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# Evaluation of Release Modifying Potential of *Artocarpus Heterophyllus* (Jackfruit) Mucilage in the Formulation of Diclofenac Sodium Sustained Release Matrix Tablets

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## ABSTRACT

The study was aimed to evaluate the release modifying potential of mucilage extracted from the *Artocarpus heterophyllus* in the formulation of oral sustained release tablets of diclofenac sodium. Preformulation studies performed on isolated mucilage involved the determination of physicochemical properties as well as flow properties of the mucilage. Compatibility studies including FTIR spectral analysis and drug-excipients compatibility studies showed no signs of incompatibility between drug, isolated gums or mucilage's and other excipients. Diclofenac sodium matrix tablet formulations were prepared by wet granulation method using different drug: mucilage ratios viz. 1:0.25, 1:0.5, 1:1 and 1:2. The prepared formulations were evaluated for pre-compression parameters like angle of repose, bulk density, tapped density, hausner's index and carr's index for granules while tablets were evaluated for various post-compression parameters like tablet thickness, hardness, weight variation, friability, content uniformity, disintegration time, swelling behaviour and in-vitro drug release study. Among all the formulations, AH-3 and AH-4 showed a slow and complete drug release of 99.21% and 98.16%, respectively, over the period of 12 hrs and thereby exhibited satisfactory sustained drug release phenomenon. All the formulations follow zero order kinetics indicating that the drug diffuses at a comparatively slower rate. Finally, it was concluded that, *Artocarpus heterophyllus* mucilage can be used as drug release modifier in a particular concentration range and serve as a good binding agent in formulating oral sustained release matrix tablets.

**Keywords:** *Artocarpus heterophyllus*, Diclofenac sodium, Mucilage, Release kinetics.

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## INTRODUCTION

Nowadays, whole world is progressively interested in natural drugs and excipients because they are non-toxic, less expensive and freely available as compared to synthetic materials. Novel and modified excipients continued to meet the needs of conventional drug delivery systems in general and particularly useful in the pharmaceutical industry for the manufacture of tablets. India has traditionally been a reliable and rich source for such products among the Asian countries[1, 2, 3]. Gums and mucilage's obtained from plant are most widely used natural material for conventional as well as novel drug delivery forms. Various gums like maize starch, potato starch, gelatin, acacia and guar gum have been used as binder in various kinds of pharmaceutical formulations. Natural materials have many advantages over synthetic and semi-synthetic materials as they are chemically inert, nontoxic, less expensive, biodegradable and wider available. Finding and establishing any natural materials as a novel binder is still useful in the pharmaceutical industry for the manufacture of tablets[2, 4]. Binders are agents used to impart plasticity and cohesive qualities to the powdered material during the production of tablets. Most commonly used binders are natural and synthetic gums or mucilage's. A number of plant gums or mucilage's have been used as binding agents in tablet formulations. They have been found useful in producing tablets with different mechanical strength and drug release properties for different pharmaceutical purposes. Binders have been used as solutions and in dry form, depending on the other ingredients in the formulations and the method of preparation[5-7]. Oral route of drug administration is the most appealing, convenient, significant and popular route for the delivery of drugs owing to ease of swallowing, self medication, and most economic. Tablets are the most popular and preferred oral formulation available in the market because of its ease of manufacturing, convenience in administration, accurate dosing, stability compared with oral liquids and because it is more tamperproof than capsules. The primary benefits of a sustained release dosage forms compared to a conventional dosage forms, is maintenance of constant plasma drug concentration and therefore maintains uniform therapeutic effect. Over the past two decades, sustained release drug delivery systems have made significant progress in terms of clinical efficacy and patient compliance. Drug-release-retarding polymers are the key performers in such systems. Regarding this, researchers investigated various natural, semi-synthetic and synthetic polymeric materials. Natural polymers have gained the attention for their use in sustained or controlled drug delivery systems due to their easy availability, non-toxic, cost effectiveness, eco-friendliness, biocompatible, capable of chemical modifications, potentially

biodegradable and degradation under natural and physiological conditions[8-16]. Matrix system is most commonly used method for modulating the drug release in oral controlled drug delivery to obtain a desirable drug release profile, cost effectiveness and broad regulatory acceptance. Matrix devices, due to their chemical inertness, drug embedding ability and drug release character, have gained steady popularity for sustaining the release of a drug[12, 17, 18]. In recent years, natural polymers are growing rapidly and it continues to remain and important in the new formulation development. Therefore, it is a novel approach to enhance the use of natural polymers in the formulation development of dosage form, because of the ease availability at an affordable price, high safety margin and higher productivity. *Artocarpus heterophyllus* (popularly called as Jackfruit) mucilage is obtained from mucilage containing part of the fruit and this plant belongs to family Moraceae. The study was conducted to evaluate the release modifying potential of mucilage extracted from the fruit of *Artocarpus heterophyllus* used in the formulating oral sustained release matrix tablets of diclofenac sodium.

