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The permutation role of fenugreek seeds starch and Gunda glue as a binder in Paracetamol tablets

Vinod Doharey* and Nisha Sharma
University Institute of Pharmacy, C.S.J.M.University, Kanpur-208024, U.P., (India)

Abstract:
Trigonella-foenum graecum (fenugreek) has been reported to contain upto 56.0% starch. The starch was extracted from the seeds of *Trigonella-foenum graecum* (fenugreek). The entire seeds were subjected to size reduction, followed by successive extractions with chlorinated hydrocarbons to separate the husk from the 'core and oily portion' to yield about 40%w/w of the husk. The dried husk was further powdered to 180 - 250 µ. The tablets prepared by using powdered husk were evaluated for hardness, friability, weight uniformity, disintegration and dissolution profiles. *Cordia gharaf*, the fruit is a green berry or ovoid drupe 1 cm in diameter, seated in a saucer-like enlarged calyx. It turns black on ripening and the pulp gets viscid. The sticky pulp is used to make glue. Acetaminophen tablets containing gelatin as a standard binder were formulated and assessed comparatively. Result obtained indicate that fenugreek starch performed as good as gelatin as binder to acetaminophen tablets.
Key words: Fenugreek, Binding agent, Permutation

INTRODUCTION

Binders are agents used to impart cohesive qualities to the powdered material during the production of tablets. They impart cohesiveness to the tablet formulation, which ensures that the tablet remains intact after compression as well as improving the free flowing quality (King 1975). Binders have been used as solutions and in dry form depending on the other ingredients in the formulations and the method of preparation.

Common Name: Gunda

Botanical Name: Cordia gheraf, Cordia myxa, Cordia dichotoma

Other Names: Gumberry, Labeda, Lasora. Gunda is a small to moderate-sized (to 5m) deciduous tree with a short trunk and spreading crown. The stem bark is greyish brown with longitudinal fissures. The leaves are broad, ovate, alternate and stalked with the spread being 7 to 15 cm x 5 to 10 cm. Flowers are short-stalked, bisexual and white in colour. The fruit is a green berry or ovoid drupe 1 cm diameter seated in a saucer-like enlarged calyx. It turns black on ripening and the pulp gets viscid.

The choice of a particular binding agent depends on the binding force required to form granules and its compatibility with the other ingredients particularly the active drug. Starches from different sources have been evaluated and used as excellent binders in either mucilage or the dry powdered form. Maize and potato starches have been in common use and recently cassava starch appeared in the British Pharmacopoeia as an official starch for use as binder (British Pharmacopoeia, 2001). Their use has increased in the tropics where previously recognized starches are unavailable apart from starches other natural gums, gelatin, basic tableting excipients despite the avalanche of unprocessed raw materials. There is the need to bridge this gap. With increasing demand and search for natural starches with desirable properties for use in the pharmaceutical industries, the present work evaluates the possible use of fenugreek starch and gunda glue as binder to paracetamol tablet.

EXPERIMENTAL

Materials: Fenugreek seeds starch (prepared in our laboratory), Paracetamol, Lactose, Maize starch, Gelatin (S.D.Fine), Magnesium stearate (Merck), Hydrochloric acid 37% (Merck).

Extraction of fenug reek sta rch and Gunda glue:

For isolation of husk, seeds of *Trigonella-foenum graecum* (fenugreek) were initially size reduced to 1000-1500 µ using a Hammer mill. These were then treated with various chlorinated hydrocarbons like chloroform, carbon tetrachloride, methylene chloride and other organic solvents. It was observed that chloroform and methylene

chloride are better solvents and were used for experimental work. These crushed seeds were soaked in chloroform for 15 min. By decantation the crushed seeds were separated into husk and core that contains oily portion. Successive extractions with chloroform removed the traces of oily portion and core. The separated husk was air dried and subjected to size reduction by using Hammer mill to 180-250 µ. The milled material was passed through 60 # sieve to get the husk of particle size less than 250 µ. Size reduction was done to increase the surface area and swelling capacity. The husk powder was evaluated for Swelling index, flow properties and particle size distribution. The swelling index is the volume in milliliter occupied by 1 g of a material, including any adhering mucilage, after it has swollen in aqueous liquid for 4 h. Gunda **(***Cordia gheraf) o*ther names; Gumberry, Labeda, Lasora. The fruit is a green berry or ovoid drupe 1 cm diameter seated in a saucer-like enlarged calyx. It turns black on ripening and the pulp gets viscid. Immature gunda berries are used as a vegetable and to make pickles after removing the stone and sticky white pulp. The sticky pulp is used to make glue.

Solubility determination:

A 2% w/w dispersion of starch was prepared in a 50 ml volumetric flask. The dispersion was shaken frequently for some time and allowed to stand for about 8 h. It was then filtered with a filter paper and 30 ml of the clear filtrate evaporated to dryness in a pre-weighed dry crucible. The weight of starch residue obtained was determined by difference. Solubility was calculated in g/dm^3 and mg %. The same procedure was repeated for gelatin powder.

