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## Formulation and Evaluation of Oral Medicated Jelly Containing Diclofenac Sodium and Dicyclomine HCl

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### ABSTRACT

Oral medicated jellies are a promising alternative dosage forms for patients who experience difficulty in swallowing the conventional dosage forms like tablets and capsules. The present study aimed to formulate and evaluate oral medicated jellies containing Diclofenac sodium, a non-steroidal anti-inflammatory drug, and Dicyclomine HCl, an antispasmodic agent, using different concentrations and combinations of gelatin and xanthan gum. Solid dispersion of Diclofenac sodium with beta-cyclodextrin was prepared by the kneading method. Nine formulations of oral jellies (F1–F9) were prepared by the heating and congealing method using gelatin, xanthan gum, and their combinations. The formulations were evaluated for physical appearance, compatibility using FTIR, weight variation, pH, syneresis, drug content, and in-vitro drug release. The dissolution studies were performed using USP apparatus II in phosphate buffer (pH 6.8) for 120 min. Dissolution efficiency (%) and mean dissolution time (MDT) were determined. The results of FTIR studies indicated compatibility between the drugs and excipients. The formulations exhibited acceptable physicochemical properties. Formulation F4 showed the highest drug release of  $91.11 \pm 0.22\%$  and  $94.81 \pm 0.21\%$  at 30 min for Diclofenac sodium and Dicyclomine HCl, respectively. The Dissolution efficiency of formulation F4 was 57.31% and 68.75% at 30 min, while the mean dissolution time was 16.56 min and 15.08 min, respectively. Formulation F4 was selected as the best formulation due to high dissolution efficiency and rapid drug release, demonstrating the potential of oral medicated jelly as a patient-friendly dosage form.

**Keywords:** Oral medicated jelly, Dissolution efficiency, Mean dissolution time.

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## INTRODUCTION

The Novel drug delivery system has become an important area of pharmaceutical research aimed at enhancing patient compliance, therapeutic efficacy, and achieving improved treatment outcomes. Among the various routes of administration of drugs, the oral route remains the most preferred because of its convenience, safety, cost-effectiveness, and greater patient acceptance. Nevertheless, conventional oral dosage forms such as capsules and tablets may pose swallowing difficulties, particularly in children, elderly individuals, and dysphagic patients. To overcome these challenges, oral medicated jellies(OMJ) have gained attention as a promising alternative dosage form. Japanese Pharmacopoeia (JP XVII) defined Oral jellies as non-flowing, gelatinous preparations possessing a definite shape and intended for oral administration. They provide multiple benefits, including ease of swallowing, improved palatability, rapid drug release, and enhanced patient acceptability. (1)

In the present study, Diclofenac sodium and Dicyclomine HCl are used as model drugs. Diclofenac sodium classified under the non-steroidal anti-inflammatory drugs (NSAIDs) primarily indicated for the alleviation of inflammation and pain. Diclofenac sodium exhibits anti-inflammatory, analgesic and antipyretic effects through the inhibition of cyclooxygenase enzyme I (COX I) and cyclooxygenase II (COX II), demonstrating a four-fold greater selectivity for the latter. Diclofenac sodium is classified under the BCS class II. The total daily dose is 150 mg per day; divided dose is given as 50mg orally 2 to 3 times a day or 75 mg 2 times a day. The half-life is 1 to 2 hours; the log P value is 4.51. Oral bioavailability of Diclofenac sodium is approximately 50-60%. Diclofenac sodium is almost completely absorbed after oral administration; it is subjected to first pass-metabolism so that nearly half of the drug reaches the bloodstream in an unchanged state. (2)

Dicyclomine HCl is a tertiary amine, an anticholinergic drug. It exhibits a non-specific relaxant effect on smooth muscle. Hence, it is used as an antispasmodic. At recommended therapeutic doses, they reduce spasms of the gastrointestinal tract, biliary tract, ureter and uterus. Dicyclomine HCl is classified under BCS class I. The total daily dose of Dicyclomine HCl is 80 mg per day, divided dose is given as 10-20 mg four times a day. The half-life of dicyclomine HCl is 1.8 to 2 hours and log P value is 4.4. Following oral administration, Dicyclomine HCl is well absorbed and undergoes substantial first-pass metabolism; the systemic bioavailability of Dicyclomine HCl is approximately 60%. Combination of Diclofenac Sodium and Dicyclomine Hydrochloride provides synergistic therapeutic benefits in the treatment of painful spasmodic conditions. Therefore, the current study was carried out to formulate and evaluate an oral medicated jelly containing Diclofenac Sodium and Dicyclomine Hydrochloride using suitable gelling polymers and

excipients, with the aim of improving patient compliance and achieving effective drug delivery. (3,14)

## MATERIALS AND METHOD

### Materials

Diclofenac sodium and Dicyclomine HCl were received from Yarrow Chemical Products, Mumbai. Gelatin was obtained from S.D. Fine-Chem, Mumbai. Xanthan gum was obtained from Himedia Laboratories Pvt. Ltd, Mumbai, and all other excipients were obtained from SD Fine Chemicals, Mumbai, India.

### Method

#### Standard Curve of Diclofenac sodium:

Accurately weighed 10mg of Diclofenac sodium was dissolved in 100 mL of phosphate buffer solution (pH 6.8) to get stock solution A. From the stock solution, 10 mL was taken and made up to 100 ml using phosphate buffer solution (pH 6.8) to get stock solution B. Different concentrations were prepared by pipetting out stock solution B as per requirement. The absorbance was recorded using a UV spectrophotometer (Shimadzu UV-1601, Japan) at 276nm, against a suitable blank. (4)

#### Standard Curve of Dicyclomine HCl:

Accurately weighed 10mg of Dicyclomine HCl was dissolved in 100 mL of Phosphate buffer solution (pH 6.8) to get stock solution A. From the stock solution, 10 mL was taken and made up to 100 ml using phosphate buffer solution (pH 6.8) to get stock solution B. Different concentrations were prepared by pipetting out stock solution B as per requirement. The absorbance was recorded using a UV spectrophotometer (Shimadzu UV-1601, Japan) at 217nm, against a suitable blank. (4)

### Drug- excipient compatibility

#### Fourier transform infrared spectroscopy

FTIR analysis was carried out using the KBr pellet method on an FTIR spectrophotometer (FTIR-8400S, Shimadzu, Japan) The material was mixed with KBr in the ratio of 1:3 and pressed in a hydraulic press at a load of 5-6 tons. The prepared pellets were scanned from 3500 to 1000  $\text{cm}^{-1}$  using an FTIR spectrophotometer. FTIR study was performed for pure Diclofenac sodium and Dicyclomine HCl and formulations F1 and F4.