## MATERIALS AND METHOD

### Materials

Diclofenac sodium was purchased from Yarrow Chem Products, Mumbai, India. Microcrystalline cellulose, magnesium stearate and talc were procured from Central Drug House, New Delhi, India. *Artocarpus heterophyllus* fruits were collected from Rajawala, Dehradun, Uttarakhand and plant sample was authenticated from Botanical Survey of India, Dehradun (Uttarakhand). All the other chemicals used were of analytical grade and were also purchased from Central Drug House, New Delhi, India.

### Isolation and Purification of *Artocarpus heterophyllus* mucilage

Fresh fruits of *Artocarpus heterophyllus* were collected and washed with water to remove dirt and debris. The outer harder scales were removed and mucilage containing part from fruit was taken and boiled with distilled water for 15-30 minutes and the mass was then filtered through Buckner funnel without filter paper. The retained residues were again boiled with some distilled water and the combined liquid was passed through eight folds of muslin cloth. The mucilage was precipitated from the filtrate by adding sufficient quantity of ethanol. The precipitated mucilage was dried in an oven below 50$^{o}$C till it was completely dried.

### Pre-formulation studies or Characterization of *Artocarpus heterophyllus* mucilage

Macroscopic properties of the mucilage were evaluated by observation of the colour, taste and odour of the powdered material. The mucilage was evaluated for solubility in water, ethanol,

acetone and chloroform in accordance with the standards. Other physicochemical properties were also determined like loss on drying, total ash, pH, angle of repose, bulk density, tapped density, hauser's index and carr's index.

**Pre-formulation studies or Characterization of Diclofenac Sodium**

Pre-formulation studies were performed on the diclofenac sodium, which included determination of solubility, melting point, λmax, calibration curve and compatibility studies.

**Preparation of Diclofenac Sodium Tablets**[19, 22]

Tablets each containing 100mg of Diclofenac sodium were prepared by wet granulation method using different drug: mucilage ratios viz. 1:0.25, 1:0.5, 1:1 and 1:2 for various formulations containing *Artocarpus heterophyllus* mucilage. Microcrystalline cellulose was used as filler to maintain the tablet weight.

**Evaluation**

The prepared formulations were evaluated for the following parameters:

**PRE-COMPRESSION EVALUATION**[19, 21, 22]

**Angle of Repose**

$$\tan \theta = h/ r \quad \text{or} \quad \theta = \tan^{-1} (h/ r)$$

Where; θ = angle of repose, h = height of the cone, and r = radius of the cone base

**Bulk Density**

$$D_b = W/ V_b$$

Where; $D_b$ = Bulk density, W = weight of granules, and $V_b$ = volume ($V_b$) of granules before tapping.

**Tapped Density**

$$D_t = W/ V_t$$

Where; $D_t$ = Tapped density, W = weight of granules, and $V_b$ = volume ($V_b$) of granules after tapping.

**Hausner's Index**

$$\text{Hausner's index} = D_t / D_b$$

Where, $D_t$ is the tapped density and $D_b$ is the bulk density.

**Carr's Index**

$$\text{Carr's Index (\%compressibility)} = [(D_t - D_b) \div D_t] \times 100$$

Where, $D_t$ is the tapped density and $D_b$ is the bulk density.

**POST-COMPRESSION EVALUATION**[20, 21]

**Tablet Thickness**

The thickness of the tablets was determined by using vernier caliper.

**Hardness**

The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in $kg/cm^2$.

**Weight Variation**

To study weight variation, tablets were weighed using a digital balance and the test was performed according to the official method.

**Friability**

The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%).

$$\% \text{ Friability} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

% Friability of tablets less than 1% are considered acceptable.

**Content Uniformity**

Drug content was determined measuring the absorbance at 276 nm using Elico SL210 UV-Visible double beam spectrophotometer. The drug content was estimated from the standard curve of diclofenac sodium.

**Disintegration Time**

Disintegration time test was carried out according to USP specification.

**Swelling Behaviour of Formulations**

The extent of swelling was measured in terms of percent weight gain by the tablet. To study the swelling behavior, one tablet from each formulation was kept in a petri dish containing 20 ml phosphate buffer pH 7.4. At the end of 1 hr, the tablet was withdrawn, kept on tissue paper and weighed. The process was continued for every 2 hr, till the end of 12 hr.

The % weight gain by the tablet was calculated by formula:

$$S.I. = \{(Mt-M0) / M0\} \times 100$$

Where, S.I. = swelling index

Mt = weight of tablet at the time (t)

Mo = weight of tablet at time 0.

***In-Vitro* Drug Release Profile Studies**

Release of Diclofenac sodium from the tablets was studied using a six basket USP dissolution apparatus taking 900 mL of 0.1 N HCl (pH 1.2) solution for first 2 hrs and phosphate buffer (pH 7.4) for next 10 hrs. The dissolution media were maintained at a temperature of 37°± 0.5°C. The

speed of rotation of basket was maintained at 50 rpm. Aliquot equal to 10 ml sample was withdrawn at specific time intervals and the dissolution media volume was complimented with fresh and equal volume of phosphate buffer. The samples were filtered and suitably scanned with appropriate dilution and amount of Diclofenac sodium released from the tablet samples was determined spectrophotometrically at a wavelength of 275 nm by comparing with the standard calibration curve.

