



ISSN: 2230-9926

Available online at <http://www.journalijdr.com>

# IJDR

International Journal of Development Research  
Vol. 15, Issue, 12, pp.69578-69584, December, 2025  
<https://doi.org/10.37118/ijdr.30347.12.2025>



REVIEW ARTICLE

OPEN ACCESS

## EVALUATION OF A SYNERGISTIC AYURVEDIC POLYHERBAL FORMULATION FOR THE MANAGEMENT OF CONSTIPATION: A PILOT CLINICAL STUDY

Suman<sup>1</sup>, S., Karthikeyan<sup>2</sup>, P., Moulishankar<sup>3</sup>, S., Aathithiah<sup>4</sup>, G.S., Vetriselvan<sup>5</sup>, M., Arunothayam<sup>6\*</sup>, M. and Niranjana Murali Mohan<sup>7</sup>

<sup>1</sup>Managing Director, Vijayani Nutraceuticals Pvt Ltd; <sup>2</sup>Director, Vijayani Nutraceuticals Pvt Ltd; <sup>3</sup>Director, Vijayani Nutraceuticals Pvt Ltd; <sup>4</sup> Medical Officer, Vijayani Nutraceuticals Pvt Ltd; <sup>5</sup> General Manager, Vijayani Nutraceuticals Pvt Ltd; <sup>6</sup> R&D Head, Vijayani Nutraceuticals Pvt Ltd, <sup>7</sup> R&D Executive, Oriens Global Marketing Pvt Ltd

### ARTICLE INFO

#### Article History:

Received 29<sup>th</sup> September, 2025  
Received in revised form  
10<sup>th</sup> October, 2025  
Accepted 24<sup>th</sup> November, 2025  
Published online 30<sup>th</sup> December, 2025

#### KeyWords:

Constipation, Polyherbal formulation, Ayurvedic medicine, Gastrointestinal health, Nutraceuticals, Herbal safety assessment, Clinical trial.

\*Corresponding author: Xiaokun Guo

### ABSTRACT

Constipation is a prevalent and multifactorial gastrointestinal disorder affecting individuals globally, with higher incidence in females. This study evaluated a synergistic polyherbal-nutraceutical formulation containing *Cassia angustifolia*, *Terminalia bellirica*, *Cassia fistula*, *Zingiberofficinale*, *Coleus forskohlii*, *Foeniculum vulgare*, and rock salt, traditionally used to support digestive health. Preclinical quality assessments confirmed the formulation's safety, potency, and compliance with pharmacopeial and regulatory standards. A 30-day open-label clinical trial involving 10 participants showed significant symptomatic improvement in 80% of cases with excellent tolerability and no adverse events. The pilot study suggests the potential benefits of this formulation in managing constipation.

Copyright©2025, Suman et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Citation: Suman, S., Karthikeyan, P., Moulishankar, S., Aathithiah, G.S., Vetriselvan, M., Arunothayam, M. and Niranjana Murali Mohan, 2025. "Evaluation of a Synergistic Ayurvedic Polyherbal Formulation for the Management of Constipation: A Pilot Clinical Study" *International Journal of Development Research*, 15, (12), 69578-69584.

## INTRODUCTION

Constipation is a complex, multifactorial gastrointestinal condition characterized by impaired stool transit through the digestive tract, from ingestion to evacuation. It is conventionally defined as unsatisfactory defecation, which may involve infrequent bowel movements, hard stool consistency, or difficulty in passing stools (Bashankaev et al., 2008; Andrews &Storr, 2011). Clinically, constipation is often identified by a defecation frequency of fewer than three bowel movements per week. However, constipation encompasses a broader range of symptoms, including excessive straining, abdominal bloating or discomfort, and the passage of small or hard stools. Chronic cases may lead to complications such as anal fissures, fistulas-in-ano, and haemorrhoids. (Johanson& Sonnenberg, 1990; Andran et al., 2003; Minguez et al., 2003; Andrews &Storr, 2011; Kalkdijk et al., 2022; Lunsford et al., 2022). Elderly individuals undergoing pharmacological treatment for lifestyle-related conditions are more susceptible to constipation, as highlighted across multiple studies (Dennison et al., 2005; Mugie et al., 2011; Bharucha et al., 2013). As lifestyle-related conditions progress, they may lead to complications such as stroke, which itself has been associated with

the development of poststroke constipation (Jin et al., 2021). In more advanced cases, individuals may depend on external methods to support bowel evacuation such as physical assistance or therapeutic interventions highlighting the functional burden associated with chronic constipation (Arce et al., 2002; Van Den Berg, 2007; Camilleri, 2011; Miller et al., 2016). Given the wide spectrum of symptoms and severity, the definition and perception of constipation can vary significantly across different geographic regions, languages, cultural contexts, and educational backgrounds (Barberio et al., 2021; Salari et al., 2023). Despite regional and cultural variations in perception, key diagnostic features of constipation remain consistent, particularly stool consistency and associated discomfort. These aspects are emphasized in widely accepted frameworks such as the Rome Criteria, which provide standardized, symptom-based definitions to support consistency in both clinical practice and research (Lin et al., 2009; Bharucha et al., 2013; Jin et al., 2021; Drossman & Tack, 2022; Parwe&Nisargandha, 2024; Killedar et al., 2024). However, despite such standardization efforts, the reported prevalence of constipation varies widely, ranging from 0.7% to 79%, with a median prevalence of 16% (Mugie et al., 2011). Epidemiological studies consistently show that constipation is more

prevalent in females than in males. Furthermore, evidence indicates that constipation affects individuals across all age groups, including children, adolescents, adults, and the elderly (Van Den Berg, 2007; Mugie et al., 2011; Rajput & Saini, 2014; Alimoradzadeh et al., 2017). Figure 1 illustrates the epidemiology of constipation, highlighting:

- The reported range of prevalence (0.7–79%, median 16%),
- Prevalence by gender (female vs. male), and
- Prevalence by age group (children, adolescents, adults, and elderly).