#### Preparation of Diclofenac Sodium Solid Dispersion by Kneading Method

Diclofenac sodium solid dispersion was prepared by the kneading method using a 1:1 drug-to-carrier ratio to enhance the drug's dissolution and ensure uniform incorporation into the oral jelly

formulation. Initially, physical mixing and solvent evaporation methods were attempted; however, the solvent kneading method produced the highest percentage yield and a more uniform dispersion and was therefore selected. Diclofenac sodium and beta-cyclodextrin were accurately weighed in a 1:1 ratio, dissolved in a suitable common solvent with continuous kneading, and the solvent was evaporated at room temperature until a dry mass was obtained. The dried mass was further dried, pulverized using a mortar and pestle, passed through sieve No. 80, and stored in a desiccator until further use. As the solid dispersion was prepared in a 1:1 ratio, 91 mg of solid dispersion was equivalent to 50 mg of Diclofenac sodium. Therefore, 91 mg of Diclofenac sodium solid dispersion (equivalent to 50 mg of Diclofenac sodium) was incorporated into each oral jelly formulation along with 10 mg of Dicyclomine HCl. (5,6)

### Preparation of Oral Medicated Jellies:

Drug-loaded OMJs were prepared using the heating and congealing method. All ingredients were weighed accurately before formulation. A sweetener base was prepared by dissolving required quantity of mannitol and sorbitol in distilled water with continuous stirring. The solution was heated to 80°C and stirred for approximately 30 minutes to obtain a clear and homogeneous syrup base. Glycerol was then incorporated into the solution to improve the texture of the jelly. The required polymers were gradually dispersed into the prepared solution while maintaining the temperature at 90°C. The mixture was continuously stirred using a magnetic stirrer for 20 minutes to ensure complete hydration and dissolution of the gelling agents. After complete dissolution of the polymers, the stabilizer and citric acid were added with continuous stirring to increase the softness of the jelly and adjust the pH of the formulation. The mixture was then heated for a few minutes, after which the preservative was incorporated and mixed thoroughly to obtain a uniform mixture. The weighed quantity of Diclofenac sodium solid dispersion (equivalent to 50 mg of Diclofenac sodium) and 10 mg of Dicyclomine HCl were incorporated into the prepared jelly base under continuous stirring to ensure uniform distribution of the drugs. The resulting mixture was mixed thoroughly and poured into the molds, which were then covered properly during the setting process to prevent contamination and exposure to the external environment and allowed to cool and set at room temperature. (7)

**Table 1: Composition of Oral Medicated Jellies loaded with Diclofenac sodium and Dicyclomine HCl**

| Ingredients (per one jelly of 2 g)                      | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---------------------------------------------------------|----|----|----|----|----|----|----|----|----|
| Diclofenac sodium solid dispersion (equivalent to 50mg) | 91 | 91 | 91 | 91 | 91 | 91 | 91 | 91 | 91 |
| Dicyclomine HCl (mg)                                    | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |

|                        |     |     |     |     |     |     |     |     |     |
|------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Gelatin (mg)           | 200 | 400 | 600 | 100 | 200 | 300 | -   | -   | -   |
| Xanthan gum (mg)       | -   | -   | -   | 60  | 80  | 100 | 120 | 160 | 200 |
| Mannitol (mg)          | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |
| Sorbitol (ml)          | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Ciric acid (mg)        | 10  | 10  | 10  | 10  | 10  | 10  | 10  | 10  | 10  |
| Glycerol (ml)          | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 |
| Methyl paraben (mg)    | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   | 1   |
| Propyl paraben (mg)    | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Peppermint oil (drops) | 3   | 3   | 3   | 3   | 3   | 3   | 3   | 3   | 3   |
| Amaranth (drops)       | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   | 2   |
| Water                  | qs  | qs  | qs  | qs  | qs  | qs  | qs  | qs  | qs  |

### Evaluation of oral medicated jellies:

#### Physical observation

The formulated jellies were visually examined for their clarity, odour, texture, and presence of any foreign particles. The texture was evaluated in terms of stickiness and grittiness by gently rubbing a small portion of jelly between two fingers. (8)

#### Weight variation

The total weight of 10 prepared jellies was obtained to determine the weight variation. The jellies were taken out from the molds in a beaker and weighed individually. The average weight of the jellies and percent deviation were determined. The results are reported as Mean $\pm$ SD, (n=10). (8)

#### pH

The pH of formulated jellies was measured using a digital pH meter (Elico Laboratories, Bengaluru, India) at room temperature ( $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ ). For this purpose, 0.5 g of jelly was dispersed in 50 mL of distilled water to make a 1% solution, and the pH was noted. The experiment was conducted in triplicate, and results are reported as Mean $\pm$ SD, (n=3). (8)

#### Syneresis

Syneresis is the contraction of the gel during storage resulting in the separation of water from the gel matrix. It is more evident in the gels, where lower concentration of gelling agent is employed. All the formulated jellies were examined for signs of syneresis at room temperature ( $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ ) and under refrigerated conditions ( $8^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ). (9,10)

#### Drug content

Five oral jellies of each formulation were selected randomly and were dissolved individually in phosphate buffer solution (pH 6.8), which was further diluted to measure the absorbance at 276 nm and 217 nm using UV- visible spectrophotometer (Shimadzu UV -1601, Japan). The content of each jelly was calculated. The experiment was conducted in triplicate and results are reported as Mean $\pm$ SD, (n=3). (11)

**In-vitro dissolution study**

In-vitro dissolution was studied using USP dissolution Apparatus II (Model no. TDT-081., Electro lab, Mumbai India). Dissolution study was performed in phosphate buffer solution (pH 6.8) (900ml,  $37 \pm 0.5^\circ\text{C}$ ) as a dissolution medium with speed of rotation of 50 rpm. 5ml samples were withdrawn at 5, 10, 15, 20, 25, 30, 45, 60, 75, 90, 105, 120 min using a prefilter. The sample was replaced by an equal volume phosphate buffer solution (pH 6.8) to maintain constant volume throughout. The percent dissolved was determined using a calibration curve at 276 nm and 217 nm respectively after dilution using suitable blank by a UV-visible spectrophotometer (Shimadzu UV-1601, Japan). The experiment was conducted in triplicate and results are reported as Mean $\pm$ SD, (n=3).

**Drug release kinetics****Model-dependent analysis**

The in-vitro drug release data obtained from all the formulations were fit into various mathematical kinetic models to determine the mechanism and pattern of drug release. The cumulative percentage drug release data were analyzed using Zero-order, First-order, Higuchi, and Korsmeyer–Peppas kinetic models. The correlation coefficient ( $R^2$ ) values obtained for each model were compared, and the model showing the highest  $R^2$  value was considered best to describe the drug release behavior of the formulation.

