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NOVEL BULK FORMING LAXATIVE FROM WATERMELON RIND

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ABSTRACT: A laxative formulations are widely used for treatment of constipation. They are classified based on their mechanism of action such as bulk forming, stool softener, osmotic, stimulant and mechanical. Bulk forming laxative is most commonly used laxative which works by absorbing water and swelling in small and large intestine to form soft and bulky stool. Presently available bulk forming laxative gives adverse effects such as stomach pain, discomfort and vomiting due to sudden swelling in stomach. Therefore present work was conducted for study of novel bulk forming laxative and minimization of associated adverse effects. Bulk laxative formulation was prepared from watermelon rind, isabgol husk and pectin. Watermelon rind powder (WRP) was prepared and analyzed for proximate composition, carbohydrate content, functional properties and performed for topography by scanning electron microscope. Further, effect of *p*H on swelling index of WRP was studied at *p*H 1.3, *p*H 4.5, *p*H 6 and *p*H 7.4. Bulk laxative formulations were developed by varying the concentration of WRP, isabgol and pectin. Developed formulations were evaluated for bulk density, tapped density, compressibility index, flowability and swelling index. High swelling index formulations were compared with market sample for *p*H dependant swelling at *p*H 1.3, *p*H 4.5, *p*H 6 and *p*H 7.4. From this study WRP was found as novel potential bulk forming laxative in combination with isabgol and pectin. Developed formulation has site specific action due to *p*H dependant swelling which might decrease the intensity of adverse effects.

INTRODUCTION: Watermelon (*Citrullus lanatus*) is one of the bulker, most abundant and cheap fruit available in India with an average production of 3 million tons per year. According to the reports from FAOSTAT (2009), India ranks second in watermelon production amongst the Asian countries. Watermelon constitutes 6-7% of overall fruit production and is high during summer [1]. In watermelon red flesh present inside is sweet, edible and used for juices and salads but the outer rind is considered as waste which has no commercial value [2]**.** Watermelon rind consists of pectin, citrulline, cellulose, proteins and carotenoids. These polymers are rich in functional groups such as hydroxyl (cellulose) and carboxyl (pectin) and can easily hold large amount of water [3].

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In our earlier report we have investigated utility of watermelon rind in hypoglycemic thepla [4]. Recently many reports have been published on utilization of watermelon rind, such as bio-sorbent for removal of trivalent chromium and copper from aqueous solution [1, 5]; as corrosion inhibitor [6]; as natural source of antioxidant and dietary fiber in cakes [7].

In addition to this microwave assisted extraction of pectin from watermelon rinds was done by Maran et al. [8]; and immobilization of yeast on watermelon rind was done for production of wine [2]. However, water melon rind has not been explored for application in bulk laxative formulation.

Constipation is condition where passage of small amount of hard, dry stool fewer than 3 times per week or significant change in one's usual routine, accompanied by straining and feeling of being bloated, or having abdominal fullness. Constipation is reported to be one the routine health problem and has been increased recently, due to increased consumption of junk food or food which lacks in natural dietary fibres [9]. Laxatives are classified on the basis of mechanism of action such as bulk forming, stool softener, osmotic and stimulant agents.

Bulk forming (fiber) laxatives pass through the body undigested. The fibers attract water to the intestine, absorb the water and swell to form a soft, bulky stool [10]. The bulky mass stimulates the intestinal muscles and speeds the stool transit time through the colon. Bulk forming laxatives will not work without increased fluid intake. Both soluble and insoluble fibers are important in the formation of stools. Fiber laxatives that contain only one type of fiber can produce stools of poor quality [11]. Insoluble fibres do not dissolve in water; they pass into the colon where they help to form stools. Soluble fibers are easily dissolved by water.

They are also passed to the colon where bacteria ferment soluble fiber into a lubricating gel that helps to make stools soft and helps to moisturize the colon lining. Bulk forming agents include psyllium hydrophilic mucilloid (Metamucil®, Karacil®), cellulose (Fibyrax®), calcium polycarbophil (Mitrolan®) and plantago (Siblin®). Bulk forming laxatives must be taken with sufficient fluid (250 ml) to prevent blockage of the gastrointestinal tract (GIT) [12]. Bloating is the most common short-term treatment side effect of bulk-forming drugs [13]. While many fear intestinal obstruction from bulk forming drugs and emphasize the importance of adequate hydration to minimize the risk, it has not been documented that this has occurred [14].

