Extraction Characterization and Evaluation of Selected Mucilage as Pharmaceutical Excipient

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Summary

Natural polymers have been used in different pharmaceutical formulations. They are easily available, non-toxic, biodegradable and cost effective to be used as pharmaceutical excipient. In present investigation mucilage was extracted from fruit of *Hibiscus esculentus* and further characterized to be used as pharmaceutical excipient. Tablets were prepared using four different concentrations (6.6%, 13.3%, 20%, 26.66%) of *Hibiscus esculentus* mucilage and potato starch to evaluate binding properties of mucilage.

Results obtained from the micromeritic characterization and flow behavior showed that *Hibiscus esculentus* mucilage is a good candidate to be used as pharmaceutical excipient. Tablets prepared using mucilage showed relatively lesser friability than prepared with starch. It was found that release of drug from tablets prepared with mucilage was less as compared to prepared with starch. Findings of the different results easily predict the fact that mucilage obtained from *Hibiscus esculentus* has characteristics to be used as pharmaceutical excipient.

Key words: pharmaceutical excipient, binding agent, *Hibiscus esculentus,* natural polymer

Charakterystyka ekstrakcji i ocena wybranych kleików roślinnych jako nośników leków

Streszczenie

Naturalne polimery są stosowane w różnych formułach farmaceutycznych. Są one łatwe do uzyskania, nietoksyczne, łatwo ulegają biodegradacji, są bardzo ekonomiczne w zastosowaniu jako nośniki farmakologiczne. W prezentowanej pracy kleik został wyekstrahowany z owoców *Hibiscus esculentus* i następnie spreparowany do zastosowania jako nośnik farmaceutyczny. Przygotowano tabletki o zawartości 6,6%, 13,3%, 20%, 26,66% kleiku z *Hibiscus esculentus* i skrobi ziemniaczanej i przebadano scalające własności kleiku.

Wyniki uzyskane z charakterystyki mikrometrycznej i badań przepływów wykazały, że kleik z *Hibiscus esculentus* jest dobrym produktem do zastosowania jako nośnik farmaceutyczny. Tabletki przygotowane z użyciem kleiku wykazały relatywnie mniejszą kruchość, niż przygotowane z użyciem skrobi. Stwierdzono także, że uwalnianie leku z kleiku było mniejsze, niż z talku skrobiowego. Wyniki badań pozwalają ocenić kleik z *Hibiscus esculentus* jako przydatny nośnik farmaceutyczny.

Słowa kluczowe: nośnik farmaceutyczny, środek wiążący, *Hibiscus esculentus*, naturalny polimer

INTRODUCTION

Mucilages are most commonly used adjuvant in pharmaceutical preparations. Plant mucilages are pharmaceutically important polysaccharide with wide range of applications such as thickening gelling agent, binding, disintegrating, suspending, emulsifying, stabilizing and gelling agents. They have been also used

as matrices for sustained and controlled release drugs. Naturally available mucilages are preferred to synthetic materials due to their non toxicity, low cost, emollient and non irritating nature [1]. Acacia, tragacanth, gum ghati, gum karaya are popular examples of plant mucilages. Present paper deals with isolation, phytochemical screening and evaluation of binding properties of *Hibiscus esculentus* mucilage. As a dose formulators essential to develop cost-effective and less tedious procedures for preparation of sustained release formulations on the industrial scale. The most commonly used method for fabricating drugs in a controlled-release formulation is by incorporating them into a matrix containing a hydrophilic rate controlling natural polymer [2].

Now a day many research are going on for the use of natural occurring biocompatible polymeric material in designing of pharmaceuticals dosage form for oral controlled release administration. Most of the natural gums are biodegradable and nontoxic, which hydrate and swell on contact with aqueous media, so these have been used for the preparation of dosage form [2]. Polysaccharide obtain from plants, has been shown to be useful for the construction of drug delivery systems. Regular research is going on in field of use of natural occurring biocompatible polymeric material in designing of dosage form for oral controlled release administration. Natural gums are biodegradable and nontoxic, which hydrate and swell on contact with aqueous media, and these have been used for the preparation of dosage form [3].