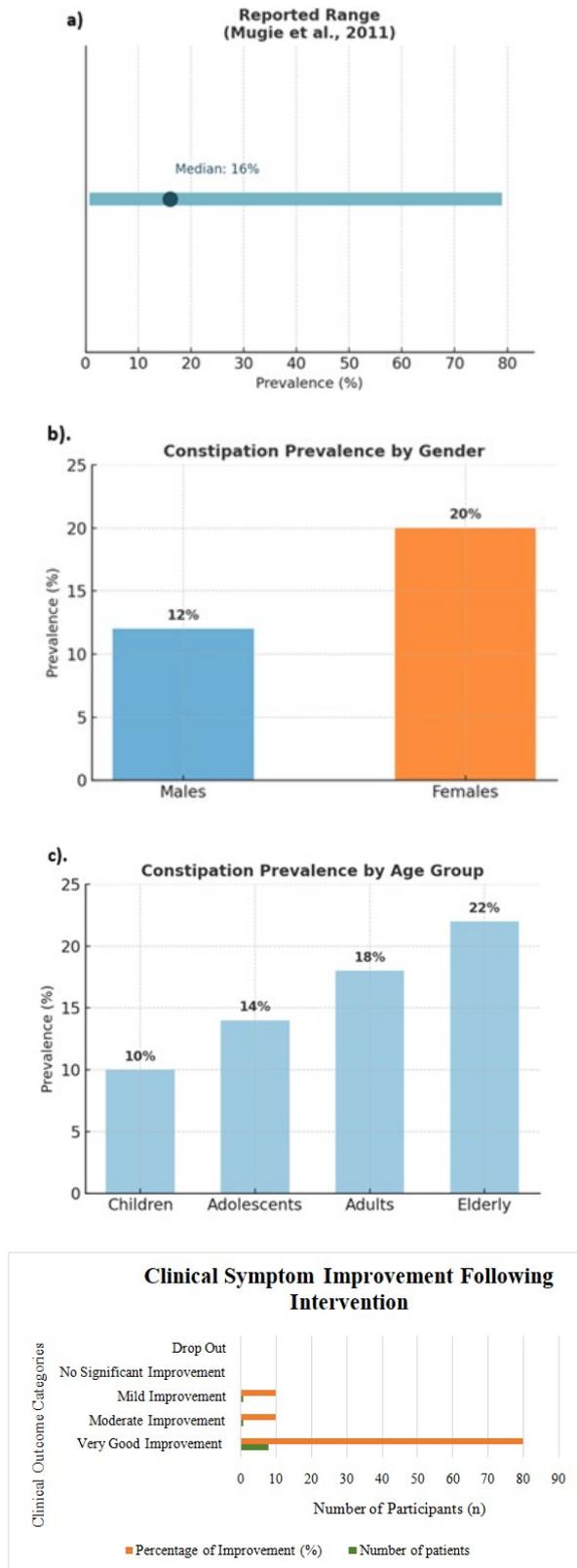


Figure 2. Overall Effect of the Intervention on Clinical Symptoms

**Contributing factors:** The prevalence data mentioned above underscores the importance of prioritizing constipation as a research focus and informing future healthcare planning (Towers et al., 1994; Müller-Lissner et al., 2005; Crowley et al., 2013; Xinias&Mavroudi, 2015; Wu et al., 2019; Thakare et al., 2020; Adibi et al., 2022; He et al., 2024; Hong et al., 2024; Yun et al., 2024; Chang et al., 2015). The Contributing factors include:

- Poor dietary habits (low fiber, high milk intake, inadequate hydration)
- Sedentary lifestyle and low physical activity
- Stress, depression, and other psychological conditions
- Obesity and hormonal imbalances
- Certain medications (e.g., iron supplements)
- Socioeconomic factors, age, and sex

Among dietary factors, fibre intake plays a key role in maintaining healthy bowel function. Soluble fibre enhances colonic function by stimulating fluid and mucus secretion, while insoluble fibre increases stool bulk, accelerates transit time, and improves stool consistency. Due to these benefits, fibre is widely recommended as a conservative strategy for managing haemorrhoids and is effective for individuals with both diarrhea and constipation (Staller & Cash, 2020; Lunsford et al., 2022). However, despite these known contributors and available conservative measures, many patients continue to experience constipation symptoms that vary in severity and often fall short of formal diagnostic thresholds. In clinical practice, individuals frequently present with mild or subthreshold symptoms of constipation or Disorders of Gut-Brain Interaction (DGBI) that, while not meeting strict diagnostic criteria, still impact quality of life and require intervention (Zhao & Yu, 2016). While such cases are often excluded from research to preserve diagnostic clarity, clinicians routinely address them by recommending non-pharmacologic options, including dietary supplements, tailored dietary changes, and lifestyle modifications (Jun et al., 2006; Drossman & Tack, 2022; Alexandre et al., 2016). For individuals with more pronounced symptoms, pharmacologic treatments such as laxatives remain a mainstay of therapy. These include agents that act through bulk-forming, osmotic, stool-softening, stimulant, or lubricant mechanisms (Liu, 2011; Tack et al., 2011; El-Salhy et al., 2014). However, their use is not without limitations. Concerns related to dependency, adverse effects, and unsuitability in certain populations such as the elderly or those with chronic conditions have been widely reported (Raahave, 2010; Alimoradzadeh et al., 2017; Serrano & Rey, 2017). In some older adults, laxatives are even used prophylactically, regardless of symptom presence, further illustrating the gap between clinical guidelines and real-world practices (Levitt et al., 2010; Werth et al., 2020). Given the heterogeneous presentations of constipation and the frequent underappreciation of its burden, there is a growing need for safe, effective, and holistic interventions. Nutraceuticals, herbal compounds, probiotics, and integrative strategies incorporating dietary and lifestyle changes have emerged as gentler alternatives, offering broader applicability and fewer side effects (Bub et al., 2006; Paknejad et al., 2019). Accordingly, this manuscript aims to evaluate the effectiveness of a holistic herbal-nutraceutical formulation in individuals experiencing constipation. The formulation includes *Cassia angustifolia*, *Terminalia bellirica*, *Cassia fistula*, *Zingiberofficinale*, *Coleus forskohlii*, *Foeniculum vulgare*, and rock salt (*Saindhavalavana*), chosen for their synergistic therapeutic properties. *Cassia angustifolia*, also known as senna or *Swarnapatri*, is a well-established Ayurvedic herb traditionally used as a stimulating laxative for treating *Vibandha* (constipation) and *Udararoga* (abdominal disorders), as documented in the Ayurvedic Pharmacopeia of India (API Vol. I). It is also recognized by the U.S. FDA as a non-prescription laxative. Its laxative action is primarily attributed to its bioactive compound, anthraquinone glycosides, which enhance peristalsis in the large intestine and modify colonic motility. These compounds promote fluid retention in the colon by altering epithelial absorption and secretion. Beyond its laxative effects, senna also exhibits mild purgative, antioxidant, antimicrobial, anti-diabetic, hepatoprotective, and hypolipidemic properties (API Vol. I, 2001; Mangmesri et al., 2013; Ramchander&Middha, 2017; Thaker et al., 2023).