Bulk and tapped densities:

Exactly 50 g of starch was weighed on chemical balance and transferred into a 100 ml measuring cylinder. The cylinder was dropped on a wooden platform from a height of 2.5 cm, three times at 2 seconds intervals. The volume occupied by the starch recorded as the bulk volume. The cylinder was then tapped on the wooden platform until the volume occupied by the starch remained constant. This was repeated three times for the gelatin powder and average bulk and tapped volumes recorded. The data generated were used in computing the compressibility index.

Formulation of Paracetamol tablets:

Two batches of the tablet containing 400 mg paracetamol were prepared. The batches contained fenugreek starch and gelatin as binder respectively in concentrations of 2, 4, 6, and 8% w/w. Maize starch at 5% w/w acted as the disintegrant with 1% magnesium stearate as lubricant. Wet granulation method was employed in the formulation of the tablet batches.

Granulation and compression:

Wet granulation method was used for all tablet production. Calculation was made for 50 tablets in each batch. In each case, accurately weighed quantities of paracetamol, lactose and disintegrant were mixed in a mortar and the binder solution (gelatin) or mucilage (fenugreek seeds starch) added to obtain a damp coherent mass. The damp mass was sieved with 1.7 mm sieve and dried at 50ºC in oven for 1 h. The dried granular mass was passed through a 1.0 mm sieve to obtain uniform sized granules. The different batches of the granules were then mixed with calculated equal quantities of magnesium stearate using mixing bottle, and then compressed into tablets under constant pressure with a Cadmach multi stationed tablet punching machine. The punch size and volume of fill were carefully adjusted to give the required tablet size and weight.

Evaluation of compressed tablets

Hardness test:

Five tablets were selected at random from each batch to perform this test. Monsanto

harness tester was used to measure the hardness. Tablet was placed between spindle and anvil of the tester and the calibrated length adjusted to zero. The knob was then screwed to apply a diametric compression force on the tablet and the position on the calibrated length at which the tablet broke was recorded in kgf units. A mean hardness was calculated for each batch and thus their standard deviations and coefficient of variations were calculated.

Weight uniformity test:

Twenty tablets from each batch were selected randomly and weighed individually using a highly sensitive electronic balance (Denver, Germany). Their mean weights, deviations and coefficients of variation for each batch were calculated.

Friability test:

Ten tablets were selected at random, dusted and weighed together using the electronic balance (Denver, Germany) and then placed in the friabiltor. The machine was operated for 4 min, at 120 rev/min and then stopped. The tablets were dusted and reweighed. The percentage losses were calculated for each batch of the tablets.

Disintegration time:

The method specified in the USP/NF (1980) was used. Disintegration medium used was 100 ml of 0.1 N HCl maintained at temperature between 35^{o}C and 39ºC throughout the experiment. Five tablets selected at random from each batch were placed one in each of the cylindrical tubes of the basket but no disc was used. The time taken for each tablet to break up into small particles and pass out through the mesh was recorded. Mean disintegration time was calculated for each batch.

Calibration curve for paracetamol

A stock solution of 100 mg% of paracetamol was prepared by dissolving 100 mg of the rug in 100 ml of 0.1 N HCL. Various dilutions of the stock were made so as to obtain 0.01, 0.02, 0.04, 0.06, 0.08, 0.10 and 0.12 mg% with 0.1 N HCl. The absorbance of the various dilutions was then taken at 245 nm using a UV-VIS spectrophotometer (Schimadzu Pharmaspec-1700). A plot of absorbance 'A' against concentration (mg %) of the drug was made from which the calibration curve K was determined from the slope of the graph.

RESULT AND DISCUSSION

Table 1 shows the various properties of the fenugreek starch powder and gunda glue in comparison to the official gelatin powder. The gunda glue exhibited a comparatively higher solubility than fenugreek starch powder and gelatin in cold water with values of 18.0, 16.0 and 13.67 g/dm^3 respectively. The cold water solubility of starches is related to their amylose/amylopectin constituents. The higher the water soluble amylopectin constituent, the higher the cold water solubility of the candidate starch while the higher the cold water insoluble amylase, the reverse becomes the case. The solubility result shows that both excipients are comparable. Interestingly there is positive correlation between starch solubility and their binding/disintegrating efficiency in tablets. The low bulk and tapped densities of both gelatin and fenugreek starch and gunda glue indicate that both materials are not highly porous and are poor flowing powders. The low bulk density results when the void spaces created by larger powder particles are not filled by smaller particles in distribution leading to consolidation of powder particles. However, fenugreek starch and gunda glue possessed better flow properties than gelatin with Carr's compressibility index of 33.88 and 41.33% respectively.

