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Research Article

Formulation And Evaluation Of Herbal Effervescent Tablets For The Treatment Of Constipation

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ABSTRACT

The formulation and evaluation of herbal effervescent tablets for constipation were conducted to develop a natural, effective, and patient-friendly treatment option. Four formulations were prepared using Indian Senna, Psyllium husk, Bael fruit pulp, and other excipients. The tablets were assessed for weight variation, hardness, friability, effervescence time, and disintegration time. All formulations met the weight variation limit, indicating uniformity in dosage. Tablet hardness ranged from 5.8 to 8.3 N, ensuring appropriate mechanical strength. Friability values were below 1%, signifying tablet durability during handling and transportation. Effervescence times ranged from 2.10 to 5.58 minutes, indicating rapid release of gas upon dissolution. Disintegration times ranged from 2.46 to 5.24 minutes, ensuring prompt tablet breakdown for optimal drug release. Among the formulations, F1 emerged as the most favorable, demonstrating consistent performance across evaluation parameters. The results confirm the feasibility of formulating herbal effervescent tablets for constipation, offering a natural, gentle, and efficient treatment option. Compliance with pharmacopoeial standards ensures quality and consistency in the dosage form, enhancing patient trust and satisfaction. Overall, the study highlights the potential of herbal effervescent tablets as a holistic approach to constipation management, addressing patient preferences for natural remedies, ease of administration, and therapeutic effectiveness. Further research and clinical trials are warranted to validate the efficacy and safety of these formulations in diverse patient populations.

INTRODUCTION

Constipation, a prevalent gastrointestinal issue, impacts individuals across all age groups from infants to old age, and regardless of gender, race,

or socioeconomic status, constipation affects a broad spectrum of individuals. It manifests as infrequent and typically challenging bowel movements and represents more than just a mere

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symptom. Constipation is a normal and common functioning digestive tract disorder that affects patients of all ages. There may be constipation which cause unsatisfactory stools, infrequent stools, hard stools walking or both accompanied by discomfort pain and rigidity (stiffness). [1,2] Constipation can significantly affect an individual's health and may lead to various complications if left unmanaged. Its impact on healthcare utilization is substantial worldwide, including in the United States. The condition encompasses various types, such as functional constipation, chronic idiopathic constipation, and secondary constipation, each with unique factors and clinical characteristics. Understanding the clinical assessment of constipated patients is crucial. This discussion explores the multifaceted nature of constipation, outlining its causes, symptoms, prevalence, and emphasizes the importance of effective treatment for overall well-being. Furthermore, it highlights the critical role of interdisciplinary teams in managing constipation among hospitalized patients.[1-4] Constipation often results in hardened, lumpy stools that may be unusually large or small. Its severity varies from person to person. While some individuals may only encounter short-term bouts of constipation, for others, it can become a chronic issue, leading to considerable pain, discomfort, and a diminished quality of life.[3,4] Severe acute constipation can lead to intestinal blockage, potentially necessitating surgical intervention. Individuals may find themselves spending prolonged periods on the toilet due to the challenging nature of bowel movements. Some may feel as though they haven't fully emptied their bowels and perceive a blockage sensation. When stool is excessively hardened, it can exert increased pressure on the muscles within the rectum. Chronic constipation is a complex situation amongst older individuals, that is characterised through hard stool passage. Constipation amongst older human beings is a

ways greater common than more younger human beings. Common reasons of constipation within the aged human beings are connected to numerous factors which includes lack of normal bowel motion or aging, inadequate dietary choices, consumption of low-fiber foods, inadequate hydration, sedentary lifestyle, infections, or medication usage can all contribute to this condition. [4] Globally, the general prevalence of constipation was roughly calculated to be around 16%, with adults aged 60 to 95 years experiencing a higher prevalence of 33.5%. The severity of constipation varies among individuals, differing from person to person.[5] As per the World Health Organization, traditional or herbal medicine encompasses a body of skills, knowledge, and practices rooted in the theories and beliefs of various cultures, aimed at maintaining health in harmony with nature—an exemplar of essential symbiotic phenomena. Throughout history, natural substances derived from plants, animals, and minerals have served as fundamental agents in treating human diseases. Saline cathartic effervescent powders were accessible as early as the 18th century and later included in official compendia as compounded effervescent powders. These mixtures gained moderate popularity over time, as they not only provided therapeutic benefits but also offered the public a distinctive and intriguing formula to prepare. Moreover, their carbonation imparted a pleasant taste, masking the disagreeable flavors of medications. The selection of ingredients for effervescent granules depends on production requirements, typically involving at least one acid and one base to facilitate the release of carbon dioxide through acid-base reactions. Commonly utilized acids include citric and tartaric acids, as using either acid alone can present challenges. Effervescent salts typically contain “sodium bicarbonate, citric acid, and tartaric acid”, which, upon dissolution in water, undergo reactions between acids and bases, liberating



