

**DESIGN AND CHARACTERIZATION OF FLAXSEED SUPPOSITORIES AS NATURAL
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ABSTRACT

These comprehensive studies highlight the formulation and evaluation of herbal suppositories aimed at improving rectal drug delivery. Suppositories are solid matrix dosage forms that melt at body temperature and are good alternatives to oral medicines, particularly if the patients suffer from problems such as vomiting, nausea, or difficulty in swallowing or when drugs undergo extensive first-pass metabolism. The study was carried out by formulating seven distinct formulations (F1-F7) based on glycerinated Gelatin, followed by evaluation of weight variation, friability, hardness, disintegration time, and in vitro drug release. The experimental results demonstrated that the suppositories had excellent pharmaceutical properties, with weight variation within the acceptable pharmacopeial limit of $\pm 5\%$, friability below 0.35%, and an immediate disintegration time of 9–10 minutes. And release was found to be more than 95% in 23 min by dissolution studies, indicating good drug delivery. This result validly proved that flaxseed suppositories are natural, safe, and effective preparations to be used for constipation, Hemorrhoids, and gastrointestinal problems and represented the integration of folk wisdom with rational therapeutic concepts, which will have greater value for patient care.

KEYWORDS: Suppository, herbal suppository, flax extract, rectal drug delivery, glycerinated Gelatin, dosage form development.**INTRODUCTION**

Suppositories are solid dosage form and are prepared to be inserted in the rectum, vagina, or urethra. They are designed to melt, soften, or dissolve at body temperature and hence are able to release the active drug to be absorbed by the body tissues. This type of administration in the urine system is helpful for patients who cannot take in medications orally due to severe vomiting, nausea, or swallowing difficulties. The method is very useful, as it bypasses the gastrointestinal system and aims to deliver medication in a more controlled and therapeutic manner.

When manufactured, these dosage forms come in many shapes and sizes with a specified purpose. Appendices, rectal, or a mix of the two may be termed bullet-shaped as a vaginal form or oval and conical in shape.

Medications such as pain relief, inflammation, bowel, or fungal suppressants may be prescribed. The active ingredient is incorporated into a suitable base, such as cocoa butter or glycerinated Gelatin, which melts or dissolves upon administration to release the medication. The effectiveness uses and ensures the safety of the therapy due to the proper positioning and hygienic hand wear.



This study focuses on the formulation and evaluation of the herbal suppositories with flaxseed (*Linum usitatissimum*) as the principal bioactive component. Flaxseed is rich in nutrients and is one of the major sources of alpha-Linolenic acid (ALA) as well as protein, dietary fiber, and certain lignans such as secoisolariciresinol diglucoside (SDG). The dietary fiber in flaxseed helps to improve and regulate bowel action. The bioactive constituents of flaxseed, also, have associated effects with cholesterol-lowering and anticancer effects.

To harness these health benefits, flaxseed extract was incorporated into suppositories to relieve some local

gastrointestinal and anorectal disorders like constipation, hemorrhoids, and some associated infections. The extract was incorporated into a glycerin-gelatin base, and several formulations were made to optimize the active ingredient concentration and the physical properties of the dosage forms. Each formulation was characterized with respect to the physicochemical properties, disintegration time, and the *in vitro* evaluation of the suppository's therapeutic potential. The findings from this study conclude that the tested formulation of suppositories with flaxseed is not only safe and effective but also a valuable natural remedy for local bowel and anorectal conditions.

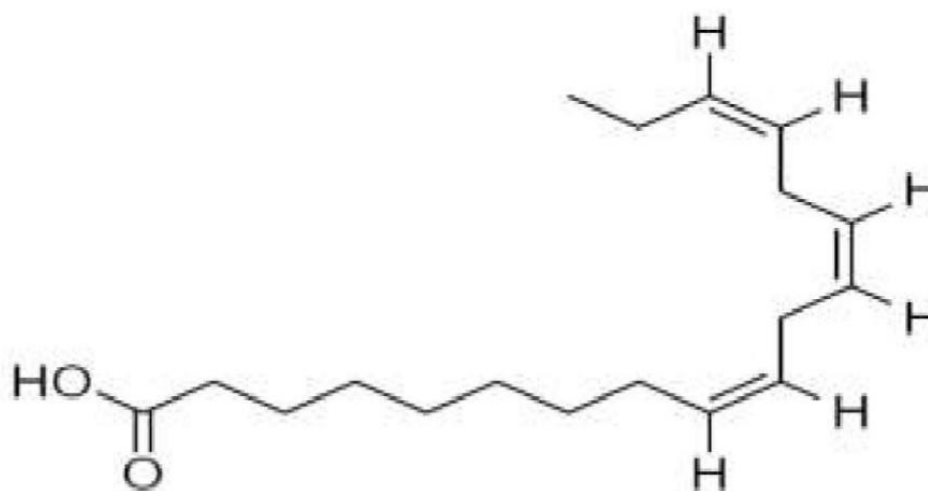


Figure 2: Alpha – linolenic acid(ALA).