**Drug Release Kinetics Studies**

To determine the drug release kinetics and mechanism, the release data were fitted to models denoting Zero order, First order, Higuchi matrix, Peppas and Hixson-Crowell. By comparing the $R^2$ values obtained through these models, the best fit model was determined. From in vitro release studies, the results were plotted in five kinetics models as follows:

1. Cumulative percentage drug release vs Time (called Zero order release kinetics).
2. Log cumulative percentage drug retained vs Time (called First order release kinetics).
3. Cumulative percentage drug release vs √T (called Higuchi matrix release kinetics).
4. Log cumulative percentage drug release vs log Time (called Peppas release kinetics).
5. Cube root of the cumulative percentage release vs time (called Hixson-Crowell release kinetics).

## RESULTS AND DISCUSSION

Preformulation studies of *Artocarpus heterophyllus* mucilage was performed for determining the macroscopic properties, solubility, pH, moisture content, total ash and flow properties of the powdered material. Macroscopic properties showed that *Artocarpus heterophyllus* mucilage, obtained after extraction from the fruits of plant, was a free flowing cream coloured powder with bland taste and characteristic odour. The mucilage was found to be soluble in water but insoluble in ethanol, acetone and chloroform. It has pH around 6.6 with acceptable limit loss on drying (6.10 %) and total ash (6.75 %). Flow properties of mucilage was determined in terms of angle of repose (29.32º), bulk density (0.64 g/ml), tapped density (0.88 g/ml), hausner's index (1.38) and carr's index (27.27 %). All these physicochemical properties were tabulated in Table 1. Preformulation studies of selected drug i.e. Diclofenac sodium was performed for determining the solubility, melting point, λmax and compatibility studies. The results showed that the drug was found to freely soluble in ethanol, acetone and methanol, sparingly soluble in distilled water and glacial acetic acid while practically insoluble in ether. Melting point of Diclofenac sodium was found to be 170°C approx. The λmax of Diclofenac sodium was found to be 275 nm in

Figure 1 and standard calibration curve of Diclofenac sodium was prepared as showed in Figure 2. Fourier transformed infrared (FTIR) spectrum of the diclofenac sodium, *Artocarpus heterophyllus* mucilage and mixture of both were obtained and showed in Figure 3, 4 and 5. Drug-excipients compatibility studies were carried out by observing any physical or chemical changes as incompatibility in various mixtures of drug and excipients in different storage conditions. Observations were recorded after every week till one month in Table 2. Diclofenac sodium tablets were prepared by wet granulation method as per the formula given in the Table 3. The granules of different formulations were evaluated for angle of repose, bulk density, tapped density, hausner's index and carr's index as pre-compression parameters and results were shown in Table 4. Angle of repose values ranged from 19.86-22.20º indicates excellant flow property of granules. The bulk density and tapped density ranged from 0.42-0.46 g/ml and 0.60-0.66 g/ml respectively were found to be within the limits as per standards. The free flowing properties of granules were then calculated by determining hausner's index and carr's index (%). The hausner's index values were ranged from 1.15-1.48 and carr's index values were ranged from 29.51-32.31 %. All the results relative to post-compression evaluation were tabulated in Table 5. Thickness of tablets in all formulations was found to be ranged from 3.96-4.02 mm. All the formulations showed reasonably good hardness values ranged from 5.89-7.80 $Kg/cm^2$. The weight variation found in the range 498-502 mg was remained within ±0.1%. The % friability of tablets was ranged between 0.62-0.86% and found to be within the pharmacopoeial limit. Content uniformity of all tablets was within the range of 99.8-101.2% indicating good uniformity among different formulations of the tablets. The disintegration time was found to be ranged from 8.50-18.63 min for all the formulations and could play a contributing role in considering the role of this mucilage as a release modifier. The swelling index was calculated with respect to time. The relationship was better interpreted by comparing the swelling behaviour of different formulations from Table 6 & Figure 6. From among all the formulations containing *Artocarpus heterophyllus* mucilage, AH-4 was found to show better swelling behaviour as compared to remaining three formulations. As time increases, the swelling index was increased, because weight gain by tablet was increased proportionally with rate of hydration up to certain limit. Later on, it decreases gradually due to dissolution of outermost gelled layer of tablet into dissolution medium. The direct relationship was observed between swelling index and mucilage concentration, and as mucilage concentration increases, swelling index was increased. The in vitro release of different formulations of Diclofenac sodium tablets was showed in Table 7. Among all the formulations, AH-3 and AH-4 showed a slow and complete drug release of

99.21% and 98.16%, respectively, over the period of 12 hrs. It has been observed that the cumulative percent drug release decreases with increasing concentration of mucilage. This slow release is because of the formation of a thick gel structure that delays drug release from tablet. To determine the drug release kinetics and mechanism, the release data were fitted to models denoting Zero order, First order, Higuchi matrix, Peppas and Hixson-Crowell. The drug release kinetic data of all the formulations was found to follow zero order kinetics ($R^2$ = 0.956 to 0.984) followed by Higuchi matrix ($R^2$ = 0.906 to 0.945), first order ($R^2$ = 0.769 to 0.914), peppas ($R^2$ = 0.843 to 0.871) and hixson-crowell ($R^2$ = 0.750 to 0.839) as shown in Table 8. The kinetic treatment reflected that release data of AH-4 showed $R^2$ = 0.984 for zero order model which is close to 1, indicating that release of drug follows zero order kinetics followed by Higuchi model ($R^2$ = 0.939) and first order ($R^2$ = 0.881).

