

**“MEDICATED GHRITA” BASED HERBAL
SUPPOSITORIES FOR THE TREATMENT OF
ANORECTAL DISORDER**

Submitted to

ATMIYA UNIVERSITY



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Declaration

We, all hereby declare the Work is presented in the project report entitled **MEDICATED GHRITA BASED HERBAL SUPPOSITORIES FOR THE TREATMENT OF ANORECTAL DISORDER**

It is an authentic record of work carried out by us during the studying period of semester 8 at and under the guidance of Atmiya University, Rajkot, and is being submitted for partial fulfillment of the requirement for the award of a bachelor's degree in B.pharm. This is not submitted anywhere else for the award of any other degree/diploma.

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Title "Medicated Ghrita" Based Herbal Suppositories For The
Treatment of Anorectal Disorders

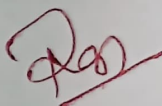
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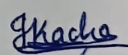



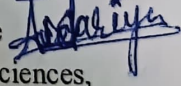
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Abstract

This study presents the development and evaluation of polyherbal suppositories containing Jatyadi Ghrita (JG) for the treatment of anorectal disorders like fissures, fistulas, and hemorrhoids. JG is a renowned Ayurvedic formulation with wound-healing properties. The suppositories were prepared by the fusion or melt process, incorporating JG along with natural beeswax as the base, and oils like Kasisadi oil, neem oil, and tea tree oil for their therapeutic benefits. Various trials were conducted to optimize the composition, and the final formulation consisted of JG (70%), beeswax (10%), Kasisadi oil (10%), neem oil (5%), and tea tree oil (5%). The optimized suppositories were evaluated for parameters like visual examination, disintegration time (28 minutes), liquefaction time (8 minutes), melting range ($37.5 \pm 2^{\circ}\text{C}$), and mechanical strength (2.26 kg). The results complied with the standard values specified in the Indian Ayurvedic Pharmacopoeia, indicating their suitability for rectal administration. The developed JG suppositories demonstrated desirable physicochemical properties and could potentially serve as a practical, non-invasive treatment option for anorectal disorders, pending further clinical studies.

Keywords: Jatyadi Ghrita; Suppository; Hemorrhoids; Tea tree oil.

1. Introduction

The main goal of fast food and Ayurveda is “Health”; changes in nutrition, schedule, and lifestyle, in addition to being sedentary, have a negative impact on the body overall, with the digestive system in particular suffering from Anorectal diseases [1].

Anorectal problems are becoming more and more common in society. These anorectal disorders can be brought on by trauma, ischemia, or high anal pressure. Less than half of the blood circulation in the anal canal occurs in the posterior midline, where fissures are most common [2]. Healing may be slowed by decreased blood flow. Studies show that in control groups, the posterior anal midline has higher blood flow than the fissure site. Anal fissures result in elevated anal canal pressure because of the heightened tone of the internal anal sphincter and spasm of the surrounding musculature. This spasm might have been brought on by the original trauma pain.

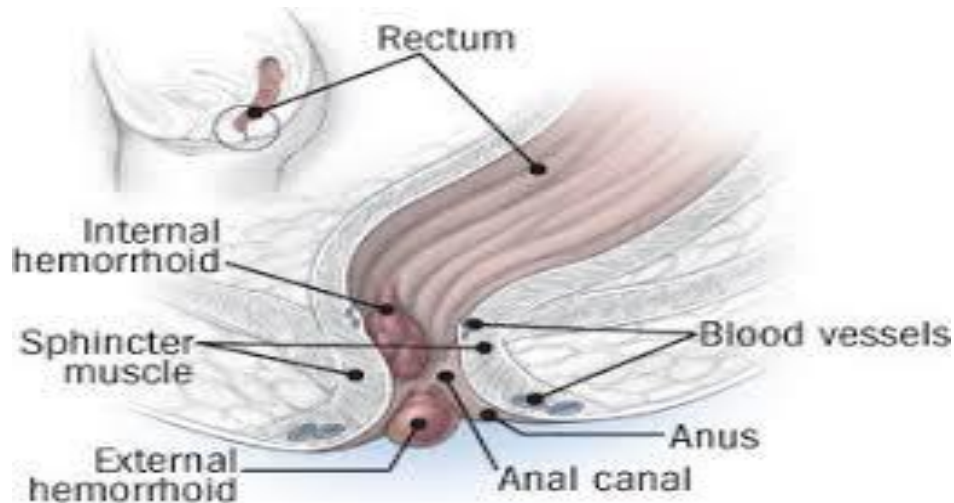


Fig.1 Diagram of Anorectal Disorder

1.1 What are Anorectal Disorders?

Diseases affecting the anus and rectum are known as anorectal diseases [3].