carbon dioxide and resulting in effervescence. The following illustrates the reaction between “acid and bicarbonate”, which releases carbon dioxide:



Medicinal plant plays an important role especially to treat constipation in developing countries due to their cost effectiveness. Plants always been a good source of drugs. Beneficial use of medicinal plants in traditional medicine of many cultures extensively documented. There were several plants used as a dietary aid and in the treatment of number diseases without even knowing about them the right functions and ingredients. Although many synthetic drugs have been developed for them to treat constipation, but safe and effective treatment paradigm has yet to be achieved in India, original medicines were used for this treatment of constipation since the time of Charaka and Sushruta.[4] Effervescent tablets, as defined by the FDA and its amendments, are tablets designed to dissolve or disperse in water before administration. Alongside the active ingredient, they typically contain a blend of acids such as “citric, tartaric, malic, or other suitable acids or acid anhydrides” and carbonates or the bicarbonates (such as sodium, potassium, or other appropriate alkali compound metal carbonates/bicarbonates). When combined with water, these tablets release CO₂ (carbon dioxide). In certain instances, the primary component functions as an acidic or key metal compound essential for the bubbling reaction. These tablets typically lack coatings and swiftly react with water to emit CO₂, requiring prior dissolution or dilution in water before application. They're commonly prescribed for medications that might cause stomach irritation or are sensitive to stomach pH, especially when taken in large quantities. Moreover, due to their liquid form when consumed, effervescent tablets are easier to ingest than traditional tablets or

capsules, which may pose difficulties for certain individuals. Typically, one tablet is dissolved in 3-4 ounces of the water. Effervescent products undergo pre-dissolution in a buffer solution, thus mitigating irritation in the stomach and intestines by not directly interacting with the gastrointestinal tract. Before consumption, the tablet is dissolved in a glass of water, and the resulting medicinal solution or dispersion should be promptly utilized. The tablet breaks down rapidly due to the interaction between tartaric acid and citric acid with alkali metal carbonates or bicarbonates in water, releasing CO₂ gas, which improves the solubility of the active pharmaceutical ingredient (API) and disguises its flavor. Effervescent tablets offer various advantages over other oral dosage forms, including enhanced taste for the developer, minimal impact on the patient and stomach, and marketing considerations.[6] Effervescent tablets, made up of acids or acid salts such as “citric, tartaric, malic, or other applicable acids or acid anhydrides” and carbonates or the bicarbonates (like sodium or potassium or others), are the tablets without coating. They contain a suitable alkali metal (carbonate or bicarbonate) that swiftly reacts with water to release carbon dioxide, resulting in the emission of CO₂ gas. This reaction enhances the water solubility of the active pharmaceutical ingredient (API) and also masks its taste.[6,7]. A single (solitary portion) of a conventional effervescent tablet, featuring a specific diameter of 1 inch and a total weight of five grams, may hold over 2000 milligrams of water-soluble active ingredients. Sachet (powder form) is a common dosing device when the required dose is greater than that. Shining in the



1930s, objects gained great importance with Alka Seltzer technology. Over time, these compounds have garnered moderate popularity because of their appealing dosage forms and the therapeutic advantages. The primary goal and purpose of this research study endeavor is to enhance the drug's absorption rate within the body (bioavailability). They should do this to avoid the first round effect has satisfactory properties, higher bioavailability of tablets is achieved better than other dosage forms patient consent. The stability of effervescent tablets and effervescent tablets can be improved needs a very humid control area. Effervescent tablets cannot be produced in the middle area where humidity and temperature are not maintained.[6]