CLASSIFICATION

A suppository is a medicated delivery system that is inserted into the rectum, vagina, and urethra. The classification of suppositories can vary based on their intended use, active ingredients, and formulation.

- Rectal suppositories are the most common type of suppositories and are used to deliver medications that act locally or systemically through the rectal mucosa. They can be used to treat constipation,

hemorrhoids, inflammatory bowel disease, nausea and vomiting, fever, pain, and other conditions.

- Vaginal Suppositories are used to deliver medications locally to the vagina for the treatment of vaginal infections such as yeast infections, bacterial vaginosis and trichomonas. They can also be used for

contraception, hormone replacement therapy and all alleviate menopause symptoms.

- Urethral Suppositories are used to deliver medications directly into the treatment of urinary tract infections, prostate problems and erectile dysfunction.

Table 1: classification of Suppositories based on the route of administration as below.

Type	Route	Shape	Main use
Rectal	Rectum	Torpedo shaped	Laxatives, fever, pain relief
Vaginal	Vagina	Oval/almond shaped	Infections, contraception
Urethral	Urethra	Pencil shaped	Urinary, prostate issues

FORMULATION

The composition of a suppository is an important factor that determines the release, stability, and medicinal effectiveness of the drug. It is in the appropriate of base is critical as it serves as the vehicle for the API (Active pharmaceutical ingredients). The optimal base should be inert, non-irritating to the mucous membranes, stable, and compatible with the drug. And on the other hand, it has to have just the right melting or dissolution properties to liberate the drug at the site of action. The main types of suppository bases are fatty bases and water-soluble or miscible bases.

Fatty bases, like semi-synthetic triglycerides (e.g., Witepsol, Suppocire) or theobroma oil, melt at body temperature, releasing the drug for absorption. The melting and solidification points of these bases are key parameters that need to be modified, usually via emulsifiers or other excipients, to prevent leakage post administration. In contrast, water-soluble bases such as PEGs or glycerinated gelatin do not melt but dissolve in the rectal fluid. PEG suppositories may attract water to the formulation, which can be mildly irritating but is helpful for drugs that need an aqueous environment for dissolution.

The choice of base is heavily dependent on the physicochemical properties of the API (Active pharmaceutical ingredients), its solubility in particular. A key challenge in suppository design is ensuring the drug is released from the base for absorption, it must be released from the base. To enable this, the drug must be poorly soluble in the base — otherwise its release can be impeded. If a drug is very soluble in the fatty base, there is a solid solution formed and the drug has no reason to exit the base. As a result, a drug that is insoluble in a fatty base but soluble in aqueous fluids is preferred for immediate release from a fatty suppository. Other excipients, like surfactants for wetting, antioxidants, and absorption enhancers are often included to optimize the drug's bioavailability and stability profile.

MANUFACTURING

Different methods are used in making drug suppositories. Whatever method used for their production depends on the drug in question as well as the amount being

manufactured. The main aim is to make sure the particulates are properly suspended and properly dosed.

Fusion Method (Molding)

This is the most common method. A base for the suppository such as cocoa butter is subjected to controlled melting. The liquid base now contains the suspended drug in uniform distribution. The entire mixture is placed in molds and is cooled until it solidifies.

Best For: Most drugs since it provides for bulk production.

Compression Method

This is the method where heat is not allowed. The drug is blended with a suppository base and both are in the powdered state. As in tablet making, the apparatus compresses the blended powders and forms a solid suppository.

Best For: Drugs where heat is lethal.

Hand Rolling Method

This is a very rudimentary technique and is on a very small scale. A soft base is mixed with the drug and is manually kneaded to form a uniform paste. The formed paste is then systematically rolled and pieces of the paste belong to a cylinder. These are obtained to be worked on individually.

Best For: Unlike others, the main purpose is not mass production. The aim of this method is to compound for pharmacy customers.

STORAGE CONDITION

Proper storage condition are important to ensure the effectiveness and safety of Suppositories. Here are some general guidelines for storing Suppositories.

- Store suppositories in a cool, dry place away from heat and light. Exposure to heat and humidity can cause Suppositories to melt, making them difficult to use and potentially reducing their effectiveness.
- Do not freeze suppositories. Freezing can cause the suppository to become brittle and break apart, making it difficult to use.