➤ Types of Anorectal Disorders:

1. Anal or rectal abscess
2. Anal fissures
3. Anal fistula
4. Hemorrhoids
5. Fecal incontinence
6. Rectal prolapse

➤ Anorectal disorders symptoms and risks:

- A visible crack in the skin of the anus.
- Bleeding after bowel movements, with or without pain.
- Diarrhea or constipation.
- Gas and bloating.
- Itching or burning in the anal area.
- Lumps or swelling within and around the anal area.
- Pain during or after a bowel movement.

➤ **Treatment:**

Ayurvedic treatment is considered to be very effective in the treatment of anorectal disorders and *JG* is considered to be best for it.

1.2 Jatyadi Ghrita:

A traditional Ayurvedic remedy called JG is used to heal different kinds of ulcers [3]. These can include deep-seated ulcers, painful ulcers, bleeding ulcers, non-healing ulcers, and oozing/weeping ulcers [4]. Because of its superior therapeutic qualities, Ayurveda suggests using JG for skin ulcers, fistula in Ano and Piles, and other bleeding ulcers [5]. To hasten the healing process, JG is applied externally to the damaged area [6]. When used as directed, JG is usually well accepted and has no negative side effects.

➤ **Benefits of JG:**

1. Skin Ulcer:

Jatayadi reduces edema, speeds up the healing of ulcers, and restores the skin's natural texture [7]. Its Ropan (healing) property is the reason for this. When applied to the affected area, its Sita (cold) nature also helps to lessen the searing sensation.

2. Piles:

Hemorrhoids, or piles, are a disorder characterized by enlarged and bulging veins in the rectal area that give the appearance of a mass surrounding the anus [8]. According to Ayurveda, piles are referred to as arsh and are brought on by a sedentary lifestyle and poor diet [9]. All three of the doshas in the body are hampered as a result, but primarily Vata. Owing to enlarged and swollen veins, there may occasionally be bleeding as well as burning in the anus [10]. Because of JG's cooling and healing qualities, applying it to the injured area instantly relieves burning and helps stop bleeding.

3. Anal fistula:

A tiny tube called an anal fistula, sometimes called fistula-in-Ano, runs from an inflamed gland inside the anus to a skin hole surrounding the anus. It could result in pain and swelling around the anus [11]. It is referred to as Bhagandara in Ayurveda. As the name implies, Bhagandara is made

up of the words Bhaga and Darana. The perineum, or space between the anus and genitals, is referred to in Sanskrit as Bhaga, and the verb darana meaning to rip or demolish [12]. Because JG is cold, applying it to the injured area instantly reduces pain and swelling. Because of healing properties, it also aids in the torn part's rapid mending.

4. Bleeding cuts:

For minor bleeding cuts on any area of the body, JG works well. Jataydi Ghrita hastens the healing process and aids in bleeding management [13]. It's cool and healing qualities are the cause of this.

5. Skin itching:

Skin irritation can result from dryness or from excessive perspiration [14]. This indicates that the majority of vata-pittas are responsible for the skin's burning or itchy feeling. Jatayadi Ghrita's oily and cool qualities aid in reducing inflammation and irritation [15].

1.3. Aim: To develop and evaluate polyherbal suppositories containing Jatayadi Ghrita (JG) for the treatment of anorectal disorders.

1.4. Objectives:

- To formulate suppositories incorporating JG as the main active ingredient, along with other herbal components like Kasisadi oil, neem oil, and tea tree oil.
- To optimize the composition of the suppository formulation, including the appropriate ratio of JG and the base (beeswax) to achieve desired physicochemical properties.
- To evaluate the developed JG suppositories using various standard tests, such as visual examination, disintegration test, liquefaction time, mechanical strength, and melting range.
- To assess the physical stability of the optimized JG suppository formulation over a specified period.
- To compare the evaluation results with the standard values specified in the Indian Ayurvedic Pharmacopoeia to ensure compliance and suitability for rectal administration.