*Terminalia bellirica*, known as *Bahera* or *Bibhitaki*, belongs to the Combretaceae family and is included in this formulation for its recognized therapeutic effects on *Vibandha* (API Vol. I, 2001; Gahatraj *et al.*, 2020). It is rich in bioactive polyphenolic compounds, particularly hydrolysable tannins such as gallic acid, ellagic acid, Gallo-tannic acid, and chebulagic acid. These constituents have been associated with anti-diabetic, anti-cancer, and gastrointestinal-supportive properties, including benefits in conditions such as constipation and diarrhea (Kumari *et al.*, 2017; Ahmed *et al.*, 2021). *Cassia fistula*, referred to as *Aragvadha* in the Ayurvedic Pharmacopoeia of India, is another key component of the formulation, traditionally valued for its therapeutic applications in managing *Vibandha* (constipation), *Udavarta* (upward movement of wind), *Gulma* (abdominal lumps), *Shoola* (colic pain), *Udararoga* (abdominal diseases), *Hridroga* (cardiac disorders), and *Prameha* (metabolic disorders including diabetes) within the classical Ayurvedic system (API Vol. I, 2001). The seeds of *Cassia fistula* are particularly noted for their mild laxative action, making them suitable for use in pediatric populations (Mozaffarpur *et al.*, 2012). Several studies have documented its beneficial effects on constipation, including more recent findings that highlight its efficacy in elderly individuals over the age of 60 (Agrawal *et al.*, 2012; Ali, 2014; Pawar&Killedar, 2017; Sepehr *et al.*, 2022). The seed's laxative properties are largely attributed to its rich phytochemical and nutritional composition, which includes anthraquinones, flavonoids, glycosides, and macronutrients such as crude fat, protein, carbohydrates, and dietary fibre, all of which contribute to its antioxidant potential (Ali, 2014; Pawar&Killedar, 2017). These attributes make *Cassia fistula* a valuable complementary herb in this synergistic formulation aimed at relieving chronic constipation through both nutritive and therapeutic mechanisms. *Zingiberofficinale*, commonly known as ginger, is another integral component of this formulation, widely recognized for its longstanding role in traditional Asian medicine systems. Frequently used across Asian households, ginger has been valued for its protective and therapeutic effects on the gastrointestinal tract, particularly in alleviating digestive discomforts such as bloating, indigestion, and constipation (Haniadka *et al.*, 2013). In Ayurvedic medicine, ginger is traditionally indicated in conditions such as *Agnimandya* (digestive weakness), *Adhmana* (abdominal distension), *Pandu* (anemia), *Shvasa* (respiratory distress), *Udararoga* (abdominal disorders), and *Amavata* (rheumatic conditions) (API Vol. 2001). The pharmacological efficacy of ginger is largely attributed to its diverse array of phytochemicals, encompassing both volatile and non-volatile

constituents. Key compounds include camphene, cineole, terpenes, zingiberol, linalool, gingerols, shogaols, paradols, and zingerone, many of which exhibit anti-inflammatory, antioxidant, carminative, and gastrointestinal-modulating properties (Haniadka *et al.*, 2013; Zadeh &Kor, 2014). Several *in vitro* and *in vivo* studies have demonstrated ginger's efficacy in enhancing colonic motility and promoting laxative effects, supporting its role as a natural remedy for constipation (Eraiah *et al.*, 2010; Iwami *et al.*, 2011; Abidi *et al.*, 2022). Its inclusion in this synergistic formulation is thus aimed at leveraging these multifaceted effects to support overall gut function and regular bowel movements. Another key botanical in this formulation is *Coleus forskohlii*, known in Ayurveda as *Gandhira*, a medicinal herb from the Lamiaceae family. Traditionally, it is used in the treatment of various conditions including *Shotha* (inflammation), *Arsha* (hemorrhoids), *Kasa* (cough), *Gulma* (abdominal masses), *Udara* (enlarged abdomen), *Pleeharoga* (splenic disorders), *Shoola* (colic pain), *Mandagni* (low digestive fire), *Mutrabandha* (urinary obstruction), and *Malabandha* (constipation) (API Vol. V, 2001). Phytochemical investigations have revealed that the primary active constituent of *Coleus forskohlii* is forskolin, a labdane diterpenoid that exerts its biological activity by directly activating the enzyme adenylyl cyclase, thereby increasing intracellular levels of cyclic adenosine monophosphate (cAMP) (Valdes *et al.*, 1987; De Souza *et al.*, 1983; Shivaprasad *et al.*, 2014). This cAMP-mediated pathway has been shown to stimulate smooth muscle relaxation, modulate intestinal peristalsis, and promote digestive secretions, all of which contribute to its therapeutic action in gastrointestinal disorders,

including constipation (Mirza *et al.*, 2024). While it is widely known for its role in weight management supplements, its gastrointestinal benefits also make a valuable addition to this multi-herbal formulation. *Foeniculum vulgare*, commonly referred to as fennel, is another important component of this synergistic herbal formulation. The seeds of *Foeniculum vulgare* have been extensively utilized in traditional medicine for their therapeutic applications in conditions such as *Agnimandya* (digestive impairment), *Ajirna* (indigestion), *Kasa* (cough), *Raktadosha* (blood disorders), *Pravahika* (dysentery), and *Arsha* (hemorrhoids), as recorded in the Ayurvedic Pharmacopoeia of India (API Vol. I, 2001). Fennel has a long-standing history of use across various traditional systems for supporting gastrointestinal health, particularly for its mild laxative properties, which are attributed to its ability to alleviate bloating and enhance bowel movement frequency. In addition, fennel demonstrates multiple other benefits including anti-emetic, carminative, and anti-flatulent actions, and is frequently used to manage colic in children.