REASON FOR CHOOSING AN EFFERVESCENT TABLET:-

- Onset of action is fast - The biggest advantage of effervescent tablets is that the drug is already in solution and absorbed; consequently, compared to the conventional tablets, absorption is simpler and more efficient. A quicker start to action is indicative of faster absorption. Drugs that are effervescent are given to the stomach at the ideal pH for absorbing substances. A lot of drugs take longer to absorb through the digestive system when combined with food or other medications.[8]
- It's not required to swallow the tablets. Administering effervescent medications in liquid form instead of tablets or capsules allows for broader accessibility, catering to individuals who struggle to swallow tablets or have an aversion to swallowing pills and capsules; typically, one dose of effervescent medication can be given. in just three or four ounces of water.[8]
- Increase portability: Since effervescent tablets don't require the addition of water before use,

they are simpler to transport than liquid medications.[11]

- Complete dissolution of the effervescent tablets in the buffer solution indicates good intestinal and gastric tolerance. Reducing localized contact in the upper gastrointestinal tract reduces discomfort and improves tolerability; additionally, buffering often prevents stomach acids from causing medication interactions, which can be a significant cause of side effects. of abdominal pain.[11]
- Dependable: The pharmacokinetics of drugs utilizing effervescent technology are more consistent, repeatable, and predictable in comparison to tablets or capsules.[12]
- Improved taste - Medicines provided in an effervescent base, more taste coverage in mixes and suspensions can be obtained by reducing unpleasant substances. properties and additional taste and smell dosage forms. An effervescent tablet essentially contains a flavoring agent that tastes much better than a water-powder mixture that is not effervescent.[12]
- Hydrophilic and hydrophobic ingredients. The dispersion of non-polar CO₂ gas molecules into the cell wall may be the cause of the increased absorption of hydrophobic active agents, as this would improve the hydrophobic environment. active agents.[3]
- Traditional Tablets frequently experience first-pass metabolism and are linked to a delayed onset of action. Effervescent tablets prevent both the rapid and primary metabolisms from effect also begins. The oral liquid also gives a quick effect; however, required a careful handling.[13]

Indian Senna (*Cassia angustifolia*) (Swarnapatri):



“*Cassia angustifolia*”, is a member of the Leguminosae family, and is recognized for its laxative properties. Commonly referred to as Indian senna, this plant is frequently employed for bowel cleansing prior to diagnostic procedures like colonoscopies. It serves as both a blood purifier and a remedy for constipation and skin ailments. The World Health Organization (WHO) approves its use, owing to the presence of the potent natural laxative anthraquinone. Senna classified as an anthranoid-type stimulant laxative, comprises “dianthrone glycosides, mucilage, tannins, and flavonoids”. Apart from serving as a dependable laxative, the leaves and pods of Indian senna also fulfill other functions like integral components in many over-the-counter laxatives. Recognized as a safe and effective solution for constipation, it initiates its detoxifying and colon-cleansing effects approximately 10-12 hours after ingestion.[14-20]



Figure 1: Indian Senna

Psyllium husk (*Plantago ovata*):

Psyllium husk, derived from the *Plantago ovata* plant of the Plantaginaceae family, serves as a natural remedy for constipation. It is recognized by several names, including “Blond plantain, Blond Plantago, Indian Plantago, Desert Indian wheat, Dietary fiber, Blond psyllium, Sand Plantain, and Isabel or ispagol”. It is grown as a lucrative (profitable) crop in various regions. like India, notably in different states like Haryana, Gujarat, Punjab and Rajasthan.[25] The intake of Ispaghula

has shown promise in relieving chronic severe constipation in many patients who don't suffer from slow colonic transit or irregular bowel movements. Conversely, a combination of fiber and lactulose has demonstrated potential in improving stool consistency for individuals with Irritable Bowel Syndrome (IBS) accompanied by constipation. Locally referred to as Isabel, the outer covering of the seeds of *Plantago ovata* (Psyllium husk) is renowned for its efficacy in treating chronic constipation. The prevailing notion regarding Psyllium's effectiveness in treating constipation attributes it to its high fiber and mucilaginous properties, which aid in promoting bowel movements.[25]