2. Materials & Methods

2.1 Materials

Individuals experiencing discomfort, per rectal bleeding, an ulcer in the front or posterior section of the anus, anal spasm, and constipation are indications and symptoms of an acute fissure in the anorectal [16]. An important factor in the formation of cracks in anorectal is diet. It was recommended to all patients that they avoid eating greasy and spicy meals, such as hot peppers and chili peppers. Constipation can be avoided by eating the correct amount of fibre-rich food and drinking enough water to avoid having too-hard stool [17].

Here in this formulation we have mainly focused on developing suppository by using following materials:

Table 1. Materials used in the formulation.

Sr. No.	Materials	Uses
1.	JG	Herbal API
2.	Bees Wax	Base (solidifying agent)
3.	Kasisadi oil	Antiseptic
4.	Neem Oil	Anti-bacterial
5.	Tea tree oil	Anti-inflammatory, Anti-fungal

1) Jatyadi Ghrita:

Due to Superior therapeutic qualities, Ayurveda suggests using JG for skin ulcers, fistula in Ano and Piles, and other bleeding ulcers. Here the JG plays an important pharmacological role[18]. It is used as main herbal API in the preparation of this formulation. It is used in wound healing, as an analgesic and to break the bonds between fecal matter and intestinal mucosa by completing the digestion process and bring quick excretion of flatus and fecal matter. Salicylic acid, having antibacterial, anti-inflammatory, and antifungal qualities, is present in it. The roots have anthelmintic, purgative, and intoxicating properties.

To hasten the healing process, JG is applied externally to the damaged area and when used as directed, JG is usually well accepted and has no negative side effects. Table 2 represents the composition of JG.

Table 2. Composition of JG

Composition		Value (%)
Jatipatra	Jasminum officinale	1.923
Nimbpatra	Azadirachta indica	1.923
Patolpatra	Trichosanthes dioic	1.923
Katuki	Pierohi zakiron	1.923

Daruharidra	Berberis aristate	1.923
Haridra	Curcuma longa	1.923
Sariva	Hemidesmus indicum	1.923
Manjistha	Rubla cordifolia	1.923
Khus	Andropogon muricatus	1.923
Mome	--	1.923
Shuddhmorthuthu	--	1.923
Yashtimadhu	Glycyrrhiza glabra	1.923
Karanj	Pongamia pinnatapierre	1.923
Goughritam	--	q.s.



Fig.2 Marketed formulation of JG

2) Bees Wax:

Natural Beeswax is a product made from the honeycomb of the honeybee and other bees. Here in this formulation we are using bees wax as a suppository base and as a solidifying agent which shows improved chemical stability, moldability, and shelf-life of the product. Drugs are dispersed in a suitable base. It may be necessary to add beeswax to raise the melting point of finished suppositories back to the desired range [19].

There are two types of suppository bases

- One is lipophilic base (e.g. bees wax, cocoa butter) which is melted at body temperature and
- Other is hydrophilic base (e.g. gelatine) which is dissolved in rectal fluid to release to drug.



Fig.3 Natural Bees Wax

3) Kasisadi oil:

Kasisadi Taila is polyherbal medicated ayurvedic oil that can be used for external application on piles, corns and warts [20]. It has antiseptic and disinfectant activities.

Jatyadi and Kasisadi oil are manufactured from natural components and have been used for years by Ayurvedic practitioners to treat a variety of health issues, including reduction in bleeding, relieving pain, decreasing swelling, relaxing the anus, reducing itchiness in the anal area, improving the texture and complexion of skin [21].



Fig.4 Kasisadi oil

4) Neem Oil:

Neem preparations are reportedly efficacious against a variety of anorectal disorders and powerfully address a range of intestinal issues such as bloating, cramping and constipation [22]. It is the oil obtained from neem seeds [23]. Applying this oil on the affected area twice a day reduces pain and itching thereby reducing the probability of hemorrhoids and related disorders [24].



Fig.5 Neem Oil

5) Tea Tree Oil:

Tea tree oil comes from the leaves of the tea tree [25]. Traditionally it is used as an anti-inflammatory, antiseptic (germ killer) and as a herbal medicine [26]. Today, external use of tea tree oil as well as in combination with herbal medicine is promoted for various anti-inflammatory conditions such as lice, piles, cuts, mite infection and in various anorectal disorders [27, 28].



