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Formulation and Evaluation Flaxseed Suppository for management of Hemorrhoids

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Abstract:
The rectal route has proven its worth in terms of achieving successful drug delivery both locally and systematically. Hemorrhoids (also called piles) are swollen veins in the lower rectum or around the anus—similar to varicose veins but in that area. Hemorrhoids affect 50% of adults >50 years. Current therapy includes synthetic antinflammatories and laxatives with side effects. Flaxseed offers a natural alternative combining demulcent, anti-inflammatory, and laxative actions in a single rectal dosage form.
A suppository comprises flax as a main active ingredient, administered through the rectal route, used as a laxative, and treatment of haemorrhoids and bacterial infections of the anus. For the formulation of the present invention, the suppository preferably comprises flax in an inert base, which may comprise any suitable inert pharmaceutical carrier.
The study aims to formulate and evaluate herbal suppositories using flaxseed mucilage and extract as the primary therapeutic agent, leveraging its anti-inflammatory, demulcent, and laxative properties for local rectal disorders like hemorrhoids, constipation, and inflammation.

Keywords: Flax extract, suppository, Gelatin, Glycerine, Herbal suppository

INTRODUCTION

Herbal medicine, also known as botanical or phytomedicine, refers to the use of plants and plant-derived substances for the prevention and treatment of diseases. It is one of the oldest forms of healthcare, practiced for thousands of years across cultures such as Ayurveda in India, Traditional Chinese Medicine in China, and various indigenous healing traditions worldwide
Herbal medicines are prepared from different parts of plants including leaves, roots, bark, seeds, and flowers. These parts contain active chemical constituents like alkaloids, glycosides, tannins, flavonoids, and essential oils, which are responsible for their therapeutic effects. Common examples include plants like Aloe vera for
Common examples include plants like Aloe vera for skin healing, Neem for its antimicrobial properties, and Turmeric known for its anti-inflammatory action
Herbal suppositories are solid dosage forms prepared using natural plant-based ingredients and intended for insertion into body cavities such as the rectum, vagina, or urethra. Once inserted, they melt, soften, or

dissolve at body temperature to release their active herbal constituents for local or systemic therapeutic effects.

The main advantages of herbal suppositories include targeted drug delivery, rapid absorption, avoidance of first-pass metabolism, and reduced systemic side effects. They are particularly useful in treating local conditions such as rectal inflammation, vaginal infections, and haemorrhoids.

SUPPOSITORIES

A suppository is a small, solid medication formulated to melt or dissolve at body temperature, designed for insertion into body cavities such as the rectum, vagina, or urethra. Common uses include treating constipation, haemorrhoids, infections, and delivering medication when oral intake is not possible due to vomiting or unconsciousness.

Types of suppositories

1. Based on Route of administration

Type	Site	Common use	Typical Wt.
Rectal	Inserted into rectum	Haemorrhoids, Constipation, nausea, fever, systemic drug	Adult: 2g Child: 1g
Vaginal/ pessaries	Inserted into vagina	Antifungals, Contraceptive, hormonal therapy, infections	3.5g
Urethral	Inserted into male urethra	Rare now Earlier for infections	Male:4g 60-75mm Length
Nasal	Inserted into nasal cavity	Rare for local effects	-1gm
Dental	Placed in dental cavity	Local Anaesthetic, antiseptic after tooth extraction	Small & Conical
Ear	Inserted into Ear canal	Very rare. For Ear infection	-1g

Table no. 1: Based on route of administration.

2. Based on Composition

Fatty (oleaginous) bases
e.g., cocoa butter
Melt at body temperature
Water-soluble bases
e.g., glycerinated gelatin, polyethylene glycol (PEG)
Dissolve slowly in body fluids
Emulsifying bases
Mix of oil and water properties
Better drug release in some cases

3. Based on Action

Local action
Acts at the site of insertion

Example: hemorrhoid relief
Systemic action
Drug absorbed into bloodstrea
Example: pain relief or fever reduction

Advantages:

1. Bypassing the digestive system and liver ("first-pass" metabolism),
2. Allowing for higher bioavailability,
3. faster action,
4.Administration to patients who cannot take oral medication (nausea, vomiting, or unconsciousness)
5. Rapid / localised action

