

# Formulation and Analytical Evaluation of Herbal Rectal Suppositories Containing Senna Extract for the Management of Constipation

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## ABSTRACT

**Background.** Senna is a commonly used stimulant laxative that is typically administered orally as a senna extract tablet to treat constipation. This study aimed to formulate rectal suppositories containing senna extract, using glycerin as a base, to achieve site-specific drug delivery and reduce systemic side effects.

**Methodology.** The prepared suppositories were evaluated for various physicochemical and performance parameters, including visual appearance, disintegration time, in vitro dissolution, melting point, weight uniformity, drug content and HPTLC. **Results.** The suppositories demonstrated satisfactory physical characteristics, with an average weight of 0.9707 g and a drug content of  $0.150 \pm 2\%$  mg per suppository. The melting point was recorded at 37°C, and the complete dispersion time was 30 minutes. In vitro drug release studies revealed that the drug was fully released within 45 minutes. High-performance thin layer chromatography (HPTLC) was utilized to confirm the presence of active constituents by comparing the sample profile with that of a standard extract. **Conclusion.** These findings suggest that senna extract suppositories are a promising alternative to oral tablets, providing targeted drug delivery through the rectal route for improved therapeutic outcomes.

**Keywords:** Glycerine, herbal suppositories, senna extract, suppositories

## INTRODUCTION

Constipation is a common gastrointestinal disorder that can arise from various factors. It is characterized primarily as a functional bowel disorder, manifesting through symptoms such as persistently complex, infrequent, or incomplete bowel movements<sup>1</sup>. Importantly, these symptoms do not align with the criteria for irritable bowel syndrome<sup>2,3,4,5</sup>. Studies indicate that the prevalence of chronic constipation among adults can vary widely, with estimates ranging from 2.6% to an alarming 26.9%<sup>6-7</sup>. As individuals age, the incidence of constipation tends to increase significantly. Research shows that among older adults<sup>8</sup>, especially those over 65 years of age<sup>9-10</sup>, the prevalence can soar to between 24% and 50%<sup>11-12</sup>. This rise in constipation rates in the elderly population is concerning and highlighted by the fact that, in nursing home settings, as many as 50% to 75% of elderly residents regularly rely on laxatives to alleviate their symptoms<sup>13-14</sup>. This reliance underscores the importance of recognizing and addressing constipation as a significant health issue within aging communities.

Despite the extensive use of herbal laxatives such as *Senna*, most formulations are available as oral preparations, which may have a delayed onset of action or cause gastrointestinal discomfort. There is a notable lack of standardized herbal rectal dosage forms, particularly suppositories, which offer site-specific delivery and faster relief in constipated patients. Furthermore, few studies have addressed the analytical evaluation and quality control of herbal suppositories, leading to variability in

therapeutic outcomes. This study aims to develop and standardize *Senna*-based rectal suppositories, addressing formulation and analytical quality gaps in the current literature<sup>15</sup>.

Rectal drug delivery serves as a valuable alternative to oral administration, particularly for patients who are unable to swallow, such as pediatric, geriatric, and comatose individuals<sup>16</sup>. Suppositories are solid dosage forms intended for insertion into body orifices, where they melt, soften, or dissolve to exert local or systemic effects. Their formulation involves careful selection of bases, drugs, and excipients to ensure stability, bioavailability, and patient acceptability<sup>17</sup>. However, concerns related to patient privacy and cultural perceptions have led to the underutilization or avoidance of rectal drug administration in certain regions, despite its therapeutic potential<sup>18-19</sup>.

Suppositories are uniquely shaped medicated solids, typically resembling conical or ovoid forms, explicitly designed for insertion into one of the body's orifices, except the oral cavity. These therapeutic agents are often utilized for both localized and systemic effects, particularly in areas such as the rectum or vagina<sup>20</sup>. Rectal suppositories primarily deliver medication for localized effects, and they are particularly effective in treating constipation. One common ingredient, glycerin, is included because it irritates the local mucosa, which subsequently acts as a gentle laxative, promoting bowel movements<sup>21</sup>.

