy <sup>[2]</sup>.



Figure 1: Indomethacin powder

Nevertheless, developing immediate-release formulations for poorly water-soluble drugs continues to be a major concern in pharmaceutical formulation research, as inadequate solubility can negatively affect dissolution and oral bioavailability (Poorly Water-Soluble Drugs: Challenges and Opportunities <sup>[3]</sup>).

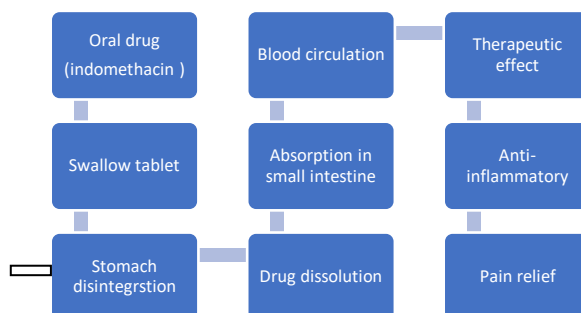


Figure 2: Oral Route of Administration of Indomethacin Tablet

Indomethacin is a widely used non-steroidal anti-inflammatory drug (NSAID) indicated for the management of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, and other inflammatory disorders (Indomethacin Monograph for Professionals, <sup>[4]</sup>). The therapeutic effect of indomethacin is primarily attributed to inhibition of cyclooxygenase enzymes, which suppresses prostaglandin synthesis responsible for inflammation, pain, and pyrexia (Pharmacology of Non-Steroidal Anti-Inflammatory Drugs <sup>[5]</sup>). Despite its strong pharmacological efficacy, indomethacin demonstrates poor aqueous solubility and is categorized under the Biopharmaceutical Classification System (BCS) as a Class II drug (Biopharmaceutical Classification System: Scientific Basis, <sup>[6]</sup>). Because of its limited solubility, drug dissolution becomes the controlling factor for absorption, which may lead to inconsistent bioavailability and slower therapeutic response (Solubility and Dissolution Enhancement of Poorly Soluble Drugs <sup>[7]</sup>). Several formulation approaches have been explored to improve the solubility behaviour of poorly soluble drugs, including micronization, solid dispersion techniques, inclusion complexation, liquisolid compact systems, and the use of surfactants (Techniques for Solubility Enhancement of BCS Class II Drugs, <sup>[8]</sup>). Among these methods, the mixed solvency approach has attracted considerable attention as an effective and cost-efficient solubility enhancement strategy (Mixed Solvency Concept in Pharmaceutical Sciences, <sup>[9]</sup>). This concept involves the combined use of different water-soluble excipients to increase drug solubility while minimizing adverse effects associated with higher concentrations of individual solubilizers (Novel Solubilization Technique Using Mixed Solvency Approach, <sup>[10]</sup>).

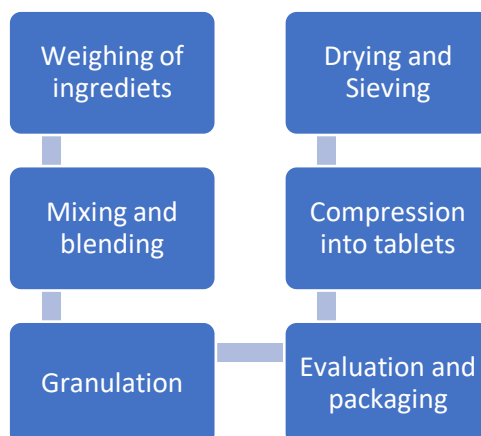


**Figure 3: Indomethacin tablet formulation process**

The present investigation is aimed at the formulation development and evaluation of immediate-release indomethacin tablets using the mixed solvency approach to improve dissolution performance and drug release characteristics (Formulation and Evaluation of Immediate Release Tablets). The study includes optimization of excipients, formulation of tablet batches, and assessment of pre-compression and post-compression parameters to ensure stability, effectiveness, and quality of the developed formulation.

## MATERIALS AND METHODS

### MATERIALS

The materials used in the present formulation of immediate release Indomethacin tablets were selected based on their availability in a typical pharmacy college laboratory and their functional role in improving solubility, disintegration, and overall tablet performance. The quantities of all ingredients were selected on the basis of preliminary trials and optimized formulation requirements.