This index as a one-point measurement does not always show the ease of consolidation of powder granules. The in-vitro tablet properties are shown in Table 2. The hardness of the tablet batches was within acceptable range of 4 - 7 kgf. It is observed

Table 1: Properties of Fenugreek starch, Gunda glue and gelatin powders

S.N.	Properties	Fenugreek starch	Gunda glue	Gelatin powder
1	Cold Water Solubility (g/dm^3)	16.00	18.00	13.67
2	Bulk Density (g/ml)	0.5560	0.5962	0.5102
3	Tapped Density (g/ml)	0.8403	0.9101	0.8696
4	Carr's Compressibility index	33.88 %	36.45%	41.33 %

Table 2: In-Vitro tablet properties with fenugreek starch and gelatin powder as binder

S.N.	Properties	Fenugreek starch with Gunda glue				Gelatin powder			
1	Binder Concentration (%)	2.0	4.0	6.0	8.0	2.0	4.0	6.0	8.0
2	Mean Table Hardness (kgf)	4.4	6.0	6.5	6.5	4.3	4.5	5.6	5.7
3	Friability (%)	1.59	1.56	1.43	0.46	1.33	3.90	0.43	0.22
4	Weight uniformity* (mg)	531.5 (13.39)	541.19 (13.01)	522.07 (14.16)	569.09 (12.70)	501.52 (10.97)	471.43 (12.00)	496.49 (15.69)	534.16 (13.71)
5	Mean Disintegration Time (min)	28.5	35.36	46.30	59.20	26.50	32.50	40.20	52.50
6	t_{50} (%)	39.50	41.90	44.40	47.00	30.00	34.60	44.90	46.30

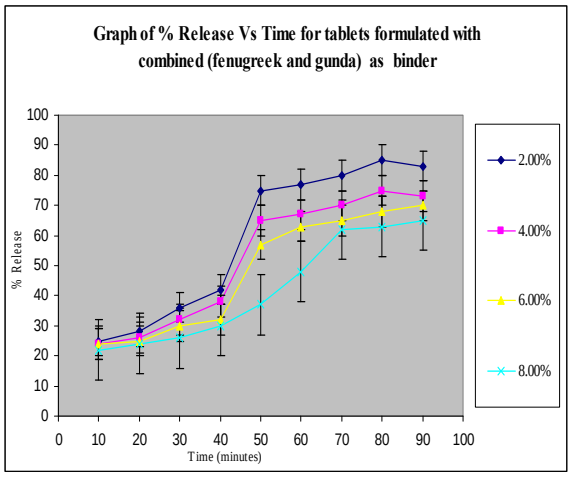

Fig.1: *Invitro* percentage release *Vs* time

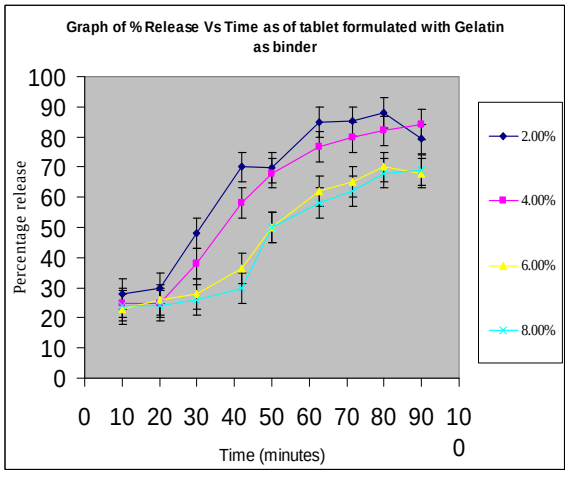

Fig.2: *Invitro* percentage release *Vs* time

that the hardness increased with increasing binder concentration. This is in agreement with previous studies on starches used as binders in comparison to other binders. The tablet hardness were generally higher with the fenugreek starch and gunda glue than gelatin at all concentrations of application, an indication that lower concentration of fenugreek starch and Gunda glue than gelatin could be used to achieve the same level of binding. The same trend was observed with the friability recorded for the two binders. Gelatin and fenugreek starch with gunda glues recorded below 1.0% friability at concentration levels of 6.0 and 8.0% in the formulation. It should be noted that Paracetamol tablets are generally prone to capping when starch binder concentration is less than 7.0%. As expected, variations in weight uniformity were less with tablets prepared using fenugreek starch and gunda glue as binder. Thus, fenugreek starch and gunda glue produced better flowing granules. The uniformity of weight also indicates probable uniformity of content & die filling of the powder will be uniform. Similarly, the disintegration time increases with increasing concentration of binder. It has been reported that starch mucilage used as binder forms a thin film around the granules with thickness increasing as the quantity of mucilage increases and this retards disintegration. The higher disintegration time for tablets prepared with fenugreek starch with gunda glue is therefore understandable. The comparative dissolution profiles of the paracetamol tablets prepared with fenugreek starch with gunda glue and gelatin as binder is shown in Figures 1 and 2 respectively. In general, the amount of drug released, decreased as the binder concentration increased. In all binder concentrations, gelatin showed a faster release, which progressed more slowly than the fenugreek starch and Gunda glue of equal concentration. The t_{50} and t_{70} of all the batches are similar, an indication that the starches are comparable. It could be said that the gelatin and fenugreek starch with gunda glue showed comparative effectiveness as binders to Paracetamol tablets. In conclusion, fenugreek starch and gunda glue could compete favourably with gelatin powder as binders in tablet formulations.

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