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# Mucilage from *Aseculus Indica* as potential pharmaceutical excipient for sustained-release matrix tablets

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**ABSTRACT**

*The efficacy of mucilage obtained from A. indica as a pharmaceutical excipient for sustained release matrix tablets was established. Gum mucilage was isolated from the bark of A. indica. The rheological behavior of the obtained gum mucilage was compared with other gums. The mucilage was further subjected to physicochemical characterization. Also, a comparative study on binding properties of gum mucilage and starch was performed. The gum mucilage obtained from the A. indica exhibited superior rheological properties. The physicochemical characterization showed good flow properties and excellent swelling ratio. The dried mucilage was evaluated as a matrix-forming material for oral sustained-released tablets using diclofenac sodium as a model drug. The diclofenac sodium tablets were prepared using dried mucilage of A. indica in various drug–mucilage ratios. The physical tests like hardness test, friability, and weight variation were performed for all formulations and found to be within the pharmacopoeial limits. The study of dimensional changes in the tablets was also carried out for 5 h in distilled water and the radial and axial swellings of the tablets were found to be increasing with increase in the proportion of the dried mucilage. The study supported the utility of A. indica gum mucilage as a cheap, economic and easily available tablet excipient of natural origin.*

**Keywords:** *Aseculus indica*, herbal excipient, tablet binder, sustain release, matrix tablets.

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## INTRODUCTION

The objective behind preparation of Sustained-release dosage forms is to achieve a desirable and predictable phamacodynamic response within appropriate pharmacokinetic parameters, improved patient compliance, reduced side effects, and maximum drug efficacy [1]. Creating drug-embedded matrix tablets using direct compression of a blend of drug, retardant material, and additives is one of the simplest approaches for a formulation. One of the most commonly used a method of modulating drug release is including polymeric material within a matrix system. Matrix systems are important because of their simplicity, low cost, the small influence of physiological variables on their release behavior, and their suitability for manufacture on modern high-speed equipment [2].

Drug-release retarding polymers are the key performers in matrix systems. Various polymers have been investigated as drug retarding agents, each presenting a different approach to the matrix system. Based on the features of the retarding polymer, matrix systems are usually classified into three main groups: hydrophilic, hydrophobic, and

plastic. Hydrophilic polymers are the most suitable for retarding drug release, and thus generate growing interest in using these polymers in sustained drug delivery [3-5].

In India, natural gums and mucilage are well known for their medicinal use. They are widely used in the pharmaceutical industry as thickeners, water-retention agents, emulsion stabilizers, gelling agents, suspending agents, binders, film formers, and sustained-release agents. They are also used in cosmetics, textiles, paints, and paper-making. Demand for these substances is increasing, and new sources are being developed. India, because of its geographical and environmental position, has traditionally been a good source for such products among the Asian countries. Natural gums and mucilage are preferred to semi-synthetic and synthetic excipients because of their lack of toxicity, low cost, availability, soothing action, and nonirritant nature [6-9]. Mucilages are hydrophilic polymers. Many plants contain mucilage, which provides high concentration of complex polysaccharides [10].

*A. indica* is an important tree of social forestry. It is popularly known as Pangar and Bankhor. It is a tree of 40m height, found in deciduous forests of India, Srilanka, Pakistan, Thailand, China and Phillipines. Flowers are pinkish white in color. Flowers and fruits can be collected in the months from March to November. The cream colored wood is used to make pots and vessels. The fruits are given to cattle. Flour from seed is mixed with wheat flour during famine. Seed paste made with oil is applied in rheumatic pain. The flowers are useful in apiculture as bee forage [11].