Dis-advantages:

1. Poor patient acceptance due to embarrassment,
2. Potential mucosal irritation, and risk of leakage.
3. They require strict storage conditions (refrigeration) to prevent melting and can lead to erratic or incomplete absorption depending on rectal contents or diarrhea.
4. Costly Manufacturing
5. Irritations And local side effects
6. Difficult self-Administration

Ideal Properties of suppositories:

1.An ideal suppository must be solid at room temperature for easy handling but melt or dissolve rapidly at body temperature (\(37^{\circ}C\)) to release medication.
2. It should be non-irritating to mucous membranes,
3. chemically/physically stable,
4. Compatible with various drugs,
5. Shrink upon cooling to allow easy removal from mold

Fig.1 Polyherbal suppositories

Review of literature:

1. Therapeutic Properties

- Prasad et al., 2019: Reported flaxseed mucilage contains 80% soluble fiber with significant anti-inflammatory and demulcent activity. Lignans like secoisolariciresinol diglycosidic (SDG) show antioxidant effects useful for haemorrhoids and anal fissures.
- Kajla et al., 2015: Highlighted flaxseed's laxative action due to high mucilage content. Swells in aqueous media, providing bulk-forming action for constipation. Supports rectal use.
- Shim et al., 2014: Reviewed omega-3 fatty acids in flaxseed oil. Demonstrated topical anti-inflammatory effects, making it suitable for inflammatory bowel conditions.

2. Herbal Suppository Formulations

Base Selection

- PEG bases: Saleem et al., 2020: Used PEG 4000:6000 blends for herbal suppositories. Water-soluble, better stability in hot climates than cocoa butter, but may cause rectal irritation.
- Glycerogelatin: Biyani et al., 2011: Recommended for extracts with high water content. Provides slower release than fatty bases.

3. Herbal Suppository Studies

- Madan et al., 2017: Formulated aloe vera suppositories for haemorrhoids using cocoa butter. Showed 89% drug release in 45 min and significant reduction in inflammation in rat models.
- Patil & Gaikwad, 2021: Developed neem-turmeric suppositories. PEG base gave better hardness and disintegration than cocoa butter. Concluded that base selection directly impacts release of herbal actives.

- Yadav et al., 2016: Prepared Moringa oleifera suppositories. Fusion moulding at 40°C preserved phytoconstituents. Stressed temperature control during formulation to avoid degradation.

4. Role of Mucilage in Suppositories

- Pawar & Domb, 2013: Reviewed natural mucilage's as excipients. Reported that mucilage's improve mucoadhesion, prolong residence time in rectal cavity, and sustain drug release.
- Kulkarni et al., 2019: Used Plantago ovata mucilage in diclofenac suppositories. Increased bio adhesive strength 2.3x vs plain cocoa butter base. Flax mucilage has similar rheological behaviour.
- Singh et al., 2020: Specifically studied flaxseed mucilage as binder in tablets. Showed excellent swelling index and thermal stability up to 60°C. Suggests viability for suppository bases.

5. Evaluation Parameters from Literature

Parameter	*Standard/Findings*	*Reference*
Weight variation	IP: Not more than 2 units deviate by >5%	Indian Pharmacopoeia, 2018
Melting range	32-37°C for rectal use	Sahoo et al., 2015
Disintegration time	<30 min for fatty base, <60 min for water-soluble	USP 43-NF 38
Drug release	>80% in 60 min for effective local action	Azevedo et al., 2018
Stability	No significant change in 3 months at 40°C/75% RH	ICH Q1A guidelines

Table no .2: Evaluation parameters from literature

AIM:

Formulation and evaluation of flaxseed suppositories for management of haemorrhoids

OBJECTIVE:

The main objectives for formulating and evaluating flax herbal suppositories are to develop a natural, effective rectal delivery system for treating localized conditions like constipation, haemorrhoids, and anorectal inflammation. The formulation aims to utilize the antioxidant, anti-inflammatory, and laxative properties of Linum usitatissimum (flaxseed) through a stable, rapid-release, and biocompatible dosage

Plain of Work:

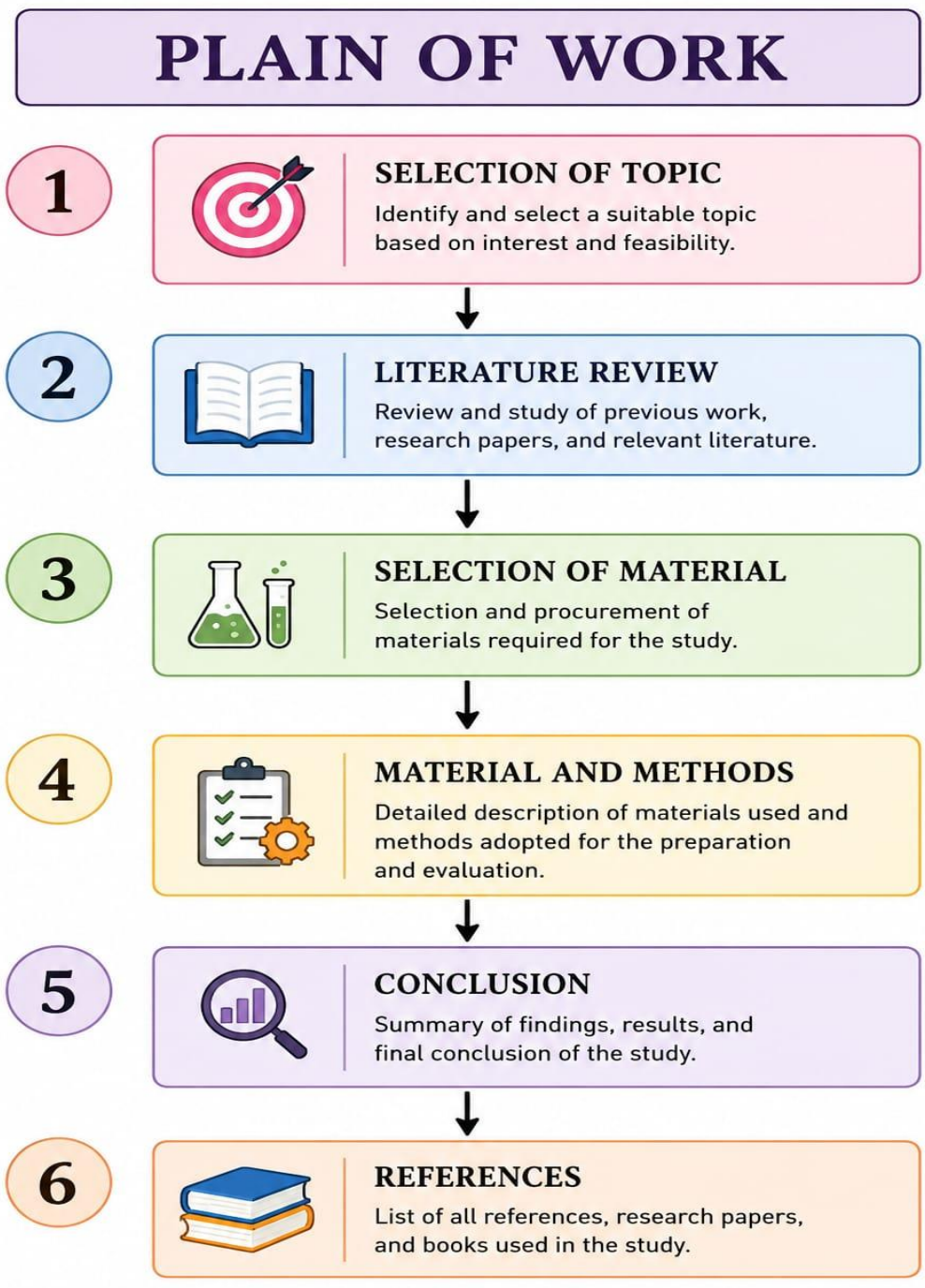

Fig.2 Plain of work

Material and methods

1.Flax seed

Flax seed (Linum usitatissimum) is widely used in herbal medicine because it is rich in omega-3 fatty acids, lignans, and mucilage (gel-forming fiber). These components give it multiple therapeutic uses. which provide soothing, anti-inflammatory, and protective effects.