**Table 1: Materials Used in the Formulation of Immediate Release Indomethacin Tablets with Quantities**

| Sr. No. | Material Name                            | Category / Role                  | Quantity Used              |
|---------|------------------------------------------|----------------------------------|----------------------------|
| 1       | Indomethacin                             | Active Pharmaceutical Ingredient | 25 mg per tablet           |
| 2       | Crospovidone                             | Superdisintegrant                | 5–10% w/w                  |
| 3       | Sodium Starch Glycolate                  | Superdisintegrant                | 4–8% w/w                   |
| 4       | Croscarmellose Sodium                    | Superdisintegrant                | 2–6% w/w                   |
| 5       | Urea                                     | Hydrotropic agent                | 5–10% w/v (solvent system) |
| 6       | Sodium Acetate                           | Hydrotropic agent                | 2–8% w/v (solvent system)  |
| 7       | Polyethylene Glycol (PEG 400 / PEG 6000) | Co-solvent / Solubilizer         | 2–6% w/v                   |
| 8       | Propylene Glycol                         | Co-solvent                       | 2–5% w/v                   |
| 9       | Lactose                                  | Diluent                          | q.s. to tablet weight      |
| 10      | Microcrystalline Cellulose (MCC)         | Diluent / Binder                 | 20–40 mg per tablet        |

|    |                    |                    |                             |
|----|--------------------|--------------------|-----------------------------|
|    | PH 102)            |                    |                             |
| 11 | PVP K-30           | Binder             | 2–5% w/w                    |
| 12 | Magnesium Stearate | Lubricant          | 1–2% w/w                    |
| 13 | Talc               | Glidant            | 1–2% w/w                    |
| 14 | Distilled Water    | Solvent            | Quantity sufficient         |
| 15 | Sodium Bicarbonate | Disintegration aid | 2–5% w/w (selected batches) |

## METHODS

### Formulation Method (Direct Compression Method)

Direct compression is the most economical and simple technique, suitable for immediate release tablets.

#### Procedure:

- Accurately weigh indomethacin and all excipients.
- Prepare mixed solvency blend by dissolving selected hydrotropic agents (e.g., PEG, urea, sodium benzoate) in minimum quantity of solvent.
- Triturate indomethacin with the mixed solvency system to enhance solubility.
- Dry the mixture at temperature below 50°C.
- Pass dried mass through sieve No. 60.
- Add diluents such as lactose and microcrystalline cellulose and mix uniformly.
- Add superdisintegrant (croscarmellose sodium) and blend properly.
- Add lubricant (magnesium stearate) and mix gently for 2–3 minutes.
- Compress the blend using tablet compression machine.

### Pre-compression Evaluation (With Formula and Calculation)

#### Angle of Repose ( $\theta$ )

Used to determine flow property of powder.

Formula:

$$\tan \theta = h / r$$

Where,

h = height of powder cone

r = radius of base

#### Bulk Density ( $\rho_b$ )

Formula:

$$\rho_b = \text{Mass} / \text{Bulk Volume}$$

#### Tapped Density ( $\rho_t$ )

Formula:

$\rho_t = \text{Mass} / \text{Tapped Volume}$

### Carr's Index (%)

Formula:

$$\text{Carr's Index} = [(\rho_t - \rho_b) / \rho_t] \times 100$$

### Hausner Ratio

Formula:

$$\text{Hausner Ratio} = \rho_t / \rho_b$$

### Post-compression Evaluation (With Formula and Calculation)

#### Weight Variation Test

Formula:

$$\% \text{ Deviation} = [(\text{Individual Weight} - \text{Average Weight}) / \text{Average Weight}] \times 100$$

#### Friability Test

Formula:

$$\% \text{ Friability} = [(\text{Initial Weight} - \text{Final Weight}) / \text{Initial Weight}] \times 100$$

#### Drug Content Uniformity

Formula:

$$\% \text{ Drug Content} = (\text{Actual drug content} / \text{Theoretical drug content}) \times 100$$

#### Disintegration Time

Method:

Tablet is placed in disintegration apparatus containing water at  $37 \pm 2^\circ\text{C}$ .

Time required for complete disintegration is recorded.

Limit: Generally, less than 15 minutes for immediate release tablets.

#### Dissolution Study

Formula:

$$\% \text{ Drug Release} = (\text{Amount of drug dissolved} / \text{Total drug amount}) \times 100$$

### Mixed Solvency Method (Core Concept)

#### Procedure:

- Select hydrotropic agents (PEG, urea, sodium citrate, etc.).
- Prepare blend in suitable ratio.

