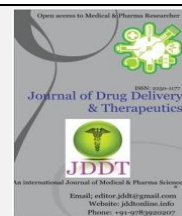


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Research Article

Isolation and Characterization of *Azadirachta indica* Gum: A Novel Controlled Release Polymer

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ABSTRACT

Oral Drug Delivery is considered as the holy grail of drug delivery due to its convenience which resulted in high patient compliance of all the drug delivery systems that have been explored, oral drug delivery is the most preferred option for systemic delivery of drug via various pharmaceutical products of different dosage forms. The advantage of administering a single dose of drug which is released over an extended period of time, instead of administering numerous doses, is now a day's area of interest for formulation scientists in the pharmaceutical industry. For this reason, the conventional dosage forms of drugs are rapidly being replaced by the new and the novel drug delivery systems. Amongst these, the controlled release dosage forms have gradually gained medical acceptance and became extremely popular in modern therapeutics. In order to control the release of drug from its dosage form, an effective controlled release polymer is essential. Though, there are several controlled release polymers available in the market, there is continuous need to develop controlled polymers which are safe and inexpensive. The aim of the work was to isolate and characterize the *Azadirachta indica* gum as novel controlled release polymer.

Keywords: Isolation, Controlled release, *Azadirachta indica* Gum.

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INTRODUCTION:

Number of natural, semi synthetic and synthetic polymer materials are used in the sustained or controlled delivery of drugs. In recent years, researchers have become increasingly interested in the utilization of natural biopolymers due to their wide ranging advantages over synthetic polymers. Natural polymers have gained the attention for their use in 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. Natural gums and mucilages are widely explored as pharmaceutical excipients.

The present investigation has been undertaken to isolate and characterize *Azadirachta indica* gum and to find out the potential of gum act as a release modifier.

Isolation of Gum from *Azadirachta indica* Bark Exude:

The *Azadirachta indica* bark exude was collected and soaked in double distilled water. After soaking, it was boiled for 5

hours in a water bath until slurry was formed. Thus formed slurry was cooled and refrigerated over-night so that most of the undissolved portion was settled out. The upper clear solution was decanted off and centrifuged at 500 rpm for 20 minutes. The supernatant was allowed to concentrate at 60°C on a water bath until the volume reduced to one-third of its original volume. Solution was cooled to room temperature and was poured into acetone (three times the volume of slurry) with continuous stirring to form precipitate. Thus formed precipitate was separated, washed repeatedly with acetone and dried under vacuum at 50°C in an oven. The completely dried gum was powdered and was passed through sieve #100, packed in a tightly closed container and stored in a dessicator for further usages.

METHODS

Physicochemical Characterization of Gum⁽¹⁻⁴⁾:

Macroscopic properties of the gum were evaluated by observation of the color, taste and odor of the powdered gum. The gum was evaluated for solubility in water, methanol and acetone in accordance with the standards.

Other physicochemical properties of gum were also evaluated like loss on drying, total ash, pH, angle of repose, bulk density, tapped density, hausner's ratio and Carr's index.

I. Angle of Repose:

The angle of repose of gum was determined by the funnel method. The accurately weighed (10gms) gum was taken in the funnel. The gum was allowed to flow freely through the funnel on to the surface. The diameter of the formed cone was measured and angle of repose was calculated using the following equation:

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

Where, θ = angle of repose,

h = height of the cone, and

r = radius of the cone base

II. Bulk Density:

Bulk density (D_b) was determined by measuring the volume (V_b) of known weighed quantity (W) of powdered gum using bulk density apparatus and can be calculated by using the formula:

$$\text{Bulk density } (D_b) = \frac{\text{Bulk volume of powder } (V_b)}{\text{Mass of powder } (W)}$$

III. Tapped Density:

Tapped density (D_t) was determined by measuring the volume (V_t) of known weighed quantity (W) of powdered gum after desired mechanical tapping using tapped density tester and can be calculated by using the formula:

$$\text{Tapped density } (D_t) = \frac{\text{Mass of powder } (W)}{\text{Tapped volume of powder } (V_t)}$$

IV. Hausner's ratio:

The Hausner's ratio was obtained by dividing the tapped density by the bulk density of the gum powder.

$$\text{Hausner's ratio} = \frac{\text{Tapped density of powder } (D_t)}{\text{Bulk density of powder } (D_b)}$$

V. Carr's Index:

The Carr's index (% compressibility) of the gum powder was calculated from the difference between the tapped and bulk densities divided by the tapped density and the ratio is expressed as a percentage.

$$\text{Carr's index } (\%) = \frac{\text{Tapped density } (D_t) - \text{Bulk density } (D_b)}{\text{Tapped density } (D_t)} \times 100$$

VI. Swelling Property:

Natural gum obtained from *Azadirachta indica* bark exude is nontoxic. 250 mg of *Azadirachta indica* bark exude gum was allowed to hydrate in 25ml of distilled water at 25°C in a 25 ml graduated cylinder and volume measured at 5 min. intervals until there was no further hydration observed. The

swelling property was determined at different time intervals.