The therapeutic potential of fennel seeds is further enhanced by their nutrient-rich profile, comprising essential lipids, dietary fibre, calcium, potassium, sodium, zinc, and other trace minerals and vitamins, all of which may contribute additional health benefits when consumed as part of a holistic formulation. These nutritional components not only complement the bioactive phytoconstituents of the other herbs included in the formulation but also support systemic health through gentle nourishment, making fennel a valuable herb in the context of managing constipation (Badgular *et al.*, 2014; Kanadje, 2014). Rock salt (*Saindhavalavana*) has been included as an additional ingredient since ancient times, valued in Ayurvedic texts for its health benefits. It is noted for its role in improving the digestive system and addressing related disorders (Wormer, 2015; Kotangale&Shirke, 2020). Its incorporation into this formulation aims to further enhance digestive function and complement the laxative and gastrointestinal-supportive actions of the herbal components. The primary outcomes include symptomatic relief, stool frequency and consistency, and overall comfort. Positioned within the global context of constipation prevalence and the rising demand for non-pharmacologic treatments, this study aims to contribute to the development of safer and more sustainable supportive therapies. This manuscript outlines the rationale for ingredient selection, details quality assessment for each component, and presents findings from a Phase I, single-centre, open-label human pilot study assessing the formulation's efficacy.

## MATERIALS AND METHODOLOGY

### Analytical and Regulatory Validation

**Sample Preparation:** Individual botanical ingredients were procured from certified suppliers complying with International Standards. Each ingredient underwent identity confirmation and quality assessment upon receipt, followed by processing into powdered form using facilities compliant with Good Manufacturing Practices (GMP). The powdered botanicals were subsequently blended and compressed into tablet form of 430 mg using standard direct compression techniques. Organoleptic evaluation was performed on individual herbal powders to assess macroscopic characteristics including color, odor, and texture. Evaluations were conducted under controlled laboratory conditions by trained personnel, based on established pharmacopeial organoleptic methods. Quantitative determination of marker compounds was conducted using validated analytical methods. High-Performance Liquid Chromatography (HPLC) was used for the estimation of gingerols (*Zingiberofficinale*), forskolin (*Coleus forskohlii*), glycosides (*Cassia fistula*), and sennosides (*Cassia angustifolia*). Total tannin content in *Terminalia bellirica* was determined using UV-Visible spectrophotometry. Volatile oil content in *Foeniculum vulgare*, specifically anethole, was analysed via Gas Chromatography-Mass Spectrometry (GC-MS). Each marker compound was quantified to confirm compliance with the minimum specified limits (NLT) defined by regulatory and pharmacopeial references. Heavy metal analysis for arsenic (As), lead (Pb), mercury

(Hg), and cadmium (Cd) was conducted using Inductively Coupled Plasma–Mass Spectrometry (ICP–MS). The results were compared against safety thresholds established by the Food Safety and Standards Authority of India (FSSAI), Bureau of Indian Standards (BIS), and World Health Organization (WHO) guidelines. Microbiological safety evaluation included the detection of *Escherichia coli*, *Salmonella spp.*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*, using methods compliant with USP 61 and 62. Both culture-based and rapid detection systems were employed to assess total viable counts and the absence of specific pathogens. Each botanical component was further assessed for regulatory compliance under relevant frameworks, including the U.S. Food and Drug Administration (FDA) Dietary Supplement Health and Education Act (DSHEA), Generally Recognized as Safe (GRAS) notices, and over-the-counter (OTC) monographs. Indian regulatory alignment was confirmed with the FSSAI Nutraceutical and Herbal Monographs (2016) and applicable BIS standards.

**Clinical Trial Methodology:** A community-based, open-label, non-randomized clinical trial was conducted under the supervision of the Ashram Siddha Research Institute (Protocol No. HI-100-04-24), with approval from the Institutional Ethics Committee in accordance with AYUSH-ICMR 2006 guidelines and the Declaration of Helsinki, and written informed consent was obtained from all participants. Ten individuals aged 20–60 years presenting with gastrointestinal symptoms were enrolled during the study period (8 April 2024 – 7 May 2024), while those above 60 years of age or with osteoarthritis, psoriatic arthritis, drug or alcohol abuse, diabetic complications, endocrine disorders, or shift work were excluded.

and 7 May 2024. Exclusion criteria included age above 60 years, a history of osteoarthritis, psoriatic arthritis, drug or alcohol abuse, diabetic complications, endocrine disorders, or night/shift work. Each participant received the investigational nutraceutical tablet once daily for 30 days. Clinical evaluations were performed at baseline (Day 1) and at study completion (Day 30) by qualified Siddha and Ayurveda practitioners, and symptomatic improvements were documented using structured case records.

## RESULTS

All six botanical ingredients used in the investigational polyherbal formulation for constipation were procured from certified suppliers and authenticated by detailed analysis. Each ingredient underwent testing for organoleptic properties, marker compound quantification, heavy metal content, and microbial safety. The results were benchmarked against specifications stipulated by international (US FDA dietary supplement guidance), national (FSSAI nutraceutical regulations), and pharmacopeial standards (BIS, WHO guidelines, and AYUSH pharmacopoeia). The consolidated tabulation (Table 1) depicts compliance of each ingredient with these regulatory thresholds and ensures that only standardized, safe, and pharmaceutically acceptable materials were included for clinical administration in the Phase 1 pilot study.

**Clinical Efficacy Outcomes:** A total of 10 participants aged between 20 and 60 years with symptoms of constipation were enrolled in this open-label, non-randomized clinical trial.

**Table 1. Quality Control Parameters for Nutraceutical Tablet Formulation**

Ingredient	Marker Compound (NLT)	Organoleptic Profile	Heavy Metals & Contaminants (Limits)	Microbiological & Pathological Safety Analysis	Regulatory Compliance (FDA/FSSAI/BIS)
Foeniculum vulgare (Fennel)	Volatile oils (like Anethole) $\geq 1\%$	Brown powder, characteristic odour	As, Pb, Hg, Cd Within Limits	<i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> are absent	Meets FDA DSHEA, FSSAI 2016, BIS herb standards
Terminalia Bellirica	Tannins $\geq 5\%$	brown, coloured free flowing powder	As, Pb, Hg Within Limits	<i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> are absent	Complies with FDA psyllium standards, FSSAI nutraceutical norms, BIS
Cassia Fistula (seed extract)	Glycosides $\geq 3\%$	Light-Dark Brown powder, typical odour	Pb, As Within Limits	<i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> are absent	Complies FDA, FSSAI, BIS pharmacopeial
Zingiberofficinale (Ginger)	Gingerols $\leq 3\%$	Brown powder, pungent odour	Pb, Hg Within Limits	<i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> are absent	FDA, FSSAI, BIS standards – spice extract-complies
Coleus forskohlii	Forskolin $\geq 10\%$	Light-dark brown powder, partially soluble in water and alcohol	Pb Within Limits	<i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> are absent	Complies FSSAI botanical list, FDA botanical guidance, BIS herb monograph
Cassia angustifolia (Senna)	Senosides $\geq 20\%$	Brown coloured powder, typical odour	Heavy metals < limits	<i>E. coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> are absent	Meets FDA, FSSAI herbal monograph, BIS Standards

Participants received the investigational nutraceutical tablet once daily for 30 days, with clinical assessments carried out at baseline (Day 1) and at the end of the study (Day 30) by qualified Siddha and Ayurveda practitioners, and symptomatic improvements were documented through structured case records.