Compared with the traditional oral route of medication administration, the rectal approach offers a significantly faster onset of action. This efficiency arises because the medicines are absorbed

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directly through the rectal mucosa into the bloodstream, bypassing the first-pass metabolism that often diminishes the effectiveness of orally ingested drugs. This method is especially advantageous for administering medications that can provoke nausea, are vulnerable to degradation by acidic stomach conditions, or may irritate the gastrointestinal tract<sup>22</sup>. Herbal suppositories are emerging as promising dosage forms that combine the benefits of plant-derived bioactive compounds with the advantages of rectal or vaginal delivery systems<sup>23</sup>.

Senna (*Cassia angustifolia* or *Cassia acutifolia*) is a well-established herbal laxative traditionally used to treat constipation. Its primary active constituents, sennosides, are anthraquinone glycosides that stimulate colonic motility and reduce water absorption, facilitating bowel movement. Senna is widely used in both conventional and herbal medicine systems for short-term relief of constipation, such as in the case of hemorrhoids or before surgical procedures involving the rectum. It has been recognized for its potent laxative properties<sup>24-25</sup>.

In the continuous search for safe and effective herbal medicines, the current study focuses on the formulation and comprehensive evaluation of suppositories containing Senna extract. This approach aims to achieve targeted, site-specific drug delivery via the rectal route, thereby increasing therapeutic efficacy while minimizing systemic side effects.

## METHODOLOGY

### Preparation of Senna Extracts and Suppositories

Dried leaves of Senna were used as the plant material for extract preparation. The leaves were finely powdered and subjected to hydroalcoholic extraction via a Soxhlet apparatus with a 70% ethanol solution as the solvent. The extraction process was continued for 6 hours to ensure the maximum yield of the active constituents. The resulting extract was concentrated under reduced pressure via a rotary evaporator and dried in a vacuum oven to obtain a stable dry extract<sup>26-27</sup>.

For the preparation of Senna suppositories, all ingredients were accurately weighed as detailed in Table 1. Glycerin and distilled water were combined in a porcelain dish and gently heated in a water bath to facilitate the dissolution of the excipients. Upon reaching a uniform temperature (~60–70 °C), the standardized Senna extract was incorporated into the mixture with continuous stirring to ensure complete solubilization and homogeneity. Subsequently, gelatin was gradually added to the blend with continued mild heating. The mixture was gently boiled until the gelatin fully melted and dispersed uniformly throughout the formulation. The final homogeneous mass was removed from heat and poured into prelubricated suppository molds to solidify at room temperature<sup>28</sup>.

Before the formulation was poured, the suppository molds were lightly coated with a thin layer of wax to facilitate easy removal of the finished product. The warm, liquefied mixture was then carefully poured into each mold cavity with precision. After standing undisturbed at room temperature for the initial setting, the filled molds were transferred to a refrigerator to ensure complete cooling and solidification. This controlled process ensured the proper formation and structural integrity of the Senna suppositories.

**Table 1. Ingredients used in the formulation.**

Sr.No	Ingredients	Quantity per Suppository	Purpose
1	Senna Extract	0.150 g	Laxative
2	Gelatin	0.32 g	Base
3	Glycerin	1.76 g	Solvent, emollient, hyperosmotic laxative
4	Purified water	2 g	Solvent

### Evaluation of suppositories:

**Visual characterization:** To evaluate the physical attributes of the suppositories, five samples from each batch were randomly selected and carefully cut longitudinally. Each cut suppository was scrutinized with the naked eye, allowing for the observation of key characteristics such as the presence or absence of fissures, pitting, fat blooming, exudation, and any migration of active ingredients. This examination is essential to ensure the overall quality, uniformity, and integrity of the formulation<sup>29,30,31</sup>.

**Length and width measurement:** Five suppositories were randomly selected from each batch for precise size assessment, and their length and width were meticulously measured via Vernier calipers. This step ensures that all suppositories are uniform in dimension, which is essential for consistent performance.