- Check the expiration date on the suppository package Before use. Do not use suppositories that have expired.
- Keep suppositories out of reach of children and pets. Suppositories can be dangerous if ingested.
- Follow any specific storage instructions provided by the manufacturer or your healthcare provider.
- Treatment of nausea and vomiting: Suppositories containing anti-nausea medications such as promethazine can be used to treat nausea and vomiting that cannot be controlled with oral medications.
- Treatment of fever: Suppositories containing acetaminophen or ibuprofen can be used to reduce fever In children and adults who cannot take oral medications.
- Hormone replacement therapy: Hormone suppositories Containing estrogen or progesterone can be used to supplement hormone levels in women who have undergone menopause

ADVANTAGES

- Avoids gastric passage: It's best for individuals who are unable to swallow pills, are nauseous, or vomiting.
- Works Faster & Better: The medication enters your bloodstream quickly because it is not destroyed by your stomach and liver first.
- Useful for Specific Problems: It's ideal for localized problems such as hemorrhoids or vaginal infection where you'd like the drug to act exactly where applied.
- Suitable for Unconscious Patients: It can be administered to unconscious or incapable patients of consuming medicine orally.

DISADVANTAGES

May Be Inconvenient: It may irritate or feel uncomfortable to use.

The Absorption May Be Irregular: At times the medicine may not be absorbed well, particularly if you have a diarrhoea or if it makes you go to the bathroom.

Inconvenient: Some people find it messy or unpleasant to administer.

APPLICATION

- Treatment of constipation: Suppositories containing laxatives such as glycerin or bisacodyl can be used to relieve constipation by stimulating bowel movements.
- Treatment of haemorrhoids: Suppositories containing medications such as hydrocortisone or witch hazel can be used to relieve the pain, itching, and swelling associated With hemorrhoids.
- Treatment of vaginal infections: Vaginal suppositories containing antifungal or antibacterial medications can be used to treat vaginal infections such as yeast infections or bacterial vaginosis.

THE STUDY OF HERBAL BASED SUPPOSITORIES

The rectal administration allows for the made-to-go directly through the rectal mucosa which is in contact with the systemic circulation, thus a fast therapeutic effect is achieved.

During the last few years, the interest in the combination of herbal and conventional pharmaceutical formulations has increased significantly. Herbal suppositories gain from the application form of the suppository and at the same time from the therapeutic advantages of the natural plant extracts. The preparations are usually utilized as their anti-inflammatory, antimicrobial, laxative, or soothing properties, thus, they become a complementary approach in the therapy of such diseases as hemorrhoids, constipation, and local infections. The use of herbal ingredients may additionally lower the risk of side effects that are caused by synthetic drugs which in turn, leads to better patient compliance.

Material and preparation of herbal suppository

Whole flaxseeds (*Linum usitatissimum*) were purchased from a local market. Gelatin and glycerin were used for the suppository base. Methylparaben was used as a preservative. Purified water was used throughout the process. All materials were of standard pharmaceutical grade. The suppository base was prepared using glycerinated gelatin. The base composition was as follows.

Table 2: Composition of suppository base.

Purified water	10%
Gelatin	20%
Glycerin	70%

Table 3: Code and composition of formulation.

Sr no	Ingredient	Use
1	Flaxseed extract	Laxative
2	Glycerin	Base
3	Gelatin	Base
4	Purified water	Base
5	Methylparaben	Preservative

FORMULATION OF HERBAL SUPPOSITORY

Seven formulations (F1 to F7) were prepared by the heat moulding method. The composition of each formulation is given in Table 4. The active ingredient (flaxseed

extract) was mixed into the molten base at 40–45 °C, poured into suppository moulds, and allowed to cool and solidify.

Table 4: Composition of flaxseed suppository formulation (F1–F7)

Formulation	Flaxseed extract (%)	Glycerinated gelatin base (%)	Special note
F1	50	50	-
F2	16	84	-
F3	40	60	-
F4	30	70	-
F5	16	84	-
F6	10	90	-
F7	50*	50	Contains flaxseed extract + aloe vera gel

The produced suppositories were put through the following tests

Visual Characterization: Suppositories in which we looked for signs of cracking, subsidence, fat bloom, exudation and migration of active ingredients.

Weight Variation Test: In each batch the weight of 20 suppositories was determined individually, the weight variation should not be over $\pm 5\%$ (with two allowed to vary by $\pm 7.5\%$).

Friability Test: The percent friability was determined by use of a Roche friabilator (100 rotations at 25 rpm) and we calculated it as.

$$\% \text{ Friability} = \frac{W_1 - W_2}{W_1} \times 100$$

Melting Point Test: The time of melting was determined at $37.5^\circ\text{C} \pm 0.5^\circ\text{C}$ and pH 7.2 in phosphate buffer.

Hardness Test: Monsanto determined the hardness of it.

Liquefaction Test: Lavage time was measured in a burette that had 5 mL of phosphate buffer at pH 7.2 at $37 \pm 0.5^\circ\text{C}$.