Synonym: Linseed, oil-rich seed, oilseed, Alsi , Tishi , Jawas , agasi

Biological Source: Flaxseed comes from the flax plant, scientifically known as linum Usitatissimum, an annual herb in the linaceae family.
Family: Linaceae

Chemical Constituents: It is including a diverse range of compounds like lipid chigh in omega – 3S, particularly alpha – linolenic acids proteins, dietary fiber (including mucilage) and bio active compounds such as lignans (like secoisotaric reciresinol diglucoside or SDG) phenolic acids (like ferulic and chlorogenic acid) & flavonoid.

Uses: Flaxseed in herbal suppositories, typically formulated with a glycerin-gelatin base, is used to treat haemorrhoids, constipation, and anal bacterial infections. The extract acts as a natural laxative, providing rapid symptom relief by utilizing high dietary fibre and omega-3 fatty acids (ALA) to reduce inflammation and promote mucosal healing.

Fig.3 Flax seed

2. Glycerine

Glycerine is highly hygroscopic, meaning it attracts and retains moisture. This property helps keep suppositories soft and prevents them from drying or cracking during storage. In rectal suppositories, glycerine also acts as an osmotic agent, drawing water into the rectum, which stimulates bowel movement and provides relief from constipation.

Synonyms of Glycerine:

Glycerol, Glycerine, Propane-1,2,3-triol,1,2,3-Propanetriol, Trihydroxy propane,

Glycyl alcohol

Biological Source:

Glycerine is mainly derived from:

1. Animal fats
2. Vegetable oil

Family:

Glycerine belongs to the alcohol family, specifically classified as a polyol or a trihydric alcohol due to its three-hydroxyl group

Chemical constituents:

It is a single pure chemical compound so it does not have Constituents like a plant extract but here's the chemical breakdown of glycerines is

- Chemical name: Propane-1,2,3-triol
- Common names: Glycerol, Glycerine, 1,2,3-Propanetriol

Uses:

Glycerine (Glycerol) plays both a therapeutic and a formulation (excipient) role in herbal suppositories. Glycerine use as Base in polyherbal suppositories.

Fig. 4 Glycerine

3.Geletin:

Gelatine (Gelatine) is a natural protein obtained by partial hydrolysis of collagen from animal tissues such as skin, bones, and connective tissues. Gelatine is a key base component for suppositories, especially when you're working with water-soluble herbal extracts like flax mucilage.

Synonyms of Gelatine:

Jelly , gel, collagen , Gelatine

Biological Source:

Gelatin is prepared from:

Animal skin (mainly bovine and porcine)

Bones

Connective tissues (tendons, ligaments)

Family:

Bovidae family (cattle, sheep) or pig skins

Chemical constituents:

Gelatin is a mixture of water-soluble proteins (98–99% dry weight) and peptides derived from partial hydrolysis of animal collagen. It is primarily composed of amino acids, dominated by glycine (26–34%), proline (10–18%), and hydroxyproline (7–15%), with high amounts of alanine, arginine, and glutamic acid

Uses:

Gelatin (Gelatin) is an important excipient in herbal suppositories, mainly used for its gelling, binding, and stabilizing properties. And it is used as based in herbal suppositories

Fig.5 Gelatine

3.Methyl paraben

Methyl paraben is a widely used preservative in pharmaceutical and cosmetic formulations, including herbal suppositories

methyl paraben plays an important role in maintaining product quality, safety, and longevity in both conventional and herbal formulations.

In herbal preparations, including suppositories, methyl paraben is often added as a preservative to protect natural ingredients from microbial contamination

Synonyms: Methyl p-hydroxybenzoate

p-Hydroxybenzoic acid methyl ester

Methyl 4-hydroxybenzoate

Nipagin (common trade name

Biological source: Methylparaben is not primarily obtained from a natural (biological) source. It is a synthetic compound prepared by esterification of p-hydroxybenzoic acid with methanol.

Family: paraben

Chemical constituents: Methylparaben is a single, well-defined chemical compound rather than a mixture, so its "constituents" refer to its molecular composition and functional groups

Uses: Methylparaben is widely used in herbal suppository formulations mainly as a preservative. Its role is important because herbal ingredients are more prone to microbial contamination.