Stool softener which includes emollients and lubricants such as docusate sodium (DSS) and docusate calcium are typically taken orally, although docusate potassium can be administered rectally [15]. Osmotic laxative agents increase intraluminal pressure and stimulate peristalsis. This class of drugs have many side effects like common side effects include abdominal cramping, water stools and the potential for dehydration. Examples of this class of drugs are lactulose, magnesium salts, hydroxide sodium salts, phosphate sodium potassium tartrate etc. Stimulant agents are anthraquinone derivatives (cascara sagrada, sennosides, danthron, and casanthrol) and the diphenylmethane derivatives (bisacodyl and phenolphthalein).

These agents stimulate intestinal motor function by affecting fluid and electrolyte transport [15]. In 1999 the FDA ruled that danthron and phenolphthalein are unsafe and prohibited their use in the United States. The FDA also recommended that all anthraquinone laxatives (aloe, cascara sagrada, and senna) and bisacoyl be tested for carcinogenicity because of their similarity to phenolphthalein [16].

TABLE 1: DRUGS COMMONLY USED IN THE TREATMENT OF CONSTIPATION (Modified from Tack et al., [17, 18])

Laxative type	Examples	Proposed mode of action	Side effects
Bulking forming laxatives	Psyllium seed husk, Methylcellulose	Luminal water binding increases stool bulk and reduces consistency	Flatulence and abdominal distension Stool impaction (rarely)
Softeners and lubricants	Sodium docusate; mineral oil	Lubricates (oil) and softens (detergent) stool (facilitates water absorption and prevents its loss)	Body develops a tolerance after long use, lipid pneumonia, malabsorption of fat-soluble vitamins,
Osmotic laxatives	Lactulose, Sorbitol, PEG, Polycarbophil, Magnesium hydroxide	Luminal water binding by creating an osmotic gradient	Bloating, flatulence and Electrolyte imbalance
Stimulant laxatives	Bisacodyl, sodium picosulfate, Senna, aloe, cascara	Act locally to stimulate colonic motility, decrease water absorption from large intestine	Abdominal discomfort, cramps, Offensive taste; prompt action;

From available literature it was found that all class of laxative agents comes with some side effects as mention in **Table. 1**. Hence there is urgent need to develop laxative formulation with minimum adverse side effect from natural sources. Hence present study was carried out to develop bulk-forming laxative formulation using watermelon rind powder in combination with other polysaccharides isabgol and pectin.

MATERIALS AND METHODS: Watermelon rind powder (WRP), pectin extra pure from S. D. Fine Ltd., Mumbai, India, isabgol husk (Sat-isabgol®) procured from local market, Mumbai, India., a market sample sold under the category of bulk forming laxative viz., FIBRIL® manufactured by Lupin, Mumbai, India was procured from local market, Mumbai. All other chemicals used for the analysis were of analytical grade from S. D. Fine Ltd., Mumbai, India.

Preparation of WRP:
Watermelon rind were separated from watermelon and finely chopped. Dried overnight in hot air oven at 70˚C, cooled in desiccators and further milled and passed through standard mesh of 0.3-0.5 mm mesh size, This powder was packed in air tight low density polyethylene (LDPE) self sealable pouches and kept under cool and dry condition until their further applications.

Carbohydrate profiling of WRP:
WRP analyzed for water-soluble reduced sugar using DNS method [19]. Percentage of starch was estimated using anthrone reagent method [20, 21]. Pectin content was determined using carbazole sulphuric acid method [21]. Cellulose content was determined using anthrone [21]. Hemicellulose and lignin were done by gravimetric method [22, 23].

Scanning Electron Microscopy analysis (SEM):
The topography of WRP was examined by Scanning Electron Microscopy (SEM, Model JSM-6380 LA from JEOL, Japan) with 20 kV acceleration voltage. Images are taken at 100X and 200X at 30 µm spot size [24].

