



Formulation and Evaluation of Moisture Protective Tablet Compression Coat Using Natural Polymers

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Abstract:

This study aims to formulate and evaluate moisture protective coat for tablets using natural polymers of Fenugreek seeds and okra fruits in different concentrations compared with synthetic moisture protective coat. Ethanolic extracts of fenugreek and okra were treated with acetone as solvent for isolation of the mucilage, which is then dried and powders obtained identified and tested for polysaccharides using Molisch's reagent, Barfoead, KOH, Fehling reagent. The physicochemical tests including pH, viscosity, moisture content, percentage yield and swelling index were also carried out. Two formulations of 150 mg Silica gel tablets weighing 300mg and 500mg using PVP, magnesium stearate and Microcrystalline cellulose (MCC) as excipients were prepared and the powder mixture of flow ability was evaluated by measuring Carr's index, Hausener ratio and Angle of repose. The compressed tablets were evaluated according to USP monograph by testing the physical test of both tablets. Two coating materials were prepared and evaluated using natural polymers in different concentration 5%w/w and 10%w/w. The coated tablets with natural and synthetic polymers were compared by observing weight and moisture change of tablets pre and after stability study for 2 weeks in stress conditions at temperature (50^o C) and RH 75 %. All the identification tests were positive indicating the presence of polysaccharides. Also, the physicochemical parameters tested were within the acceptable limits. Both fenugreek and okra mucilage's as polymers in low concentration 5%w/w revealed much better results regardless of weight of tablets. Coat defects were observed in tablets coated with 10%w/w of the polymers. The standard film coating polymer showed better moisture protection as moisture

content about 4%. coating materials were successfully prepared and evaluated as moisture protective coat of silica gel tablets. Optimum coating formulations were found at 5%w/w concentration for mucilage's of both fenugreek and okra.

Keywords: Compression coating, Fenugreek, Okra. Mucilage's

Introduction:

Polymers are the major components of the film coating process; most polymers used in pharmaceutical formulations are aqueous or organic system or hydro alcoholic systems [1]. Natural polymers such as protein, enzyme, muscle fibers, and polysaccharides are effectively used in formulating the variety of pharmaceutical products. Natural gum found into three groups according to nature state and extraction methods of each gum, it divided into: natural gum are produced to wounding "exudates gums" and extracted from seeds of some legumes "extracted gums" such as gum Arabic, and modified gum are chemically modified natural gums or derivatives of naturally occurring materials such as cellulose or starch, and synthetic gum are completely synthesized chemical products such as polyvinyl pyrrolidone and ethylene oxide polymers[2].

Fenugreek is small annual leguminous herb belonging to the family leguminous and genus *Trigonella* with scientific name *Trigonella foneum Graceum* and other names of herbs fenugreek include: Greek-hay and methibrid's [3]. The yield

potential of Fenugreek is realized as the total biomass produced agricultural important part of the crop [3]. The metabolic reaction of the fenugreek plant may governed by internal conditions which involved the major factors known as climate and environment [4] in other instance fenugreek seed extracts are used in pharmaceutical purposes as matrix formulation [5] and also used as binder in tablet formulation, gelling agent, and mucoadhesive agent [6, 7]. Mucilage is hydrocolloid which is a polymer of monosaccharide its common constituent of plants such as Okra and other plants [8] Okra belonging to the Family name *Fabaceae*, genus *Abelmoschus* with scientific name *Abelmoschus Esculantus*. It is used naturally as a vegetable and also as thickening agent for thick soups and stews according to high amount of thick slimy polysaccharides [9,10]. Okra plant extract is also used as anticancer, antimicrobial and hypoglycemic agent [11]. The chemical composition, molecular structure, glycoside linkage configuration and side chain are some of the factors that can affect the functional properties

of natural mucilage and therefore alert the use of specific plant [12]. There are different studies that had been carried out to investigate use of natural polysaccharides in formulation of drug as suspending agent, film former, mucoadhesive, binder of tablet, tablet matrix and sustained release and many other uses.