Disintegration Test: During a disintegration test we used a disintegration apparatus with phosphate buffer pH 7.2 at $37 \pm 0.5^\circ\text{C}$.

In-vitro Drug Release Study: The study was performed in a USP Type I rotating basket apparatus which had 900 mL of phosphate buffer at pH 7.2 at $37 \pm 0.5^\circ\text{C}$ and 50 rpm. At various intervals we took samples which we analysed at 304 nm with a UV spectrophotometer.

RESULT AND DISCUSSION

The flaxseed suppositories were successfully made using the heat moulding method with a glycerinated gelatin base. We evaluated the formulations through a series of physicochemical tests, and the findings are detailed and discussed below.

Table 5: physicochemical Evaluation of alpha Linolenic Acid (ALA).

Sr no	Characteristics	Result
1	Colour	Clear colourless
2	Taste	Bitter
3	Solubility	Soluble in ethanol and chloroform
4	Melting point	-11.3°C to -11°C

Table 6: Physical Parameters of the Prepared Suppositories.

Formulation code	Length(cm)	Width (cm)	Weight variation(gm)
F1	1.74	0.65	1.689 ± 0.12
F2	1.75	0.70	1.679 ± 0.10
F3	1.73	0.65	1.712 ± 0.11
F4	1.76	0.68	1.668 ± 0.10
F5	1.71	0.70	1.753 ± 0.10
F6	1.80	0.90	1.675 ± 0.12
F7	1.79	0.89	1.649 ± 0.10

Table 7: Melting Behaviour and Friability of Suppositories.

Formulation	Melting Temp	Melting (Min)	Friability (%)
F1	37	25.0 ± 0.24	0.27
F2	38.1	24.5 ± 0.25	0.33
F3	37	25.0 ± 0.34	0.28
F4	38.2	24.4 ± 0.34	0.27
F5	37.5	25.0 ± 0.15	0.30
F6	37	26.0 ± 0.34	0.32
F7	38.2	27.0 ± 0.25	0.31

Table 8: Mechanical Strength and Release Characteristics.

Formulation code	Hardness	Liquefaction time	Disintegration time
F1	1.50 ± 0.18	2.35 ± 0.56	10.00 ± 0.038
F2	2.01 ± 0.24	2.53 ± 0.01	9.58 ± 0.05
F3	1.42 ± 0.25	1.46 ± 0.05	9.26 ± 0.024
F4	1.50 ± 0.11	2.52 ± 0.21	9.28 ± 0.031
F5	2.05 ± 0.14	1.48 ± 0.43	9.56 ± 0.08
F6	2.06 ± 0.14	1.78 ± 0.06	9.87 ± 0.11
F7	2.50 ± 0.25	2.55 ± 0.21	10.00 ± 0.025

The flaxseed suppositories had been made and tested with positive results. All the batches were uniform in structure, of good strength, and had a quick melting rate at a body temperature. The tested samples allowed the active substance to be released by more than 50% within 20 minutes and almost all of the medicine within 30 minutes. Such a rapid release of the drug, together with the natural laxative properties of flaxseed, provides the suppositories with the possibility of quick alleviation of the symptoms of constipation and hemorrhoids. The base of glycerinated gelatin was very suitable for the production of herbal suppositories.

FUTURE SCOPE

(I) Targeted Treatment: A product like suppositories is perfect for small local problems, e.g. hemorrhoids (witch hazel), vaginal infections (tea tree oil), and prostate health by delivering the herbs right at the site.

(II) Natural Alternative: The patient demand for healthcare products that are plant-based, and free of chemicals is the leading factor of the market growth.

(III) Bypassing Digestion: The product is perfect for patients who are not able to swallow pills or are nauseous since the absorption takes place through rectal/vaginal membranes.

CHALLENGES

- **Standardization & Quality:** It is quite hard to achieve the potency of an herbal extract and its effect of each batch to be the same.
- **Scientific Evidence:** There are not many clinical trials that are large-scale and safety and effectiveness as a conclusion for suppositories for specified diseases.
- **Regulatory Hurdles:** The laws that govern herbal medicines are sometimes quite ambiguous or strict, and this makes approval and marketing a complicated process.

- **Patient Acceptance:** The patient group that suffers culturally and personally from the suppository route of discomfort in administration may be limited in its use.

CONCLUSION

Suppositories are valuable dosage form alternative to oral administration particularly in cases of when patient can't swallow pills. A study with flaxseed (a natural plant) to make a suppository. They mixed flaxseed with gelatin and glycerin to create a solid form that melts inside the body. It worked really excellent—the suppository melted quickly and released the medicine properly. This shows that natural ingredients like flaxseed can be turned into modern medicines that are easy to use and work fast. This demonstrates that natural ingredients successfully incorporated into modern pharmaceutical formulations. So, suppositories are useful, and using plants like flaxseed in them is a smart idea.

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