Effect of pH on swelling index of WRP
Effect of pH on swelling was studied by adding 1gm of sample in different buffer system as pH = 1.2 (0.1 N HCl and 0.1 N NaOH), pH = 4.5 (0.1 M citrate buffer), pH = 5.8 (0.1 M phosphate buffer) and pH = 6.8 (0.1 M phosphate buffer).

Formulation of bulk forming laxative: Granules were prepared by wet granulation method using water as humectant and pectin as binder. Ten formulations were prepared by combining various concentrations of WRP, pectin and isabgol which is given in **Table 2**. Water was added in given formulation to form dough. This dough was sieved through 16 mesh by hand pressing. Further these granules were dried at 60˚C for 12 hr. The dried mass was again passed through 16 mesh sieve to get uniform granules and stored in self sealable pouches in desiccators till its further used [25].

TABLE 2: FORMULATIONS OF BULK FORMING LAXATIVE

Sr. No.	Formulation Code	WRP (% W/W)	Pectin (% W/W)	Isabgol husk (% W/W)
1	WP1	30	70	-
2	WP2	40	60	-
3	WP3	50	50	-
4	WP4	60	40	-
5	WP5	70	30	-
6	WPI1	60	10	30
7	WPI2	50	10	40
8	WPI3	40	10	50
9	WPI4	30	10	60
10	WPI5	20	10	70

Note: W=WRP; P= Pectin; I=Isabgol husk

Evaluation of bulk forming laxative formulation:
Evaluations of developed formulations were done on the basis of following parameters:

Bulk Density and tapped density:
For determination of bulk density, a 10 gm of the sample was filled in 100 mL measuring cylinder and the volume occupied by granules was noted.

$$\text{Bulk density in gm/mL (X)} = \frac{\text{Weight in gm}}{\text{Untapped bulk volume in mL}}$$

For determination of the tapped density, 10 gm of sample was taken in 100 mL graduated cylinder. The cylinder was tapped till no further reduction in powder bed volume noted [26].

The tapped bulk density Y was calculated as

$$\text{Tap density in gm/mL (Y)} = \frac{\text{Weight in gm}}{\text{Tapped volume in mL}}$$

Compressibility index:
Compressibility index was determined according to Carr's index [27],

$$\text{Carr's index} = \frac{\text{Tapped density (Y) - Bulk density (X)}}{\text{Tapped density (Y)}} \times 100$$

Flowability:

Flowability of granules was determined according to Hausner ratio [28].

It was computed from the tapped and bulk densities as,

$$\text{Hausner's ratio} = \frac{\text{Tapped density (Y)}}{\text{Bulk density (X)}}$$

Swelling Index:

Swelling index was determined according to British Pharmacopoeia; 1 gm of sample was taken in a glass measuring cylinder of 0.5 ml divisions. Different *p*H buffer was added as required and shaken vigorously after every 10 minutes for 1hr and then allowed to stand for 3 hr. The swelling index was calculated from the mean of three determinations [29].

Comparative study of selected formulation with Fibril® for swelling index at different *p*H:

Combinations of WRP and isabgol husk formulations were compared with Fibril® for *p*H dependant swelling index at *p*H 1.2, *p*H 4.5, *p*H 6 and *p*H 7.4. Swelling index was determined as described above in respective *p*H using specific buffer system.

RESULTS AND DISCUSSION:

Carbohydrate profiling of WRP:

In our previous publication, we reported the proximate composition of WRP [4]. From that study we observed that WRP has very high percentage of carbohydrate 79.4 % w/w. Hence in the present paper WRP carbohydrate profiling was done. From **Table 3** it can be seen that WRP contains 29.1 % w/w cellulose, 15.9 % w/w pectin and 10.9 % w/w hemicelluloses. WRP have been reported for their good water holding capacity (WHC) 14.1 g/g [4]. WHC is the abilities of a material to retain water after centrifugation. Various parameters affect the water holding capacity such as surface properties, microstructure, structural property of substances and chemical composition. WHC is important property for bulk forming formulations [30].