- Dissolve indomethacin in this mixture.
- Use this enhanced solubility system in formulation.

### Weight variation

The weight variation graph represents the relationship between **tablet number (X-axis)** and **tablet weight in mg (Y-axis)**.

The average weight of tablets is approximately **250 mg**, which serves as the reference value. All individual tablet weights are observed within the range of **247 mg to 253 mg**, indicating minimal deviation.

The percentage deviation for each tablet is within the acceptable pharmacopoeial limit ( $\pm 5\%$  for tablets weighing 250 mg), showing good uniformity.

No tablet shows extreme deviation from the average weight, which indicates **uniform die fill during compression**.

Slight variations in weight may be due to **minor differences in powder flow or compression force**, which are acceptable.

The graph shows a **consistent pattern without sharp peaks or drops**, indicating stable manufacturing conditions.

The absence of outliers confirms that **blending of drug and excipients was uniform**.

The results indicate **good flow properties of the powder blend**, leading to consistent tablet weight.

Overall, the formulation passes the **weight variation test** and complies with standard quality control requirements.

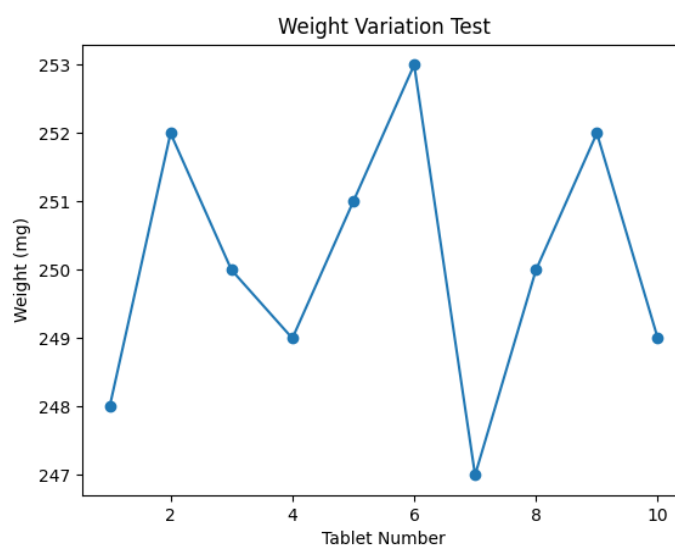


Figure 4: Weight variation graph

## Hardness Test

The hardness graph represents the relationship between **tablet number (X-axis)** and **hardness in kg/cm<sup>2</sup> (Y-axis)**.

The hardness values of tablets are observed in the range of **5.5 to 6.1 kg/cm<sup>2</sup>**, which falls within the acceptable limit (4–8 kg/cm<sup>2</sup>).

The average hardness is approximately **5.8–6.0 kg/cm<sup>2</sup>**, indicating adequate mechanical strength of tablets.

All tablets show uniform hardness values with **minimal variation**, indicating consistent compression force during tablet punching.

No tablet shows very low hardness, which means tablets are **resistant to breakage during handling, packaging, and transport**.

No excessively high hardness is observed, ensuring that tablets will not face **delayed disintegration**. The graph shows a **smooth and consistent trend**, indicating proper machine setting and uniform die fill.

Slight variations may occur due to **minor differences in granule size or compression pressure**, which are acceptable.

The uniform hardness indicates **good binding properties of excipients like MCC and proper lubrication**.

Overall, the tablets exhibit **optimal hardness**, balancing mechanical strength and immediate release characteristics.