**Table 1: Physicochemical Properties of Isolated Mucilage**

| S.No. | Parameters | | Results |
|---|---|---|---|
| 1 | Macroscopic Property | Colour | Cream |
| | | Taste | Bland |
| | | Odour | Characteristic |
| 2 | Solubility | Water | Soluble |
| | | Ethanol | Insoluble |
| | | Acetone | Insoluble |
| | | Chloroform | Insoluble |
| 3 | Loss on Drying (%) | | 6.10 |
| 4 | Total Ash (%) | | 6.75 |
| 5 | pH | | 6.6 |
| 6 | Angle of Repose (º) | | 29.32 |
| 7 | Bulk Density (g/ml) | | 0.64 |
| 8 | Tapped Density (g/ml) | | 0.88 |
| 9 | Hauser's Index | | 1.38 |
| 10 | Carr's Index (%) | | 27.27 |

**Table 2: Compatibility Study of Drug and Excipients**

| Combinations | Storage Conditions | Time Period | | | |
|---|---|---|---|---|---|
| | | 1st week | 2nd week | 3rd week | Last week |
| DS + *AH* mucilage | 4ºc | No Change | No Change | No Change | No Change |
| | RT | No Change | No Change | No Change | No Change |
| | 40ºc | No Change | No Change | No Change | No Change |
| DS + *AH* mucilage + Other Excipients | 4ºc | No Change | No Change | No Change | No Change |
| | RT | No Change | No Change | No Change | No Change |
| | 40ºc | No Change | No Change | No Change | No Change |

**Table 3: Formulation of Diclofenac Sodium Tablets**

| Ingredients | Formulations (mg/tablet) | | | |
|---|---|---|---|---|
| | AH-1 D:M (1:0.25) | AH-2 D:M (1:0.5) | AH-3 D:M (1:1) | AH-4 D:M (1:2) |
| Diclofenac Sodium | 100 | 100 | 100 | 100 |
| *Artocarpus heterophyllus* Mucilage | 25 | 50 | 100 | 200 |
| Microcrystalline Cellulose | 360 | 335 | 285 | 185 |
| Magnesium Stearate | 10 | 10 | 10 | 10 |
| Talc | 5 | 5 | 5 | 5 |
| **Total** | **500** | **500** | **500** | **500** |

* AH- *Artocarpus heterophyllus*, * D: M = Drug: Mucilage ratio

**Table 4: Pre-Compression Evaluation of Diclofenac Sodium Granules**

| S.No. | Parameters | Formulations | | | |
|---|---|---|---|---|---|
| | | AH-1 | AH-2 | AH-3 | AH-4 |
| 1. | Angle of Repose (º) | 21.06±0.06 | 22.20±0.14 | 19.86±0.01 | 20.64±0.16 |
| 2. | Bulk Density (g/ml) | 0.44±0.03 | 0.42±0.02 | 0.46±0.01 | 0.43±0.02 |
| 3. | Tapped Density (g/ml) | 0.65±0.04 | 0.60±0.01 | 0.66±0.02 | 0.61±0.01 |
| 4. | Hausner's Index | 1.48 | 1.43 | 1.22 | 1.15 |
| 5. | Carr's Index (%) | 32.31 | 30.00 | 30.30 | 29.51 |

*Values are in mean±s.d. (n=3) (s.d.= standard deviation)

**Table 5: Post-Compression Evaluation of Diclofenac Sodium Tablets**

| S.N. | Parameters | Formulations | | | |
|---|---|---|---|---|---|
| | | AH-1 | AH-2 | AH-3 | AH-4 |
| 1. | Tablet Thickness (mm) | 3.98±0.12 | 3.96±0.18 | 4.00±0.24 | 4.02±0.38 |
| 2. | Hardness ($Kg/cm^2$) | 5.89±1.01 | 6.50±1.44 | 6.94±1.10 | 7.80±1.26 |
| 3. | Weight Variation (mg) | 501±0.54 | 502±0.44 | 498±1.05 | 498±0.11 |
| 4. | Friability (%) | 0.66±0.33 | 0.86±0.03 | 0.78±0.99 | 0.62±0.30 |
| 5. | Content Uniformity (%) | 100.8±0.67 | 99.8±0.64 | 100.7±1.10 | 101.2±0.39 |
| 6. | Disintegration Time (min) | 8.50±1.02 | 13.30±0.92 | 15.44±1.65 | 18.63±1.54 |

*Values are in mean±s.d. (n=3) (s.d. = standard deviation)

**Table 6: Swelling Behaviour of Diclofenac Sodium Tablets**

| S.N. | Time (hr) | Swelling Index (%) | | | |
|---|---|---|---|---|---|
| | | AH-1 | AH-2 | AH-3 | AH-4 |
| 1. | 1 | 6.66 | 11.82 | 18.08 | 20.89 |
| 2. | 2 | 11.41 | 26.32 | 38.00 | 42.10 |
| 3. | 4 | 22.43 | 36.43 | 54.36 | 69.95 |
| 4. | 6 | 31.60 | 56.40 | 65.55 | 78.76 |
| 5. | 8 | 22.63 | 68.65 | 73.12 | 93.43 |
| 6. | 10 | 11.62 | 78.43 | 66.67 | 97.27 |
| 7. | 12 | 1.50 | 87.10 | 59.10 | 98.45 |