Diclofenac sodium is reported to be a potent non-steroidal anti-inflammatory drug that has anti-inflammatory, analgesic, and antipyretic properties. It is generally used to treat degenerative joint diseases like rheumatoid arthritis, osteoarthritis, and ankylosing spondilitis. Diclofenac sodium is rapidly dissolved in intestinal fluid and reaches its maximum blood concentration ($C_{max}$) within 30 min. It is metabolized mainly by hepatic hydroxylation and subsequent conjugation [12]. In healthy human volunteers, mean plasma clearance of diclofenac sodium was 16 L/h, and the mean elimination half-life of the terminal phase was found to be 1.2–1.8 h [13]. To diminish diclofenac sodium gastrointestinal irritation, which is a common problem with all non-steroidal anti-inflammatory agents; effective enteric-coated dosage forms are used. Food, however, effectively delays the absorption of the drug, which causes a non reproducible pharmacokinetic profile, and the drug has no immediate therapeutic effect [14]. In case of multiple-dosing regimens of immediate-release formulations, diclofenac sodium has propensity of systemic accumulation leading to sever toxicity in central nervous system, gastrointestinal system and cardiovascular system when used for long-term treatments of various arthritic conditions. Low oral bioavailability (60%), short biological half life (1.1- 4.0 h) and low therapeutic index suggest need for sustained release formulation of diclofenac sodium. Therefore, it was chosen as a model drug for the present study.

*A. indica* is available locally in India in abundance and has not been explored as a pharmaceutical excipient. The aim of this study was to extract mucilage from the bark of *A. indica* and to study the various pharmaceutical properties of the mucilage to assess its functionality as an excipient in sustained-release formulations.

## MATERIALS AND METHODS

Diclofenac sodium was obtained as a gift sample from Cadila Pharmaceuticals (India). Starch was procured from E. Merk (India) Ltd., Mumbai, India. *A. indica* bark was collected from Garhwal region of Himalaya's, India in the month of April. The tree was identified by Prof. R.D. Gaur, Department of Botany, HNB, Garhwal University and was also entered in the Herbarium of the University (GUH-8812). All other chemicals used were of analytical-reagent grade, if not otherwise mentioned.

### Extraction of Mucilage

The bark of *A. indica* was cut into small pieces with help of sharp knife. The small pieces were taken and washed with water to remove dirt and debris. The bark was soaked in water for 5–6 h, boiled for 30 min, and left to stand for 1 h to allow complete extraction of the mucilage into the water. The mucilage was extracted using an eight-layer muslin cloth bag to remove the marc from the solution. Acetone (three times the volume of filtrate) was added to precipitate the mucilage. The mucilage was separated, dried in an oven at a temperature of less than 50 °C, collected, ground, passed through a # 80 sieve (nominal aperture size of 180 μm) and stored in a desiccator at 30°C and 40% relative humidity until used [15].

**Physicochemical and microbial properties of *A. indica* mucilage**
The obtained dried mucilage was studied for percentage yield, chemical test, particle size, weight loss on drying, solubility, viscosity, pH, swelling index, bulk and tapped density, angle of repose, compression properties, and microbial load.

**Chemical test**
The dried powder of mucilage was treated with Molisch's reagent and ruthenium red for the purpose of identification.

**Weight loss on drying**
Weight loss on drying was determined for an appropriate quantity of mucilage at 105°C for 2h [16].

**Particle size**
The particle size of the dried-powder mucilage was determined by the microscopic method. The study was carried out in triplicate.

**pH of solution**
The pH of the 1% w/v solution was measured with a pH meter.

**Density**
A 0.5% w/v solution of dried mucilage was prepared and transferred to a density-measurement bottle. An empty bottle with distilled water was weighed. The density of the dried mucilage was calculated.

**Charring**
A defined quantity of dried mucilage was placed in a melting-point apparatus. The temperature was taken and recorded when the material started to char.

**Swelling ratio**
Swelling characteristics of the separated mucilage powder were studied in different media such as 0.1N HCl, Phosphate buffer (pH- 7.4) and distilled water. The study was carried out using a 100-mL stoppered graduated cylinder. The initial bulk volume of 1 g of dried mucilage was recorded. Water was added in sufficient quantity to make up the volume up to 100 mL of the dispersion. The sediment volume of the swollen mass was measured after 24 h at room temperature. The swelling ratio was calculated by taking the ratio of the swollen volume to the initial bulk volume [17].