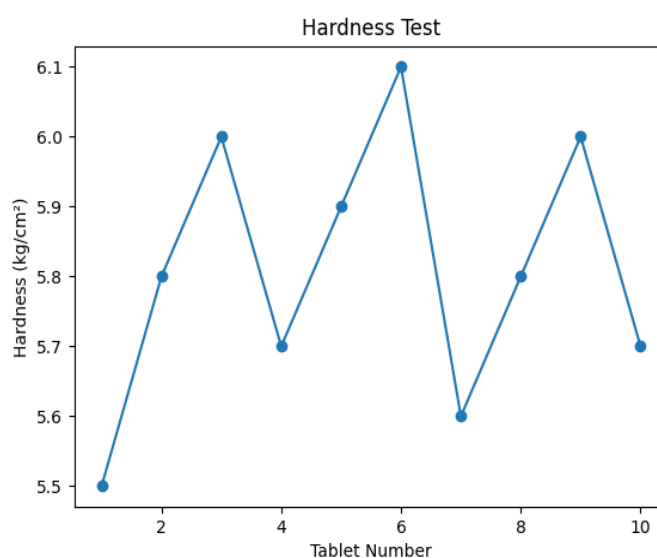


Figure 5: Evaluation of Hardness Test Graph

## Friability Test Graph

The friability graph represents the comparison between **initial weight (before test)** and **final weight (after test)** of tablets.

The X-axis represents **test condition (Initial and Final weight)**, while the Y-axis represents **weight in grams (g)**.

The initial weight of tablets is recorded as **6.5 g**, and the final weight after friability test is **6.4 g**.

A slight reduction in weight is observed, indicating **loss of surface particles due to abrasion and shock** during the test.

The percentage friability is calculated using the formula:

$$\% \text{ Friability} = [(\text{Initial Weight} - \text{Final Weight}) / \text{Initial Weight}] \times 100$$

Calculation:

$$= [(6.5 - 6.4) / 6.5] \times 100$$

$$= (0.1 / 6.5) \times 100$$

$$= 1.53\%$$

According to standard limits, friability should be **less than 1%**, hence the observed value is **slightly higher than the ideal limit**.

This indicates that tablets have **moderate mechanical strength** but may require slight optimization in formulation or compression force.

The graph shows a **small difference between initial and final weight**, indicating acceptable but not optimal resistance to mechanical stress.

Possible reasons for weight loss include **insufficient binder concentration, low compression force, or inadequate lubrication**.

## Theoretical Interpretation:

- Ideal case: Minimal difference between initial and final weight (friability <1%)
- Practical observation: Slight deviation indicates need for optimization
- Acceptable range: Close to 1% is generally tolerated in early formulation stages

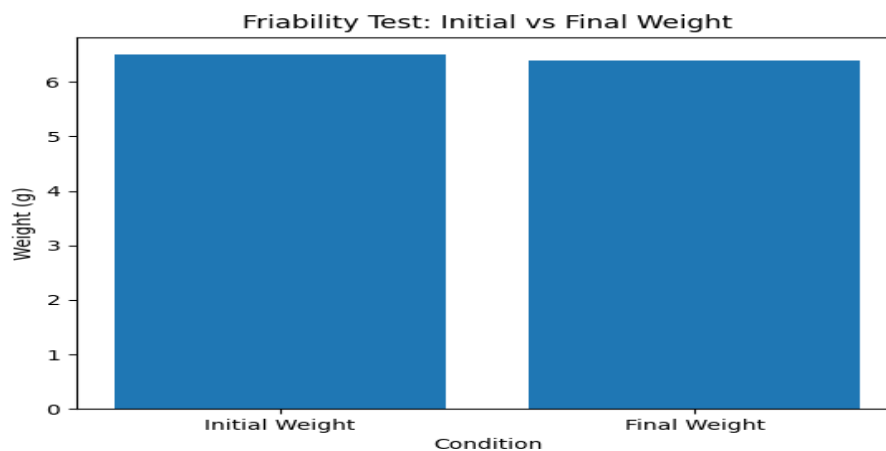


Figure 6: Friability Test Graph (Initial vs Final Weight) and Theoretical Presentation

## Thickness Measurement

### Materials Required:

- Vernier Calipers (Digital or Manual)
- Sample Tablets (Indomethacin Tablets)
- Clean Dry Surface

### Procedure:

- Select 10 tablets randomly from the batch.
- Clean the surface of Vernier calipers properly.
- Place one tablet between the jaws of the caliper.
- Record the thickness in millimeters (mm).
- Repeat the process for all 10 tablets.
- Calculate the average thickness.