Natural plants are playing an important role as pharmaceutical excipients. These are easily available, biodegradable and having economic. Bio-compatibility of these natural polymers promotes their use as in pharmaceutical formulations. Present work used granulation compression technique to prepare tablets. In present study Diclofenac sodium, a non-steroidal anti-inflammatory drug is selected as model drug. It is an acetic acid derivative non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. Diclofenac sodium is used to treatment of pain, dysmenorrhea, ocular inflammation, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and actinic keratosis [4].

MATERIALS AND METHODS

The plant materials were purchased from local market of Meerut. Diclofenac sodium was used as model drug in the study and it was obtained as a gift sample from GlaxoSmithKline Pharmaceuticals limited Mumbai. All the other materials such as potato starch, sodium saccharine, microcrystalline cellulose (MCC), talc and magnesium stearate are purchase from CDH Laboratory Reagent, Central Drug House (P) LTD New Delhi.

Extraction of mucilage

Mucilage was extracted from plant material in following two steps.

Step 1. Extraction of mucilage. *Hibiscus esculentus* fruit were used for isolation of mucilage. Fruit were washed with water to remove dirt and crushed into in a mixer. The crushed fruit material was soaked in warm water for 4 h, boiled for 2 h and kept aside for 2 h for release of mucilage into water. The material was squeezed in a muslin bag to remove the mark from the filtrate.

Step 2. Isolation of mucilage. Equal volume of ethyl alcohol was added to filtrate to precipitate the mucilage, the mucilage was separated, dried in oven at about 45°C, powdered and passed through sieve # 80. The powdered mucilage was stored in desicator until further use [5].

Physicochemical Characterization of Isolated Mucilage

Identification tests for carbohydrates, proteins, mucilage and gums. Aqueous solution of extracted mucilage was used for chemical characterization. Test for carbohydrates, proteins, mucilage, alkaloids, fats, tannins amino acids and gums were performing according to standard procedure [6].

Organoleptic Evaluation of Isolated mucilage. The isolated mucilage was characterized for organoleptic properties such as color, odor, taste, fracture and texture [6].

Solubility Behavior mucilage. One part of dry mucilage powder was shaken with different solvents and the solubility was determined [6].

pH of mucilage. The mucilage was weighed and dissolved in water separately to get a 1%w/v solution. The pH of solution was determined using digital pH meter [6].

Swelling Index of Isolated mucilage. The swelling index is the volume (in ml) taken up by the swelling of 1 g of test material under specified conditions. The swelling index of the mucilage was determined by accurately weighing 1g of mucilage, which was further introduced into a 25ml glass-Stoppard measuring cylinder. 25ml of water was added and mixture was shaken thoroughly every 10 min for 1 h. It was then allowed to stand for 3h at room temperature. Then the volume occupied by mucilage, was

measured. The same procedure was repeated thrice and the mean value was calculated [6].

EVALUATION OF BINDING PROPERTIES OF MUCILAGE

Preparation of Granules. The *Hibiscus esculentus* mucilage was evaluated for its granulating and binding properties in tablets using paracetamol as model drug. Granules are prepared by four concentrations (6.6%, 13.3%, 20%, 26.66%) of *Hibiscus esculentus* mucilage and potato starch by wet granulation technique (Table 1).

Evaluation of granules. Prepared granules were evaluated for following parameters

Bulk Density and Bulkiness. The inverse of bulk density is called as bulkiness. Accurately weighed quantity of (50 g) was introduced into a graduated measuring cylinder. The cylinder was fixed on the bulk density apparatus and the volume occupied by the powder was noted. Then, the powder was subjected to tapping in a bulk density apparatus until constant volume was obtained. The final volume (bulk volume) was noted [7].

Powder Flow Property. The flow characteristics were measured by angle of repose. The experiment was repeated thrice. Using the readings and the formula, the angle of repose was calculated [7].

Powder Compressibility. This property is also known as compressibility. The finely powdered mucilage (5g) was transferred into a measuring cylinder and calculations were done using bulk density apparatus [7].

Fabrication of Tablets. The dried granules were compressed using Cadmach punching machine, with the help of 12 mm flat faced punches.

Technological Parameters. Prepared tablets were evaluated for different technological parameters such as hardness, friability, thickness, diameter, drug content and *in vitro* drug release according to official guidelines [8, 9].

