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EXTRACTION AND USE OF *LALLEMANTIA ROYLEANA* SEED MUCILAGE AS A PHARMACEUTICAL EXCIPIENT

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ABSTRACT

The objective of the present study was to develop excipients of natural origin that have the ability to swell up rapidly on coming in contact with fluids. The advantages offered by natural polymers have been documented in many previous studies. The focus of the present investigation was to evaluate the seeds of *Lallemantia royleana*, also known as sweet basil as a potential candidate for superdisintegrant action. The seeds of the plant have been used since long times as a food additive thereby eliminating the need for toxicological studies. The present work evaluates powdered seeds and the polymer obtained from aqueous extraction of the seeds for use as a superdisintegrant in tablet formulation. The powders were evaluated for various properties like swelling index, particle size, their micromeritic properties, density and viscosity. On the basis of the above examinations, it was discovered that the aqueous acetone extract of the seeds had better swelling characteristics and the tablets prepared from the polymer showed considerably lesser disintegration times than those prepared using powdered seeds. The only problem being encountered during the study was lower yield of the extraction process. Further research is needed to discover better methods of polymer extraction.

KEYWORDS: Mucilage, swelling ability, seed, excipient, suspending, superdisintegrant.

INTRODUCTION

With the drug discovery pipelines turning dry, more and more efforts are being directed towards optimizing the already available drugs in the arsenal of mankind to increase their efficacy and improving their therapeutic profile. Moreover pharmaceutical companies

nowadays are also placing increased impetus on the development of patient compliant dosage forms. All these efforts are focused towards the main aim of improving the life cycle of the drugs already known in the market. So in order to achieve these objectives, the main avenues being explored for potential possibilities include researching newer technologies for drug delivery, trying non conventional routes for drug administration, using newer polymers such as IPN systems, development of new co-processed excipients, extraction and characterization of newer excipients of natural origin.

Excipients are the substances which form the bulk of the pharmaceutical preparations in addition to the active pharmaceutical ingredient. An excipient is a natural or synthetic substance formulated alongside the active ingredient of a medication, included for the purpose of bulking-up formulations that contain potent active ingredients (thus often referred to as "bulking agents," "fillers," or "diluents"), or to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as facilitating drug absorption or solubility.[1] Suitable dosage are generally used for the administration of drug with the help of excipients, which provide various functions such as binding, lubricating, gelling, suspending, flavouring, sweetening and bulking agent along with others. Excipients are the major part of any pharmaceutical formulation. They can be of natural or synthetic origin.[2] Though excipients were at one time considered to be "inactive" ingredients, they are now understood to be "a key determinant of dosage form performance".[3]

Excipients are additives used to convert pharmacologically active compound into pharmaceutical dosage forms suitable for administration to patients.[4] They also serve as an inert support to the active principles. Another important role of excipients lies in taste masking where the active principle is having certain objectionable flavor or odour to it and the selection of proper excipient blends also ensures that the right amount of API makes it to right spot in the body at the right time.[5] The selection of appropriate excipients also depends upon the route of administration and the dosage form, as well as the active ingredient and other factors.

Polymers are made up of repeating structural units and these are generally large molecules. Natural polymers are used because they are economical, readily available and non toxic. Also chemical modifications in natural polymer can be easily done. They are also biodegradable and biocompatible with few exceptions. Extraction of newer safer natural polymer alternatives to the already available synthetic alternatives is in itself an entire rather complete

field of research. Variety of pharmaceutical products is formulated using natural polymers. Chitosan, carrageenan, acacia, agar, gelatin, shellac, guar gum are the well known natural polymers. These natural polymers are widely used as emulsifying agents, suspending agents, adjuvants and adhesives in packing.[6]

Natural polymers are classified on the basis of their origin as:

1- Plant origin: Cellulose, Hemicellulose, Agar, Starch, Pectin, Rosin, Gaur gum, Acacia

2- Animal origin: Chitin and gelatin.

Limitations of Natural Polymers[7]

Some of the limitations of natural polymers are as under:

Difficult to process

- Generally insoluble in organic solvents
- Not optimal for conventional industrial methods

Fragile

- Poor mechanical properties
- Stability concerns
- Fast degradation
- Difficult control their rate of degradation
- Inconsistent chemical composition

GUM AND MUCILAGE[8]

Both gums and mucilages are obtained from plants. Gums are considered to be pathological products formed following injury to the plant or owing to unfavorable condition such as droughts by a breakdown of the cell walls (extra cellular formation). Thus gums are produced by the plants during adverse conditions or when going through stressful and traumatic conditions. Gums readily dissolve in water and these are plant hydrocolloids.