**Weight variation assessment:** Twenty suppositories from each batch were weighed individually on an electronic balance to determine weight consistency. The average weight was calculated, and no individual suppository needed to deviate from this average by more than 5%. However, allowances were made for two suppositories, which could differ by a maximum of 7.5%. This strict evaluation helps maintain the dosage accuracy and reliability of the suppositories.

**Melting Point Analysis:** A macro melting range test was conducted to examine the melting behavior of the entire suppository. Each formulation was placed into a test tube containing phosphate buffer at a pH of 7.2, which was rigorously maintained at a constant temperature of 37 ± 0.5°C. The time it took for the entire suppository to either melt or disperse within this medium was meticulously noted. Understanding the melting time is fundamental, as it directly influences the release rate of active ingredients, thereby impacting the efficacy of the suppository.

**Disintegration test:** The disintegration time of the suppositories was determined via a disintegration test apparatus. The disintegration time of the entire suppository was recorded via phosphate buffer (pH 7.2) maintained at 37±0.5°C for this test.

The determination of drug content was performed via spectrophotometric analysis. A single suppository was dissolved in 200 mL of phosphate buffer (pH 7.2) and maintained at 37 ± 0.5 °C until complete melting occurred. A 1 mL aliquot of the solution was subsequently withdrawn and diluted to 100 mL with the same buffer. The senna content was quantified via a UV-visible spectrophotometer, with absorbance readings recorded at 340 nm and 266 nm.

### In vitro dissolution study:

The in vitro release of sennosides from the formulated suppositories was assessed via a Type II USP dissolution testing apparatus (paddle method). The study was performed in 900 mL of phosphate buffer (pH 7.2) maintained at 37 ± 0.5 °C with a paddle rotation speed of 100 rpm to ensure uniform mixing. At specific intervals, 5 mL aliquots were withdrawn and immediately replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The samples were filtered through Whatman filter paper and analyzed via a UV-visible spectrophotometer. The absorbance readings were recorded at the relevant wavelengths to quantify the drug release profile.

### HPTLC Analysis of Senna Suppositories

**Standard stock solution preparation:** An accurately weighed 1 mg quantity of sennoside was transferred to a 10 mL volumetric flask and dissolved in methanol. The solution was then diluted to volume with the same solvent to obtain a stock solution with a 100 µg/mL concentration. This stock prepared a working standard solution containing 10 µg/mL sennoside by appropriate dilution with methanol<sup>32-33</sup>.

**Sample Solution:** An aliquot of 1 mL from the senna suppository formulation was accurately transferred to a 10 mL volumetric flask and dissolved in methanol. The volume was then adjusted to the mark with the same solvent to obtain a stock solution containing 100 µg/mL sennoside. From this mixture, 1 mL was diluted to 10 mL with methanol in a separate volumetric flask to prepare a working sample solution with a final 10 µg/mL concentration.

### Instrumentation and chromatographic conditions:

The analysis was performed via a CAMAG system consisting of a Linomat IV sample applicator, a Twin Trough chamber for development, and a TLC Scanner III for densitometric scanning. The chromatographic procedure involved the marker compound (senna extract, 10 µg/mL) and the sample (senna suppository extract, 10 µg/mL), each dissolved in methanol. Chromatographic separation was carried out on precoated silica gel 60 F254 plates (Merck), which were prewashed with methanol before use. The mobile phase consisted of dichloromethane and methanol at a ratio of 99:1 (v/v). A 10 µL volume of each sample was applied to the plate, and nitrogen gas was used during development. The developed plates were dried and scanned at a wavelength of 350 nm following densitometric evaluation at an oven temperature of 120 °C (Figure 2).