Fig.6 Tea Tree Oil

2.2 Methods

2.2.1 Preparation of JG suppository

Measure 7 ml of JG and transfer it into a porcelain dish. Subsequently, measure 0.5 ml of Neem Oil and 1 ml of Kasisadi Oil, and blend them with JG. Maintain the mixture at a constant temperature of 40° C. Accurately measure 1 gm of Beeswax and subject it to thorough washing to eliminate all the impurities. Proceed by transferring the purified beeswax into a porcelain dish, and then apply controlled heating within the temperature range of 62 to 65° C to facilitate melting of beeswax [29].

Transfer the JG mixture into the beeswax mixture with continuous swirling to ensure thorough homogenization. Finally, incorporate 0.5 ml of Tea Tree Oil into the formulated mixture. The mold is refrigerated to facilitate the solidification process of the suppository [30]. Following this, the formulated liquid is swiftly dispensed into the mold using a sterilized syringe. Each suppository should be filled with 10 to 15 tappings of the mold. It's important not to tightly pack the mold to allow adequate space for vapours to escape, thus preventing the formation of a hole at the center of the suppository [30]. Keep the mold at room temperature for 5 minutes. Then keep the mold for refrigeration for 1 hour.

Table 3. Formulation of suppository

Sr. No.	Ingredients	Quantity
1.	JG	7 ml
2.	Beeswax	1 gm
3.	Kasisadi Oil	1 ml
4.	Neem Oil	0.5 ml
5.	Tea Tree Oil	0.5 ml

2.2.2 Preparation of Phosphate Buffer

Accurately measure 6.8 gm of Potassium Dihydrogen Orthophosphate and add 1.56 gm of Sodium Hydroxide in 900 ml of water [31]. Adjust the pH 7.4 with sodium hydroxide solution and add q.s. water upto 1000 ml [32].



Fig.7 Prepared Herbal Suppository

2.3 Methods of Evaluation Tests

2.3.1 Visual Examination:

The suppository's colour and surface features are comparatively simple to evaluate. It's critical to make sure there are no signs of fat blooming, fissuring, pitting, exudation, sedimentation, or active ingredient migration. Both the whole suppository and a longitudinally split specimen can be

examined [33].

2.3.1.1 Shape: Whether the suppository is in the right shape or not, it is still advisable to check its consistency and stability.

2.3.1.2 Surface condition: The following can be checked: brilliance, dullness, mottling, cracks, dark regions, axial cavities, bursts, air bubbles, holes, etc.

2.3.1.3 Colour: The intensity, nature and homogeneity of the colour should be verified.

2.3.1.4 Odour: When processing comparable suppositories, it can be helpful to confirm the smell as it also defines the degradation of suppository.

2.3.1.5 Size and weight: Size and weight of 10 suppositories are measured and if weight is found to be less than the ideal then it is advisable to check whether the mould is evenly filled or not. The weight of the suppositories can be measured by automatic balance machine [34].

2.3.2 Pharmacopoeial tests:

2.3.2.1 Disintegration Test:

The basket rack assembly is placed in a 1-liter beaker of water, simulated gastric fluid, or simulated intestinal fluid at $37^{\circ}\text{C}\pm 2^{\circ}\text{C}$ so that the suppository stays 2.5 cm from the bottom of the beaker. The disintegration time of the suppositories is measured using the disintegration test apparatus. A typical motor moves the basket up and down at a frequency of 28 to 32 CPM (cycles per minute) over a distance of 5 to 6 cm. Specialty If all of the suppositories dissolve and the particles pass through the #10 mesh, the disintegration test will be successful screen in the allotted time.



Fig.8 Disintegration Apparatus

2.3.3 Non pharmacopoeial Tests:

2.3.3.1 Mechanical Strength/Crushing Test:

Suppositories can be categorized as elastic or brittle based on how much force is needed to shatter them. The mass (in kilos) that a suppository can support without breaking has been measured through tests. A satisfactory outcome is a pressure of at least 1.8–2 kg. Weights are applied to the suppository in an increasing amount while it is upright until it loses structural integrity and

crumbles. The test's goal is to confirm that the suppository can be moved under in typical circumstances, and given to the patient.