TABLE 3: CARBOHYDRATE PROFILING OF WRP

Parameters	Water rind powder (WRP)*
Free Reducing Sugar in water (% w/w)	7.1 ± 0.17
Starch (% w/w)	5.3 ± 0.15
Pectin (% w/w)	15.9 ± 0.83
Cellulose (% w/w)	29.1 ± 0.36
Hemicellulose (% w/w)	10.9 ± 0.42
Lignin (% w/w)	7.3 ± 0.54
Others (% w/w)	3.76

*Values are mean ± standard deviations (*n* = 3) and all parameters are expressed on dry weight basis

Scanning Electron Microscopy analysis (SEM):

Scanning electron microscopy revealed presence of porous structure in WRP (**Fig. 1**). It has been studied that porous structure helps water molecules to diffuse into the amorphous regions of the WRP matrix and break inter-molecular hydrogen bonds.

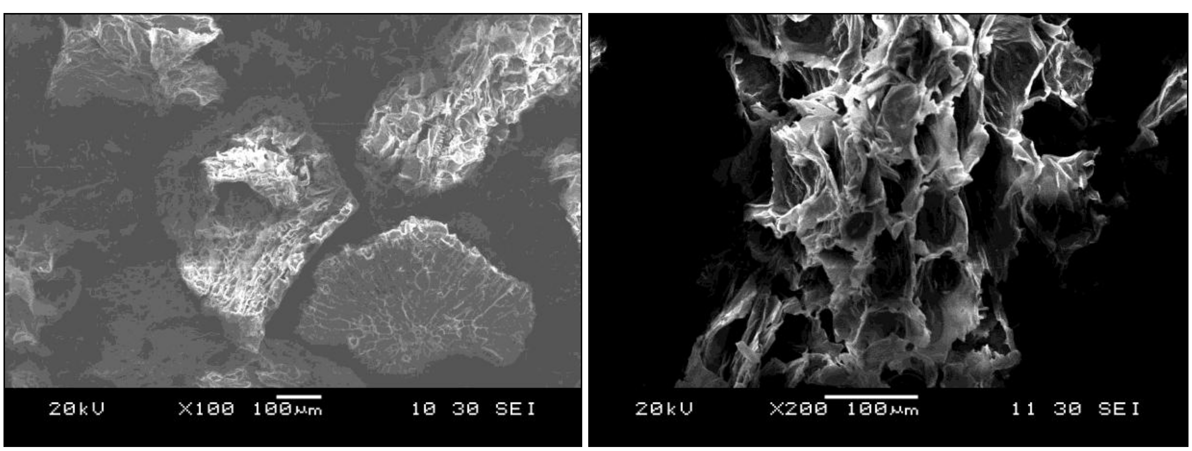

FIG. 1: SCANNING ELECTRON MICROSCOPY OF WATERMELON RIND POWDER A) IMAGE MAGNIFIED BY X100 B) IMAGE MAGNIFIED BY X200

Thus this allows an increase in the inter-molecular distance of the cellulose chains, which results into high swelling index value [31]. Similar findings were obtained by Bristow who studied the influence of porous structure on water absorption and swelling. He described that the sorption of water into fibers as a complex diffusion process, involving vapour phase diffusion pores, surface diffusion along the fibers, and bulk diffusion through the fibrous material [32].

Effect of *p*H on swelling index of WRP

From **Fig. 2** it was observed that as *p*H changed from acidic to neutral an increase in the swelling index was observed. Thus, a *p*H dependant swelling property of material makes it attractive for use in novel bulk forming agent which also can be used for treatment of obesity by making product target for specific *p*H GIT environment [33]. *p*H dependant swelling might be due to presence of large amount of free hydroxyl groups on cellulose in WRP [34]. *p*H depending swelling processes lead to a change in the surface composition and, therefore, the actual number of surface group's increases. It depends on material surface dynamic where reorientations of surface group occur as function of adjusting environment. SEM of WRP shows highly porous microstructure resultant higher surface area for mobility as compared to those in the material in bulk [35].