**Analytical Procedure:** Both the standard and sample extracts were prepared in methanol to obtain a final concentration of 10 µg/mL. Before sample application, the silica gel 60 F254 plates were preheated to eliminate residual moisture. The prepared extracts and standard solutions were applied onto precoated plates via a CAMAG Linomat IV sample applicator. Chromatographic development was performed in a CAMAG Twin Trough chamber using a mobile phase comprising dichloromethane and methanol at a 99:1 (v/v) ratio. Following development, the plates were air-dried at room temperature and scanned at 350 nm via the CAMAG TLC Scanner III. The drug content was quantified by comparing the peak area of the sample with that of the standard, and the results were recorded accordingly Figure 3&4.

## RESULTS AND DISCUSSION

**Preparation of suppositories:** The suppositories were formulated via the fusion method, wherein the selected base was gently melted and the senna extract was incorporated with continuous stirring to ensure uniform dispersion. The molten mixture was then poured into prelubricated molds and solidified at room temperature. The final suppositories are depicted in Figure 1.

### Evaluation of suppositories:

**Visual characterization:** The visual characterization results are summarized in Table 2.



Figure 1: Senna suppositories.

Table 2. Visual Characterization of Senna Suppositories.

Parameters	1	2	3	4	5
Migration	No	No	No	No	No
Crack	No	No	No	No	No
Pitting	No	No	No	Yes	No
Exudation	No	No	No	No	No
Fat Blooming	No	No	No	No	No

Note: Suppository 4 shows visible pitting, whereas all the other samples appear visually normal.

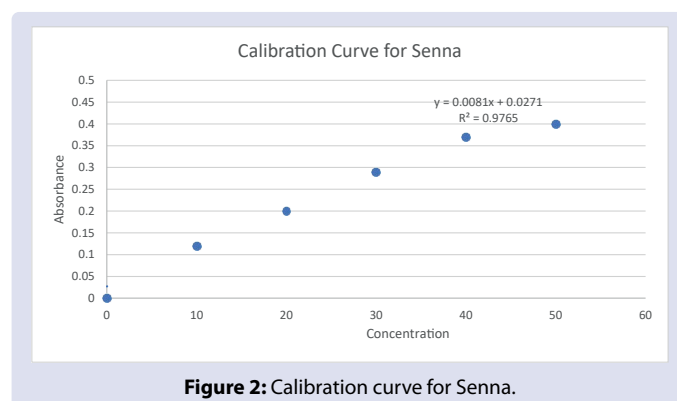


Figure 2: Calibration curve for Senna.

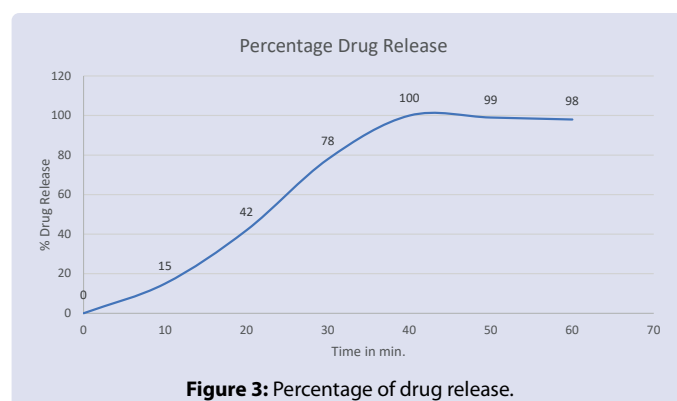


Figure 3: Percentage of drug release.

**Weight variation test:** The average weight of the 20 suppositories was found to be 0.9707 g. According to the United States Pharmacopeia (USP) specifications for the uniformity of dosage units, this batch complies with the weight variation requirements.

### Length and width Test:

#### Observations:

- **Length:** Ranges from **2.01 cm to 2.36 cm**, indicating a variation of **0.35 cm** across samples.
- **Width:** Ranges from **0.81 cm to 0.84 cm**, showing relatively minor variation (**0.03 cm**).

The suppositories demonstrate acceptable uniformity in both length and width, with only minor dimensional differences. This level of consistency suggests that the molding and manufacturing processes are well controlled. The slight variations observed are within typical tolerances for manually or semiautomatically produced suppositories and are unlikely to affect dosage accuracy or patient experience (Table 3).