Mucilages: These are the metabolic products formed within the cell (intracellular formation) or product without injury to the plant. These forms slimy masses in water and these are physiological products of plant and are often represent a storage material, a water storage reservoir or offering defense to the germinating seeds. They are a part of normal plant metabolism and are frequently present in seed coats, bark and roots.

This research article deals with the extraction and characterization of mucilage extracted from an annual herb *Lallemantia royleana* belonging to the family Lamiaceae to act as a superdisintegrant in orally disintegrating tablets. Common name of *Lallamantia royleana* in English and Urdu are Lady's mantle and Tukhummalanga.[9] Some of the other vernacular names of the plant include Tukhm balangu, Balangu shirazi and Tukhm malunga, with its seeds being recognized as officinal and said to possess cooling and sedative properties.[10] *Lallemantia royleana* is frequently used as a palatable ingredient in cooling drinks and the high mucilaginous nutlets have numerous applications in traditional medicine. It is cultivated throughout western Asia, India, Pakistan and Northern of Iraq.[11] Figure 1 a) shows the seeds of the plant and b) depicts the swelling of seeds on contact with water.

Fig.1: a) Seeds of *Lallemantia royleana* b) Swelling of seeds on contact with water

Seeds of *Lallemantia royleana* were collected from P.A.U., Ludhiana. The plant was identified by Botany Department, Gautam Buddh University, Gr. Noida and voucher specimens were deposited in that department.

Extraction Procedure- Seeds of *Lallemantia royleana* are a good source of polysaccharides, fiber, oil and protein.[12] An important aspect of its physiological fiber behavior is its high viscosity and gel like character in water. This property in turn is related to the function associated with its high molecular weight polysaccharides.[13] Balangu seeds have a good water absorbing capacity and become mucilaginous on coming in contact with water and further produce a sticky, turbid and tasteless liquid on additional dilution.[14] However the major problem in isolation of mucilage is that it swells but does not separate from the seeds.[15] Extraction was done by the following method:

Step 1- Extraction of mucilage[16]: Weighed seeds of *Lallemantia royleana* were used for the extraction of mucilage. The seeds were taken in a 1000ml beaker containing 900 ml of distilled water and allowed to boil for at least 4-5 hr with continuous stirring and heating at

40ºC-60ºC for sufficient release of mucilage in water. The solution was concentrated until it becomes half of its initial volume. Concentrated solution was then filtered through muslin cloth in order to separate marc from the filtrate and then cooled it at room temperature.

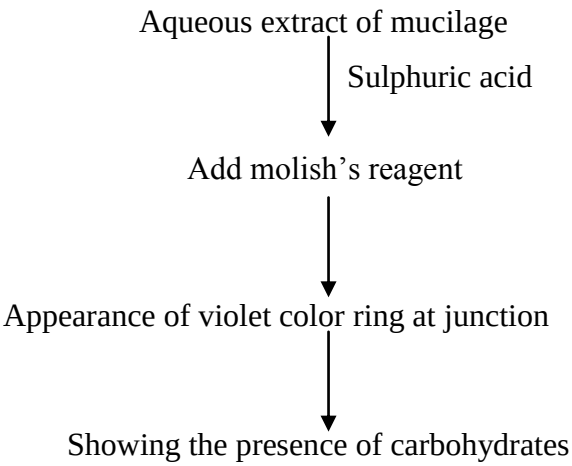
Step 2- Isolation of mucilage[15]: To the extract, equal volume of acetone was added for the precipitation of mucilage. Continuous stirring was done during the addition of acetone to cause rapid precipitation of mucilage. The precipitated mucilage was treated with acetone and then collected through filtration by muslin cloth. Obtained mucilage was further dried in hot air oven at 45ºC. Hard mucilage cake was grinded and passed through sieve #22.

PHYSICOCHEMICAL CHARACTERIZATION OF ISOLATED MUCILAGE

Isolated mucilage was characterized by performing the following tests

Organoleptic characterization of isolated mucilage[17]: Color, odor, texture and fracture are the parameters for the organoleptic characterization of isolated mucilage.

Identification Tests [18]: Molish reagent test, Benedicts and Fehling reagent test were performed for the presence of carbohydrates and reducing sugars as a positive control test for confirmation of existence of the polysaccharides from the seeds in the extracted mucilage. In this test:



Determination of purity of mucilage: Different chemical tests were performed to determine the purity of mucilage. These tests were performed for the confirmation of alkaloids, protein, gum, fat, tannins and amino acids.

