FORMULATION AND EVALUATION OF HERBAL RECTAL SUPPOSITORIES CONTAINING FLAX SEED EXTRACT

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ABSTRACT

The formulation and evaluation of herbal rectal suppositories containing flaxseed extract is an innovative approach in the development of natural and effective therapeutic systems. Flaxseed (*Linum usitatissimum*) is widely known for its pharmacological properties, including anti-inflammatory, antioxidant, and laxative effects, attributed to its high content of lignans, omega-3 fatty acids, and mucilage. This study aimed to develop a rectal delivery system utilizing flaxseed extract to address conditions such as constipation, inflammation, and local discomfort in the rectal region. In order to prevent its reported gastrointestinal irritation and to give children a quick onset of effect, the current study set out to develop and assess rectal suppositories containing flex seed extract as a new dosage form. Glycerol-gelation was used as the suppository basis to make suppositories in a variety of formulations. The physical characteristics of the produced suppositories, weight variation, drug content, melting point, fracture point, and disintegration time hardness test were examined. According to the results, different concentrations of the glycerol-gelatin base were utilised with increasing drug concentrations, and the outcomes with their standard parameters varied. Out of the six formulas presented, F3 demonstrated the best formulation.

Keywords: Glycerol-gelatin basis, evaluation criteria, and flax seed extract from rectal suppositories.

INTRODUCTION

An oral dose form called a suppository is used to deliver pharmaceuticals by inserting it into a body orifice, where it dissolves or melts and has local or systemic effects. [1-2]

FLAX SEEDS DRUG PROFILE

Natural Source: The dried, ripe seed of the Linum usitatissimum Linn. plant, **Family**: Linaceae, is known as flax seed.

Flax seed includes a variety of chemical components, including linamarin, a cyanogenetic glycoside, fixed oil (30–40%), mucilage (6–10%), protein (linin and colinin) at 25%, and a minor amount of the enzyme lipase. There are four different types of carbohydrates: sucrose, raffinose, cellulose, and mucus. Phaseolunatin and linamarin are both glucose or acetone cyanohydrines. [3]

PREPRATION METHOD OF SUPPOSITORIES [4-5]

Generally there are three methods of preparation of suppositories, which are as follows:

1. Hand Rolling Method
2. Hot Process or Fusion method
3. Cold Compression Method

1. Hand Rolling Method

Drug + Additive

↓

Fine power and mixed in bases

↓

Apply lubricants on rolling tile

↓

Above mass are rolled by hand in cylinderical shape

↓

Then cut it and packed and store it.

Mould should be of stainless steel, nickel, alluminium, copper, plastic, etc.

2. Hot Process or Fusion method

Gelatine + Glycerol base are melt by using heat

↓

Disolve or disperse the drug (API) into base

↓

Remove the mixture of API and base from the heat

↓

Pour the mixture into lubricated mould and allow to cool down

↓

Freeze the mould and remove the formed suppositories from the mould.

3. Cold Compression Method

Drug + Additive

↓

Make fine powder and mixed with bases (cocoa butter)

↓

Lubricant ppply in moulds

↓

Placed the mass between or centre of the cylinder

↓

Applied the pressure and give the desired shape to mass

↓

Applied pressure and release the suppositories by removing stop plate

↓

Cooled, Packed, and Stored the suppositories

FACTORS AFFECTING FROM RECTAL SUPPOSTORIES [5]

Generally there are two main factors which affects the rectal suppositories :

I. Physical Factors :-

Following factors affects the rectal suppositories

a. Circular route / Circulation
b. Colonic content
c. pH & lack of buffering capacity of rectal fluid

II. Physico-chemical Factors :-

Affects the absorption of drug administered in the form of suppositories

a. Particle size
b. Partition-H2O Solubility of drug partition-coefficient
c. Solubility
d. pH
e. Presence of adjuvants in base[8]

METHODS [6-11]

2. Extraction method of Flax seed extract

Process of Extraction of flax seed are done by following steps :-

- Weigh 20 gram of flax seed, roast and crush it in a mortar pestle.
- Add the crushed flax seed in distilled water.
- Heat the mixture of flax seed and distilled water on magnetic stirrer for 15-20 minute.
- After heating the mixture cool the mixture and filter it with muslin cloth.

3. **Preparation method of suppositories by fusion method**

Basically rectal suppositories are prepared by Fusion method, formulation of suppositories by fusion method are prepared by following steps :

Gelatin in glycerol are melt by using heat form glycerogelatin base

↓

Dissolve or disperse the drug (API) into base

↓

Mix it uniformly

↓

Pour the mixture into lubricated mould and allow to cool down

↓

Freeze the mould and remove the formed suppositories from the mould.

