



Formulation and Evaluation of Herbal Laxative Tablet from Flaxseeds

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ABSTRACT

Constipation is one of the most widespread chronic gastrointestinal diseases in the world and is managed or treated using a variety of techniques. Chronic or acute constipation is treated or managed using laxatives. However, herbal meals should be taken into account as an alternative to these laxatives as a result of the negative side effects they are associated with. The laxative potential of plant-based medications used to treat constipation is explored in this article. Numerous factors, including a person's diet, lifestyle, stage of pregnancy, and even some medications, can contribute to constipation. Constipation that is chronic is linked to a number of health problems. To treat or control constipation, pharmacological and non-pharmacological approaches are used.(1). The present invention relates to an herbal laxative formulation containing flaxseeds and method of preparation for 500 mg tablet for treating constipation by administrating the formulation of the present invention. The formulation having laxative properties is gentle, safe and effective, free of undesirable side effects and capable of relieving severe constipation. Along with flaxseeds other excipients are also added like binder- gum acacia, talc- glidant, starch- disintegrant, magnesium stearate - lubricant, MCC- compressible vehicle to formulate a tablet. Flaxseed has been used over the years as a home remedy over the problems related to digestive tract. Flaxseeds when having as a whole seed there is a chance that it may passed through intestine undigested which means we won't get all the benefits. On the other hand, ground flaxseeds are easier to digest with all benefits. Flaxseeds shows both the properties ,laxative and antidiarrheal. For granule formulation , dry granulation technique is used further compression of tablet is done by using hand processing tablet compression instrument. Evaluation of granules and tablet is done to give satisfactory results.

Keywords: - Constipation Gastrointestinal, Laxative, Excipients

Introduction

Constipation is a frequent functional gastrointestinal condition affecting people of all ages. (1-10). Constipation can cause unpleasant defecation, infrequent stools, difficult stool transit, or both, as well as discomfort and stiffness. (1-20). Acute constipation can induce intestinal closure, which may necessitate surgery. (10-25). They might require to spend longer in the toilet as passing stools gets more difficult. Some persons have the sensation of an incomplete bowel movement and an obstruction. When the stools are overly firm, the rectum muscles are put under extra tension. As a result, the patient's history and physical examination can be regarded as the primary initial procedures for identifying constipation. (1-33). Long-term constipation is a challenging illness that affects the elderly and is characterised by poor stool transit. (1-30). Constipation is significantly more difficult to digest. Constipation episodes may even occur as a side effect of taking certain medications. Some people experience constipation when they travel or are away from their homes. Since these happen infrequently, and these episodes do not pose a serious problem. When constipation starts to occur regularly, then it is a matter of concern. Any person constipated for more than three days a week, then a doctor is likely to diagnose that person is suffering from chronic constipation. Constipation causing toxins in the colon should not be taken lightly as purgatives. These toxins can have detrimental effects not just the colon but on a few other organs.) Occasional spells of constipation can also develop as a result of eating difficult-to-digest foods.prevalent in elderly persons than in youngsters (1-35). The most common causes of constipation in the elderly include a lack of normal bowel movements or ageing, a poor diet, low-fibre food consumption, a lack of adequate fluid intake, a lack of sufficient physical activity, an illness, or drug use. (1-38). Furthermore, elderly females have far more constipation than males. (1-25). Occasional episodes of constipation can also be occurred due to consumption of food that is Constipation bouts can potentially develop as a side effect of some drugs. When people travel or are away from their homes, they may have constipation.

Flaxseeds are also known as linseed. Flaxseeds are also popularly known as Alsi, Jawas Aksebija in Indian languages. Flax is a dried, flat, seeds from *Linum usitatissimum* belonging to the family Lineaceae. *Linum usitatissimum* is blue flowering annual herb that produces small flat seeds varying from golden to reddish brown color. Flaxseed measures about 2.5 * 5.0 * 1.5 mm .

Humans have been consuming flaxseeds since ancient times. It has been cultivated for fibres and other medicinal purposes and as nutritional product. [39].

