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## **Development and Evaluation of Herbal Laxative Granules**

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### **ABSTRACT**

*Sterculia gum is a complex polysaccharide of high molecular weight. The rapid swelling of gum particles, their relative insolubility and their unusual resistance to bacterial and enzymatic breakdown make this gum suitable as a bulk laxative. The present work deals with development of granular formulation using Sterculia gum and its evaluation. The evaluation includes size gradation using sieve analysis, granular friability, percent compressibility (Carr's Index) and swelling Index. The present formulation was found to be comparable with other marketed laxative formulations containing Isapgol husk.*

**Keywords:** Sterculia gum, gum karaya, bulk laxative, constipation, swelling index, polysaccharide.

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### **INTRODUCTION**

Bulk Forming Laxative are those which when consumed with sufficient liquid, absorbs water in colon, thereby softening the faeces and expanding their bulk and cause emptying of bowel. These are various natural or semi synthetic polysaccharides and cellulose derivatives, which when given orally are not absorbed and increase the indigestible residue. These agents absorb water and swell up, thus providing the stimulus of mechanical distention for evacuations.

Sterculia gum (Gum karaya) is a hydrophilic colloid obtained from the exudates of *Sterculia uren* trees (Family: Sterculiaceae). Sterculia gum is a complex polysaccharide of high molecular weight. The rapid swelling of gum particles, their relative insolubility and their unusual

resistance to bacterial and enzymatic breakdown make this gum suitable as a bulk laxative. It absorbs water and swells 60 to 100 times their original volume, forming discontinuous type of mucilage. It is neither digested nor absorbed in body and hence it is a good bulk laxative [1, 2, 3].

Sterculia gum is a general food additive and accepted as a generally recognized as safe (GRAS) in USA since 1961, was accepted temporarily as a food additive by the EEC in 1974. Since then no adverse incident involving human health has been attributed to the ingestion of Sterculia gum. Dietary studies in man indicate that it is tolerated at dose level of 10.5gm/day without any adverse effect.

The present research work deals with the development of granular formulation of Sterculia gum and its comparative evaluation with other marketed laxative formulations containing Isapgol [4, 5].

## EXPERIMENTAL SECTION

### Materials:

Gum karaya, directly compressible lactose and Magnesium stearate of Indian Pharmacopoeial grade were obtained from store of principal K. M. Kundnani College of Pharmacy, Mumbai. All other chemicals used were of LR Grade.

### Formulation Methodology:

[A] Optimized Formula for 1000gms granules

| Sr.No. | Ingredients                   | Quantity |
|--------|-------------------------------|----------|
| 1      | Sterculia gum                 | 500g     |
| 2      | Directly compressible Lactose | 490g     |
| 3      | Magnesium stearate (1%)       | 10g      |

[B] Methods of Preparation: (Direct Compression Granulation)

Sterculia gum was mixed with directly compressible lactose and magnesium stearate. The blended mass was compressed into slugs using flat faced punches on a single punch compression machine (Cadmech). The slugs were then reduced to granules by passing through sieve no.16. The granules of #16 size were kept in air-tight container till further use.

### Evaluation of Granules:

The quality of the granular formulation was evaluated by checking following parameters:

(i) Bulk Density and Tapped Density:

To measure density, the granules were filled in a 100ml capacity measuring cylinder up to at least 3/4<sup>th</sup> height (Bulk Density Apparatus, Shivani Scientific Inds., Mumbai). Bulk density is the quotient of weight to the volume of the sample. Tapped density is the quotient of weight of the sample to the volume after taping a measuring cylinder 500 times from a height of ~ 1.5 in [6].

(ii) Carr's Index:

The percentage compressibility (Carr's index) was calculated as 100 times the ratio of the difference between tapped density and bulk density to the tapped density [7].

(iii) Angle of Repose:

Angle of repose was measured by the fixed funnel method. The sample were graded as excellent, good, fair or meager if the angle of repose found to be in the range of 30°-32°, 32°-35°, 35°-37° or 37°-45° respectively [8].