VII. Loss on Drying:

5 gm gum was dried at 105 ± 5 °C till the constant weight of gum was obtained. The loss on drying was found to be less than 7%w/w.

VIII. Ash Value:

1gm of gum was accurately weighed and evenly distributed it in the crucible. It was dried at 105°C for one hour and ignited in muffle furnace at 600 ± 25 °C. Percentage of ash content was found to be less than 8 % w/w.

IX. pH:

The pH of gum was determined by using digital pH meter. The binder gum is natural and 2 to 8 % w/w gum solutions have pH 6.0 to 6.5 or 5.1 to 5.9.

X. Determination of Viscosity:

1 g of dried and finely powdered gum was suspended in 75 ml of distilled water for 5 h. Distilled water was added up to 100 ml to produce the concentration of 1 % w/v. The mixture was homogenized for 2 h using a mechanical stirrer and its viscosity was determined using a Brookefield viscometer, spindle-LV2 (Brookefield LV-II, USA) at 20 rpm and 25°C.

Phytochemical Examination⁽⁵⁻¹²⁾:

For the detection of the presence of carbohydrates, reducing sugars, tannin's, mucilage and peroxide enzymes the standard tests Molisch's test for carbohydrate, reduction of Fehling's solution for reducing sugars, ferric chloride test for tannins, ruthenium red test for *Azadirachta indica* gum were done.

1. Test for Carbohydrates (With aqueous test solution):

Molisch's Test: To the aqueous solution of *Azadirachta indica* gum, few drops of α -naphthol were added and to it few drops of concentrated sulphuric acid was added through sides of the test tube.

2. Test for Proteins:

Ninhydrine Test: To the aqueous solution of *Azadirachta indica* gum ninhydrine solution was added and then this solution was boiled.

3. Test for Alkaloids:

Wagner's Test: To the aqueous solution of *Azadirachta indica* gum, Wagner's reagent was added.

4. Test for Tannins:

Ferric Chloride Test: The extract was treated with ferric chloride solution.

5. Fehling's Test:

To the aqueous solution of gum, few drops of Fehling's reagent was added.

RESULTS AND DISCUSSION

Physicochemical Characterization of gum

Macroscopic properties showed that *Azadirachta indica* bark exude gum obtained after extraction from its bark was an amorphous, free flowing powder, with yellow color, sweet in taste and with characteristic sweetish odor. The gum was found to be soluble in water and gave viscous solution on standing but practically insoluble in ethanol, acetone and

chloroform. Its pH was found to be around 6.4 with acceptable limit of loss on drying (7.15%) and total ash (2.85% or 3.5%).

Flow properties of gum were determined in terms of angle of repose (28.80°), bulk density (0.54g/cc), tapped density

(0.69g/cc), hausner's index (1.28) and Carr's index (21.74%). All these physicochemical properties are tabulated in Table 1. The results of phytochemical tests are tabulated in Table 2

Table 1: Physicochemical properties of *Azadirachta Indica* Bark Exude gum

S.No.	Parameters	Results	
1.	Macroscopic Property	Color	Yellow
		Taste	Sweet
		Odor	Characteristic sweetish
2.	Solubility	Water	Soluble
		Ethanol	Insoluble
		Acetone	Insoluble
		Chloroform	Insoluble
3.	Angle of Repose (°)	28.80	
4.	Bulk Density (g/cc)	0.54	
5.	Tapped Density (g/cc)	0.69	
6.	Hausner's ratio	1.28	
7.	Carr's Index (%)	21.74	
8.	pH	6.4	
9.	Loss on Drying (%)	7.15	
10.	Swelling Property	Gum has swelled to larger extent indicating its suitability for controlled release of drug.	
11.	Ash value (%)	2.85	

Table 2: Phytochemical Screening of *Azadirachta indica* gum

S.NO	Tests	Observation
1	Test for Carbohydrates (Molisch's test)	+
2	Test for proteins (Ninhydrine test)	+
3	Test for alkaloids (Wagner's test)	+
4	Test for Tannins (Ferric chloride test)	-
5	Reducing sugars (Fehling's test)	+

CONCLUSION

The results of the present study demonstrated that the *Azadirachta indica* gum obtained from the bark excude is yellow colored granular powder which is amorphous in nature. It is slightly soluble in water, practically insoluble in alcohol, chloroform and acetone and forms thick gel can control the drug release. Gum showed good flow property with swelling nature. Results suggested that the gum is suitable for use as a release retardant for the manufacture of controlled release tablets.

Since the primary ingredients are inexpensive, devoid of toxicity, biocompatible, biodegradable and easy to manufacture, they can be used in place of currently marketed controlled release polymers. Moreover, as this tree is widely distributed in nature, available chiefly in India and many other countries and easily available option without destroying the natural sources as compared to that of the other available natural option will be one of the suitable options to utilize as pharmaceutical controlled release polymer.

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