**Bulk and tapped density**
A pre-weighed, pre-sieved quantity of dried mucilage was poured into a graduated cylinder, and the volume was recorded. The cylinder was tapped until the powder-bed volume reached a minimum value, and the tapped volume was recorded. The bulk and tapped densities were calculated [18-19].

**Determination of viscosity of the mucilage**
The viscosity of the mucilage was determined with a Brookfield Viscometer at room temperature ($30^0$C).

$$\eta = C\frac{T}{v}$$

Where C is an instrumental constant, T is the torque reading and v is the speed of the cone in revolution per minute.

**Microbial count**
The microbial count of the dried mucilage was determined using the method given in the *Indian Pharmacopoeia* for total aerobic microbial count of bacteria and fungi using the plate count method [20].

**Preparation and characterization of matrix tablets**
Matrix tablets were prepared using diclofenac sodium as a model drug [21] and different ratios of dried A. indica mucilage as per the composition given in Table no 2. Different batches of the matrix tablets ($A_1$ to $A_4$) with almost constant theoretical weight of 400 mg were prepared. In all the formulations, ingredients were passed through sieve

# 120. Then the ingredients were accurately weighed and granulated using isopropyl alcohol. Granules were allowed to dry at room temperature (27±2 $^0$C). Dried granules after lubricating with magnesium stearate were compressed using 9 mm round flat-faced punches on a motor-operated single-punch tablet machine and were evaluated for the following parameters: hardness, friability, and uniformity of weight [22].

**Table 1: Physiochemical and microbial properties of dried powder mucilage**

| S. No | Properties | A. indica mucilage |
|---|---|---|
| 1 | Percentage Yield | 15 |
| 2 | Particle Size (µm) | 168.82 |
| 3 | Weight loss on drying | 4.7 |
| 4 | Swelling Ratio | 40 |
| 5 | pH | 6.3-7.0 |
| 6 | Solubility | Slightly soluble in water ; produce haze and viscous solution |
| 7 | Charring | 221$^0$C |
| 8 | Density of liquid (0.5%weight/volume) | 0.999 |
| 9 | Microbial count | Bacteria : 5 cfu*/gm<br>Fungi : 2 cfu*/gm |

**cfu is colony forming unit*

**Table 2: Formulation of diclofenac sodium matrix tablets**

| Ingredients | Drug mucilage ratio $A_1$ (1:0.5) (mg) | Drug mucilage ratio $A_2$ (1:1) (mg) | Drug mucilage ratio $A_3$ (1:1.5) (mg) | Drug mucilage ratio $A_4$ (1:2) (mg) |
|---|---|---|---|---|
| Diclofenac Sodium | 100 | 100 | 100 | 100 |
| Dried Mucilage | 50 | 100 | 150 | 200 |
| Dicalcium Phosphate | 242 | 192 | 142 | 92 |
| Mag. stearate | 8 | 8 | 8 | 8 |

## Evaluation of granules [18-19]

### Bulk Density

Both bulk density and tapped bulk density were determined and calculated.

### Carr's index and Hausner ratio

Carr's index and Hausner ratio were calculated from the bulk and tapped densities[19].

### Angle of repose

The angle of repose was determined by the fixed-height funnel method and calculated using the following equation:

$$\text{Angle of repose} = \text{Tan}^{-1}\ \frac{h}{r} \qquad [1]$$

Where *h* is the height of the powder heap and *r* is the radius of the powder heap.