Composition

Nutrients

- Moisture
- Protein
- Fat
- Mineral
- Total Dietary Fiber
- Carbohydrates
- Energy
- Potassium
- Calcium
- Phosphorous
- Iron
- Vitamins

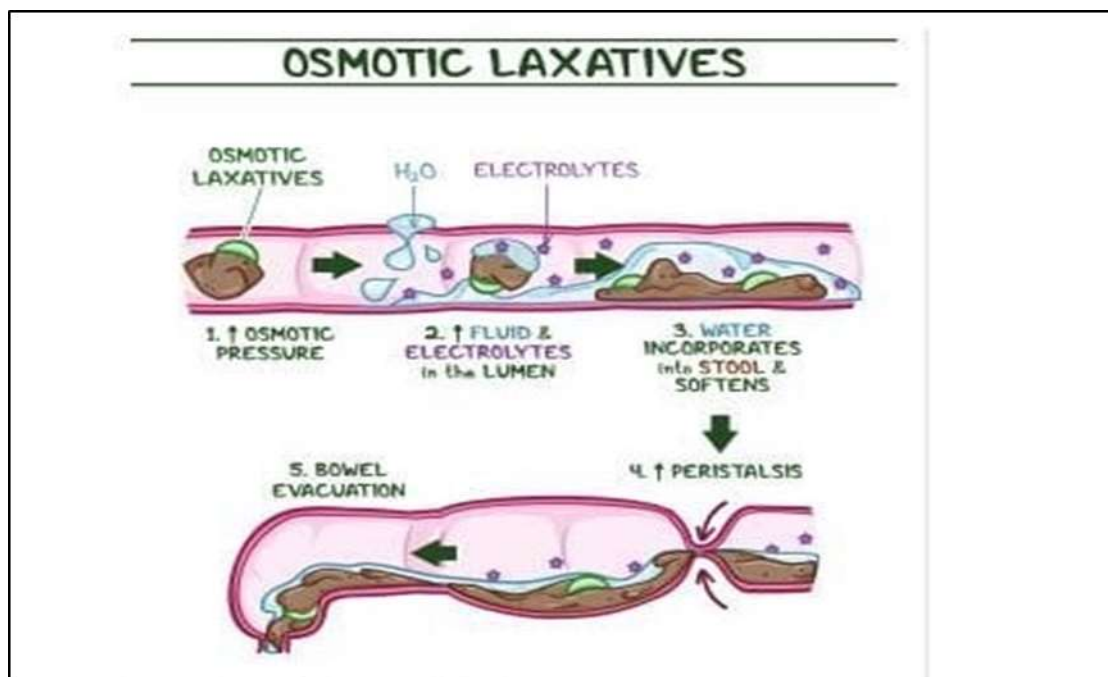
Flaxseeds contain soluble and insoluble dietary fibers in proportion that varies between 20:80 and 40:60. The major insoluble fiber fraction consist of Cellulose and Lignin. The soluble fiber fraction is consist of Mucilage and Gum. Dietary fibers and functional fibers are not digested and absorbed by the small intestine of human body and, therefore, passed relatively intact into the large intestine.

Types of laxatives:-

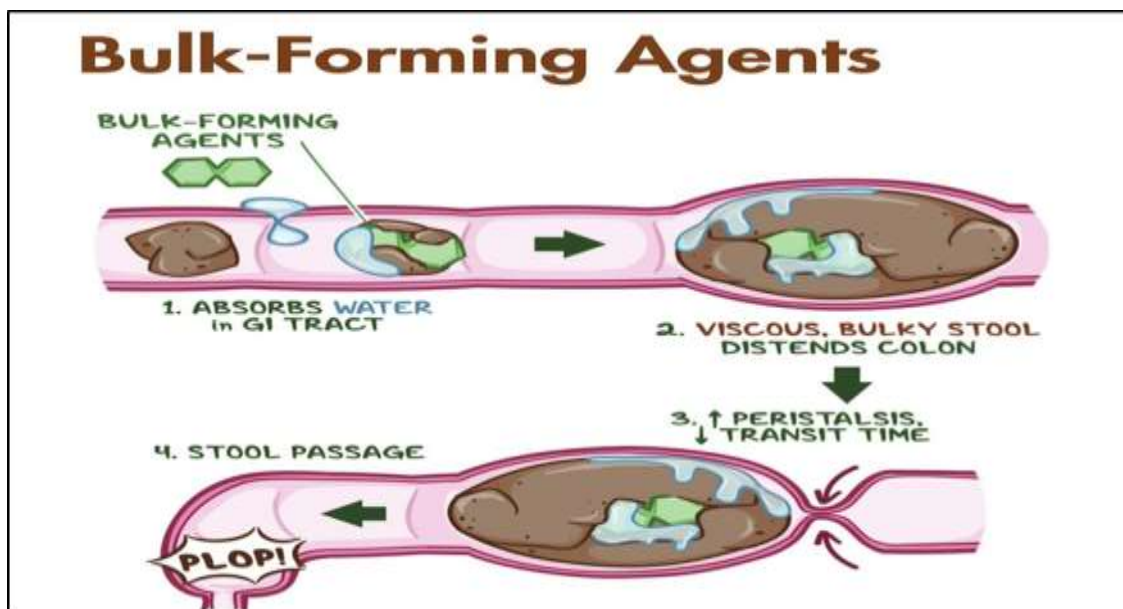
1. Bulk forming laxative
2. Stool softener
3. Stimulant
4. Osmotic laxatives

The present invention is directed towards the bulk forming laxative and osmotic laxative.