Effect of moisture in pharmaceutical products:

The active pharmaceutical ingredients in dosage form need to be stable until the end of shelf life, moisture can affect the shelf life and stability of drug by causing hydrolysis. Stability problems can occur by thermal degradation, oxidation, light, microorganism or any other chemical reactions that render the active components ineffective for its specific purpose [13]. Moisture also can influence the glass transition temperature TG and this will affect the stability of such system. Hydrolysis of active pharmaceutical compound is caused by seeping the moisture, or by re-opening of container and this problem is solved by protecting the compound by appropriate packaging or protecting the core with moisture barrier film coat [14]. The degradation arises as a function of free water, due to its ability to change the pH of the surfaces of drug and excipients [15].

Compression coating:

Is a mechanically complex procedure that needs careful formulation and processing of the coating layer [16] the process differs completely from film coat and sugar coat in that: the compression coating involves compaction of granular materials around a pre-formed tablet core. The techniques of compression coating depend firstly on preparation of tablets core then transferring on the same machine to another slightly larger die that had partially filled with coating powder and compressing for final after addition of the remaining part of coating material [16].

Materials

fully ripe fenugreek seeds, fresh green okra fruits. Acetone LR, Propanone Dimethyl ketone, Microcrystalline cellulose (MCC) gift from blue Nile pharmaceutical company, Polyethylene Glycol (PEG6000), Titanium dioxide (TiO₂), magnesium stearate (Worli -Road Mumbai-400-030), Talc powder (Mumbai –India Industrial Estate-248-Worli Road Mumbai-30), citric acid monohydrate (General drug house CP ltd New Delhi), amaranth color (LOBA CHEMIE PVT), poivdone (PK30) (Mumbai–India) silicone dioxide, Colorcon opadary white coating material (COLORCON Dartford, UK Gift from Azal pharma company) and ethanol absolute analytical grade were pharmaceutical grade of different

commercial sources and were generously donated from Azal laboratories LTD (Khartoum Sudan).

Equipment:

Analytical balance (Germany), Digital pH meter (Vernier software & technology, LLC/USA), Oven (GENLAB/UK), Coating pan 5kg lab scale (India), rotary Tablet Compression machine (SHAKIT-Germany), Stability chamber (Azal pharmaceutical company), Moisture analyzer apparatus (Prime for Scientific & Technical Supplies), Hardness tester (GmbH/D-63150), Friability tester (Germany), Homogenizer mixer (Prime for scientific & technical supplies Khartoum Sudan), Viscometer (FUNGILAB s.aVisco Basic plus- Spain), water bath (Germany) and thermometer.

Methods:

Collection and authentication of plant materials:

The seeds of fenugreek "*Trigonella foenum graceum*" plant and okra fruits "*Abelmoschus esculantus*" used for isolation of mucilage were collected from local market of Sudan and authenticated in the National research center of Sudan.

Extraction of mucilage from Fenugreek seeds:

250g of fenugreek "*Trigonella foenum graceum*" was weighed and washed with purified water and

soaked in double distilled water for about 6hrs, then reduced to small particle size using blender, after that allowed to stand for 12hrs in refrigerator then the slurry was heated in water bath at (60°C) for 10 minutes to concentrate the solution, after cooling the solution was squeezed by muslin cloth, this procedure was repeated to complete all the solution obtained. The solution obtained was treated with two volumes of acetone to separate the mucilage's gum, then dried in oven and finally the mucilage sample was powdered using mortar and pestle, sieved in sieve No. 500, weighed and stored in a closed container till used [17].