**Table 7: *IN VITRO* Release Data of Diclofenac Sodium Tablets**

| S.N. | Time (hr) | % Cumulative Drug Release (Mean ± S.d., n=3) | | | |
|---|---|---|---|---|---|
| | | AH-1 | AH-2 | AH-3 | AH-4 |
| 1. | 0 | 0 | 0 | 0 | 0 |
| 2. | 1 | 4.30±0.45 | 6.02±0.31 | 5.54±0.12 | 7.74±0.23 |
| 3. | 2 | 29.64±0.24 | 17.85±0.02 | 21.23±0.49 | 19.34±0.23 |
| 4. | 3 | 48.75±0.15 | 30.31±0.08 | 36.14±0.33 | 28.54±0.34 |
| 5. | 4 | 64.21±0.65 | 48.32±0.01 | 45.58±0.43 | 38.43±0.45 |
| 6. | 5 | 76.65±0.56 | 59.39±0.22 | 52.54±0.02 | 44.12±0.11 |
| 7. | 6 | 89.65±0.43 | 72.12±0.54 | 66.47±0.32 | 59.21±0.89 |
| 8. | 7 | 99.29±0.52 | 83.65±0.35 | 74.23±0.21 | 71.65±0.87 |
| 9. | 8 | - | 91.02±0.21 | 89.34±0.89 | 77.82±0.45 |
| 10. | 9 | - | 96.22±0.75 | 94.54±0.67 | 81.91±0.34 |
| 11. | 10 | - | 97.87±0.11 | 97.76±0.76 | 91.53±0.11 |
| 12. | 11 | - | - | 98.09±0.88 | 96.62±0.09 |
| 13. | 12 | - | - | 99.21±0.03 | 98.16±0.56 |

*Values are in mean±s.d. (n=3) (s.d. = standard deviation)

**Table 8: Regression Co-Efficient ($R^2$) Values of Kinetic Models**

| Formulations | Regression co-efficient ($R^2$) Value of Kinetic Models | | | | |
|---|---|---|---|---|---|
| | Zero order | First order | Higuchi matrix | Peppas | Hixson-Crowell |
| AH-1 | 0.982 | 0.769 | 0.906 | 0.859 | 0.839 |
| AH-2 | 0.975 | 0.914 | 0.922 | 0.871 | 0.806 |
| AH-3 | 0.956 | 0.913 | 0.945 | 0.850 | 0.750 |
| AH-4 | 0.984 | 0.881 | 0.939 | 0.843 | 0.780 |