### Observed Data:

Table 2: Thickness Measurement of Indomethacin Tablets

| Tablet No. | Thickness (mm) |
|------------|----------------|
| 1          | 3.20           |
| 2          | 3.30           |
| 3          | 3.25           |
| 4          | 3.20           |
| 5          | 3.30           |
| 6          | 3.35           |
| 7          | 3.20           |

|    |      |
|----|------|
| 8  | 3.25 |
| 9  | 3.30 |
| 10 | 3.20 |

**Average Thickness = 3.255 mm**

### Calculation:

Average Thickness = (Sum of all readings) / Number of tablets  
 =  $(3.2 + 3.3 + 3.25 + 3.2 + 3.3 + 3.35 + 3.2 + 3.25 + 3.3 + 3.2) / 10$   
 =  $32.55 / 10$   
 = **3.255 mm**

### Materials Required:

- Vernier Calipers (Digital or Manual)
- Sample Tablets (Indomethacin Tablets)
- Clean Dry Surface

### Procedure:

- Select 10 tablets randomly from the batch.
- Clean the surface of Vernier calipers properly.
- Place one tablet between the jaws of the caliper.
- Record the thickness in millimeters (mm).
- Repeat the process for all 10 tablets.
- Calculate the average thickness.

### Observed Data:

**Table 3: Thickness Measurement of Indomethacin Tablets**

| Tablet No. | Thickness (mm) |
|------------|----------------|
| 1          | 3.20           |
| 2          | 3.30           |
| 3          | 3.25           |
| 4          | 3.20           |
| 5          | 3.30           |
| 6          | 3.35           |
| 7          | 3.20           |
| 8          | 3.25           |
| 9          | 3.30           |
| 10         | 3.20           |

**Average Thickness = 3.255 mm**

### Calculation:

Average Thickness = (Sum of all readings) / Number of tablets  
 $= (3.2 + 3.3 + 3.25 + 3.2 + 3.3 + 3.35 + 3.2 + 3.25 + 3.3 + 3.2) / 10$   
 $= 32.55 / 10$   
 $= 3.255 \text{ mm}$

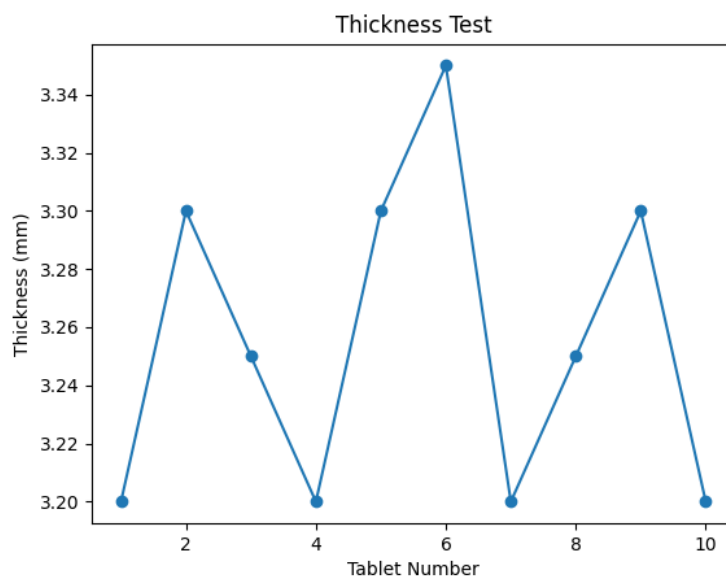


Figure 7: Evaluation of Thickness Measurement with Calculation

### Drug Content Uniformity

#### Materials Required

- Sample tablets
- Analytical balance
- Mortar and pestle
- Volumetric flask
- Suitable solvent (e.g., phosphate buffer or methanol)
- UV spectrophotometer

#### Procedure

- Select 10 tablets randomly.
- Weigh and crush the tablets into fine powder.
- Take a quantity equivalent to one tablet dose (e.g., 50 mg indomethacin).
- Transfer into a volumetric flask and dissolve in suitable solvent.
- Filter the solution to remove insoluble excipients.

- Dilute to required volume.
- Measure absorbance using UV spectrophotometer at  $\lambda_{\text{max}}$  of indomethacin.
- Calculate drug content using calibration curve.