**Zero-order model:**

The cumulative percentage of drug released was plotted against time.

$$Q_t = Q_0 - K_0 t$$

Where:

$Q_t$  = amount of drug released at time t

$Q_0$  = initial amount of drug

$K_0$  = zero-order release constant

**First-order model:**

The logarithm of the percentage drug remaining was plotted against time

$$\log Q_t = \log Q_0 - K_1 t / 2.303$$

where:

$Q_t$  = at time t

$K_1$  = first-order release constant

**Higuchi model:**

The cumulative percentage drug released was plotted against the square root of time.

$$Q = K_H t^{1/2}$$

Where:

Q = amount of drug released

$K_H$  = Higuchi dissolution constant

### **Korsmeyer–Peppas model:**

The logarithm of cumulative percentage drug released was plotted against the logarithm of time.

$$\frac{M_t}{M_\infty} = K t^n$$

where:

$M_t / M_\infty$  = fraction of drug released at time t

K = release rate constant

n = release exponent indicating the mechanism of drug release

The release exponent (n) was used to predict the mechanism of drug release. The model with the highest correlation coefficient ( $R^2$ ) was considered the best fit for the release kinetics.

### **Model-independent analysis**

#### **Dissolution efficiency**

Dissolution efficiency is used to translate the profile difference into a single value. Dissolution efficiency was calculated by using the following equation.

$$DE = \int_0^t y \, dt / y_{100} \cdot t \times 100$$

Where y is the drug percent dissolved at time t.

#### **Mean dissolution time**

Mean dissolution time represents the mean time for drug molecules to completely dissolve. It is useful parameter for characterizing the rate of drug release from a dosage form and indicates the drug release retarding efficiency of the polymer. MDT was determined by using the following equation.

$$MDT = \frac{\sum t_{mid} \Delta M}{\sum \Delta M}$$

Where:

‘i’ is the dissolution sample number

‘n’ is the number of dissolution sample times

‘t mid’ is the time at the midpoint between ‘i’ and ‘i-1’

‘M’ is the amount of drug dissolved between ‘i’ and ‘i-1’

### **Stability studies**

For the stability studies, the selected jelly formulation F4 was packed in aluminium foil, transferred to a high-density polyethylene container, tightly closed, and stored at room temperature ( $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ ) and  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75 \pm 5\%$  relative humidity for 90 days as per the International Conference on Harmonization guidelines. The samples were characterized for changes in physical parameters like appearance, pH, drug content, and in vitro studies at the end of 90 days. A freshly made sample was used as a reference standard for subjective evaluations. (12)

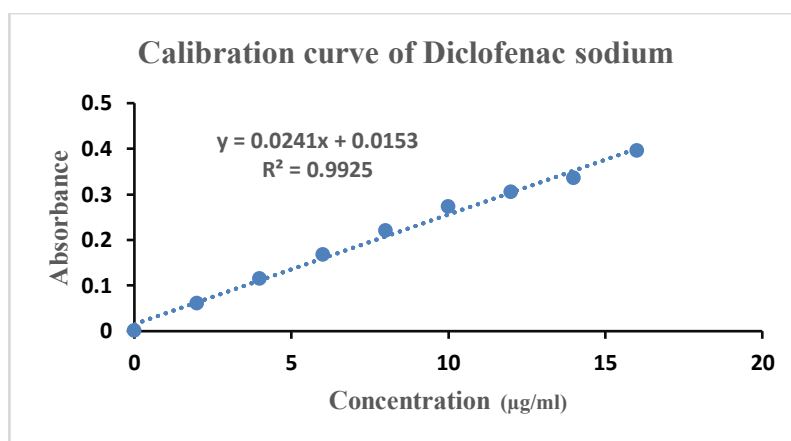
## RESULTS AND DISCUSSION

### Standard plot for combined drug (Diclofenac sodium and Dicyclomine HCl):

The data for standard curve drug solution in phosphate buffer (pH 6.8) are reported in Table 2 and 3. The absorbance maxima were obtained at 276 nm and 217 nm, respectively. The calibration curve was plotted and is shown in Figure 1 and 2.

**Table 2: Standard plot data for the estimation of Diclofenac sodium:**

| SL. NO | Concentration ( $\mu\text{g/ml}$ ) | Absorbance (276 nm) |
|--------|------------------------------------|---------------------|
| 1      | 0                                  | 0                   |
| 2      | 2                                  | 0.061               |
| 3      | 4                                  | 0.115               |
| 4      | 6                                  | 0.167               |
| 5      | 8                                  | 0.219               |
| 6      | 10                                 | 0.273               |
| 7      | 12                                 | 0.304               |
| 8      | 14                                 | 0.335               |
| 9      | 16                                 | 0.395               |

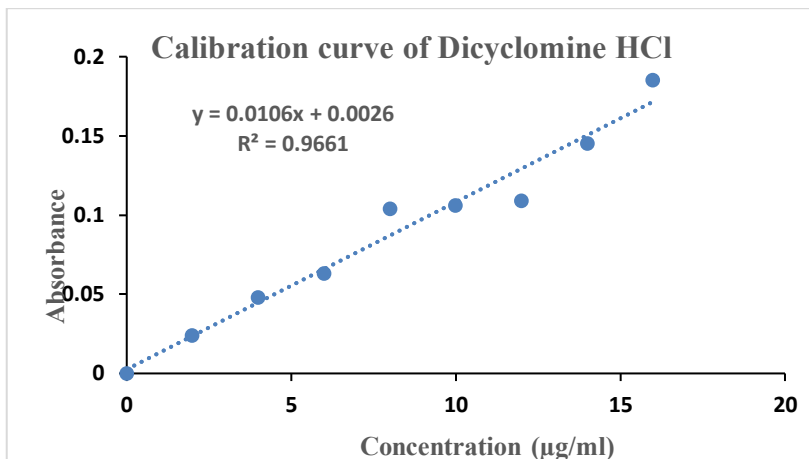


**Figure 1: Calibration curve of Diclofenac sodium in phosphate buffer (pH 6.8)**

**Table 3: Standard plot data for the estimation of Dicyclomine HCl:**

| SL. NO | Concentration ( $\mu\text{g/ml}$ ) | Absorbance (217 nm) |
|--------|------------------------------------|---------------------|
| 1      | 0                                  | 0                   |
| 2      | 2                                  | 0.024               |