**Study Design, Participants, and Intervention:** A community-based, open-label, non-randomized clinical trial was conducted under the supervision of the Ashram Siddha Research Institute (Protocol No. HI-100-04-24), with ethical approval obtained from the Institutional Ethics Committee in accordance with AYUSH-ICMR 2006 guidelines and the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrolment. A total of ten individuals aged 20–60 years presenting with symptoms of constipation were enrolled between 8 April 2024

All participants completed the 30-day supplementation period with the investigational polyherbal Ayurvedic tablet, with no dropouts or adverse events reported. Clinical evaluations conducted at baseline (Day 1) and at study completion (Day 30) demonstrated notable symptomatic improvements across all participants. The distribution of improvement levels is summarized in Table 2. As shown, the intervention demonstrated favourable outcomes in the enrolled participants where 80% of participants experienced very good improvement in their constipation symptoms following 30 days of supplementation. The remaining 20% of participants reported moderate to mild improvements. No participant exhibited a lack of response to the treatment. Figure 1 illustrates the overall effect of the polyherbal tablet on the clinical symptoms, highlighting the favourable response pattern among the study cohort. Throughout the study period, no adverse events or safety concerns were noted, and all

Table 2. Clinical Improvement in Participants (n=10)

Results	Number of Patients	Percentage of Improvement (%)
Very Good Improvement	8	80
Moderate Improvement	1	10
Mild Improvement	1	10
No Significant Improvement	0	0
Dropouts	0	0

participants complied fully with the intervention regimen. These findings indicate the investigational formulation was well tolerated and demonstrated preliminary efficacy in managing constipation symptoms within this community-based sample.

## DISCUSSION

Constipation is a prevalent, multifactorial condition affecting individuals across all age groups globally, with a notably higher incidence in females (Mugie *et al.*, 2011; Van Den Berg, 2007). Its complex etiology involves dietary habits, physical inactivity, psychological factors, medication use, and socioeconomic influences (Rajput & Saini, 2014; Wu *et al.*, 2019; Bloor *et al.*, 2021). Although over the counter pharmacologic treatments are available, concerns about dependency and adverse effects limit their long-term use, especially in vulnerable populations such as the elderly (Raahave, 2010; Alimoradzadeh *et al.*, 2017). Our study evaluated a synergistic herbal-nutraceutical formulation composed of traditionally validated botanicals including *Cassia angustifolia*, *Terminalia bellirica*, *Cassia fistula*, *Zingiber officinale*, *Coleus forskohlii*, *Foeniculum vulgare*, and rock salt.

These ingredients collectively target key aspects of gastrointestinal health such as motility, stool consistency, and gut comfort through mechanisms like enhanced peristalsis, mucosal hydration, anti-inflammatory, and antioxidant effects (Agrawal *et al.*, 2012; Abidi *et al.*, 2022; Mirza *et al.*, 2024). Preclinical quality assessments confirmed the formulation's consistency, potency, and safety. All core botanicals met pharmacopeial standards, with marker compound analyses demonstrating therapeutic levels of bio actives such as gingerols, forskolin, sennosides, glycosides, tannins, and volatile oils. Heavy metal content was well within acceptable limits, and microbial testing confirmed the absence of harmful pathogens. Compliance with national and international regulatory standards (including FSSAI, BIS, and U.S. FDA designations) further supports the formulation's safety and market readiness. The 30-day open-label clinical evaluation involving 10 participants revealed encouraging outcomes, with 80% reporting significant symptomatic improvement and the remainder experiencing moderate to mild benefits. No adverse events or dropouts were reported, highlighting excellent tolerability and compliance. These results suggest that healthy Intestine's (HI) formulation could act as a comprehensive digestive aid, likely attributable to the complementary actions of its ingredients. In summary, this study, supported by rigorous quality assurance and real-world data, provides promising preliminary evidence for the safety and efficacy of this Ayurvedic-based polyherbal formulation as a supportive intervention for constipation and overall gastrointestinal health.

## CONCLUSION

The study presents promising preliminary evidence supporting the safety and efficacy of a traditional Ayurvedic polyherbal formulation as a complementary intervention for constipation. Quality control measures ensured consistency and safety, while clinical evaluation indicated significant symptomatic relief and good tolerability in most participants. Overall, this formulation offers a potential holistic approach to improving gastrointestinal health and managing constipation.

## ACKNOWLEDGEMENT

The authors wish to sincerely thank the Directors of Vijayani Nutraceuticals Pvt. Ltd Chennai- Mr. Karthikeyan. P (CEO), Mr. Moulishankar. S., (COO) and Mr. Suman S, (CFO) for providing us the laboratory facilities and financial aid necessary to carry out this study. We would also like to express our sincere gratitude to the General manager Mr. M. Vetrivelvan for their exceptional leadership, guidance, and continuous support throughout this project. G.S. Aathithiah, and M. Arunothayam have all assisted in the research and development of the product and its manufacturing. Niranjana Murali Mohan contributed to the writing and initial preparation of the manuscript. G.S. Aathithiah and M. Arunothayam were also responsible for revising and finalizing the manuscript.