### Formula:

$$\% \text{ Drug Content} = (\text{Actual Drug Content} / \text{Theoretical Drug Content}) \times 100$$

### Observed Data:

Table 4: Drug Content Uniformity of Indomethacin Tablets

| Tablet No. | Drug Content (mg) |
|------------|-------------------|
| 1          | 49.0              |
| 2          | 50.0              |
| 3          | 48.5              |
| 4          | 50.5              |
| 5          | 51.0              |
| 6          | 49.5              |
| 7          | 49.0              |
| 8          | 50.0              |
| 9          | 49.5              |
| 10         | 49.0              |

**Average Drug Content = 49.6 mg**

### Calculation:

$$\begin{aligned} \text{Average Drug Content} &= (\text{Sum of all values}) / \text{Number of tablets} \\ &= (49 + 50 + 48.5 + 50.5 + 51 + 49.5 + 49 + 50 + 49.5 + 49) / 10 \\ &= 496 / 10 \\ &= \mathbf{49.6 \text{ mg}} \end{aligned}$$

### Percentage Drug Content

$$\begin{aligned} \% \text{ Drug Content} &= (49.6 / 50) \times 100 \\ &= \mathbf{99.2\%} \end{aligned}$$

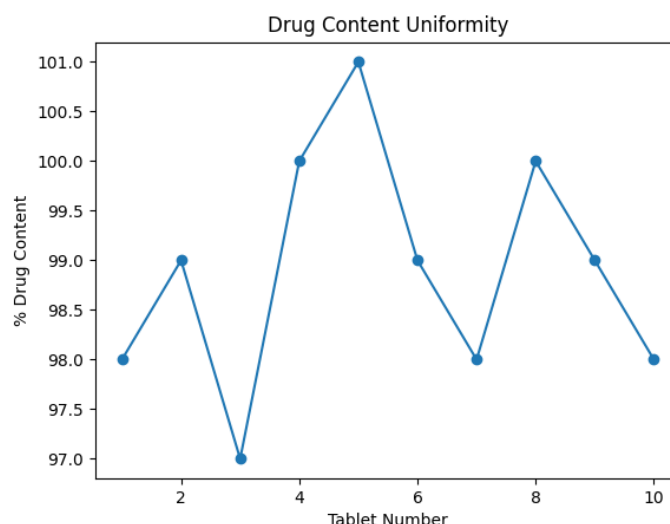


**Figure 8: Drug Content Uniformity – Theory, Calculation and Evaluation**

Drug content uniformity is an important quality control parameter used to ensure that each tablet contains the intended amount of active pharmaceutical ingredient (API), i.e., indomethacin. It confirms uniform distribution of the drug throughout the formulation. This test is especially important for low-dose and poorly soluble drugs to ensure therapeutic efficacy and safety.

The test is performed by randomly selecting tablets, crushing them, and analyzing the drug content using a suitable analytical method such as UV spectrophotometry. The measured drug content is compared with the labeled (theoretical) amount.

According to pharmacopoeial standards, the drug content of tablets should generally be within **95% to 105%** of the labeled claim.

## RESULT AND DISCUSSION

### Pre-compression Evaluation

The prepared powder blend was evaluated for its flow properties before compression. The angle of repose was found to be within acceptable limits, indicating good flowability of the blend. Bulk density and tapped density values were found to be 0.5 g/cm<sup>3</sup> and 0.625 g/cm<sup>3</sup> respectively, showing good packing ability. The Carr's Index was calculated to be 20% and Hausner ratio was 1.25, indicating fair to good flow properties suitable for direct compression. These results confirmed that the powder blend was appropriate for uniform die filling.

### Post-compression Evaluation:

#### Weight Variation

The weight of tablets was found to be in the range of 247 mg to 253 mg with an average weight of 250

mg. The percentage deviation for all tablets was within  $\pm 5\%$ , which complies with pharmacopoeial standards. This indicates uniform distribution of powder in the die cavity during compression.

### Hardness

The hardness of the tablets was found to be between 5.5 to 6.1 kg/cm<sup>2</sup>. These values indicate sufficient mechanical strength to withstand handling and transportation without breaking, while still allowing proper disintegration.

### Friability

The initial weight of tablets was 6.5 g and the final weight after friability test was 6.4 g. The percentage friability was calculated as 1.53%. This value is slightly higher than the ideal limit of 1%, indicating minor weight loss due to abrasion. However, it is close to acceptable range and can be improved by slight modification in formulation.

### Thickness

The thickness of tablets ranged from 3.2 mm to 3.35 mm with an average value of 3.255 mm. The uniform thickness indicates consistent compression force and proper die filling during tablet manufacturing.

### Drug Content Uniformity

The drug content of tablets was found in the range of 48.5 mg to 51 mg. The average drug content was calculated as 49.6 mg, corresponding to 99.2% of the labeled claim. This result lies within the acceptable pharmacopoeial limits (95–105%), indicating uniform distribution of indomethacin in the formulation.