Method of preparation

Step 1: Preparation of Flaxseed Extract:

1. Collect clean flaxseeds and remove any impurities or dust.
2. Dry the flaxseeds properly.
3. Grind the dried flaxseeds into coarse powder using a grinder.
4. Transfer the powder into a clean container.
5. Add water or hydroalcoholic solvent to the powder.
6. Keep the mixture for maceration or heat gently for extraction of active constituents.
7. Filter the mixture using muslin cloth or filter paper.
8. Concentrate the filtrate by heating on a water bath until a thick extract is obtained.
9. Store the prepared flaxseed extract for further use.

Step 2: Preparation of Glycerinated Gelatin Base:

1. Accurately weigh gelatin, glycerin, and purified water.
2. Take water in a beaker and heat it on a water bath.
3. Add gelatin slowly into warm water with continuous stirring.
4. Continue stirring until gelatin dissolves completely.
5. Add glycerin to the gelatin solution and mix uniformly.
6. Add methyl paraben as preservative.
7. Heat gently until a clear and homogeneous base is obtained.

Step 3: Incorporation of Flaxseed Extract:
1. Measure the required quantity of flaxseed extract.
2. Add the extract slowly into the molten glycerinated gelatin base.
3. Stir continuously to ensure uniform mixing and distribution.
4. Continue stirring until a homogeneous mixture is formed.

Step 4: Moulding of Suppositories:
1. Clean and dry the suppository moulds.
2. Lubricate the moulds lightly if required.
3. Pour the prepared molten mixture carefully into the mould cavities.
4. Fill each cavity uniformly.
5. Avoid air bubble formation during pouring.

Step 5: Cooling and Solidification:
1. Keep the filled moulds at room temperature for initial cooling.
2. Transfer the moulds to a refrigerator.
3. Allow the suppositories to solidify completely.

Step 6: Removal and Packaging:
1. Remove the solidified suppositories carefully from the moulds.
2. Check for smoothness and proper shape.
3. Wrap each suppository individually using aluminium foil or butter paper.
4. Store the suppositories in a cool and dry place until use.

Evaluation Tests for Flaxseed Suppositories

Evaluation tests are performed to determine the quality, safety, stability, and effectiveness of flaxseed herbal suppositories. The following tests are commonly carried out:

1. Physical Appearance Test:
- Parameters Evaluated
- Shape
- Colour
- Surface texture
- Smoothness
- Presence of cracks or air bubbles
- Importance
- Ensures uniformity of formulation
- Improves elegance and acceptability of suppositories

2. Weight Variation Test:

Procedure:
1. Select 20 suppositories randomly.

2. Weigh each suppository individually.
3. Calculate the average weight.
4. Compare individual weights with the average weight.

Importance

- Ensures uniform distribution of formulation
- Confirms each suppository contains the correct amount of medicament

3. Hardness Test:

- Purpose
- Determines the mechanical strength of suppositories.
- Importance
- Prevents breakage during handling and transportation
- Maintains stability during storage

4. Melting Point / Liquefaction Time Test:

- Purpose
- Measures the time required for suppositories to melt or soften at body temperature.
- Importance
- Ensures proper drug release after rectal administration
- Confirms suitability of the suppository base

5. Disintegration Test:

- Purpose
- Determines the time required for suppositories to break down in suitable medium at body temperature.
- Importance
- Evaluates drug release characteristics
- Indicates effectiveness of formulation
- Drug Content Uniformity Test

Purpose:

- Checks whether the active ingredient is uniformly distributed throughout the suppositories.
- Importance
- Ensures accurate dosage
- Provides uniform therapeutic effect

7. Dissolution Test:

Purpose

- Measures the rate and extent of drug release from the suppository base.

Importance

- Evaluates bioavailability of the drug
- Determines effectiveness of the formulation

8. Stability Study:

Procedure:

- Suppositories are stored under different temperature and humidity conditions.
- Parameters Evaluated

- Colour change
- Odour
- Texture
- Drug content
- Melting behaviour

Importance:

- Determines shelf life of the formulation
- Establishes suitable storage conditions

9. Microbial Limit Test:

Purpose

- Ensures that suppositories are free from harmful microorganisms.