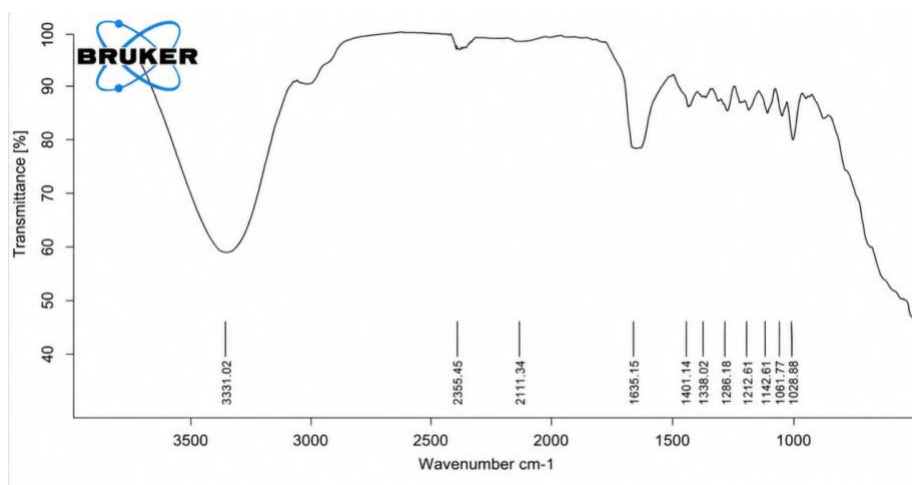
|   |    |       |
|---|----|-------|
| 3 | 4  | 0.048 |
| 4 | 6  | 0.063 |
| 5 | 8  | 0.104 |
| 6 | 10 | 0.106 |
| 7 | 12 | 0.109 |
| 8 | 14 | 0.145 |
| 9 | 16 | 0.185 |



**Figure 2: Calibration curve of Dicyclimine HCl in phosphate buffer (pH 6.8)**

#### Compatibility study by FTIR spectrophotometer

Pure drugs Diclofenac sodium and Dicyclimine HCl and selected formulations F1 & F4 were subjected to FTIR analysis to assess compatibility and determine whether any chemical interaction occurred between the drug and the excipients used. The FTIR spectra results of the pure drug and formulations are reported in Figures 3-6.