The yield potential of fenugreek can be defined as the total biomass produced or agricultural important part of the crop. The total biomass is a result of the integration of metabolic reactions in the plants; consequently, any factors influencing the metabolic activity of the plant at any period of its growth can affect the yield.

$$\% \text{ yield} = \frac{\text{practical yield}}{\text{Amount powder mat.used}} * 100$$

Extraction of mucilage from Okra Fruits:

Two kg of fresh okra fruits was accurately weighed then washed and allowed to dry in shade for 10 days for complete drying. After that okra fruits were weighed again (450g) and the upper and lower ends were cut and the size was reduced to small pieces before milling to obtain a powder

which was sieved with sieve No. 500. The final yield was found to be 270g. This powder was heated in mantle set at (60°C) in double distilled water and the temperature was maintained at (60°C). The above set up was kept for 4hrs for complete recovery of mucilage by continuous stirring every 15 mins using glass rod. The filtrate was kept in room temperature in a beaker for 5hrs for sedimentation. The decanted filtrate was taken out and supernatant was poured in to clean beaker (1.5L), after cooling the solution was squeezed by eight-fold muslin cloth to get the pure solution, then the solution was treated with three volumes of acetone to isolate the mucilage's from solution by precipitation method. The mucilage was dried by air and oven at (50°C); the final substance was milled and sieved using sieve No.600 and kept until used [18].

Determination of pH:

One g of fenugreek mucilage powder and okra powder were weighed and dissolved in 9 ml distilled water then completed to 10 ml and filtered by using filter paper. After that introduced in a flask 25ml and pH determined using digital pH meter (Vernier software & technology, LLC/USA)

Determination of swelling Index:

one g of powder was introduced in 25ml ground glass stoppered cylinder graduated to 25ml. 25 ml of distilled water was added to mucilage powder and shaken vigorously every 10 min for 1hr and allowed to stand for 24hrs. Then the volume of mucilage was measured. Another procedure, for swelling index is calculated by measuring the swelling ratio of polysaccharide is equal to weight of dry powder before swollen (w1) and weight after swollen (w2) using equation:

$$SI\% = \frac{w2-w1}{w1} \times 100$$

Determination of viscosity:

One g of mucilage powder was suspended in 75ml of distilled water for 2hrs and completed to 100ml of distilled water and mixed using homogenizer mechanical stirrer (Mixing solution) for 30mins and the viscosity was determined by viscometer (FUNGILABS. a Visco Basic plus- Spain).

Determination of moisture content:

One g of mucilage powder was put it in moisture analyzer apparatus to determine the amount of moisture in each polymer powder before formulation of tablets coat (Prime for Scientific & Technical Supplies).

Phytochemical tests of mucilage powder:

Carbohydrate test:

One g powder sample were weighed and dissolved in 10 ml of water then filtered using filter paper

and divided into three test tubes to determine the presence of carbohydrate by using Molisch's reagent, Fehling's, and Barfoead's reagents.

Preparation and formulation of tablets:

Pre-compression tests were performed to select the method of tablet production by measuring flow ability and compressibility of powder using angle of repose, Carr's index and Hausner ratio. The tablets were directly compressed using rotary Punch tableting machine.

Angle of repose:

This was calculated according to the fixed funnel method which is the maximum angle viable between the surface of a pile of the powder and horizontal air craft

$$\tan \Theta = \frac{H}{R} \quad H = \text{height, } R = \text{radius}$$

Bulk density:

Bulk volume V_b was measured by gently pouring 25g of powder in a measuring cylinder. The bulk density was determined by dividing the weight of powder (25g) by bulk volume, V_b . The bulk density is equal to:

$$\text{Bulk density} = \frac{M}{V_b}$$

Where M = weight of accurately weighed powder
 V_b = the volume of the powder loosely introduced to a graduated measuring cylinder.