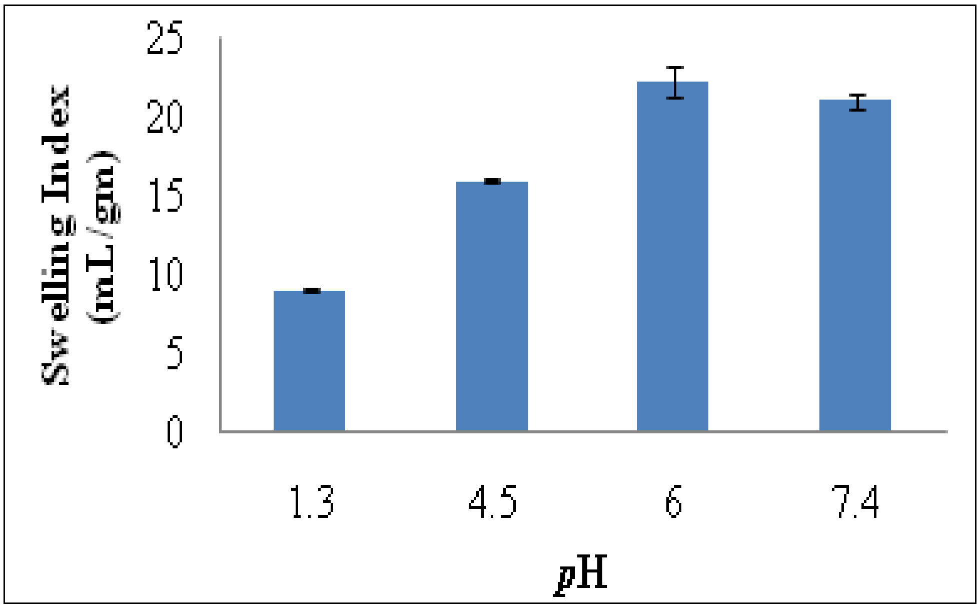

FIG. 2: EFFECT OF pH ON SWELLING INDEX OF WATERMELON RIND POWDER (WRP) (N=3)

Evaluation of bulk forming laxative formulation:

From **Table 4** Carr's Index and Hausner's ratio of all prepared formulation showed excellent flowability [27]. Uniform particle sizes of all formulations might be the major reason for the excellent flowability as all formulations have been passed through mesh 16; generally particle size influences the powder compaction, flowability, segregation and other factors [36].

In case of bulk forming laxative formulations, granules were prepared by passing through mesh then dried and further dried granular mass were again pass through sieve therefore granular formulation have uniform size and less moisture. Due to drying and uniform particle size of all formulations attribute to excellent flowing properties.

Those flowing properties help in handling of products at large scale [37]. **Table 4** Shows that as pectin concentration increases from 30-70%; swelling index decreases from 12 mL/gm to 8 mL/gm respectively. Swelling index was decreased with increased pectin concentration. This might be because of the increased pectin concentration resulted into hard granules after drying. Hence, these hard granules were not able to easily disperse in the buffer solution.

As isabgol husk concentration increased from 30 to 70% swelling index was increased from 16 to 40 mL/gm respectively. The Formulation **WPI3** and **WPI4** may be more preferred because it had both soluble and insoluble dietary fibers in balance proportion as well as it had comparably good *p*H dependant swelling [38].

TABLE 4: EVALUATION OF BULK FORMING LAXATIVE FORMULATIONS

Sr. no.	Formulation Code	Bulk Density (gm/mL)	Tap Density (gm/mL)	Carr's Index (%)	Hausner's Ratio	Swelling Index at *p*H 7 (mL/gm)
1	WP1	0.26 ± 0.01	0.30 ± 0.01	13.3 ± 0.06	1.2 ± 0.01	8.1 ± 0.41
2	WP2	0.25 ± 0.01	0.28 ± 0.01	12.5 ± 0.04	1.1 ± 0.03	8.1 ± 0.63
3	WP3	0.23 ± 0.01	0.26 ± 0.01	11.8 ± 0.23	1.1 ± 0.03	8.6 ± 0.34
4	WP4	0.23 ± 0.03	0.26 ± 0.01	11.8 ± 0.31	1.1 ± 0.02	12.5 ± 0.91
5	WP5	0.22 ± 0.01	0.25 ± 0.01	11.1 ± 0.17	1.1 ± 0.04	12.4 ± 0.75
6	WPI1	0.30 ± 0.01	0.33 ± 0.01	7.7 ± 0.09	1.1 ± 0.01	16.6 ± 0.50
7	WPI2	0.33 ± 0.01	0.36 ± 0.01	8.3 ± 0.13	1.1 ± 0.03	22.5 ± 1.2
8	WPI3	0.40 ± 0.01	0.44 ± 0.01	10.0 ± 0.37	1.1 ± 0.03	28.0 ± 1.1
9	WPI4	0.44 ± 0.01	0.50 ± 0.01	11.1 ± 0.41	1.1 ± 0.04	36.3 ± 1.5
10	WPI5	0.44 ± 0.01	0.50 ± 0.02	11.1 ± 0.28	1.1 ± 0.01	40.4 ± 2.1