**Figure 3: FTIR Spectra of Diclofenac sodium**

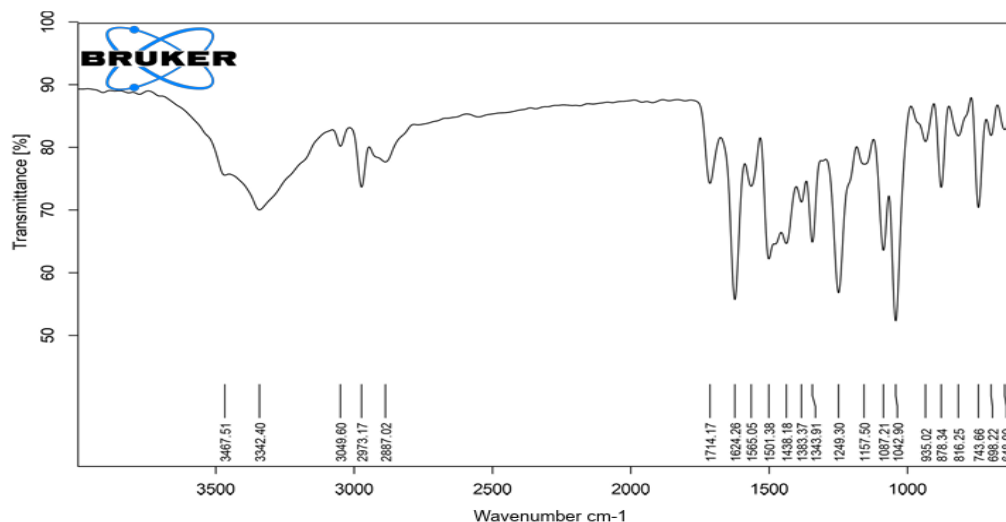


Figure 4: FTIR Spectra of Dicyclomine HCl

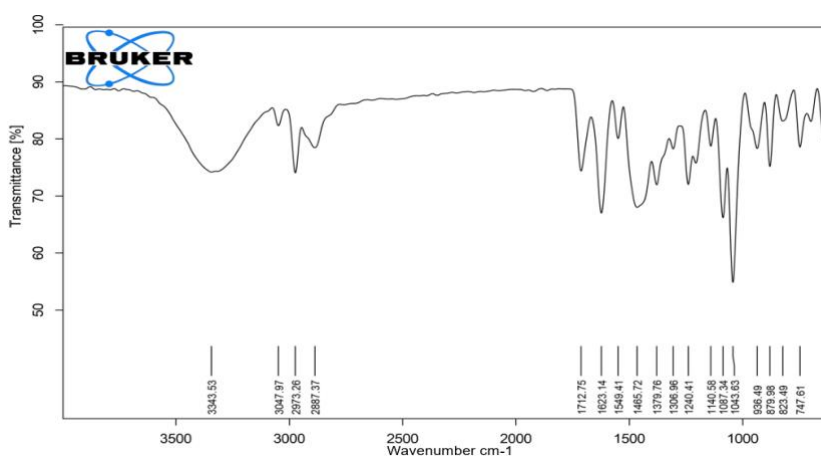


Figure 5: FTIR Spectra of formulation F1

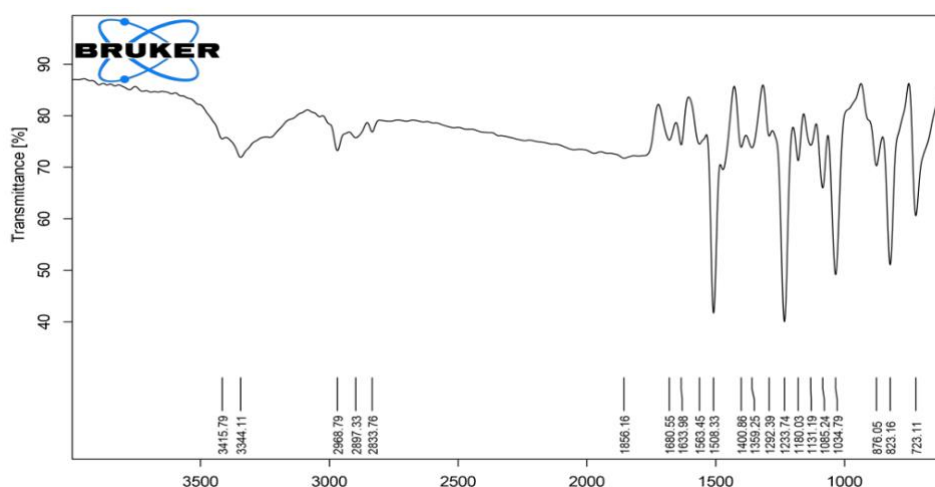
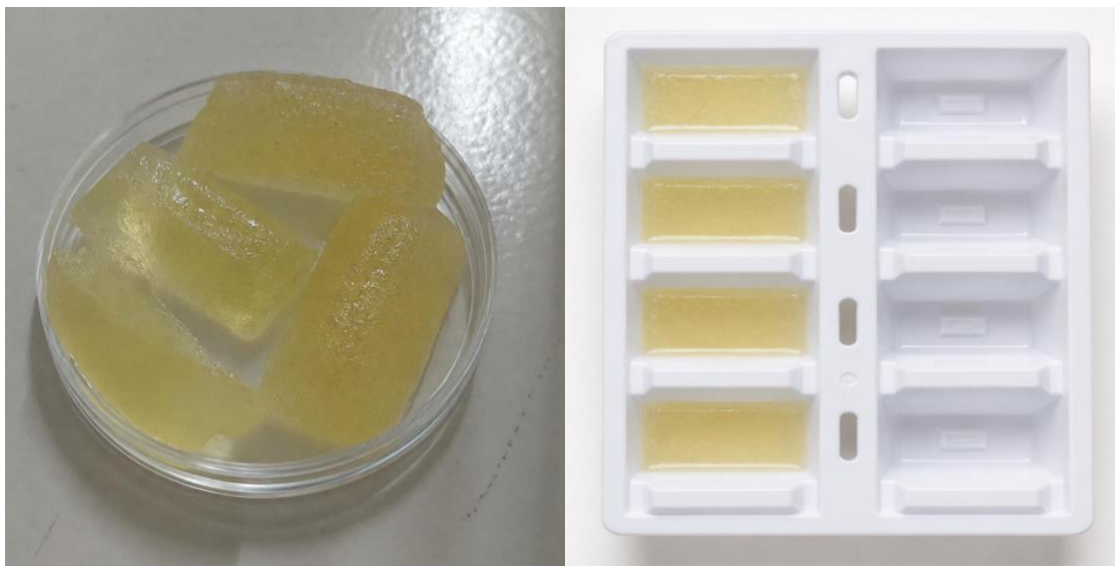


Figure 6: FTIR Spectra of formulation F4

The FTIR spectrum of pure Diclofenac Sodium showed characteristic peaks at  $3283.02 \text{ cm}^{-1}$  (O–H stretching),  $2935.58 \text{ cm}^{-1}$  (C–H stretching),  $1695.58 \text{ cm}^{-1}$  (C=O stretching),  $1494.74 \text{ cm}^{-1}$  (aromatic C=C stretching), and  $1048.66 \text{ cm}^{-1}$  (C–N stretching). Dicyclomine HCl exhibited

characteristic peaks at  $3467.51\text{ cm}^{-1}$ ,  $2973.17\text{ cm}^{-1}$ ,  $1714.17\text{ cm}^{-1}$ ,  $1501.38\text{ cm}^{-1}$ , and  $1042.90\text{ cm}^{-1}$ , corresponding to its major functional groups.

The FTIR spectra of formulations F1 and F4 showed all the characteristic peaks of Diclofenac Sodium and Dicyclomine HCl with only minor shifts in wavelength numbers. No significant disappearance or appearance of new peaks was observed. This indicates that there was no chemical interaction between the drugs and excipients used in the oral medicated jelly formulation. Therefore, the FTIR study confirmed the compatibility of Diclofenac Sodium and Dicyclomine HCl with the selected formulation components, supporting the stability of the developed oral jelly.



**Photo 1: Trial batch of formulation F1**



**Photo 2: Oral Jellies of formulation F4**

**Physical evaluation:****Table 4: Physical appearance of medicated jellies (F1-F9)**

| Formulation code | Clarity     | Colour       | Consistency | Stickiness      | Grittiness |
|------------------|-------------|--------------|-------------|-----------------|------------|
| F1               | Transparent | Reddish pink | Stiff       | Non sticky      | Non gritty |
| F2               | Transparent | Reddish pink | Stiff       | Slightly sticky | Non gritty |
| F3               | Transparent | Reddish pink | Stiff       | Non sticky      | Non gritty |
| F4               | Opaque      | Reddish pink | Stiff       | Non sticky      | Non gritty |
| F5               | Opaque      | Reddish pink | Stiff       | Non sticky      | Non gritty |
| F6               | Opaque      | Reddish pink | Stiff       | Non sticky      | Non gritty |
| F7               | Opaque      | Reddish pink | Soft        | Slightly sticky | Non gritty |
| F8               | Opaque      | Reddish pink | Soft        | Slightly sticky | Non gritty |
| F9               | Opaque      | Reddish pink | Stiff       | Non sticky      | Non gritty |

All the formulations were evaluated for physical appearance; formulations F1, F2, F3 are transparent and formulations F4, F5, F6, F7, F8, F9 were opaque, having soft to stiff nature with varying degrees of consistency. A non-sticky texture was observed in formulations F1, F3, F4, F5, F6, F9.

**Table 5: Physical properties of different formulations**

| Formulation code | Weight variation in gm Mean $\pm$ SD (n=10) | pH Mean $\pm$ SD (n=3) | Syneresis |
|------------------|---------------------------------------------|------------------------|-----------|
| F1               | 2.11 $\pm$ 0.02                             | 6.58 $\pm$ 0.01        | No        |
| F2               | 2.16 $\pm$ 4.02                             | 6.65 $\pm$ 0.02        | No        |
| F3               | 1.99 $\pm$ 1.99                             | 6.92 $\pm$ 0.02        | No        |
| F4               | 2.26 $\pm$ 2.92                             | 7.48 $\pm$ 0.01        | No        |
| F5               | 2.20 $\pm$ 1.41                             | 7.05 $\pm$ 0.02        | No        |
| F6               | 2.04 $\pm$ 2.78                             | 7.12 $\pm$ 0.01        | No        |
| F7               | 1.69 $\pm$ 0.27                             | 7.24 $\pm$ 0.02        | No        |
| F8               | 1.89 $\pm$ 0.79                             | 7.36 $\pm$ 0.02        | No        |
| F9               | 1.98 $\pm$ 3.25                             | 6.38 $\pm$ 0.01        | No        |

**Weight variation**

The weight of jelly formulations was between 1.69 $\pm$ 0.27 to 2.26 $\pm$ 2.92 gm for all prepared jellies. The percent deviation in weight was found to be within acceptable limits.

**Determination of pH**

The pH of the formulations influences the taste and stability of oral jellies. The pH of the formulations was found in the range of 6.38 $\pm$ 0.01 to 7.48 $\pm$ 0.01.