## REFERENCES

- Bashankaev, B., Weiss, E. G., & Khaikin, M. (2008). Constipation: evaluation and management. *Ambulatory Colorectal Surgery*, 141-161.
- Andrews, C. N., & Storr, M. (2011). The pathophysiology of chronic constipation. *Canadian Journal of Gastroenterology and Hepatology*, 25, 16B-21B.
- Johanson, J. F., & Sonnenberg, A. (1990). The prevalence of hemorrhoids and chronic constipation: an epidemiologic study. *Gastroenterology*, 98(2), 380-386.
- Andiran, F., Dayi, S., & Mete, E. (2003). Cows milk consumption in constipation and anal fissure in infants and young children. *Journal of paediatrics and child health*, 39(5), 329-331.
- Minguez, M., Herreros, B., & Benages, A. (2003). Chronic anal fissure. *Current Treatment Options in Gastroenterology*, 6(3), 257-262.
- Kalkdijk, J., Broens, P., Ten Broek, R., van der Heijden, J., Trzpis, M., Pierie, J. P., & Klarenbeek, B. (2022). Functional constipation in patients with hemorrhoids: a systematic review and meta-analysis. *European journal of gastroenterology & hepatology*, 34(8), 813-822.
- Lunsford, T. N., Atia, M. A., Kagbo-Kue, S., & Harris, L. A. (2022). A pain in the butt: hemorrhoids, fissures, fistulas, and other anorectal syndromes. *Gastroenterology Clinics*, 51(1), 123-144.
- Dennison, C., Prasad, M., Lloyd, A., Bhattacharyya, S. K., Dhawan, R., & Coyne, K. (2005). The health-related quality of life and economic burden of constipation. *Pharmacoeconomics*, 23(5), 461-476.
- Mugie, S. M., Benninga, M. A., & Di Lorenzo, C. (2011). Epidemiology of constipation in children and adults: a systematic review. *Best practice & research Clinical gastroenterology*, 25(1), 3-18.
- Bharucha, A. E., Pemberton, J. H., & Locke III, G. R. (2013). American Gastroenterological Association technical review on constipation. *Gastroenterology*, 144(1), 218.
- Jin, C., Jang, B. H., Jeon, J. P., Lee, Y. S., Yang, S. B., & Kwon, S. (2021). Traditional East Asian herbal medicines for the treatment of poststroke constipation: A protocol for systematic review and meta-analysis. *Medicine*, 100(15), e25503.
- Arce, D. A., Ermocilla, C. A., & Costa, H. (2002). Evaluation of constipation. *American family physician*, 65(11), 2283-2291.
- Van Den Berg, M. M. (2007). Childhood constipation: abnormalities in the colorectal function. *Universiteit van Amsterdam [Host]*.
- Camilleri, M. (2011). Inclusion criteria for pharmacodynamic and clinical trials in chronic idiopathic constipation: pitfalls in using Rome III for functional constipation. *Therapeutic Advances in Gastroenterology*, 4(3), 159-163.
- Miller, L. E., Ibarra, A., Ouwehand, A. C., & Zimmermann, A. K. (2016). Normative values for stool frequency and form using Rome III diagnostic criteria for functional constipation in adults: systematic review with meta-analysis. *Annals of Gastroenterology: Quarterly Publication of the Hellenic Society of Gastroenterology*, 30(2), 161.