- Mechanism Of Action of a laxative tablet: -



Mechanism of action of bulk forming laxatives (Figure no.1)



Mechanism of action of Osmotic laxative (Figure no.2)

Material

Flaxseeds and Milk of magnesia were collected from the pharmacognosy lab, powdered and used for preparation of tablet to cure constipation. The other ingredients used in formulation are microcrystalline cellulose as a compressible vehicle, sucrose as a filler, talc as a glidant and pleasure appearance of tablet, starch as a disintegrant and gum acacia as a binder.

Material

(Table no. 2)

Sr.no	name	Diagram	Chemical constituent	category
1	Flaxseeds		Dietary fibres (cellulose and lignin) which are insoluble, alpha linolenic acid, lignans, proteins, antioxidants	Laxative – bulk forming laxatives
2.	Milk of magnesia		Occur naturally in the form of the mineral brucite	Laxative – osmotic laxative

Excipients

(Table no.3)

1.	Microcrystalline Cellulose		Compressible vehicle/ diluent
2.	Sucrose		filler
3.	Talc		Glidant
4.	Magnesium Stearate		Lubricant
5.	Potato starch		disintegrant
8	Gum acacia		binder

Formulation Table: -

(Table no. 4)

Sr. no.	Ingredients	Quantity per 500 mg tab	Sr. no.
1.	Flaxseeds	100 mg	1.
	Milk of magnesia	100mg	
4.	Microcrystalline cellulose	190mg	4.
5.	Sucrose	80mg	5.
6.	talc	1mg	6.
7.	Magnesium stearate	10mg	7.
8.	Gum acacia	10 mg	8.
9.	starch	9mg	9.

Method

Preparation of dry powder of flaxseeds, Milk of magnesia.

Flaxseeds, were triturated separately with help of mortar and pestle.

Fine core powder was prepared.

Other required ingredients were collected from laboratory in college.

MCC, sucrose, talc, starch and acacia were collected from laboratory and triturated along with the other ingredients.

Tablet formulation was done by dry granulation method and further compression by using tablet punching machine.

Dry granulation method: -

All the ingredients were taken in appropriate quantity as given in a table no. 2. All the ingredients are weighed and triturated in a mortar and pestle. The prepared fine powder was sieved with sieve no. 20.

Evaluation [35]

- Evaluation of pre formulation: -

1. Bulk density: -

Prepared powder was poured into the 100 ml measuring cylinder and bulk density was calculated using following formula;

$$\text{Bulk density} = \frac{\text{mass of the powder}}{\text{Bulk volume of a powder}}$$

3. Tapped density: -

Powdered granules poured into the 100 ml measuring cylinder were tapped for 100 times and then volume of a measuring was observed. Tapped density were calculated according to the following formula;

$$\text{Tapped density} = \frac{\text{mass of the powder}}{\text{Tapped volume of a powder}}$$

4. Hausner's ratio: -

Calculated by using the following formula;

$$\text{Hausner's ratio} = \frac{\text{tapped density}}{\text{Bulk density}}$$

5. Carr's index: -

Compressibility index is determined by following formula;

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

6. Angle of repose: -

Angle of repose were determined by using funnel method.

Following formula was used;



Funnel method (Figure no.3)

$$\Theta = \tan^{-1} [h/r]$$

Where,

h = height of powder cone formed.

r = radius of the powder formed Funnel method (Figure no.3)

Scale of flowability

(Table no. 5)

Flow character	Hausner's ratio	Carr's index	Angle of repose
Excellent	1.00-1.11	≤ 10	25-30
Good	1.12-1.18	11-15	31-35
Fair	1.19-1.25	16-20	36-40
Passable	1.26-1.34	21-25	41-45
Poor	1.35-1.45	26-31	46-55
Very poor	1.46-1.59	32-37	56-65
Very, very poor	> 1.60	> 38	> 66

- Physical evaluation of tablet: - (36-37)

1. General appearance: -

Colour: sandstorm

Shape: cylindrical

2. Weight variation test: -

Weight variation test were performed by determining the average weight of 20 tablets

$$X = (X_1 + X_2 + X_3 + X_4 + \dots + X_{20}) / 20$$

Individual weight of the tablet was compared with the upper and lower limit. Not more than two tablets differ from the average weight more than the % error listed in the below table.