**Syneresis**

Jellies experience syneresis or de-swelling as a consequence of liquid expulsion, resulting in shrinkage of jellies and reduced quality was observed after 24 hours of jelly preparation. Syneresis

was more pronounced in the jellies where a lower concentration of gelling agent was employed. Syneresis was not observed in any of the prepared jelly formulations.

#### Drug content:

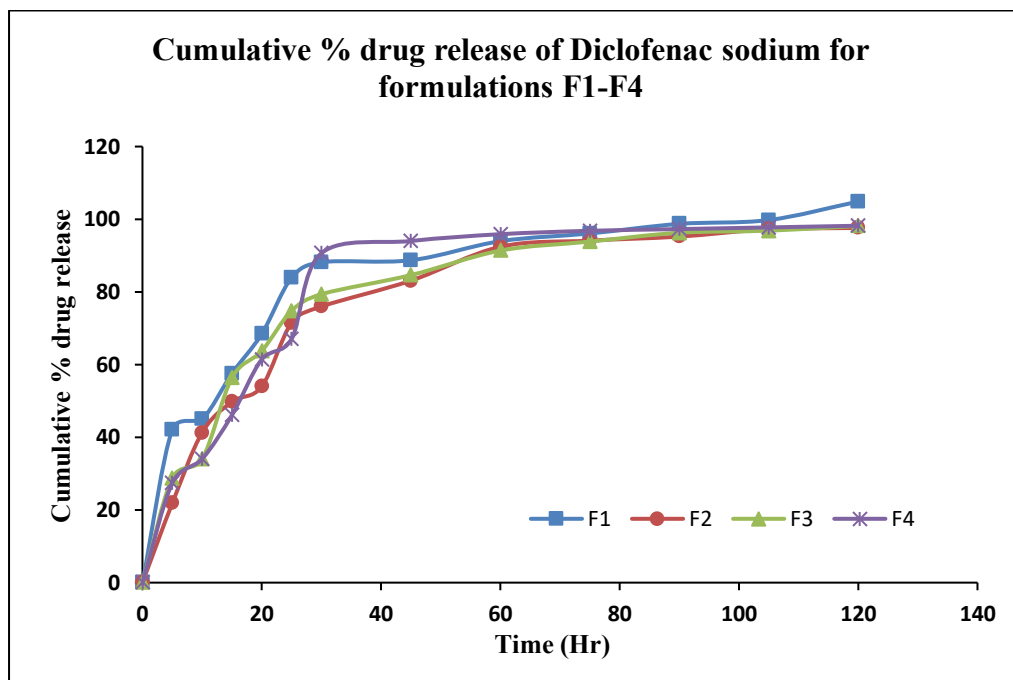
**Table 6: Determination of Drug content of prepared oral jelly formulations**

| Formulation code | Drug content (%)  |                 |
|------------------|-------------------|-----------------|
|                  | Diclofenac sodium | Dicyclomine HCl |
| F1               | 88.04±1.63        | 89.2±2.0        |
| F2               | 84.46±1.57        | 85.4±1.98       |
| F3               | 82.40±1.84        | 83.1±1.97       |
| F4               | 99.80±2.04        | 97.6±1.5        |
| F5               | 90.10±2.53        | 90.8±1.54       |
| F6               | 93.68±1.76        | 94.1±1.87       |
| F7               | 81.38±1.78        | 81.8±2.34       |
| F8               | 79.80±1.76        | 78.8±1.89       |
| F9               | 74.21±2.30        | 73.6±1.90       |

Values are in mean ± SD, (n=3)

The percentage drug content was found to be in the range of 74.21 to 99.80 % and 73.6 to 97.6 % as shown in (table 6) indicating uniform drug within the oral jellies of all the formulations. The percent was found to be lower due to entrapment of drug in gelling polymer matrix.