16. Barberio, B., Judge, C., Savarino, E. V., & Ford, A. C. (2021). Global prevalence of functional constipation according to the Rome criteria: a systematic review and meta-analysis. *The Lancet Gastroenterology & Hepatology*, 6(8), 638-648.
17. Salari, N., Ghasemianrad, M., Ammari-Allahyari, M., Rasoulpoor, S., Shohaimi, S., & Mohammadi, M. (2023). Global prevalence of constipation in older adults: a systematic review and meta-analysis. *Wiener Klinische Wochenschrift*, 135(15), 389-398.
18. Lin, L. W., Fu, Y. T., Dunning, T., Zhang, A. L., Ho, T. H., Duke, M., & Lo, S. K. (2009). Efficacy of traditional Chinese medicine for the management of constipation: a systematic review. *The Journal of Alternative and Complementary Medicine*, 15(12), 1335-1346.
19. Parwe, S., & Nisargandha, M. (2024). An Ayurvedic Approach to Constipation.
20. Killedar, R. S., Angadi, S., Shetti, U., Patil, M., Shinde, P. S., & Bolaj, S. K. (2024). Efficacy of Whole System Approach Ayurveda Interventions in Vibhanda WSR Old Age Constipation—A Randomized Control Clinical Trial. *Journal of Ayurveda*, 18(3), 181-188.
21. LeLeiko, N. S., Mayer-Brown, S., Cerezo, C., & Plante, W. (2020). Constipation. *Pediatrics in review*, 41(8), 379-392. <https://doi.org/10.1542/pir.2018-0334>
22. Drossman, D. A., & Tack, J. (2022). Rome Foundation clinical diagnostic criteria for disorders of gut-brain interaction. *Gastroenterology*, 162(3), 675-679.
23. Rajput, M., & Saini, S. K. (2014). Prevalence of constipation among the general population: a community-based survey from India. *Gastroenterology Nursing*, 37(6), 425-429.
24. Alimoradzadeh, R., Mokhtare, M., & Agah, S. (2017). Comparing the prevalence of constipation risk factors in the elderly with and without constipation in Hazrat-e Rasoul (PBUH) Hospital. *Iranian Journal of Ageing*, 12(1), 78-89.
25. Thakare, S. H. (2020). Assessment of role of diet, life style & stress in the etiopathogenesis of constipation in geriatric patients. *Int J Mod Agric*, 9(3), 137-41.
26. Hong, Y., Chen, X., & Liu, J. (2024). Analysis of factors associated with constipation in the population with obesity: evidence from the national health and nutrition examination survey. *Obesity Facts*, 17(2), 169-182.
27. Towers, A. L., Burgio, K. L., Locher, J. L., Merkel, I. S., Safaeian, M., & Wald, A. (1994). Constipation in the elderly: influence of dietary, psychological, and physiological factors. *Journal of the American Geriatrics Society*, 42(7), 701-706.
28. Müller-Lissner, S. A., Kamm, M. A., Scarpignato, C., & Wald, A. (2005). Myths and misconceptions about chronic constipation. *Official journal of the American College of Gastroenterology | ACG*, 100(1), 232-242.
29. Jun, D. W., Park, H. Y., Lee, O. Y., Lee, H. L., Yoon, B. C., Choi, H. S., & Kee, C. S. (2006). A population-based study on bowel habits in a Korean community: prevalence of functional constipation and self-reported constipation. *Digestive diseases and sciences*, 51(8), 1471-1477.
30. Alexandre, V., Bertin, C., Boubaya, M., Airinei, G., Bouchoucha, M., & Benamouzig, R. (2016). Randomized clinical trial: efficacy of a food supplement, TRANSITECH, on healthy individuals with mild intermittent constipation. *European Journal of Gastroenterology & Hepatology*, 28(9), 1087-1093.
31. Crowley, E. T., Williams, L. T., Roberts, T. K., Dunstan, R. H., & Jones, P. D. (2013). Does milk cause constipation? A crossover dietary trial. *Nutrients*, 5(1), 253-266.
32. Xinias, I., & Mavroudi, A. (2015). Constipation in Childhood. An update on evaluation and management. *Hippokratia*, 19(1), 11.
33. Wu, J. X., Frank, P. N., & Yeh, M. W. (2019). Fatigue, Constipation, and Depressed Mood. In *Surgery: A Case Based Clinical Review* (pp. 127-137). Cham: Springer International Publishing.
34. Adibi, P., Abdoli, M., Daghighzadeh, H., Keshteli, A. H., Afshar, H., Roohafza, H., ... & Feizi, A. (2022). Relationship between depression and constipation: results from a large cross-sectional study in adults. *The Korean journal of gastroenterology*, 80(2), 77-84.
35. Yun, Q., Wang, S., Chen, S., Luo, H., Li, B., Yip, P., ... & Tang, J. (2024). Constipation preceding depression: a population-based cohort study. *EClinicalMedicine*, 67.
36. He, Z., Yu, Q., He, B., Liu, J., Gao, W., & Chen, X. (2024). Can depression lead to chronic constipation, or does chronic constipation worsen depression? NHANES 2005-2010 and bidirectional mendelian randomization analyses. *BMC gastroenterology*, 24(1), 361.
37. Bloor, S. R., Schutte, R., & Hobson, A. R. (2021). Oral iron supplementation—gastrointestinal side effects and the impact on the gut microbiota. *Microbiology Research*, 12(2), 491-502.
38. Chang, L. L., Lin, Y. C., Lo, T. C., Chen, M. C., & Kuo, H. W. (2015). Understanding the lifestyle correlates with chronic constipation and self-rated health. *Food and Nutrition Sciences*, 6(4), 391-398.
39. Staller, K., & Cash, B. D. (2020). Myths and misconceptions about constipation: A new view for the 2020s. *Official journal of the American College of Gastroenterology | ACG*, 115(11), 1741-1745.
40. Zhao, Y., & Yu, Y. B. (2016). Intestinal microbiota and chronic constipation. *Springerplus*, 5(1), 1130.
41. Levitt, M. A., Kant, A., & Peña, A. (2010). The morbidity of constipation in patients with anorectal malformations. *Journal of pediatric surgery*, 45(6), 1228-1233.
42. Werth, B. L., Williams, K. A., Fisher, M. J., & Pont, L. G. (2020). Use of over-the-counter laxatives by community-dwelling adults to treat and prevent constipation: a national cross-sectional study. *European journal of clinical pharmacology*, 76(7), 1003-1010.
43. Liu, L. W. C. (2011). Chronic constipation: current treatment options. *Canadian Journal of Gastroenterology and Hepatology*, 25, 22B-28B.
44. Tack, J., Müller-Lissner, S., Stanghellini, V., Boeckxstaens, G., Kamm, M. A., Simren, M., ... & Fried, M. (2011). Diagnosis and treatment of chronic constipation—a European perspective. *Neurogastroenterology & Motility*, 23(8), 697-710.
45. El-Salhy, M., Svendsen, R., Hatlebakk, J. G., Gilja, O. H., & Hausken, T. (2014). Chronic constipation and treatment options. *Molecular medicine reports*, 9(1), 3-8
46. Raahave, D. (2010). Faecal retention: A common cause in functional bowel disorders, appendicitis and haemorrhoids. *J Gastroenterol*, 45, 592-602.
47. Serrano-Falcón, B., & Rey, E. (2017). The safety of available treatments for chronic constipation. *Expert opinion on drug safety*, 16(11), 1243-1253.
48. Bub, S., Brinckmann, J., Cicconetti, G., & Valentine, B. (2006). Efficacy of an herbal dietary supplement (smooth move) in the management of constipation in nursing home residents: a randomized, double-blind, placebo-controlled study. *Journal of the American Medical Directors Association*, 7(9), 556-561.
49. Paknejad, M. S., Motaharifard, M. S., Barimani, S., Kabiri, P., & Karimi, M. (2019). Traditional, complementary and alternative medicine in children constipation: a systematic review. *DARU Journal of Pharmaceutical Sciences*, 27(2), 811-826.
50. Government of India. (2001). *Cassia angustifolia* (Vol. 1, pp. 180-181). In *The Ayurvedic Pharmacopoeia of India*. Ministry of Health and Family Welfare, Department of AYUSH.
51. Mangmesri, P., Wongsuphasawat, K., Gritsanapan, W., & Viseshsindh, W. (2013). Laxative effectiveness of cassia angustifolia in thai constipated patients. *The Thai Journal of Pharmaceutical Sciences*, 38, 268-270.
52. Ramchander, P. J., & Middha, A. (2017). Recent advances on senna as a laxative: a comprehensive review. *J PharmacognPhytochem*, 6(2), 349-53.
53. Soyuncu, S., Cete, Y., & Nokay, A. E. (2008). Portal vein thrombosis related to Cassia angustifolia. *Clinical Toxicology*, 46(8), 774-777.
54. Thaker, K., Patoliya, J., Rabadiya, K., Reddy, N. R. R., & Joshi, R. (2023). Senna (*Cassia angustifolia* Vahl.): A comprehensive review of ethnopharmacology and