RESULTS AND DISCUSSION

After isolation of mucilage from *Hibiscus esculentus* by ethyl alcohol the percentage yield of mucilage was found 9.17%. Phytochemical investigation of isolated mucilage showed the presence of carbohydrates while gum, tannins, alkaloids and proteins shows negative test. Results obtained after phytochemical test mention in table 2.

Table 2. Chemicals characterization of isolated mucilage

Tabela 2. Charakterystyka chemiczna izolowanego kleiku

Tests	Present/Absent
Carbohydrates	+
Hexose Sugar	–
Monosaccharides	–
Proteins	–
Fats and oils	–
Tannins	–
Alkaloides	–
Amino acids	–
Mucilage	+
Gums	–

+Present; –Absent.

Table 1. Formulation compositions of *Hibiscus esculentus* mucilage matrix tablets

Tabela 1. Przepis formowania tabletek z kleiku *Hibiscus esculentus*

Ingredients (mg)	Formulations							
	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F7	Batch F8
Diclofenac sod.	50	50	50	50	50	50	50	50
Bhindi mucilage	–	–	–	–	20	40	60	80
Potato starch	20	40	60	80	–	–	–	–
Sodium saccharine	12	12	12	12	12	12	12	12
MCC	197.6	177.6	157.6	137.6	197.6	177.6	157.6	137.6
Menthol	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Talc	9	9	9	9	9	9	9	9
Magnesium stearate	9	9	9	9	9	9	9	9

Organoleptic properties of mucilage found to be acceptable and shown in table 3.

Table 3. Organoleptics properties of mucilage

Tabela 3. Własności organoleptyczne kleiku

Colour	Odour	Taste	Fracture	Texture
Brown	Odour-less	Charac-teristics	Rough	Irregu-lar

Ash value of isolated mucilage was found 0.412%. It was found after solubility analysis that *Hibiscus esculentus* mucilage soluble in hot water, swell in cold water and insoluble in most of organic solvents (Table 4).

Table 4. Solubility profile of mucilage

Tabela 4. Profil rozpuszczalności kleiku

Solvents	Solubility
Cold water	Swell to form a gel
Hot water	Soluble
Methanol	Insoluble
Ethanol	Insoluble
Benzene	Insoluble
Acetone	Insoluble

The pH of 1% solution of *Hibiscus esculentus* mucilage was found to be 6.3 which indicate that this mucilage was less irritating in GIT and suitable for uncoated tablet. Swelling index of mucilage was found to be 11.2 for isolated mucilage. Results obtained from micromeritic studies were shown in table 5 and predict the fact that bulk density and tapped density of bhindi mucilage were more than that of potato starch.

Carr's index of the bhindi mucilage was greater than potato starch, and it shows the better compressibility of granules prepared with mucilage. Calculated data of post compression studies of tablets such as thickness, diameter, hardness, friability and drug contents were shown in table 6. It was found that tablets prepared using mucilage has better hardness and lesser friability than tablets prepared with starch. All the post compression parameters were found according to official limit.

From the graph showing percent drug release (Figure) F3 batch showed a sharp increase in drug release, almost 100% at 90 minutes. F8 batch also showed a steep increase in drug release after 30 minutes which approached 100% in 90 minutes.

F1 batch showed a linear drug release whereas F2 and F7 batch showed a slight increase in drug release after 30 minutes 40 minutes respectively. F4 showed similarity in drug releasing properties to F2 batch. F5 and F6 showed little drug release almost identical to 82.1%. It was found that tablets prepared using mucilage as binding agents showed relatively less drug release than the tablets prepared with potato starch as