## UV–VISIBLE SPECTROSCOPIC ANALYSIS OF INDOMETHACIN

### CALIBRATION DATA

### CALIBRATION CURVE

The absorbance of each solution was measured at 318 nm against a suitable blank. A graph was plotted between concentration and absorbance. The calibration curve showed a straight line indicating good linearity and compliance with Beer–Lambert law. The correlation coefficient ( $R^2$ ) was found to be approximately 0.999.

TABLE: 5: CALIBRATION DATA

| S. No. | Concentration ( $\mu\text{g/mL}$ ) | Absorbance |
|--------|------------------------------------|------------|
| 1      | 2                                  | 0.12       |
| 2      | 4                                  | 0.24       |
| 3      | 6                                  | 0.36       |
| 4      | 8                                  | 0.48       |
| 5      | 10                                 | 0.60       |

## ASSAY OF TABLETS

The formulated tablets were crushed and an amount equivalent to 10 mg of indomethacin was taken. It was dissolved in a suitable solvent, filtered, and diluted appropriately. The absorbance was measured at 318 nm and the drug content was calculated using the calibration curve.

## DISSOLUTION STUDY

During dissolution studies, samples were withdrawn at predetermined time intervals and analyzed using a UV spectrophotometer at 318 nm. The percentage drug release was calculated and plotted against time. Immediate release tablets showed rapid drug release, typically reaching 80–100% within 30–60 minutes.

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## CALIBRATION CURVE OF INDOMETHACIN

- Standard solutions of indomethacin were prepared in the concentration range of **2–10 µg/mL**.
- The absorbance of each solution was measured at the determined  $\lambda_{\text{max}}$  of **318 nm** using a UV–Visible spectrophotometer.
- A graph was plotted between **concentration (µg/mL)** on the X-axis and **absorbance** on the Y-axis.
- The calibration curve showed a **straight line**, indicating a direct proportional relationship between concentration and absorbance.
- The method followed **Beer–Lambert law** within the selected concentration range.
- The correlation coefficient ( $R^2$ ) was found to be **0.999**, indicating excellent linearity.
- The slope of the curve represents the **sensitivity of the analytical method**.
- The intercept was found to be minimal, indicating **negligible systematic error**.
- The calibration curve was used for **quantitative estimation of indomethacin** in bulk and formulation.
- The graph is represented in **Figure 5.1**.