**Table: 3 : Pre-compression properties of granules**

| Properties | Formulation | | | |
|---|---|---|---|---|
| | $A_1$ | $A_2$ | $A_3$ | $A_4$ |
| **Bulk density (g/cm$^3$ )** Mean ±SD (n=3) | 0.372 ± 0.015 | 0.403 ± 0.020 | 0.413 ± 0.022) | 0.421 ± 0.030 |
| **Tapped density (g/cm$^3$ )** Mean ±SD (n=3) | 0.423 ± 0.024 | 0.432 ± 0.017 | 0.442 ± 0.023 | 0.468 ± 0.031 |
| **Carr's index** Mean ±SD (n=3) | 12.056 ± 0.29 | 6.712 ± 0.35 | 6.56 ± 0.29 | 10.042 ± 0.34 |
| **Hausner's ratio** Mean ±SD (n=3) | 1.137 ± 0.28 | 1.071 ± 0.30 | 1.048 ± 0.24 | 1.016 ±0.22 |
| **Angle of repose (º)** Mean ±SD (n=3) | 27.32 ± 0.025 | 27.70 ± 0.020 | 24.49 ± 0.023 | 22.54 ±0.023 |

**Evaluation of matrix tablets**

The diameter and thickness of matrix tablets were measured by Vernier calliper, and the hardness was determined by Monsanto hardness tester. The friability test was conducted using Roche friabilator. For each batch, 20 randomly drawn tablets were checked for weight uniformity.

**Drug content determination [23]**

For drug content, 20 tablets were weighed and powdered. Powder equivalent to 50 mg of diclofenac sodium was shaken with 60 ml of methanol in 200 ml volumetric flask, and volume was further adjusted with methanol. Finally, 5 ml of this was diluted to 100 ml with methanol, and drug content was determined by UV-spectrophotometer (UV-1601, Shimadzu, Japan) at 276nm.

**Table: 4: Evaluation parameters of tablets**

| Formulation code | Average Weight (mg) Mean±SD (n=20) | Hardness (kg/cm$^2$) Mean±SD (n=3) | Friability (%) Mean±SD (n=3) | Drug content (%) Mean±SD (n=3) |
|---|---|---|---|---|
| **$A_1$** | 397±0.20 | 5.13±0.07 | 1.10±0.04 | 98.26±1.27 |
| **$A_2$** | 386± 0.15 | 5.38± 0.05 | 1.09±0.02 | 99.07±1.33 |
| **$A_3$** | 393±0.25 | 5.46± 0.03 | 0.95±0.03 | 99.41± 0.58 |
| **$A_4$** | 398± 0.10) | 5.65±0.06 | 0.89±0.02 | 99.29±0.45 |

**Tablet swelling index**

Tablets of equal weight were immersed in 50 mL of distilled water on a watch glass. At specific time intervals, tablets were carefully removed from the watch glass and blotted with filter paper to remove the water present on their surface and weighed accurately. The experiment was performed for 5 h. The swelling index was calculated using the following formula [24]:

$$\text{Swelling index of tablet} = \frac{(\text{Wet weight} - \text{Dry weight})}{\text{Dry weight}} \qquad [2]$$

**Radial and axial swelling of the tablet**

The initial diameter and height of the tablet were measured, and the tablet was stored in distilled water. The increase in diameter and height were measured at selected time intervals up to 5 h. The equilibrium degree of swelling ($Q$) was calculated from the radial and axial swelling ratio using the following equation:

$$Q = \frac{V_t}{V_o} = \left(\frac{R_t}{R_o}\right)^2 \times \left(\frac{I_t}{I_o}\right) \qquad [3]$$

Where $V_t$ and $V_o$ are the tablet volumes, $R_t$ and $R_o$ are the radii, and $I_t$ and $I_o$ are the heights at time $t$ and zero, respectively [25].