2.3.3.2 Liquefaction Time:

Testing for liquefaction gives insight into how a suppository behaves at a maximum temperature of 37 °C. The most widely used test is Krowczynski's method, which calculates how long it takes a suppository to liquefy in the presence of water at 37°C at pressures that are comparable to those in the phosphate buffer (in rectum). The process of liquefaction should not take more than thirty minutes [35]. The apparatus for Krowczynski's approach is a 235 mm long glass tube with a 16 mm diameter and a base diameter decrease of roughly 6 mm[36]. To make cleaning easier after use, a tiny rubber stopper blocks one end. There is a thermostat that is calibrated in tenths of a degree Celsius. Water at 37 °C in a water bath is placed at consistent temperature to move about [37] .

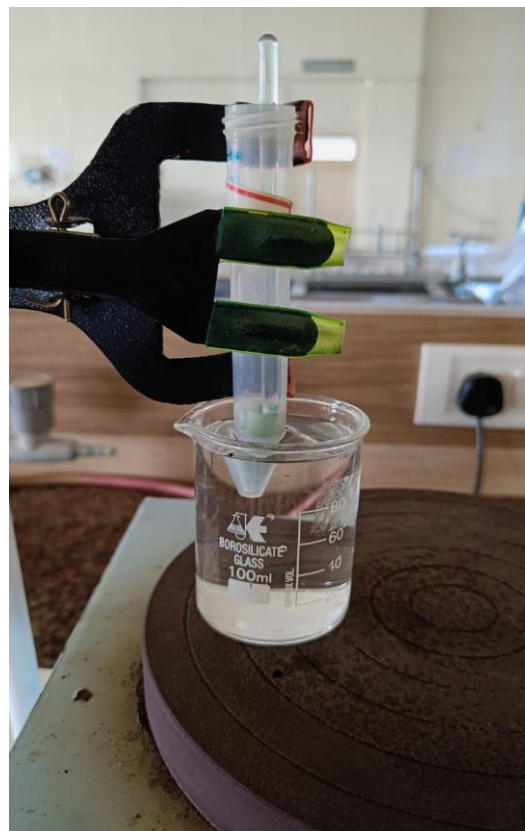


Fig.9 Liquefaction Apparatus

2.3.3.3 Melting Range:

The melting point should be equal to or less than 37°C [38]. A non-destructive method must be used because if the suppository is melted before a measurement is made, the suppository constituents may be transformed into a metastable state [39]. The melting test consists of placing a suppository on the surface of water thermostatically controlled at 37°C and verifying the complete melting of the suppository within few minutes [40].

3. Results and Discussion

This study presents the findings and interpretations of the study aimed at developing and evaluating herbal suppositories containing JG for the treatment of anorectal disorders. Table 4 summarizes the results of the evaluation tests performed on the optimized formulation of JG suppositories.

Table 4 Various Batch Trials for the development of herbal suppositories.

Trials	Composition	Observation	Inference
Trial 1	JG (78%) and Shea Butter (22%).	The suppositories were not solidified from inside and thus remained loose.	Thus, we inferred that the quantity of base should be increased and quantity of JG should be decreased.
Trial 2	JG (50%) and Shea Butter (50%).	The suppositories were intact but the quantity of JG was decreased.	Thus, we inferred that the shea butter should be changed.
Trial 3	JG (60%) and Cocoa Butter (40%).	The suppositories were loose and got easily melted.	Thus, we inferred that the cocoa butter should be changed.
Trial 4	JG (60%) and Gelatin (40%).	The suppositories were very hard.	Thus, we inferred that the base should be decreased.
Trial 5	JG (90%) and Gelatin (10%).	The suppositories were still very hard and intact.	Thus, we inferred that gelatin cannot be used.
Trial 6	JG (70%), Shea Butter (25%) and Gelucire 50/13 (5%).	Melting Time: 2 hours	The result doesn't comply with the standard.
Trial 7	JG (60%), Shea Butter (30%), Gelucire 50/13 (8%), Coconut Oil (1%) and Rose Oil (1%).	The suppositories were intact and not loose but, it took more time than usual to solidify and eject from the mold. There is no significance of rose oil.	Thus, we inferred that there is no need of rose oil and the quantity of shea butter should be increased.
Trial 8	JG (50%), Shea Butter (35%), Gelucire 50/13 (9%), Coconut Oil (1%) and Aloe Vera Extract (5%).	The suppositories were intact and not loose but, the quantity of JG was decreased. There is no significance of coconut oil and aloe vera extract.	Thus, we inferred that the shea butter quantity should be decreased.
Trial 9	JG (80%), Shea Butter (15%) and Gelucire 50/13 (5%).	It took more time for freezing (5 hours) and got easily melted.	The result doesn't comply with the standard.
Trial 10	JG (80%), Shea butter (10%) and Gelucire 50/13 (10%).	The suppositories were difficult to remove from the mold and got broke.	Thus, we inferred that the Gelucire 50/13 quantity should be decreased.
Trial 11	JG (80%), Shea butter (12%) and Gelucire 50/13 (8%).	The mold was smaller and thus the quantity of JG was less per suppository.	Thus, we inferred that the mold should be changed.