* Values are mean ± standard deviations (*n* = 3); Note: W=WRP, P= Pectin, I=Isabgol husk

Comparative study of selected formulation with Fibril® for swelling index at different *p*H:

Four formulations were compared for *p*H dependant swelling index against market sample Fibril®. From **Fig. 3** showed a combination of WRP and isabgol husk worked better therefore these formulations were compared with Fibril® for *p*H dependant swelling index. It was found that prepared formulation had *p*H dependant swelling index. At acidic *p*H the swelling observed was less compared to neutral *p*H. The *p*H dependant swelling may reduce the stomach paining, feeling of unconscious and vomiting as it has less swelling index in stomach where as high swelling index in small and large intestine [39]. Site specific action could be achieved using formulation WPI3 and WPI4. Formulation WPI3 has swelling index 16 mL/gm in acidic *p*H 1.3 and higher swelling toward neutral *p*H. Same in case of WPI4 have low swelling index at acidic and high swelling index toward neutral *p*H. Hence those formulations might minimize the adverse effect occur due to sudden swelling of bulk laxative formulation in stomach [39].

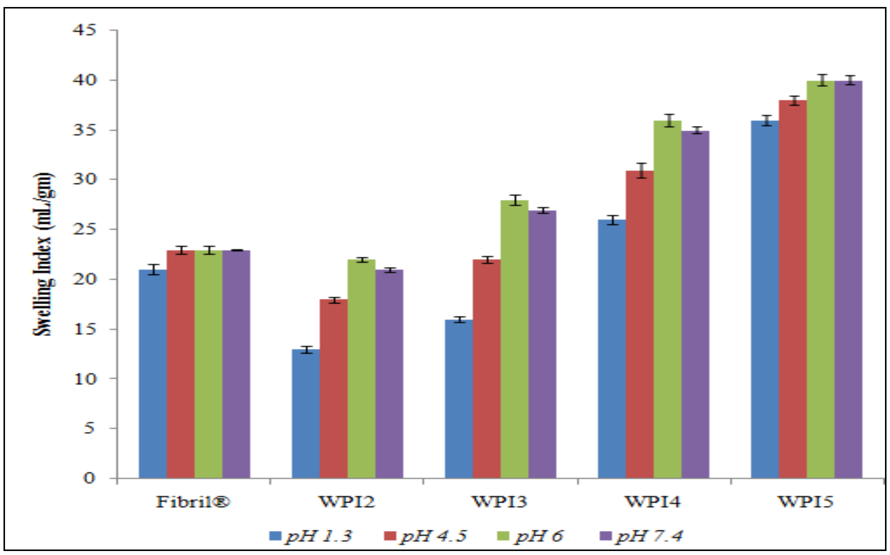

FIG. 3: COMPARATIVE STUDY OF SELECTED FORMULATION WITH MARKETED FORMULATION FOR SWELLING INDEX AT DIFFERENT pH (n=3)

CONCLUSIONS: Granular formulation prepared using WRP and isabgol husk was shown pH dependant swelling property. The prepared formulation was beneficial over Fibril® as this formulation may help in decreasing the intensity of adverse effect like stomach pain, feeling of unconscious and vomiting. WRP was majorly composed of polysaccharides and having micro porous structure resultant high water holding capacity and high swelling index. This work is exploring functional properties of WRP and its novel application in bulk forming laxative formulation. Since formulation was devoid of any constituent who stimulates the intestinal peristalsis and only acts by its bulk forming property, it is suitable for people suffering from habitual constipation. The bulk forming laxative prepared from WRP and isabgol were found to be better as compared with market sample (Fibril®). WRP can also be used in innovative product such as hypoglycemic and anti-obesity product as it contains high percentage of soluble and insoluble fibers.

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