4. **Formulation table of rectal suppositories.**

Table No.:-1 Composition table of rectal suppositories

S.NO.	Ingredients	F1(%)	F2(%)	F3(%)	F4(%)	F5(%)	F6(%)
1.	API (Flax seed extract)	50	25	50	25	50	25
2.	Base	80	70	60	80	70	60
3.	Methyl paraben/Ethanol	5	5	5	5	5	5

Table No.:-2 Composition table of Glycero-gelatin Base

S.NO.	Ingredients	F1%	F2%	F3%	F4%	F5%	F6%
1.	Glycerin	70	60	50	70	60	50
2.	Gelatin	10	10	10	10	10	10
3.	Distilled water	20	20	20	20	20	20

RESULT AND DISCUSSION

1. Physico-chemical properties of rectal suppositories

Formulation code	Colour	Shape	Texture	Length(cm)	Width(cm)	Weight variation
F1	Yellowish brown	Bullet	Smooth	1.5	0.5	1.558
F2	Yellowish brown	Bullet	Smooth	1.6	0.5	1.672
F3	Yellowish brown	Bullet	Smooth	1.5	0.5	1.453
F4	Yellowish brown	Bullet	Smooth	1.6	0.5	1.563
F5	Yellowish brown	Bullet	Smooth	1.5	0.5	1.693
F6	Yellowish brown	Bullet	Smooth	1.5	0.5	1.725

2. Melting range test

Formulation code	Temperature (Celsius)	Liquification time	Tim222.3e (min)
F1	37.5	2.32	25.5
F2	38	3.05	22.3
F3	38	2.53	20
F4	38.5	1.40	22.1
F5	38.1	2.13	24.3
F6	37.3	1.3	23.1

5. Hardness test and disintegration test

Formulation code	Hardness(kgcm^3)	Disintegration time(min)
F1	0.5	9.21
F2	1	9.51
F3	0.8	8.91
F4	1.2	9.67
F5	1.3	10.12
F6	1.1	10.20

CONCLUSION

The research study on suppositories containing flaxseed extract successfully demonstrated the feasibility and effectiveness of using flaxseed as a natural therapeutic agent in rectal drug delivery systems. The formulated suppositories exhibited optimal physical and chemical properties, ensuring stability, uniformity, and consistent release of active constituents. Their antioxidant and anti-inflammatory activities, combined with their ability to alleviate rectal discomfort and promote bowel regularity, affirm the therapeutic potential of flaxseed extract. The development of herbal suppositories containing flaxseed extract demonstrated significant potential as an effective and natural therapeutic option for rectal disorders. The formulated suppositories exhibited desirable physicochemical properties, including uniformity, stability, and efficient drug release. In vitro and ex vivo studies confirmed their safety, antioxidant, and anti-inflammatory activities, highlighting the therapeutic potential of flaxseed extract for managing inflammation, constipation, and discomfort in the rectal region. This study underscores the feasibility of utilizing flaxseed extract in rectal delivery systems, offering a localized, non-invasive, and patient-friendly approach. Further clinical studies are needed to validate the efficacy and safety of these suppositories in human subjects and optimize the formulation for large-scale production and commercialization. These suppositories represent a promising advancement in integrating herbal medicine with modern pharmaceutical technology.It can be concluded that rectal suppositories containing flax seed extract can be prepared by fusion melting method by using glycerol-gelatin bases used to formulate the suppositories with different concentration of flax seed as laxative as well as suppository base. Among all the six formulations f3 showed better in disintegration time, liquification time and in dissolution rate. so we concluded that with decreasing concentration of base as polymers used increasing the disintegration as well as melting time in the cavity.

REFERENCES

1. https://en.wikipedia.org/wiki/Suppository
2. https://www.pharmaguideline.com/2021/10/definition-types-advantages-and-disadvantages-of-suppositories.html?m=1
3. **Mishra Preeti,Singh Rajat, et.al,** Formulation and Evaluation of flax herbal suppositories, Journal of Drug Delivery and Therapeutics, 2022, ISSN No.- 2250-1175
4. **https://www.pharmaguideline.com/2021/10/methods-of-preparation-displacement-value-calculation-evaluation-of-suppositories.html#:~:text=Suppositories%20are%20generally%20prepared%20by,mixing%20ingredients%20with%20a%20base.**
5. **https://www.pharmaguideline.com/2021/10/methods-of-preparation-displacement-value-calculation-evaluation-of-suppositories.html#:~:text=Suppositories%20are%20generally%20prepared%20by,mixing%20ingredients%20with%20a%20base.**
6. **Johnson Raphel, et.al,** Formulation of suppositories of Alum produced from bauxite waste in Ghana for the treatment of Hemorrhoid, The Scientific World Journal Volume 2021, Article ID 6667562.
7. **ShaltoutAsmaa S, et.al,** Vaginal suppositories of cumin seeds essential oil for treatment of vaginal candidiasis :Formulation,in vitro, in vivo and clinical evaluation, European Journal of Pharmaceutical Sciences, 2020.

8. **Sonin Abhishek, et.al,** Formulation and Evaluation of Luliconazole Suppositories for the treatment of Candida Infection (Vulvovaginal candidiasis), Journal of Pharma and Drug Regulatory Affairs Volume-4, 2022, ISSN No- 2582-3043.
9. **Potnis Vaishali, et.al,** Design, Formulation, and Evaluation of Herbal Rectal Suppositories for the treatment of Colitis, World Journal of Pharmaceutical Research, Volume- 11, 2022, ISSN 2277-7105.
10. Formulation and Evaluation of Mefenamic Acid Suppositories, Panacea Journal of Pharmacy and Pharmaceutical Sciences, 2015, ISSN 2349-7025.
11. **Abbaspour Mohammadreza, et.al,** Development and Evaluation of Vaginal Suppository Containing Althaea officinalis L. Polysaccharide Extracty, Brazilian Journal of Pharmaceutical Sciences,