Tapped density:

The tapped volume V_t was calculated by pouring the 25g of the powder in a measuring cylinder and tapping by dropping the cylinder from a known height till the volume is constant.

$$\text{Tapped density} = M / V_t$$

The tapped density is equal to the same mass of powder used in the calculation of bulk density divided by the powder volume after dropping the cylinder from a known height (tapping) for many tapping till the volume is constant e.g 100 times. The volume of the powder decreased from the original volume V_b , which gave tapped density higher than bulk density.

$$\text{Carr's Index} = \frac{(\text{Tapped density} - \text{bulk density})}{\text{Tapped density}} \times 100$$

Tablet core formulation:

About 1 Kg of silica powder and dry components of povidone, MCC, and magnesium stearate were used in formulation of two 150 mg silica gel batches of tablets, one weighing 300mg and the other weighing 500mg. The tablets were compressed using rotary punch tablet press equipped with size 8 mm die and punch. Tablets were divided equally and stored into six plastic containers; five containers contain the average tablets weight of 300mg each and last one for 500mg weight.

Evaluation of tablets:

The quality control tests were carried out according to BP 2002 {19}, that include the weight variation of tablets, hardness test, uniformity of diameter, friability test, and moisture content.

Weight variation test:

20 tablets were weighed individually. The average weight was calculated and compared with individual tablets weight to the average, the standard deviation (SD) and (RSD) were calculated using equation:

$$\text{Standard deviation (SD)} = \sqrt{\frac{\sum (x-x^2)}{n-1}}$$

Where x is the individual weight of tablets

x^2 is mean weight of the tablets

N is the number of tablets in the test

The RSD "Relative standard deviation" was calculated from equation:

$$\text{RSD} = \frac{\text{SD}}{\text{mean wt of tablets}} * 100$$

Hardness test:

10 tablets of each batch were tested individually by using hardness tester and the force required to crush the tablet were measured.

Uniformity of Diameter:

10 tablets of each batch were measured with Vernier caliper and mean value was recorded as the diameter value

Friability test:

20 tablets of each batch were weighed together after removing loose dust with aid of air, tablets were placed in the friability tester drum, and the drum was adjusted at 25 RPM for 4 min. then removed and cleaned from the loose dust by the same methods. The tablets were weighed again and the percentage loss was calculated by equation
 $\text{Friability (\%)} = \frac{W1 - W2}{W1} * 100$

Where, w1= weight of tablets initial before tumbling & w2= weight of tablets after tumbling

Moisture Content:

10 tablets of each batch were weighed initially and introduced in to stability chamber for 2 weeks and calculated the amount of moisture step inside using silica tablets as absorbing agent and determine the amount of moisture seeping to core by comparing the different weight before and after coat and after stress condition using Excel program.

Preparation and Formulations of compression coating materials:

After obtaining the mucilage extracted from fenugreek seeds or Okra fruits, the amount of mucilage in the coating formulations were 5%w/w and 10%w/w. Other additives in formulation of natural tablets coating materials were: Poly ethylene glycol (PEG 6000), Titanium dioxide, Citric acid monohydrate, Talc, Amaranth red as

coloring agent, Poly vinyl pyrrolidone (PVP) and ethanol used for dissolving color in wet granulation. The moist mass was granulated and dried in oven at (50° C) for 15 mins, after drying the mass was passed through sieve No. 710, and the powder was stored in a well closed container till used. The 300mg weight silica gel tablets were divided into six groups; two groups were coated with 5%w/w of Okra and Fenugreek mucilage and the second two group's with 10%w/w of both mucilage to select the best coat for deterring the moisture reach the core. The rest two groups were uncoated for comparison between coated and uncoated tablets. The method of compression was carried out by weighing 200 mg of coating powder divided in to 2 parts. 100 mg was introduced inside the 10mm die, then the tablet core was introduced, the rest coating powder (100 mg) was poured on the tablet and compressed to a final weight of 500 mg each. The final coated tablets were evaluated by stress tested at relative humidity RH75% and temperature (50°C), for all coated tablets. Finally, coated tablets in weight 500mg compared with the standard moisture protective non aqueous coat and the tablet coat were observed [16].