(iv) Granular Friability:

Twenty-five grams of granules were subjected to friabilator (Model EF2, Electrolab, Mumbai) at 25 rpm. After 4min, the granules were sieved on a 200mesh. The amount of granules passed through 200mesh was calculated as percentage granular friability [9].

(v) Particle size Distribution:

Particle size distribution was performed on random sample using nest of standard sieves (16, 30, 60,100,150,200 mesh). The sieves were agitated mechanically for 10minutes on a sieve shaker & the weight of granules retained on each smaller sieve was noted. The mean granule size was calculated from the % weight retained on each sieve [10].

### **Comparative Evaluation with Marketed Formulation:**

As these agents act purely because of their physical property, swelling index was selected as a parameter for comparing bulk forming ability of Sterculia gum formulation with that of other marketed laxative formulations containing Isapgol husk.

#### **Swelling Index:**

Swelling index is the volume in ml occupied by 1gm of drug; including any adhering mucilage after it has swollen in an aqueous liquid for 4hr. Swelling index of Sterculia gum and other marketed formulations containing Isapgol husk was determined using BP method.

One gram of each formulation was taken in a 25ml glass stoppered cylinder graduated over a height of 120 to 130mm in 0.5ml divisions. About 25ml of water was added and shaken vigorously every 10min. for 1hr and then allowed to stand for 3hr. The volume occupied by the formulation including adhering mucilage was measured. The swelling index was calculated from the mean of three determinations [11].

## **RESULTS AND DISCUSSION**

The values of physical parameters evaluated are shown in table-1. The value of Carr's index between 5 and 15 indicates excellent flow. The percentage granular friability was near to one indicating the toughness of granules.

The particle size distribution (Sieve analysis) of the granules is shown in table-2. About 98.4% particles were of size greater than 120# indicating the better quality & uniformity of the granules. The mean granule size was found to be 433.7µm.

The swelling index of the formulations is shown in table-3. It has been found that swelling index of the Sterculia gum formulation is comparable to that of marketed bulk laxative formulations containing Isapgol husk.

**Table-1: Physical characterization of Sterculia gum granules**

| Sr.No. | Parameter           | Value      |
|--------|---------------------|------------|
| 1      | Bulk Density        | 0.625gm/ml |
| 2      | Tapped Density      | 0.667gm/ml |
| 3      | Carr's Index        | 16%        |
| 4      | Hausner's Ratio     | 0.93       |
| 5      | Angle of Repose     | 26° 56''   |
| 6      | Granular friability | 0.8%       |

**Table-2: Sieve analysis of the granules**

| Sieve No. | Arithmetic Mean Size of Opening (µm) | Weight Retained on Sieve(g) | % Retained on Sieve | Mean granular size(µm) |
|-----------|--------------------------------------|-----------------------------|---------------------|------------------------|
| 30        | 462.5                                | 22                          | 88                  | 433.7                  |
| 36        | 337.5                                | 1.2                         | 4.8                 |                        |
| 60        | 187.5                                | 0.8                         | 3.2                 |                        |
| 120       | 115.5                                | 0.6                         | 2.4                 |                        |
| 150       | 106                                  | 0.4                         | 1.6                 |                        |

**Table-3: Swelling Index of Formulation**

| Sr.No. | Formulation               | Swelling Index |
|--------|---------------------------|----------------|
| 1      | Sterculia gum Formulation | 16ml/g         |
| 2      | Marketed Formulation No.1 | 15ml/g         |
| 3      | Marketed Formulation No.2 | 18ml/g         |

## CONCLUSION

The granular formulation prepared by using Sterculia gum as a major constituent has been found to possess excellent palatability. Since the product is devoid of any constituent which stimulates the intestinal peristalsis and acts only by its bulk forming property, it is suitable for people suffering from habitual constipation.

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