Trial 12	JG (80%), Shea butter (12%) and Gelucire 50/13 (8%).	The suppositories were very hard as the size of the mold was changed.	Thus, we inferred that the size of the mold and composition should be altered.
Trial 13	JG (85%) and Beeswax (15%).	The suppositories were loose and got easily broke.	Thus, we inferred that Gelucire 50/13 should be added.
Trial 14	JG (85%), Beeswax (10%) and Gelucire 50/13 (5%).	The suppositories still remained loose and broke while removing from the mold.	Thus, we inferred that Gelucire 50/13 should be increased.
Trial 15	JG (85%), Beeswax (7.5%) and Gelucire 50/13 (7.5%).	The suppositories were intact but again the mold was small and thus the quantity of JG was less per suppository.	Thus, we inferred that the size of the mold and composition should be altered.
Trial 16	JG (90%), Beeswax (5%) and Gelucire 50/13 (5%).	Melting Time: 2 minutes	The result doesn't comply with the standard.
Trial 17	JG (90%), Beeswax (2.5%) and Gelucire 50/13 (7.5%).	Melting Time: 15 minutes	The result doesn't comply with the standard.
Trial 18	JG (80%), Beeswax (10%), Gelucire 50/13 (5%) and Tea Tree Oil (5%).	The suppositories were loose and not intact. Tea tree oil masks the smell of JG.	Thus, we inferred that the quantity Gelucire 50/13 should be increased.
Trial 19	JG (80%), Beeswax (10%), Gelucire 50/13 (8%) and Tea Tree Oil (2%).	The suppositories were loose and not intact.	Thus, we inferred that the quantity of Gelucire 50/13 should be increased.
Trial 20	JG (80%), Beeswax (10%), Gelucire 50/13 (9%) and Tea Tree Oil (1%).	The suppositories were loose and not intact.	Thus, we inferred that there was no significant impact by increasing the composition of Gelucire 50/13 and hence quantity of beeswax should be increased.
Trial 21	JG (80%), Beeswax (15%), Gelucire 50/13 (4%) and Tea Tree Oil (1%).	The suppositories were good and intact. Freezing Time: 30 minutes Hardness: 2.1 kg	Thus, we inferred that the composition of Gelucire 50/13's composition should be reduced as it is synthetic.
Trial 22	JG (80%), Beeswax (17%), Gelucire 50/13 (2%) and Tea Tree Oil (1%).	The suppositories were unstable in terms of shape.	Thus, we inferred that the quantity of beeswax should be increased.
Trial 23	JG (75%), Beeswax (22%), Gelucire 50/13 (2%) and Tea Tree Oil (1%).	Melting Time: 10 minutes	The result doesn't comply with the standard.