Preparation of synthetic coat:

The coat material used for this process was OPADRY^(R) complete film coating system OY-S-7191 white powder. The ingredients of coat are; Hypromellose, Titanium dioxide, Propylene glycol and Ethyl cellulose. 10% w/v of OPADRY[®] was used as concentration of coat material in 90% ethanol (96%) to prepare the coating solution (white film coat solution) by mixing for 45mins using homogenizer mixer. The mechanism of coating by using coating pan machine: Rotating at Pan speed 2-4 rpm and temperature (30-32°C), this process continued till all the tablets in the pan were coated with solution using spray gun for spreading the coat solution. The final coated tablets were dried and weighed, then introduced in the stability chamber using the same parameters.



Figure 1: Sample coated with 5% w/w Okra mucilage



Figure 2: Sample coated with 10% w/w Okra mucilage



Figure 3: Sample coated with 5% w/w Fenugreek mucilage



Figure 4: Sample coated with standard coat (synthetic)



Figure 5: Uncoated 300mg tablets Sample

Evaluation of the coated tablets:

Randomly selected samples of compression coated tablets were subjected to evaluation with regard to their pharmaceutical properties. Coated tablets were weighed to compare between initial weight and weight after coat.

Stability study of coated tablets with Okra and Fenugreek polymers in different concentrations:

Based on the visual evaluation results, compression coated tablets of different concentrations of okra and fenugreek polymers and tablets coated with standard polymer (OPADRAY®) were subjected to the stability testing using stability chamber set at temperature (50°C) and relative humidity RH75% as stress conditions for two weeks. At the end of testing duration, coated tablets were investigated for changes in their appearance, weight variation, moisture content and coat properties.

Results and discussion:**Final powder mixture:****Table 1.** Precompression study of powder

flowability:

Test	Silica powder	Silica powder mixture
Angle of repose	23.19°	30.96°
Carr's index	20%	14.28%
Hausner ratio	1.25	1.16

Carr's index is a parameter for measurement of powder flow. Smaller values of Carr's index indicate enhanced flowability. The results obtained in the final mixture shows its suitability for the direct compression.

Table 2. Physicochemical properties of the two uncoated silica tablets:

Weight of tablets	Weight variation (RSD)	Hardness	Friability	Moisture content	Thickness
300mg	±2.8%	5.8±0kg	0.088%	1.63%	0.6±0cm
500mg	±4.7%	6.2±0kg	0.025%	0.75%	0.8±0cm

The results obtained in table 2 shows that the hardness, friability, thickness and moisture content were within acceptable limits of the BP. The tablets are suitable for coating. Increase of

moisture content in tablets weighing 300mg was attributed to the presence of higher ratio of the silica gel (absorbing agent) in the tablets.

Table 3. Phytochemical properties of the natural polymers:

Type of mucilage	Presence of polysaccharides	Reducing sugar	Presence of monosaccharide's	presence of starch	presence of mucilage
Okra mucilage	+	+	+	-	+
Fenugreek mucilage	+	+	+	-	+

Table 4. Physicochemical characteristics of natural polymers:

Natural polymer	Viscosity	pH	Swelling index (SI)		Moisture content	Yield %
			method 1	method 2		
Fenugreek	110cp	8.13± 0.2	20	160	5.71%	12.8%
Okra	84cp	8.52± 0.2	10	120	2.45%	14%

Key; in Method 1 the swelling index was obtained according to volume concentration

In Method 2 swelling index was obtained according to weight of powder (swelling ratio)

All the identification tests of the mucilage's were positive indicating the presence of polysaccharides and absence of starch.