Table 5. Precompression parameter of granules

Tabela 5. Parametry granulek przed sprasowaniem

Parameters	Formulations							
	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F7	Batch F8
Bulk density (g/cm^3)	0.489 ± 0.005	0.452 ± 0.008	0.477 ± 0.004	0.532 ± 0.012	0.575 ± 0.008	0.612 ± 0.020	0.625 ± 0.010	0.655 ± 0.021
Tapped density (g/cm^3)	0.592 ± 0.021	0.491 ± 0.010	0.544 ± 0.016	0.572 ± 0.011	0.608 ± 0.014	0.673 ± 0.012	0.681 ± 0.008	0.694 ± 0.009
Bulkiness (cm^3/g)	2.04 ± 0.004	2.21 ± 0.005	2.09 ± 0.004	1.87 ± 0.009	1.73 ± 0.012	1.63 ± 0.018	1.60 ± 0.020	1.52 ± 0.008
Carr's index	17.39 ± 0.008	7.90 ± 0.009	12.31 ± 0.003	6.99 ± 0.004	5.40 ± 0.021	9.04 ± 0.030	8.22 ± 0.024	5.60 ± 0.006
Hausner's ratio	1.21 ± 0.004	1.04 ± 0.005	1.14 ± 0.002	1.07 ± 0.002	1.05 ± 0.020	1.09 ± 0.024	1.08 ± 0.020	1.05 ± 0.004
Angle of repose (°)	29.9 ± 0.003	24.5 ± 0.003	27.2 ± 0.001	23.5 ± 0.003	21.2 ± 0.018	25.6 ± 0.020	24.9 ± 0.021	21.8 ± 0.006

Table 6. Postcompression parameters of fabricated tablets

Tabela 6. Parametry wytworzonych tabletek po sprasowaniu

Parameters	Formulations							
	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F7	Batch F8
Thickness (mm)	2.20 ± 0.065	2.18 ± 0.0202	2.13 ± 0.054	2.56 ± 0.055	2.36 ± 0.012	2.30 ± 0.033	2.38 ± 0.034	2.41 ± 0.010
Diameter (mm)	12.05 ± 0.012	12.05 ± 0.032	12.03 ± 0.026	12.05 ± 0.028	12.04 ± 0.021	12.05 ± 0.012	12.06 ± 0.22	12.05 ± 0.015
Hardness (N)	20.16 ± 0.029	20.20 ± 0.017	20.10 ± 0.018	20.13 ± 0.019	20.33 ± 0.014	20.03 ± 0.025	20.10 ± 0.22	20.03 ± 0.012
Friability (%)	0.64 ± 0.020	0.66 ± 0.016	0.64 ± 0.021	0.32 ± 0.019	0.32 ± 0.011	0.32 ± 0.015	0.31 ± 0.014	0.32 ± 0.016
Drug content (mg)	49.38 ± 0.18	49.71 ± 0.029	49.08 ± 0.041	49.63 ± 0.018	49.49 ± 0.073	49.88 ± 0.051	48.97 ± 0.071	49.89 ± 0.038

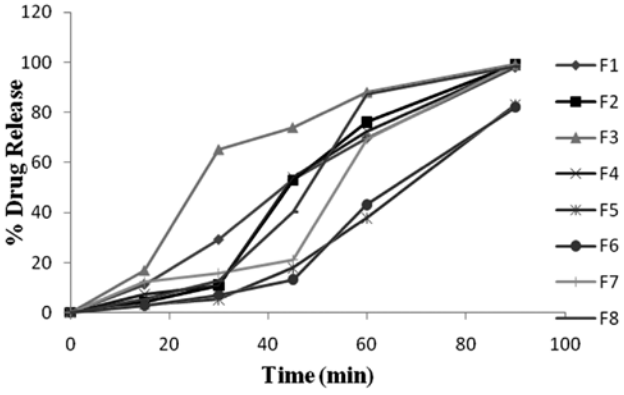

Fig. Graph showing drug release from prepared tablets

Ryc. Wykres pokazujący uwalnianie leku z przygotowanych tabletek

binding agents. It may be due to the gelling properties of mucilage. Mucilage used in the tablets, swells to from a gel layer and further drug release retarded up to certain extent. At higher concentration mucilage used in the tablets, swells and further drug release was increased due to burst effect.

CONCLUSIONS

It was concluded that the mucilage isolated from *Hibiscus esculentus* showed the presence of carbohydrates and was found acceptable for all the tested organoleptic properties. From solubility analysis it was found to be soluble in hot water, swell in cold water and insoluble in most of organic solvents. It shows slightly acidic pH which indicate that this mucilage was less irritating in GIT and suitable for uncoated tablet. Surface tension was found to be good in strength. The bulk density, tapped density and Carr's index of bhindi mucilage were more than that of potato starch showing the better compressibility of granules prepared with mucilage. Post compression parameters suggested that tablets prepared using mucilage has better hardness and lesser friability than tablets prepared with starch. From the graph showing percent drug release F3 and F8 batch showed a sharp increase in drug release whereas F5 and F6 showed less drug release compared to other batches.

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Declaration of interest. Research has no conflict of interest.

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