Importance

- Maintains product safety
- Prevents microbial contamination

10. pH Test:

Purpose:

- Measures the pH of the suppository formulation.

Importance

- Prevents irritation to rectal mucosa
- Ensures compatibility with body tissue

Evolution test result:

1. Organoleptic evaluation: All formulations showed acceptable organoleptic properties with uniform appearance, smooth texture, and characteristic herbal odour suitable for rectal suppository preparation.

Sr. no.	Parameter	F1	F2	F3
1.	Colour	Light Brown	Brown	Dark Brown
2.	Odour	Mild characteristic	Pleasant characteristic	Slightly strong Herbal
3.	Shape	Bullet Shape	Bullet Shape	Bullet Shape
4.	Surface texture	Smooth	Smooth & Glossy	Smooth with slight softness
5.	Appearance	Uniform & elegant	Uniform without cracks	Uniform with slightly surface

Table no. 3 -Organoleptic evaluation

2. Physico chemical evaluation : Physico-chemical evaluation is performed to determine the quality, stability, safety, and effectiveness of flaxseed rectal suppositories.

Sr. no.	Parameter	F1	F2	F3
1.	Wt variation (g)	1.92 ± 0.03	1.95 ± 0.02	1.98 ± 0.04
2.	Hardness (kg/cm^2)	2.1	2.4	2.7
3.	Melting Point (^0C)	34.2	35.6	36.8
4.	Disintegration time (in Minute)	12	15	18
5.	PH	6.7	6.8	6.9
6.	Moisture content (%)	1.8	1.5	1.3

Table no.4 -Physicochemical evaluation

Discussion:

Flaxseed was selected because of its therapeutic properties such as anti-inflammatory, antioxidant, soothing, and laxative effects, which may be beneficial in the management of rectal disorders like hemorrhoids and constipation.

prepared suppositories of formulations F1, F2, and F3 showed satisfactory physical appearance with smooth texture, uniform colour, and absence of cracks or air bubbles, indicating proper molding and formulation compatibility. All formulations exhibited acceptable hardness, ensuring adequate mechanical strength during handling and storage.

The weight variation test showed minimal deviation among suppositories, confirming uniform distribution of the formulation mixture in each mold cavity. Drug content uniformity results indicated even distribution of flaxseed extract throughout the suppositories, which is essential for accurate dosing and therapeutic effectiveness.

melting point and liquefaction time of the suppositories were found to be suitable for rectal administration. The pH values of all formulations were near neutral, suggesting that the suppositories are less likely to cause irritation to rectal mucosa.

Among all formulations, F3 showed comparatively better results in terms of hardness, drug content uniformity, melting point, and stability. Therefore, F3 may be considered the optimized formulation for flaxseed rectal suppositories.

Selected formulation of polyherbal suppositories

Sr. no	Ingredients	Quantity taken	Therapeutic uses
1.	Flexseed extract	5 gm	Active herbal ingredient
2.	Gelatin	10gm	Suppositery base
3.	Glycerin	35gm	Plastisizer & base
4.	Purified water	4ml	Moistering agent
5.	Methyl paraben	0.1gm	Preservative

Table no.6: Selected formulation of polyherbal suppositories

Conclusion:

The present study successfully formulated and evaluated flaxseed rectal suppositories using suitable suppository bases and excipients. The prepared formulations showed satisfactory physicochemical properties including uniform appearance, acceptable hardness, proper melting point, suitable disintegration time, and good drug content uniformity.

The evaluation studies confirmed that the suppositories were stable, smooth, and compatible for rectal administration. The pH of the formulations was found to be near neutral, indicating minimal chances of irritation to rectal mucosa. The suppositories melted at body temperature and released the active constituents effectively, which may help in improving therapeutic action.

Among all formulations, F3 showed comparatively better results in terms of stability, hardness, melting behavior, and drug content uniformity, and was considered the optimized formulation.

Flaxseed possesses natural anti-inflammatory, soothing, antioxidant, and laxative properties, making it a promising herbal ingredient for rectal drug delivery systems. Therefore, flaxseed rectal suppositories may serve as a safe, effective, and economical herbal alternative for the management of anorectal disorders such as hemorrhoids and constipation.

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