pH of 1% solution of both fenugreek and Okra mucilage's were found 8.13± 0.2 and 8.52± 0.2 respectively. This result is in agreement with recent studies which used both Fenugreek and Okra at pH range (7.0-9.2) as flocculating agent [20]. In addition, recent study using Fenugreek (TFG) in compression coated tablets as water extracted natural polysaccharide and evaluated carried by dissolution study was performed at pH ranging from 1.2-7.4 with rat cecal material [21] Further study using film coating potential of Okra using paracetamol tablets as model drug [22] Difference in swelling index may be attributed to

the difference in the viscosity of the two polymers. The difference in viscosity may be due to variation of two mucilage and techniques or apparatus that was used, also viscosity decrease during the storage period of time. Also, weight gain by mucilage was proportional to rate of hydration. The direct relationship was observed between swelling index and mucilage concentration. Recent studies concerned the development of high viscosity of fenugreek mucilage as mucoadhesive agent for nasal gel drug delivery [23]. Variation in percentage yield between two natural polymers may affected by metabolic reaction and any factors affect the internal activity may affect the yield.

Table 5. Organoleptic Properties of coated and uncoated tablets after stability study:

Observed characteristics	300mg tablets			500mg Tablets	
	Uncoated	Coated		Uncoated	Opadry® coated
		F1 (5% w/w)	F2 (10% w/w)		
Surface	Smooth	Smooth	Rough	Smooth	Smooth
Shape	Convex	Convex	Convex	Convex	Convex
Color	Uniform	Uniform	Pale	Uniform	Uniform
Defects	None	None	Cracked	None	None

Uncoated tablets displayed convex shape and smooth surface which appears in uniform white color and free of defects. These characters render the tablets suitable for the coating process without need for further intervention. Similarly, coated tablets of formula F1 with concentration 5% w/w of the two polymers revealed uniform colored with no change in the appearance, while F2 with the two polymers concentration of 10 % w/w showed surface defect, pale color and cracked rough tablets surface as in figure (2). Whereas in standard tablets coat in 500 mg weight coated with Opadry® moisture barrier white film, the coat appear in a uniform color and smooth surface, free

from defect as in figure (4) Cracked film and pale color might be attributed to high concentration of polymer from fenugreek and okra, which was in agreement with recent studies as binder in concentration 2.5% that sustain the dissolution rate of water-soluble drugs [24]. As the result implies, tablets coated with coat containing 5% w/w of polymer and PEG6000 and TiO₂ have established more satisfactory properties. PEG act as plasticizer and decreasing hygroscopicity in high amount whereas titanium dioxide act as coating agent owing to its high refractive index as coat modification [25].

Table 6: Effect of storage condition on tablets coated with natural polymer and synthetic polymer:

Type of polymer	tablets Initial weight (g)	Tablets Weight after coating (g)	weight change after 2 weeks in stability chamber	Variation of weight between coated tablets and tablets after stability testing (g)	Percent increase

Okra 10% w/w	0.3139 g	0.5059 g	5.8254 g	0.07664 g	23%
Okra 5 %w/w	0.2981 g	0.5043 g	0.61721 g	0.11291 g	18%
Fenugreek 10 %w/w	0.3009 g	0.501g	0.54025 g	0.03925 g	26%
Fenugreek 5 %w/w	0.3042 g	0.5042 g	0.63303 g	0.12883 g	17%
Opadry®(synthetic coat)	0.5001 g	0.51184 g	0.52421 g	0.01237g	4%

Key: percent increase is a result of variation of weight between 10 tablets coated and 10 tablets after stress resting

all weight of tablets is equal to average of 10 tablets each. Variation of weight between coated tablets and weight of tablets after stress testing in concentration 5%w/w of okra and fenugreek which were calculated via Excel program, showed explain the amount of moisture entering the core as 18% and 17% of both polymers respectively. Whereas in high concentration of polymer 10%w/w appear coat defects and higher moisture content.

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Conclusion:

Natural coating materials were successfully prepared and evaluated as moisture protective compression coating materials of silica gel tablets. Optimum coating formulations were found at 5% w/w concentration for mucilage's of both Fenugreek and okra.

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