#### In-vitro drug release of Diclofenac sodium formulations



**Figure 7 In-vitro drug release of Diclofenac sodium from formulations F1-F4**

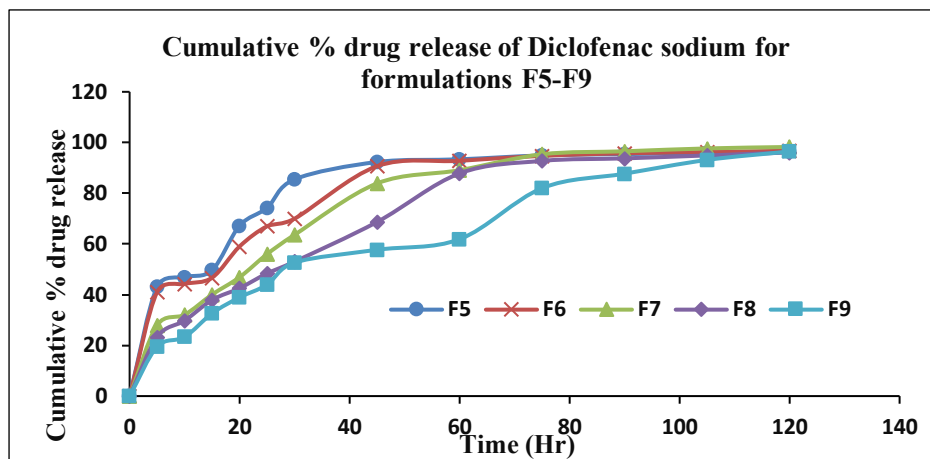


Figure 8: In-vitro drug release of Diclofenac sodium from formulations F5-F9

#### In-vitro drug release of Dicyclomine HCl formulations

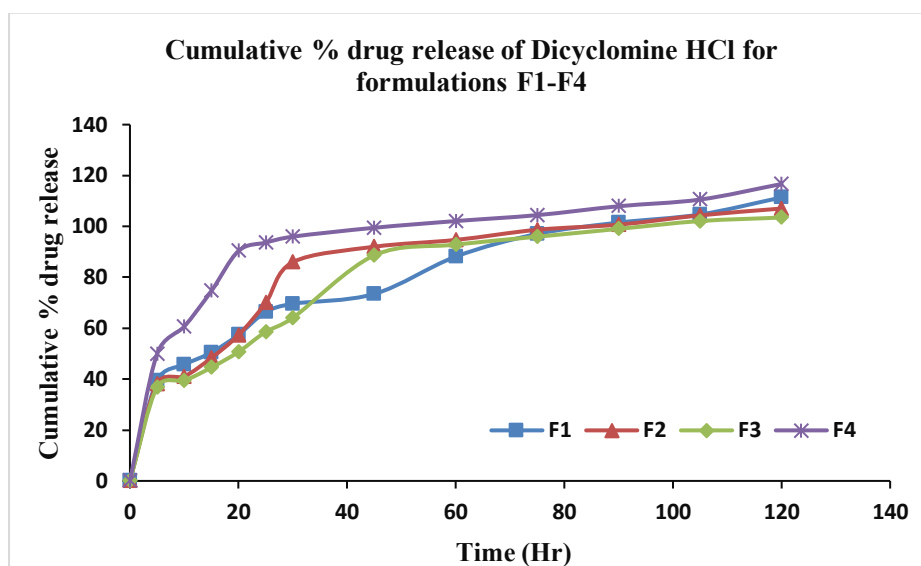


Figure 9: In-vitro drug release of Dicyclomine HCl from formulations F1-F4

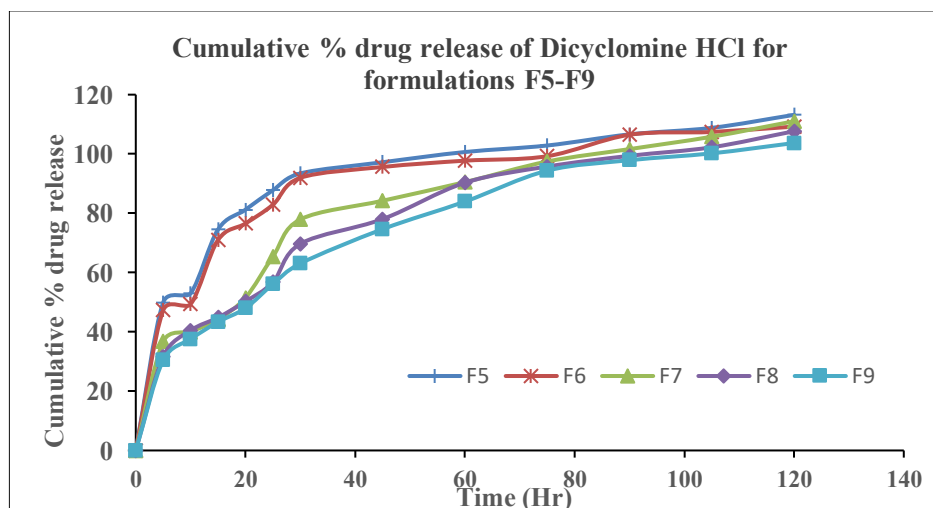


Figure 10: In-vitro drug release of Dicyclomine HCl from formulations F5-F9

The In-vitro dissolution study was carried out using the USP apparatus II (Paddle type) to compare the drug release of the prepared jellies. The In-vitro drug release study of prepared jellies was performed in phosphate buffer solution (pH 6.8) for 2 hours. In-vitro release profile of all the prepared formulations is shown in Figures 7-10. Formulations of Diclofenac sodium F1, F2 and F3, prepared with only gelatin, showed drug release of  $87.64 \pm 0.76$  %,  $75.97 \pm 0.41$  %, and  $79.55 \pm 0.21$  % in 30 minutes. Formulations F4, F5, and F6, prepared from both gelatin and xanthan gum, showed drug release of  $91.11 \pm 0.22$  %,  $86.01 \pm 0.37$  %, and  $70.48 \pm 0.10$  % in 30 minutes. The formulations F7, F8, and F9, prepared with only xanthan gum, showed drug release of  $67.97 \pm 0.61$  %,  $53.62 \pm 0.54$  %, and  $53.30 \pm 0.85$  % in 30 minutes.

Similarly, Dicyclomine HCl, release from formulations F1, F2, F3 was  $71.19 \pm 0.34$  %,  $76.29 \pm 0.38$  %,  $63.04 \pm 0.72$  % in 30 minutes. Formulations F4, F5, F6 showed the drug release of  $94.81 \pm 0.21$  %,  $92.49 \pm 0.39$  %,  $91.04 \pm 0.85$  % in 30 minutes. The formulations F7, F8, F9 showed the drug release of  $77.58 \pm 0.28$  %,  $68.62 \pm 0.80$  %,  $61.90 \pm 0.51$  % in 30 minutes.

Among all the formulations, Formulation F4 exhibited the highest and fastest drug release for both Diclofenac sodium ( $91.11 \pm 0.22$  %) and Dicyclomine HCl ( $94.81 \pm 0.21$  %) at 30 minutes, with cumulative drug release of  $99.68 \pm 0.78$  % and  $115.70 \pm 0.98$  %, respectively, at 120 minutes. These findings indicated that the formulation containing a combination of gelatin and xanthan gum (Formulation F4) provided superior dissolution characteristics compared to formulations prepared with either gelatin or xanthan gum alone. Hence, formulation F4 was selected as the best formulation for further evaluation. It was observed that there was a decrease in drug release with increase in polymer concentration for all the formulations. All the formulations showed good drug release.

### Model-independent Analysis

**Table 7: Model-independent analysis of dissolution data (Diclofenac sodium and Dicyclomine HCl)**

| Formulation | MDT in min<br>(Diclofenac<br>sodium) | MDT in min<br>(Dicyclomine<br>HCl) | % DE at 30 min<br>(Diclofenac<br>sodium) | % DE at 30 min<br>(Dicyclomine<br>HCl) |
|-------------|--------------------------------------|------------------------------------|------------------------------------------|----------------------------------------|
| F1          | 15.75                                | 17.92                              | 56.47                                    | 49.89                                  |
| F2          | 22.30                                | 19.04                              | 46.06                                    | 46.12                                  |
| F3          | 20.52                                | 20.16                              | 49.50                                    | 42.53                                  |
| F4          | 16.56                                | 15.08                              | 57.31                                    | 68.75                                  |
| F5          | 18.70                                | 16.54                              | 50.91                                    | 64.67                                  |
| F6          | 18.94                                | 17.34                              | 49.28                                    | 61.34                                  |
| F7          | 24.56                                | 21.73                              | 39.97                                    | 45.37                                  |
| F8          | 29.01                                | 22.89                              | 35.28                                    | 42.14                                  |
| F9          | 39.13                                | 24.27                              | 31.34                                    | 40.10                                  |

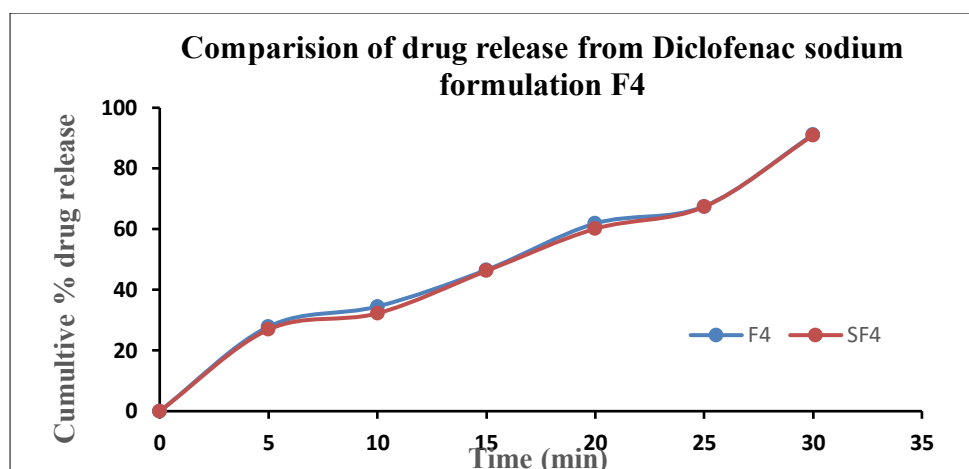
**Stability studies:**

The stability study was performed on formulation F4 at room temperature ( $40 \pm 0.5^\circ\text{C}$ ) and  $75\% \pm 5\%$  after 90 days.