#### Melting Point:

The melting point of the prepared Senna suppositories was 37 °C, which was reached after 45 minutes.

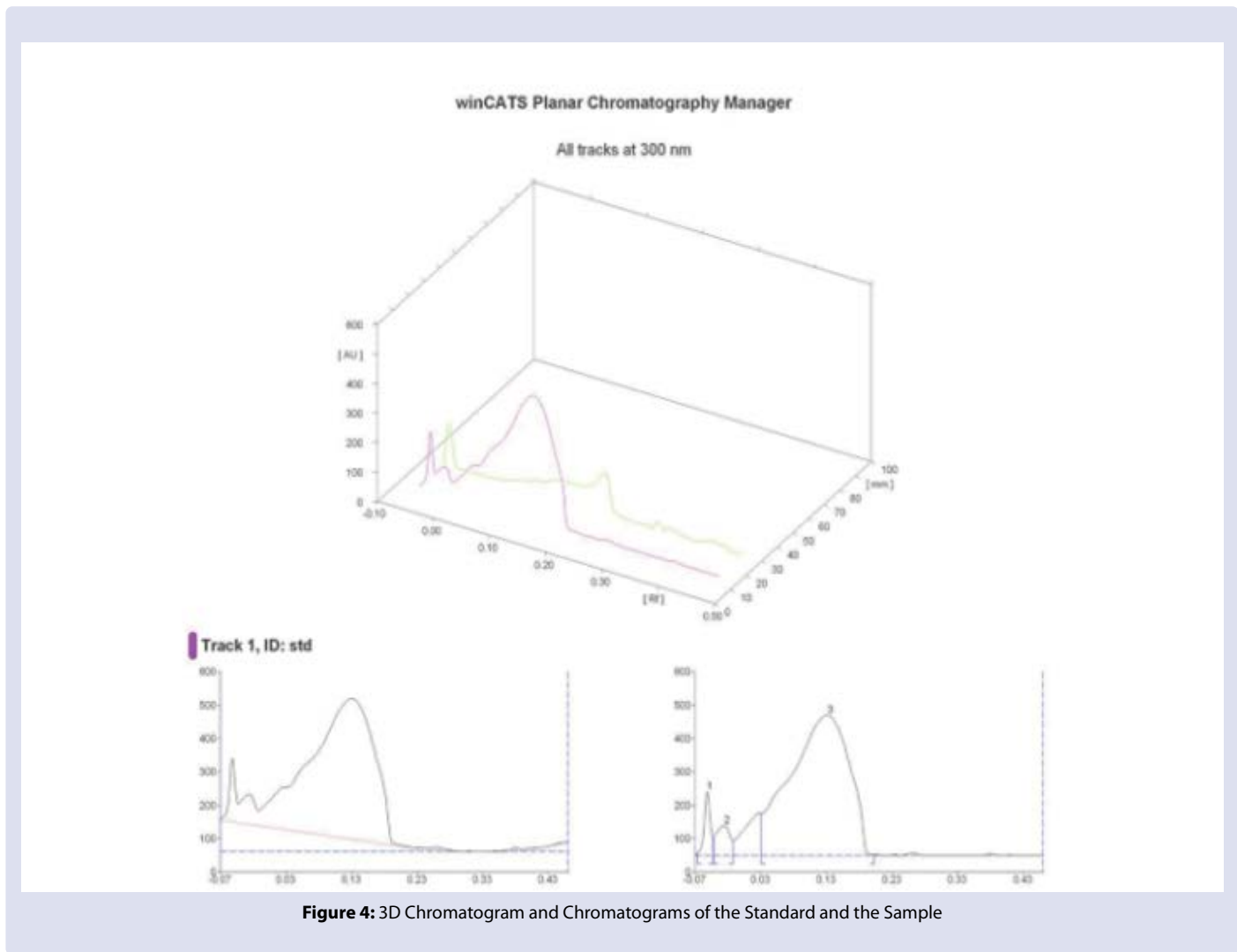


Figure 4: 3D Chromatogram and Chromatograms of the Standard and the Sample

Table 3. Weights of the suppositories.