Trial 24	JG (70%), Beeswax (27%), Gelucire 50/13 (2%) and Tea Tree Oil (1%).	The quantity of JG was less per suppository.	Thus, we inferred that the composition of JG should be increased.
Trial 25	JG (70%), Beeswax (15%), Gelucire 50/13 (10%) and TPGS (5%).	There was no significant effect of TPGS.	Thus, we inferred that TPGS should be removed.
Trial 26	JG (80%), Beeswax (10%), Gelucire 50/13 (9%) and Tea Tree Oil (1%).	The hardness of the suppository was increased because large mold was used. Disintegration Time: 1.5 hours	The result doesn't comply with the standard.
Trial 27	JG (80%), Beeswax (15%), Gelucire 50/13 (4%) and Tea Tree Oil (1%).	The suppositories were still hard.	Thus, we inferred that the composition of base should be decreased.
Trial 28	JG (85%), Natural Beeswax (14%) and Tea Tree Oil (1%).	The suppositories were intact and perfect.	Thus, we inferred that the quantity of base should be decreased.
Trial 29	JG (90%), Natural Beeswax (9%) and Tea Tree Oil (1%).	The suppositories were intact and perfect. Disintegration Time: 22 minutes	The result doesn't comply with the standard.
Trial 30	JG (75%), Natural Beeswax (15%), Kasisadi Oil (5%), Neem Oil (4%) and Tea Tree Oil (1%).	There is significant effect of Kasisadi oil and neem oil in the composition. The suppositories were quite hard. Melting Time: 8 minutes	Thus, we inferred that the quantity of base should be decreased.
Trial 31	JG (70%), Natural Beeswax (10%), Kasisadi Oil (10%), Neem Oil (5%) and Tea Tree Oil (5%).	The suppositories were perfectly intact and hard. Hardness: 2.26 kg Melting Time: 8 minutes Disintegration Time: 28 minutes	The result perfectly complied with the standard.

Table 4 presents the final standardized parameters for the optimized JG suppository formulation. Here, Trial 31 suppositories were prepared using the fusion or melt process, where JG was combined with Neem Oil, Kasisadi Oil, Beeswax, and Tea Tree Oil. Beeswax was used as the base to provide suitable hardness to the suppositories. The ingredients were melted at specific temperature ranges, mixed thoroughly, and poured into refrigerated molds for solidification.

The various evaluation parameters were performed and elaborate following:

Visual Examination: This qualitative assessment ensures the product's physical appearance, including shape, surface condition, colour, odour, size, and weight, meets the desired specifications.

Disintegration Test: This test evaluates the ability of the suppository to soften or disintegrate within a prescribed time when placed in an immersion fluid at $37.5 \pm 2^\circ\text{C}$, simulating body temperature. The JG suppositories disintegrated within 28 minutes, indicating their suitability for rectal administration.

Liquefaction Test: This test measures the time taken for the suppository to liquefy at 37°C , simulating rectal conditions. The JG suppositories exhibited a liquefaction time of 8 minutes, which is within the acceptable range of 30 minutes.

Melting Range: The melting range test ensures that the suppository melts at or below 37°C , facilitating its disintegration and release in the rectum. The JG suppositories met this requirement, melting at $37.5 \pm 2^\circ\text{C}$.

Mechanical Strength: This test evaluates the hardness of the suppository by measuring the force required to distort its structure. The JG suppositories exhibited a mechanical strength of 2.26 kg, indicating their ability to withstand handling and transportation without compromising their integrity.

Physical Stability: The suppositories were observed for four weeks at room temperature, and no changes in colour, smoothness, or shape were observed, demonstrating their physical stability during the study period.

The results obtained were compared with the standard values found in the Indian Ayurvedic Pharmacopoeia, and the optimized JG suppositories were found to comply with all the standard values of the evaluation tests, indicating their suitability for the intended purpose.

4. Conclusion

Based on the study, polyherbal suppositories containing Jatyadi Ghrita (JG) were successfully developed and evaluated for the treatment of anorectal disorders such as fissures, fistulas, and hemorrhoids. The optimized formulation consisted of JG, natural beeswax, Kasisadi oil, neem oil, and tea tree oil. The suppositories exhibited desirable physicochemical properties, including a bullet shape, smooth surface, mint colour, and camphoraceous odour. The suppositories demonstrated satisfactory performance in evaluation tests, with a disintegration time of 28 minutes at $37.5 \pm 2^\circ\text{C}$, liquefaction time of 8 minutes, mechanical strength of 2.26 kg, and a melting range of $37.5 \pm 2^\circ\text{C}$. These results comply with the standard values specified in the Indian Ayurvedic Pharmacopoeia, indicating their suitability for rectal administration.

The findings suggest that the developed JG suppositories could potentially serve as a practical, affordable, and non-invasive treatment option for anorectal disorders. However, further studies with larger sample sizes and longer follow-up periods are recommended to establish the generalizability and long-term efficacy of these polyherbal suppositories in clinical settings. Overall, this study contributes to the development of an alternative therapeutic approach for managing anorectal disorders using traditional Ayurvedic formulations in a modern dosage form.

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