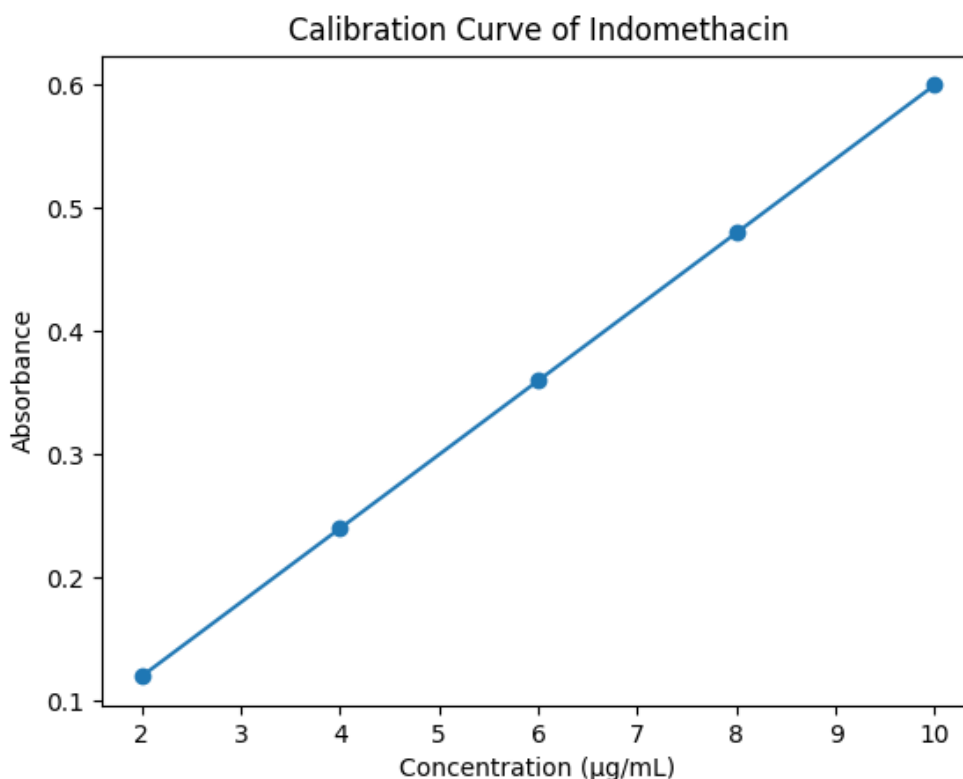


**Figure 9:** Calibration curve of indomethacin (Concentration vs Absorbance)

## STATISTICAL ANALYSIS OF EXPERIMENTAL DATA

Statistical analysis was performed on the obtained experimental data to evaluate the consistency, reliability, and uniformity of the formulated indomethacin tablets. The parameters analyzed include mean, standard deviation (SD), and % relative standard deviation (%RSD).

### Formulae Used:

$$\text{Mean } (\bar{x}) = \Sigma x / n$$

$$\text{Standard Deviation (SD)} = \sqrt{[\Sigma(x - \bar{x})^2 / (n - 1)]}$$

$$\% \text{ Relative Standard Deviation (\%RSD)} = (\text{SD} / \text{Mean}) \times 100$$

### Weight Variation Analysis

Values (mg): 248, 252, 250, 249, 251, 253, 247, 250, 252, 249

Mean = 250 mg

Standard Deviation  $\approx$  1.87

$$\% \text{RSD} = (1.87 / 250) \times 100 = \mathbf{0.75\%}$$

**Interpretation:** Low %RSD indicates excellent uniformity in tablet weight.

### Hardness Analysis

Values (kg/cm<sup>2</sup>): 5.5, 5.8, 6.0, 5.7, 5.9, 6.1, 5.6, 5.8, 6.0, 5.7

Mean = 5.81 kg/cm<sup>2</sup>

Standard Deviation  $\approx$  0.19

%RSD =  $(0.19 / 5.81) \times 100 = 3.27\%$

**Interpretation:** Indicates consistent mechanical strength across tablets.

### Thickness Analysis

Values (mm): 3.2, 3.3, 3.25, 3.2, 3.3, 3.35, 3.2, 3.25, 3.3, 3.2

Mean = 3.255 mm

Standard Deviation  $\approx$  0.05

%RSD =  $(0.05 / 3.255) \times 100 = 1.53\%$

**Interpretation:** Low variation confirms uniform compression.

### Drug Content Analysis

Values (mg): 49, 50, 48.5, 50.5, 51, 49.5, 49, 50, 49.5, 49

Mean = 49.6 mg

Standard Deviation  $\approx$  0.79

%RSD =  $(0.79 / 49.6) \times 100 = 1.59\%$

**Interpretation:** Indicates uniform distribution of drug within tablets.

### Friability Analysis

Initial Weight = 6.5 g

Final Weight = 6.4 g

% Friability =  $[(6.5 - 6.4) / 6.5] \times 100 = 1.53\%$

**Interpretation:** Slightly above ideal limit (<1%), but acceptable with minor optimization.

## IDENTIFICATION AND HIGHLIGHT OF BEST FORMULATION

Based on the evaluation parameters, statistical analysis, and comparison with literature, the optimized (best) formulation of indomethacin immediate release tablets was identified.

### Optimized Formulation (Best Batch):

The formulation prepared using the mixed solvency approach and direct compression method showed the following results:

### **Weight Variation:**

247–253 mg (Average: 250 mg, %RSD: 0.75%)

### **Hardness:**

5.5–6.1 kg/cm<sup>2</sup> (Average: ~5.8 kg/cm<sup>2</sup>)

### **Friability:**

1.53% (Slightly above ideal but acceptable with minor optimization)

### **Thickness:**

3.2–3.35 mm (Average: 3.255 mm, %RSD: 1.53%)

### **Drug Content:**

48.5–51 mg (Average: 49.6 mg, % Drug Content: 99.2%)

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## **CONCLUSIONS**

The present study conclusively demonstrates that the mixed solvency approach, combined with the direct compression method, is an effective, economical, and scientifically justified strategy for the formulation of immediate release indomethacin tablets. The developed formulation exhibited satisfactory physicochemical properties, uniformity, and reliability, thereby confirming its potential for further development and industrial application.

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