**Table: 5: Radial and axial swelling of tablets in distilled water[#]**

| Time (h) | Formulation code | Normal diameter (mm) | Normal Thickness (mm) | Diameter after Swelling (mm) | Thickness after swelling (mm) |
|---|---|---|---|---|---|
| 5 | $A_1$ | 6.39 | 2.74 | 7.9 | 4.4 |
| 5 | $A_2$ | 6.81 | 3.3 | 8.4 | 5.5 |
| 5 | $A_3$ | 7.58 | 3.5 | 9.1 | 5.9 |
| 5 | $A_4$ | 8.23 | 3.89 | 9.8 | 6.7 |

[#] *n=3*

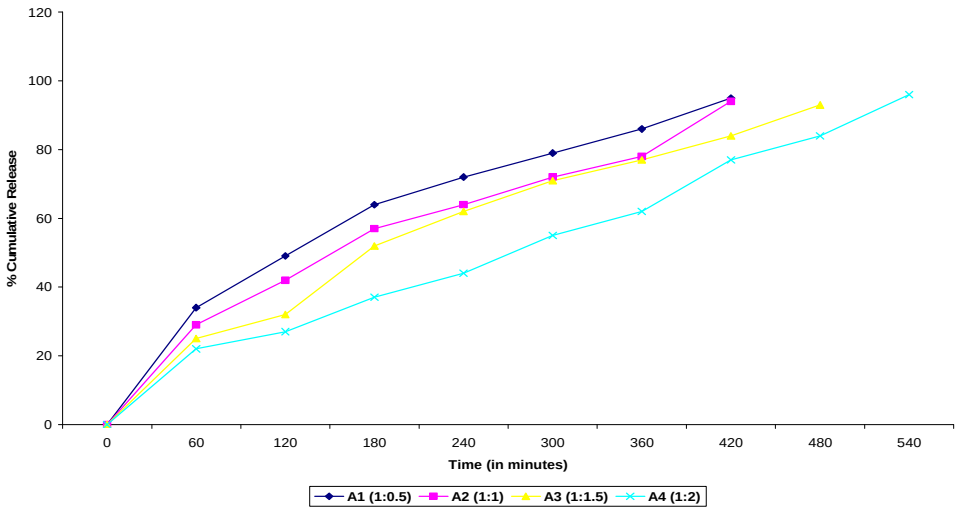
**Dissolution-rate study [26]**

*In-vitro* dissolution studies of prepared tablets were performed using USP apparatus type-II at 50 rpm in pH 7.8 phosphate buffer (900 ml) medium at the temperature 37±0.5$^o$C. At specified intervals, 5ml of sample was withdrawn and filtered. From this filtrate 1ml was taken into 10ml volumetric flask and volume was made up to the mark. After removal of each sample, the 5ml of fresh dissolution medium was added to the vessel to maintain the constant volume. The samples were then analyzed at 276 nm by UV-Visible spectrophotometer (Shimadzu-1700).

**Table: 6 Comparative effects of different concentration levels of *A. indica* mucilage used as binding agent on the release of diclofenac sodium tablet.**

| S. N | Time (minutes) | % cumulative drug release | | | |
|---|---|---|---|---|---|
| | | $A_1$ | $A_2$ | $A_3$ | $A_4$ |
| 1 | 60 | 34 | 29 | 25 | 22 |
| 2 | 120 | 49 | 42 | 32 | 27 |
| 3 | 180 | 64 | 57 | 52 | 37 |
| 4 | 240 | 72 | 64 | 62 | 44 |
| 5 | 300 | 79 | 72 | 71 | 55 |
| 6 | 360 | 86 | 78 | 77 | 62 |
| 7 | 420 | 95 | 94 | 84 | 77 |
| 8 | 480 | 0 | 0 | 93 | 84 |
| 9 | 540 | 0 | 0 | 0 | 96 |

**Figure:1: Comparative effects of different concentration levels of A. indica mucilage used as binding agents on the release of diclofenac sodium tablet.**