- phytochemistry. Pharmacological Research-Natural Products, 1, 100003.
55. Government of India. (2001). *Terminalia bellirica* (Vol. 1, pp. 44-45). In *The Ayurvedic Pharmacopoeia of India*. Ministry of Health and Family Welfare, Department of AYUSH.
  56. Gahatraj, S., Bhusal, B., Sapkota, K., Dhama, B., & Gautam, D. (2020). Common medicinal plants of Nepal: A review of Triphala: Harro (*Terminalia chebula*), Barro (*Terminalia bellirica*), and Amala (*Emblica officinalis*). *Asian J. Pharmacogn*, 4(3), 5-13.
  57. Kumari, S., Krishna, M. J., Joshi, A. B., Gurav, S., Bhandarkar, A. V., Agarwal, A., ... & Gururaj, G. M. (2017). A pharmacognostic, phytochemical and pharmacological review of *Terminalia bellerica*. *J. Pharmacogn. Phytochem*, 6(5), 368-376.
  58. Ahmed, S., Ding, X., & Sharma, A. (2021). Exploring scientific validation of TriphalaRasayana in ayurveda as a source of rejuvenation for contemporary healthcare: An update. *Journal of Ethnopharmacology*, 273, 113829.
  59. Government of India. (2001). *Cassia fistula* (Vol. 1, pp. 12-14). In *The Ayurvedic Pharmacopoeia of India*. Ministry of Health and Family Welfare, Department of AYUSH.
  60. Agrawal, K., Ghildiyal, S., Gautam, M. K., Joshi, V. K., & Goel, R. K. (2012). Studies on laxative effect of extract of dried fruit pulp of *Cassia fistula*. *J Nat Remedies*, 12(2), 119-28.
  61. Mozaffarpur, S. A., Naseri, M., Esmailidooki, M. R., Kamalinejad, M., & Bijani, A. (2012). The effect of cassia fistula emulsion on pediatric functional constipation in comparison with mineral oil: a randomized, clinical trial. *DARU Journal of Pharmaceutical Sciences*, 20(1), 83.
  62. Ali, M. A. (2014). *Cassia fistula* Linn: a review of phytochemical and pharmacological studies. *Int J Pharm Sci Res*, 5(6), 2125-2130.
  63. Sepehr, F., Shirafkan, H., Behzad, C., Memariani, Z., & Mozaffarpur, S. A. (2022). The effect of *Cassia fistula* L. syrup in geriatrics constipation in comparison with the lactulose: A randomized clinical trial. *Journal of Ethnopharmacology*, 297, 115466.
  64. Pawar, A. V., & Killedar, S. G. (2017). Uses of *Cassia fistula* Linn as a medicinal plant. *International Journal for Advance Research and Development*, 2(3).
  65. Government of India. (2001). *Zingiberofficinale* (Vol. 1, pp. 177-179). In *The Ayurvedic Pharmacopoeia of India*. Ministry of Health and Family Welfare, Department of AYUSH.
  66. Haniadka, R., Saldanha, E., Sunita, V., Palatty, P. L., Fayad, R., & Baliga, M. S. (2013). A review of the gastroprotective effects of ginger (*Zingiberofficinale* Roscoe). *Food & function*, 4(6), 845-855.
  67. Zadeh, J. B., & Kor, N. M. (2014). Physiological and pharmaceutical effects of Ginger (*Zingiberofficinale* Roscoe) as a valuable medicinal plant. *European journal of experimental biology*, 4(1), 87-90.
  68. Eraiah, M. M., MTveter, K., Lincy Joshua, V. S., & VThomas, J. (2010) Efficacy of Standardized Ginger Extract in Subjects with Occasional Constipation: A Randomized, Double-Blind, Parallel, Placebo-Controlled Study. *Journal of Nutrition and Health*, 10(1).
  69. Iwami, M., Shiina, T., Hirayama, H., Shima, T., Takewaki, T., & Shimizu, Y. (2011). Inhibitory effects of zingerone, a pungent component of *Zingiberofficinale* Roscoe, on colonic motility in rats. *Journal of natural medicines*, 65(1), 89-94.
  70. Abidi, C., Rtibi, K., Boutahiri, S., Tounsi, H., Abdellaoui, A., Wahabi, S., ... & Sebai, H. (2022). Dose-dependent action of *Zingiberofficinale* on colonic dysmotility and ex vivo spontaneous intestinal contraction modulation. *Dose-Response*, 20(3), 15593258221127556.
  71. Government of India. (2001). *Coleus forskohlii* (Vol. 5, pp. 58-60). In *The Ayurvedic Pharmacopoeia of India*. Ministry of Health and Family Welfare, Department of AYUSH.
  72. Mirza, F. H. H., Sadashiva, C. T., Benny, N., Yoganand, R., & Singh, N. (2024). A Novel Approach to Defeat Obesity: An in vitro and in vivo Evaluation of the Active Diterpene in *Coleus forskohlii* (Forclim™). *International Journal of Pharmacology*, 20(1), 72-80.
  73. Valdes, L. J., Mislankar, S. G., & Paul, A. G. (1987). *Coleus barbatus* (*C. forskohlii*) (Lamiaceae) and the potential new drug forskolin (Coleonol). *Economic botany*, 41(4), 474-483.
  74. De Souza, N. J., Dohadwalla, A. N., & Reden, Ü. (1983). Forskolin: a labdane diterpenoid with antihypertensive, positive inotropic, platelet aggregation inhibitory, and adenylate cyclase activating properties. *Medicinal research reviews*, 3(2), 201-219.
  75. Shivaprasad, H. N., Pandit, S., Bhanumathy, M., Manohar, D., Jain, V., Thandu, S. A., & Su, X. (2014). Ethnopharmacological and phytochemical knowledge of *Coleus forskohlii*: an approach towards its safety and therapeutic value. *Oriental Pharmacy and Experimental Medicine*, 14(4), 301-312.
  76. Government of India. (2001). *Foeniculum vulgare* (Vol. 1, pp. 148-150). In *The Ayurvedic Pharmacopoeia of India*. Ministry of Health and Family Welfare, Department of AYUSH.
  77. Badgujar, S. B., Patel, V. V., & Bandivdekar, A. H. (2014). *Foeniculum vulgare* Mill: a review of its botany, phytochemistry, pharmacology, contemporary application, and toxicology. *BioMed research international*, 2014(1), 842674.
  78. Kanadje, S. (2024). Evaluating the Efficacy of Herbal Medicines in the Management of Constipation: A Comprehensive Review. *Journal of Drug Delivery and Biotherapeutics*, 1(03), 12-20.
  79. Wormer, E. J. (2015). Blood, sweat, and tears—salt in medical history.
  80. Kotangale, A. J., & Shirke, U. J. (2020). The Conceptual Study of SaindhavaLavana (Rock Salt) in Ayurveda and its Relevance in Moderna Era-A Review. *Ayush International Interdisciplinary Research Journal*, 7(7), 6-10.

\*\*\*\*\*