Swelling Index[19]: The seeds of the plant show considerable ability to absorb water. The swelling index of the seeds was calculated as follows-

Weighing a butter paper of size 2x2cm

↓

This butter paper was reweighed after wetting it with water

↓

Weigh 10 mg of powdered sample and kept it on a butter paper and then placed it on a petridish containing 15 ml of water

↓

Now the swelling index was taken out at different interval (15, 30 45, 60,120,240,360 mins)

Swelling index was calculated by using this formula:

$$Swelling\ index = \frac{Initial\ weight - Final\ weight}{Initial\ weight} * 100 \ldots\ldots \quad \text{Eqn} \quad (1)$$

pH of mucilage- It is very important to determine the pH of extracted polymer to determine whether it is compatible with the formulation or not. It was measured by using pH meter or pH paper with help of 1% solution of the extract in water.

Determination of flow properties of powdered extract- Flow properties of powdered extract were determined for various parameters as listed below.[20]

1) Bulk density and Bulkiness- Bulkiness is the inverse of the bulk density. Apparent bulk density is determined by pouring a weighed quantity of the powered blend into graduated cylinder and measuring the volume and weight.

2) Tapped density- Placed the graduated cylinder containing a weighed quantity of the powered blend on the tapped density apparatus until a constant volume was obtained. Obtained volume was noted down.

3) Angle of repose- Accurately weighed blend was taken in a funnel and the height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. Polymer was allowed to flow through the funnel freely on the surface. The diameter of the powder cone was measured and angle of repose was calculated using the equation for calculation of angle of repose.

4) Compressibility index and Hausner's ratio- Both properties are calculated from the bulk density and tapped density. Both of these properties are used for the knowing the compressibility of the powder.

5) Particle size determination- Particle size was determined by using the optical microscope. Accurate amount of polymer was put on slide and mounted with glycerine. Particle was determined under microscope with the help of eye piece using 10 x lens.

6) Surface tension- Drop weight method was used for the determination of surface tension using stalagmometer. Surface tension may influence the binding properties of polymer.

7) Viscosity- Ostwald viscometer was used for the determination of viscosity of isolated mucilage. For this determination, a 0.5% polymer solution was used and compared the flow time of isolated polymer solution to that of the known viscosity liquid.

Above parameters can be calculated by using following formulas-

S.No.	Parameters	Formula
1.	Bulk density and Bulkiness	**Bulk density**= Weight of powder/ Weight of apparent volume **Bulkiness=**1/ bulk density
2.	Tapped density	**Tapped density** = Weight of powder/ Tapped volume
3.	Angle of repose	tan =h/r
4.	Compressibility index	**Carr's index=**(Tapped density-Bulk density/ Tapped density)x 100
5.	Hausner's ratio	Hausner's ratio= Tapped density/ Bulk density
6.	Surface tension	**Surface tension=** (No. of drop of water x Density of test soluation/ No. of drop of test soluation x Density of water) x 71.8
7.	Viscosity	$\eta_1/\eta_2=d_1t_1/d_2t_2$
8.	Particle size determination	**Size of individual particle**= No. of individual in eye piece x calibration factor **Calibration factor** = (Stage reading/ Occular reading) x 100

RESULTS AND DISCUSSION

Results obtained after performing various tests are represented in following tables-

Table 1: Organoleptic characterization of *Lallemantia royleana*

S.No.	Color	Odor	Taste	Texture	Fracture
1	Greyish	Characteristics	Tasteless	Irregular	Rough

Table 2: Phytochemical tests of the isolated mucilage

S. No.	Test	Present/Absent
1.	Carbohydrates	+
2.	Hexose sugar	+
3.	Protein	-
4.	Alkaloids	-
5.	Tannins	-
6.	Amino acids	-

Table 3: Micromeritic study data of isolated mucilage

S.No.	Parameters	Values
1.	Angle of repose (º)	28.400 ±0.01
2.	Carr's Index (%)	7.152±0.001
3.	Hausner's Ratio	1.078±0.003
4.	Tapped Density (gm/ml)	0.766±0.004
5.	Bulk Density (gm/ml)	0.713± 0.001
6.	Bulkiness (ml/gm)	1.401± 0.002
7.	Mean Particle Size (µ)	92.964± 46.040
8.	Swelling Index	116.610±1.46
9.	pH	6.900± 0.057
10.	Surface tension (dyne/cm)	52.296±1.24
11.	Viscosity (poise)	15.766±.189

IR study of the extracted mucilage gave the following absorption peaks:

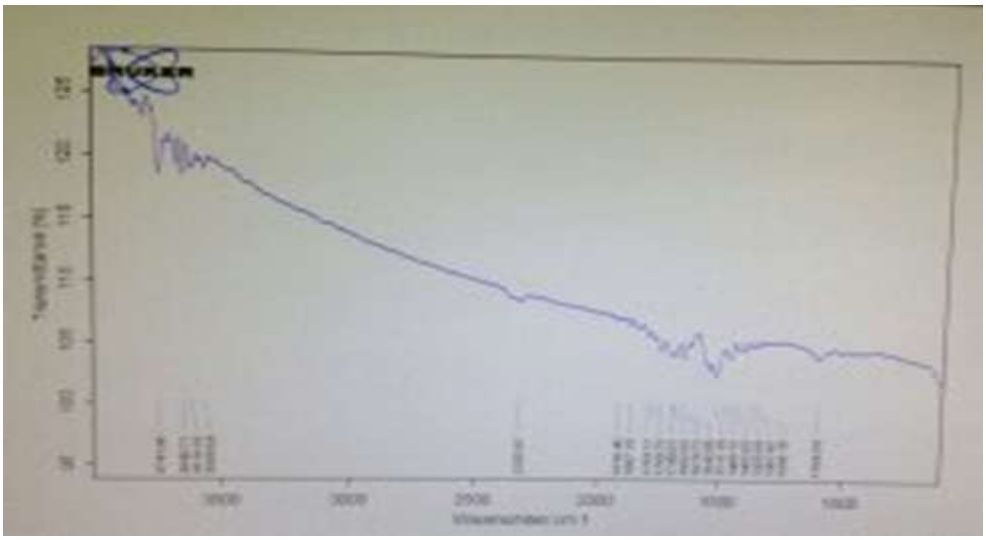


Figure 2: IR Spectra of the extracted mucilage

Table 4: Functional groups and peaks observed in IR spectra data of *Lallemantia royleana* mucilage

S.No.	Wave number(cm^{-1})	Functional Group
1.	1515.19	C-C Aromatic
2.	1678.72	C=C
3.	1740.81	C=O (Anhydride)
4.	1793.17	C=O (Ketone)
5.	2320.97	Broad O-H str
6.	3566.64-3648.71	-OH
7.	3741.45	$-NH_2$

DISCUSSION

Isolated mucilage was evaluated for organoleptic properties. It is tasteless, greyish in color and shows characteristic odour. Fracture and texture was found to be rough and irregular.All these properties are shown in table no. 1.

Mucilage isolated from *Lallemantia royleana* was soluble in warm water and slightly soluble in cold water and showed insolubility in benzene, chloroform ethanol, acetone.

Isolated mucilage was subjected to tests to evaluate various parameters. Various chemical tests were performed for confirmation of various phytoconstituents. Mucilage which was obtained from *Lallemantia royleana* gave positive test for carbohydrates and hexose sugars and show negative test for alkaloids, tannins, proteins and amino acids. Thus it confirms that the mucilage contains carbohydrates and hexose sugar and phytoconstituents were absent in isolated mucilage as shown in table no 2.

Various micromeritic studies were done for the mucilage as carr's index, angle of repose, bulk density, tapped density, bulkiness for flow behavior. The angle of repose of the isolated mucilage was found to be 28.4±0.01°. It shows that it has excellent flow property.

pH of 1% solution was found to be 6.9±0.057 which is slightly acidic to neutral and non irritating to mucous membrane. Swelling index of isolated mucilage was found to be 116.61±1.46 which was similar to the value obtained by using powdered seeds having a value of show that it have high swelling property and this property can be used as suspending and super disintegrating agent in various pharmaceutical formulations. Surface tension of 0.5% solution was found to be 52.296±1.24 which shows better penetrating and wetting ability of mucilage dispersion over the powder mass. Viscosity of 0.5% solution was found to be 15.766±.189. All these results are shown in table no. 3.

A brukerATR (Moddle- ALPHA, laser class1, Serial no. 200301, made in Germany) spectra showed that *Lallemantia royleana* mucilage contains alkane alkene, anine hydroxyl group etc. as shown in fig 1 and the peak of these groups shown in table no-4.

CONCLUSION

From the whole study, it can be concluded that isolated mucilage from the seeds of *Lallemantia royleana* shows good flow properties, has great swelling property and is non irritating in nature to the mucosal membrane. All the studies hence show that the mucilage obtained from the seeds of *Lallementia royleana* can act as a potential good candidate for various pharmaceutical formulations for its high swellability on coming in contact with water. Thus it can be used as a thickening agent, suspending agent or as a superdisintegrant in ODT formulations.

CONFLICT OF INTEREST

The author declare that they do not have any conflict of interest.

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