## RESULTS AND DISCUSSION

Various physiochemical and microbial characteristics of the extracted mucilage from *A. indica* were investigated. The presence of mucilage in extracted material was confirmed using Molisch's test and by treatment with ruthenium red. Both tests were positive for the presence of mucilage. The results of other investigations like percentage yield, particle size, pH of solution, density, and charring are shown in Table 1. The loss on drying was well within official limits and the weight loss on drying indicates the amount of moisture present in the material which shall be available to interact with other materials during processing. The result of microbial testing of the mucilage was within official limits {less than 100 colony-forming units (cfg)/g}. The swelling ratio of mucilage was determined in different media and ratio was found to be highest in distilled water i.e., 40. A significant change in swelling was found by the end of the study, which indicated that the mucilage had excellent swelling properties. Swelling characteristics studies revealed that the swelling was affected by pH of the medium.

The viscosity of the extracted dried mucilage was compared with starch and was noted to be comparable to starch.
The result of evaluation of granules including bulk and tapped density, Carr's index, the Hausner ratio, and the angle of repose, were assessed and are shown in table 3. The compressibility index and angle of repose indicated that the powder have good flow with moderate compressibility. It can be concluded that the dried mucilage has flow properties suitable for a direct-compression method.

The physical tests like hardness test, friability, and weight variation were performed for all formulations. Mean hardness for all formulations was found between 5 to 6 kg/cm$^2$ , friability was less than 1%, and the weight-variation

results for the matrix tablets complied with pharmacopoeial limits (Table-4). From the data it can be inferred that dried mucilage possesses good tablet-forming properties.

The study of dimensional changes in the tablets was carried out for 5 h in distilled water and the results are shown in Table 5. Both radial and axial swellings of the tablets were found to be increasing with increase in the proportion of the dried mucilage. The swelling of the tablet was found to be lowest for formulation $A_1$. On increase in the ratio, the radial and axial swelling increased proportionally. The swelling of the tablet in the axial direction was found to be more as compared with the radial direction.

The dried mucilage was evaluated as a matrix-forming material for oral sustained-released tablets using diclofenac sodium as a model drug. The tablets, each containing 100 mg of diclofenac sodium, were prepared using dried mucilage of *A. indica* in various drug–mucilage ratios (1:0.5, 1:1, 1:1.5, and 1:2). An ideal modified-release dosage form should release a loading dose (20–25%) in the first hour. Later, the remaining drug should be released at a constant rate over an extended period. An ideal release pattern was calculated according to these criteria. Diclofenac sodium release profiles of the mucilage matrix tablets were recorded (Table-6), and are shown in Figure-1. A decrease in drug release rate was observed when *A. indica* mucilage contents in the matrix were increased and the reason behind this may that the mucilage in higher concentrations in the tablets might have produced dense matrix around the drug particles, providing more barriers for them to escape and dissolve. Further, these matrixes when they are hydrophobic in nature may be expected to favor less penetration of the dissolution medium in the tablet. Probably this may be the auxiliary reason for obtaining slow drug release profiles through *A. indica* matrix tablets. Batches $A_1$ and $A_2$, at lower ratios (1:0.5 and 1:1 respectively), released 34 and 29% of the drug in the first hour, and the remaining drug was released within 7 h. This result occurred probably because of insufficient polymer in the formulation. In batch $A_4$, where the drug-mucilage ratio was 1:2, 22% of the drug was released in the first hour, and the remaining drug was released during 9 h. The rate of release was faster in batch $A_1$ and slower in batch $A_4$. This result showed that as the proportion of mucilage increased, the overall time of release of the drug from the matrix tablet increased. Drug release from swellable and erodible hydrophilic matrices can be attributed to polymer dissolution, drug diffusion through gel layer, or a combination of both.

## CONCLUSION

From the study, the mucilage extracted from *A. indica* appears suitable for use as a pharmaceutical excipient in the formulation and manufacture of sustained-release matrix tablets because of its good swelling, good flow, and suitability for direct-compression formulations. From the dissolution study, it was concluded that the dried mucilage can be used as an excipient for sustained-release, modified-release, and fast-release tablets with suitable modifications.

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