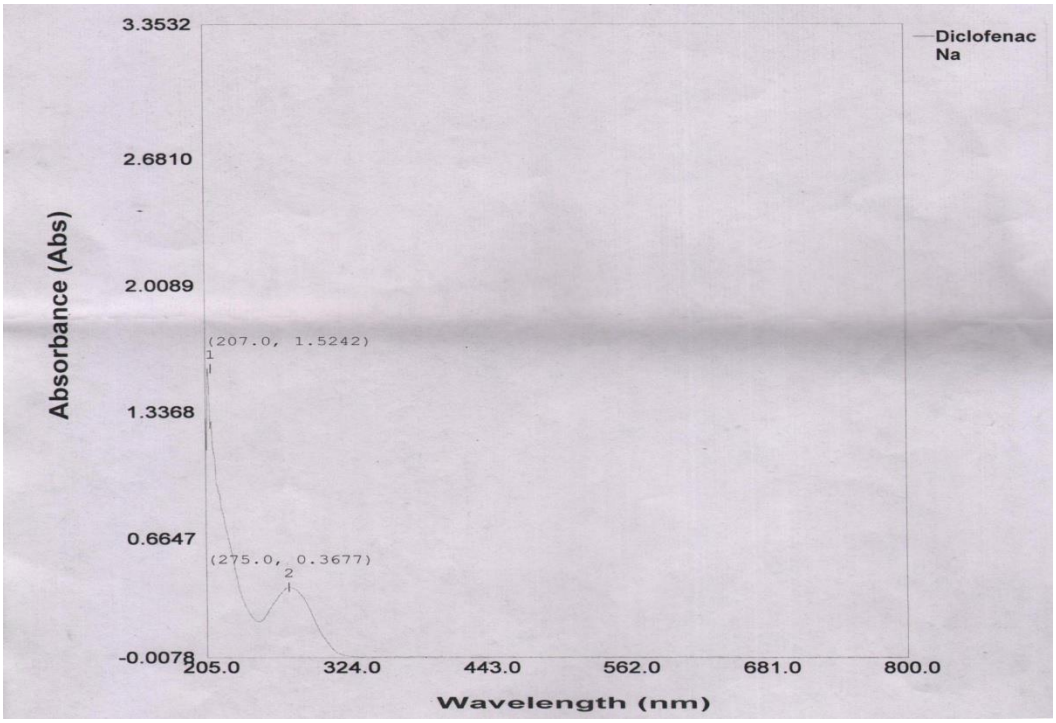


**Figure 1: UV absorption spectra of Diclofenac sodium**

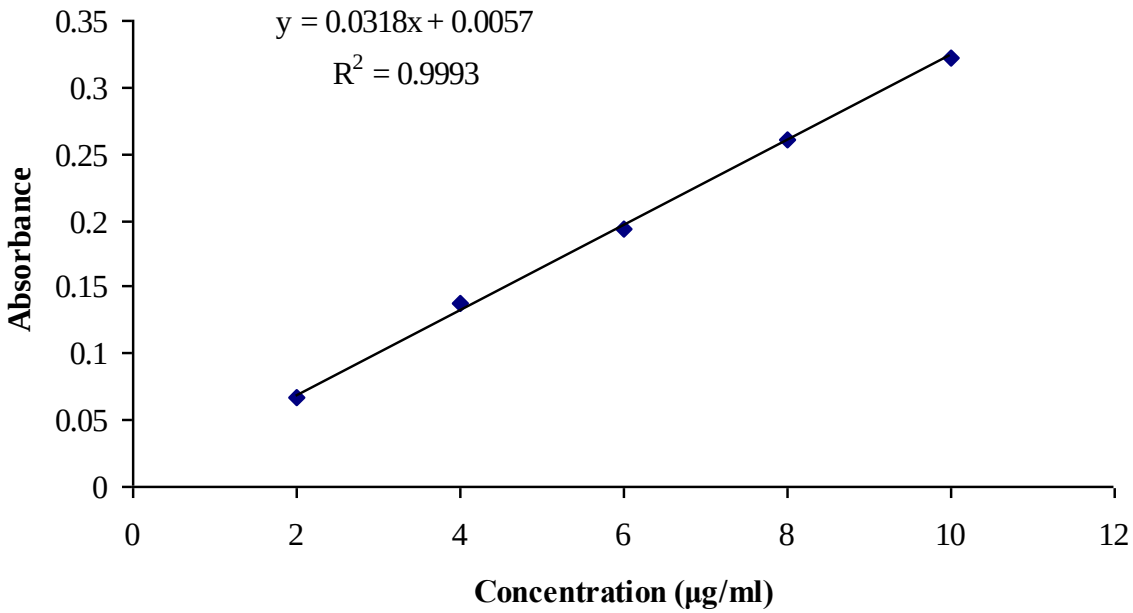


**Figure 2: Standard calibration curve of Diclofenac sodium**

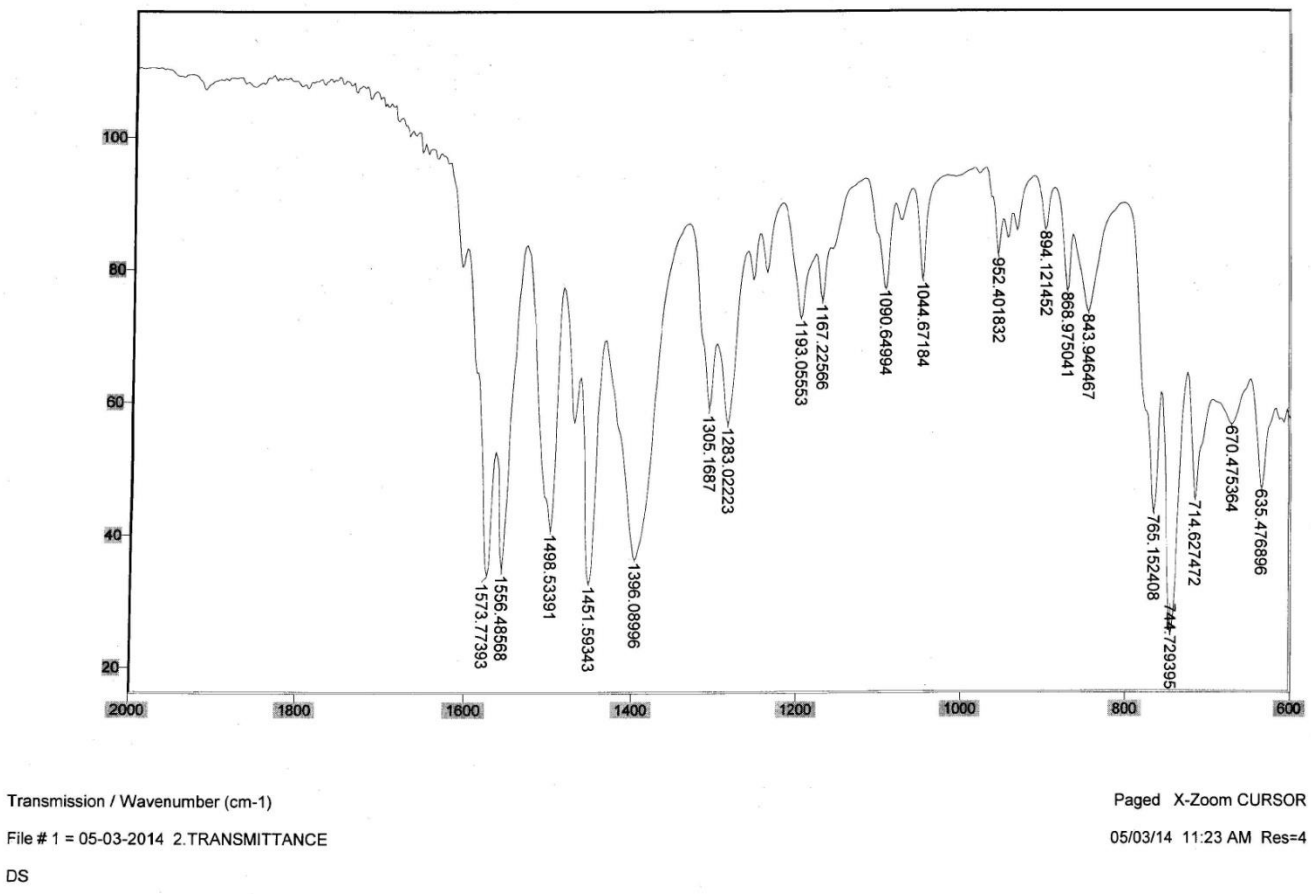


**Figure 3: IR spectrum of Diclofenac sodium**

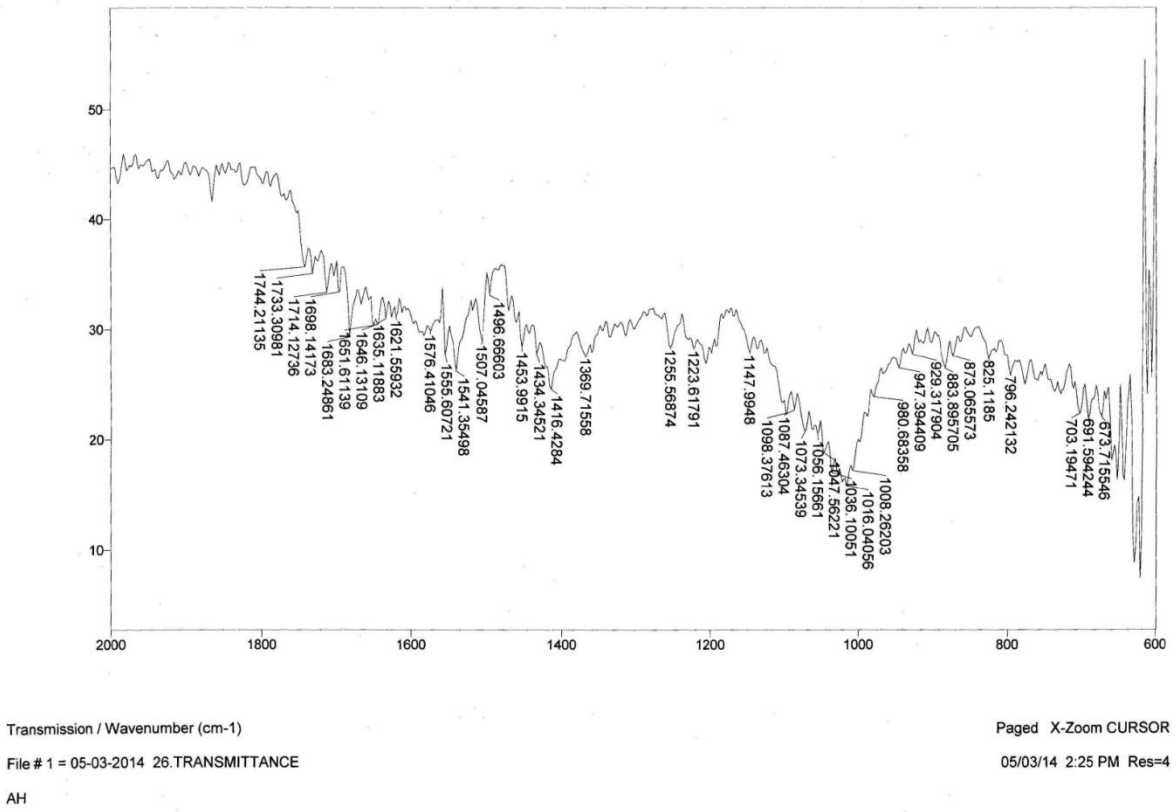


**Figure 4: IR spectrum of *Artocarpus heterophyllus* mucilage**

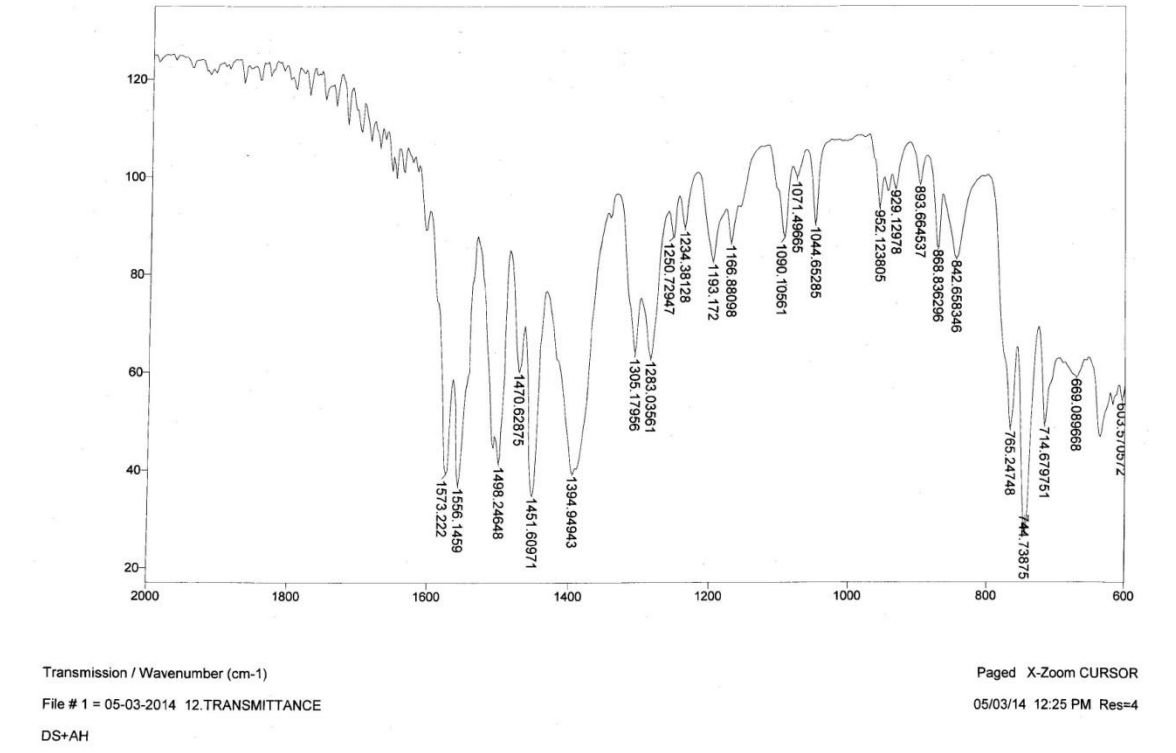


**Figure 5: IR spectrum of Diclofenac sodium and *Artocarpus heterophyllus* mucilage**

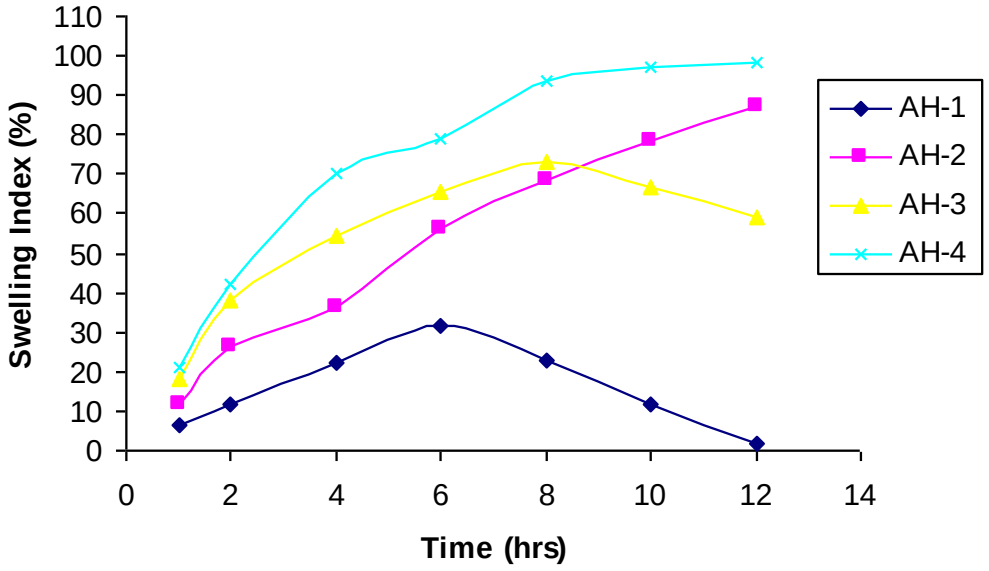


**Figure 6: Swelling behaviour of Diclofenac sodium tablets**

## CONCLUSION

The study revealed that *Artocarpus heterophyllus* mucilage appears to be suitable for use as a release modifier in formulating sustained release tablets of diclofenac sodium by evaluating the pre-compression and post-compression parameters for different formulations containing variable ratios of drug and mucilage. By observing the good swelling index and appropriate drug release pattern in tablet formulations, it was revealed from the study that among all the formulations, AH-3 and AH-4 were found to release the drug in a slow, controlled manner with maximum drug release of 99.21% and 98.16%, respectively, over the period of 12 hrs. All the formulations follow zero order kinetics as correlation coefficient ($R^2$) values are higher than other kinetic models. The kinetic treatment showed that AH-4 preferentially follows zero order kinetics indicating that the drug diffuses at a comparatively slower rate. Hence it can be concluded that, the *Artocarpus heterophyllus* mucilage can be used as drug release modifier in a particular concentration range and serve as a good binding agent in formulating oral sustained release matrix tablets.

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