Weight variation tolerance

(Table no.6)

Sr.no.	Average weight of tablet in mg	Mass percentage difference is allowed
1.	80 or less	10%
2.	80-250	7.5%
3.	More than 250	5%

3. Hardness and thickness:

Hardness and thickness of a tablets were determined by using Monsanto hardness tester and Vernier Calliper respectively.



Vernier Caliper
(Figure no. 4)



Monsanto hardness tester
(Figure no. 4)

4. Friability test: [38]

It is a parameter used to test the ability to resist chipping and breaking during shipment and handling. Friability is measured under standard conditions by weighing out certain number of tablets (20 or more than 20). If a tablet weighs more than friability of tablets was evaluated by using Roche Friabilator. Friabilator was set at 25 rpm for 100 revolutions for 4 minutes. Compress tablet loss less than 0.5% - 1.0% of the tablet weight are considered acceptable. To calculate the loss of tablet we can use the following method.

$$\% \text{ loss} = \text{Final weight} / \text{Initial weight} * 100$$

Result

1] Evaluation of pre formulation parameters of the tablet

(Table no. 7)

Sr. no.	Pre-formulation parameters	Results
1.	Bulk density	0.4gm/ml
2.	Tapped density	0.47gm/ml
3.	Carr's index	15.96%
4.	Hausner's ratio	1.9
5.	Angle of repose	44.4°C

According to IP, pre formulation evaluation is performed to determine the rheology of the powder or granules. According to results powder flow were passable applicable to compress tablets.

2] Weight variation test: -

(Table no.8)

Sr. no.	Weight of a tablet (mg)	Sr. no.	Weight of a tablet (mg)
1.	500	11.	500
2.	510	12.	500
3.	500	13.	510
4.	500	14.	500
5.	500	15.	510
6.	510	16.	500
7.	510	17.	510
8.	500	18.	500
9.	510	19.	510
10.	500	20.	500

Total weight of 20 tablets=10,080

Average weight=504

5% of 504mg = 25.2

Weight variation range is + or - 25.2mg

$$\begin{aligned} \text{Lower limit} &= \text{average weight} + (\text{average weight} * \% \text{ error}) \\ &= 504 - 25.2 \end{aligned}$$

$$\text{Lower limit} = 478.8$$

$$\begin{aligned} \text{Upper limit} &= \text{average weight} + (\text{average weight} * \% \text{ error}) \\ &= 504 + 25.2 \end{aligned}$$

$$\text{Upper limit} = 529.2$$

According to IP, average weight of tablet more than 250 allows 5% of variation. All the individual weight of tablet is within the upper and lower limit.

3] Hardness and Thickness of tablet: -

Sr. no.	Thickness (mm)	Sr. no.	Hardness (Kg/cm ²)
1.	8 mm	1.	2.9
2.	7 mm	2.	2.8
3.	8 mm	3.	3
Average	7.6 mm	Average	2.9

(Table no. 9)

4] Friability Test: -

20 tablets are weight together

Initial weight = 10,080mg

Final weight (after rotation) = 10,080mg

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} * 100$$

$$\text{Friability} = \frac{10,080 - 10,080}{10,080} * 100$$

Discussion

Flaxseeds are medicinal seeds obtain from linum usitatissimum (Linn.) having various medicinal activities like laxative, antidiarrheal, helps in cardiac diseases, cancer, arthritis, osteoporosis, autoimmune and neurological disorders. But present invention focuses on the laxative property of the tablet. The combination of bulk forming laxative and osmotic laxative forms a better treatment for constipation. Pre formulation and formulation was done to give satisfactory results.

Conclusion

Flaxseed and milk of magnesia were used in the present invention to treat constipation. The present invention were satisfactorily passed with all the test performed and concluded that the invention is satisfactory for use in constipation, to treat constipation.

Summary

Flaxseed is a traditionally used overs a years to treat the problems related to the gastrointestinal tract as it is free from all the undesired side effects. On the other hand it contain more insoluble fibres, and also it is used as a supplementary diet as it contain high amount of proteins, fats, vitamins and dietary fibers.

Flaxseeds along with milk of magnesia which is a osmotic laxative helps in safe, easy and effective treatment over constipation.

The present invention is about the preparation of tablet by using flaxseeds and milk of magnesia. The evaluation of tablet is done to give satisfactory results to check safety and effectiveness of tablet.