**Table 8: Cumulative % drug release of Diclofenac sodium oral jellies of formulation F4 after stability study**

| Time (min) | Cumulative % drug release of formulation F4 at room temperature | Cumulative % drug release of formulation F4 at $40\text{C} \pm 0.5\text{C}$ temperature and $75\% \pm 5\%$ after 90 days |
|------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0          | 0                                                               | 0                                                                                                                        |
| 5          | $27.87 \pm 0.13$                                                | $26.91 \pm 0.11$                                                                                                         |
| 10         | $34.50 \pm 0.32$                                                | $32.25 \pm 0.65$                                                                                                         |
| 15         | $46.55 \pm 0.12$                                                | $46.21 \pm 0.32$                                                                                                         |
| 20         | $61.87 \pm 0.41$                                                | $60.11 \pm 0.31$                                                                                                         |
| 25         | $67.51 \pm 0.12$                                                | $67.36 \pm 0.75$                                                                                                         |
| 30         | $91.11 \pm 0.22$                                                | $90.89 \pm 0.35$                                                                                                         |

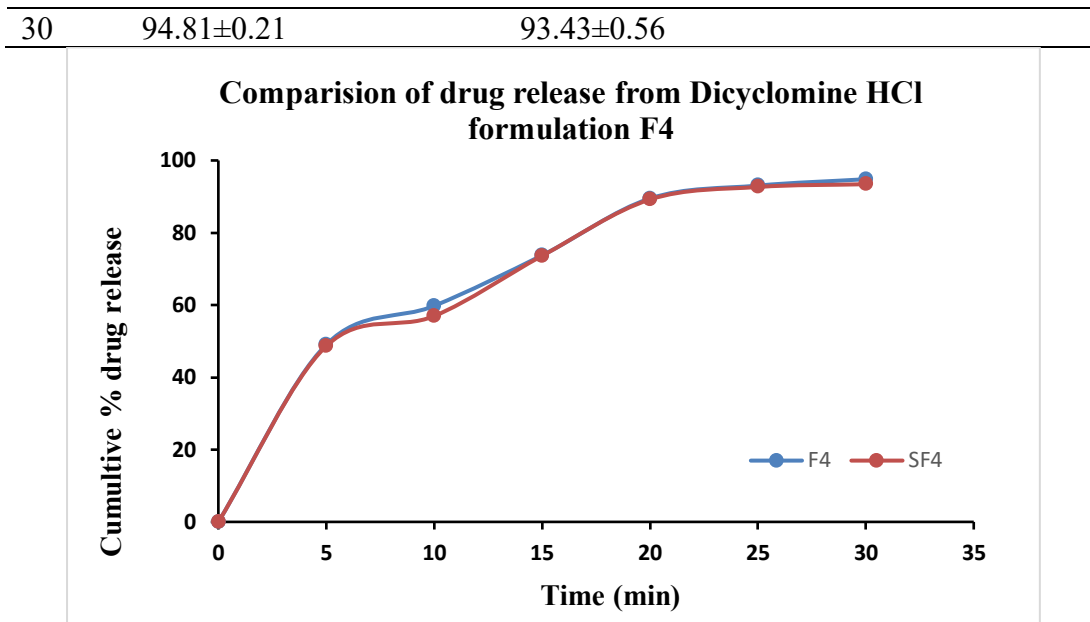
Values are in mean  $\pm$  SD, (n=3)



**Figure 11: Comparison of drug release from formulation F4 before stability study and after 90 days**

**Table 9: Cumulative % drug release of Dicyclomine HCl oral jellies of formulation F4 after stability study**

| Time (min) | Cumulative % drug release of formulation F4 at room temperature | Cumulative % drug release of formulation F4 at $40\text{C} \pm 0.5\text{C}$ temperature and $75\% \pm 5\%$ after 90 days |
|------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0          | 0                                                               | 0                                                                                                                        |
| 5          | $49.06 \pm 0.44$                                                | $48.65 \pm 0.16$                                                                                                         |
| 10         | $59.77 \pm 0.13$                                                | $56.95 \pm 0.25$                                                                                                         |
| 15         | $73.75 \pm 0.18$                                                | $73.62 \pm 0.50$                                                                                                         |
| 20         | $89.48 \pm 0.24$                                                | $89.21 \pm 0.21$                                                                                                         |
| 25         | $93.05 \pm 0.28$                                                | $92.66 \pm 0.25$                                                                                                         |



**Figure 12: Comparison of drug release from formulation F4 before stability study and after 90 days**

Values are in mean  $\pm$  SD, (n=3)

The formulation F4 was subjected to accelerated stability studies for 90 days at 25C/75% RH, In-vitro dissolution study was performed and showed negligible change in the dissolution profile. The oral jellies subjected to stability studies were found to be smooth and flexible, with no change in the physical appearance. The In-vitro dissolution profile of formulation F4 after the stability study was not significantly different ( $p > 0.05$ ).

## CONCLUSION

In this present study, oral medicated jellies containing Diclofenac Sodium and Dicyclomine HCl were successfully formulated and evaluated. The prepared oral jelly formulations exhibited acceptable physicochemical properties, including appearance, pH, viscosity, syneresis, and drug content. In-vitro dissolution studies demonstrated satisfactory drug release from all formulations. Among the developed formulations, Formulation F4 was identified as the best formulation, exhibiting the highest drug release for both Diclofenac Sodium and Dicyclomine HCl. The results indicated that the concentration and combination of gelatin and xanthan gum significantly influenced the physicochemical properties and drug release characteristics of the oral medicated jellies. Therefore, it can be concluded that oral medicated jellies containing Diclofenac Sodium and Dicyclomine HCl can be successfully formulated as a patient-friendly dosage form with acceptable quality attributes and effective drug release characteristics.

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