Suppository	Weight (in grams)
1	0.998
2	0.975
3	0.986
4	0.977
5	0.959
6	0.957
7	1.004
8	1.002
9	0.966
10	1.003
11	0.999
12	0.889
13	0.950
14	0.972
15	1.002
16	1.015
17	0.948
18	0.922
19	0.935
20	0.956

**Disintegration Test:**

The time taken for the suppositories to disperse completely was 30 minutes.

**Drug Content:**

The drug content in each suppository was 0.150 mg ± 2%.

**In vitro dissolution study:**

**HPTLC studies of Senna:**

HPTLC analysis of the prepared Senna suppositories was conducted at a detection wavelength of 300 nm via WinCATS Planar Chromatography Manager.

The Rf value observed for the Sample Senna extract in the HPTLC chromatogram was 0.15, which corresponds closely to the standard Rf of 0.14, indicating the presence of active constituents responsible for its laxative effect. The peak purity was assessed via the spectral correlation at the peak's start, apex, and end positions confirming the absence of coeluting impurities. This affirms the specificity of the method and supports the presence of a chemically consistent Senna extract in the suppository formulation.

The 3D chromatogram further confirmed the peak pattern and intensity similarity between the standard and the sample tracks, indicating

**Table 4. Dimensions of the suppository.**

Suppositories	Length (cm)	Width (cm)
1	2.05	0.83
2	2.36	0.84
3	2.23	0.81
4	2.01	0.81
5	2.32	0.83

**Table 5. RF values and percentage area.**

Compound	Start Rf	Max Rf	Area	Area Percentage
Standard Senna Extract	0.03	0.14	33194.9	91.11
Sample Senna Suppository	0.02	0.15	4130.2	38.73

successful incorporation and stability of the active compound during suppository formulation. Additionally, the absence of significant interfering peaks in the sample chromatogram suggests acceptable specificity and minimal interference from excipients or degradation products. These findings support the identity and compositional integrity of the active ingredient in the dosage form, validating HPTLC as a reliable and routine quality control method for herbal suppository formulations (Table 4).

The formulated Senna suppositories in this study demonstrated desirable physicochemical properties and satisfactory *in vitro* release profiles. These findings are in line with earlier research by Ebrahimi et al.<sup>34</sup>, who reported comparable rectal delivery performance using herbal suppositories in traditional systems. Similarly, Bonati<sup>35</sup> emphasized that dry herbal extracts such as Senna are practical bases for rectal formulations, provided that suitable excipients and melting points are ensured. Compared with these methods, our study offers the added benefit of integrating analytical evaluation and a reproducible preparation method, contributing to standardization efforts in herbal rectal dosage forms (Table 5).

## CONCLUSIONS

In this study, Senna-based herbal rectal suppositories were successfully formulated and evaluated via physicochemical, *in vitro* release, and HPTLC techniques. The suppositories demonstrated acceptable stability, specific analytical profiles, and potential therapeutic utility for the management of constipation. These findings support the feasibility of standardized herbal rectal dosage forms and validate HPTLC as a suitable tool for routine quality control in phytopharmaceutical development.

The rectal route of administration offers a practical advantage for geriatric and pediatric patients, particularly those who experience difficulty swallowing or require rapid relief. The successful formulation of Senna-based suppositories provides a promising alternative to oral laxatives in these populations, combining traditional herbal therapy with modern pharmaceutical design.

The standardized formulation and validated analytical profile of the Senna-based suppositories indicate potential for scale-up and industrial production. Additionally, incorporating HPTLC for marker-based quality control aligns with regulatory expectations for herbal medicines, supporting future development and possible clinical application.

Future studies will focus on accelerated stability testing to determine the long-term shelf-life of the formulation. In addition, clinical evaluation in human subjects is essential to confirm the efficacy and

safety of Senna suppositories in managing constipation, particularly in target populations such as pediatric and geriatric patients.

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