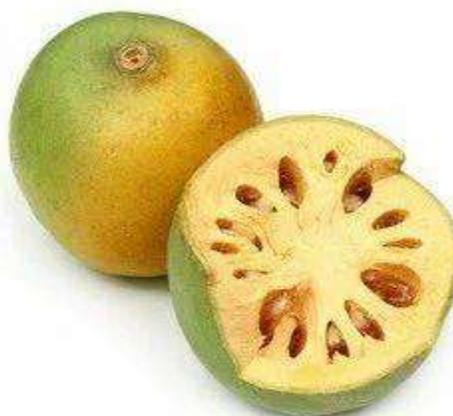
Figure 2: Psyllium husk (*Ispaghula*)

Triphala:

Triphala, a prominent Ayurvedic laxative, is a tri-herbal formulation from India. The term “Triphala” in Sanskrit translates to “three fruits,” reflecting its composition. This well-known Ayurvedic remedy comprises dried fruits from three distinct plant species native to the Indian subcontinent: “*Embolica officinalis*” (“Amalaki or the Indian Gooseberry”) from the “Euphorbiaceae” family, “*Terminalia bellirica*” (“Bibhitaki or Karitaki”) from the “Combretaceae” family, and “*Terminalia chebula*” (“Haritaki”) also from the “Combretaceae” family.[21-23] Indian health experts recommend the daily consumption of Triphala for a duration of one to two weeks to effectively manage constipation. To incorporate Triphala into one's routine, fresh fruits can be dried, powdered, and mixed with warm water or milk. A typical

recommendation involves mixing two tablespoons of powdered form Triphala extract with either mildly hot water or milk to address constipation.[21-23]

along with one teaspoon of the jaggery may help in relieving constipation.[23]



Bael fruit pulp (Aegle marmelos):

“Aegle marmelos”, a member of Rutaceae family, serves as a significant medicinal tree indigenous to India and the country Sri Lanka. The flesh of the Bael (wood apple) fruit is acknowledged as a powerful Ayurvedic treatment for constipation. Moreover, it is believed that ingesting half a cup measure of Bael fruit pulp

Figure 4: Bael Fruit Pulp

MATERIALS AND METHODS

The powder extract of Indian Senna (Cassia angustifoli), Psyllium husk (Ispaghula), Bael fruit pulp (Aegle marmelos) and Stevia were collected and purchased from the local market near Paltan Market (Shop Name- Arya Vastu Bhandar) of Dehradun, Uttarakhand, India.

Table 1: Ingredients with their properties

Ingredients	Properties
Indian Senna	Natural Laxative
Bael	Laxative
Ispaghula	Laxative, Bulking agent, Regulates bowel movement
Sodium Bicarbonate	Effervescent Agent
Citric acid	Effervescent Agent
Stevia	Sweetener
Maize Starch	Binders
Talc	Lubricant

The effervescent tablet of 500 mg was prepared as followings:-

Table 2: Formulation table of herbal effervescent tablets for constipation

INGREDIENTS	F1 (in mg)	F2 (in mg)	F3 (in mg)	F4 (in mg)
Bael	100	100	100	100
Indian Senna	50	50	50	50
Ispaghula	50	50	50	50
Stevia	20	30	10	15
Sodium Bicarbonate	200	200	215	215
Citric Acid	50	50	65	50
Maize Starch	20	10	-	10
Talc	10	10	10	10



Figure 5: Formulation F1



Figure 6: Formulation F2



Figure 7: Formulation F3



Figure 8: Formulation F4

The methods will be used in this study are:-

Ingredient Measurement:

- Determine therapeutic dosage for each ingredient, considering efficacy and safety.
- Establish a balanced ratio of Senna, Ispaghula and Bael for the intended treatment.

Powder Blending:

- Weigh and thoroughly blend Senna, Ispaghula and Bael powders by mortar and pestle to achieve a homogeneous mixture.

Alkalizing Agent Addition:

- Add sodium bicarbonate to the herbal blend to enhance effervescence.
- Optionally, include citric acid for additional effervescence.

Flavoring and Sweetening (Optional):

- Add Stavia (flavoring agents and sweeteners) to improve taste, making the tablet more palatable.

Binder Incorporation:

- Gradually introduce a suitable binder (Starch) to the powder mixture to enhance tablet cohesion.
- Add Talc as a lubricant in the tablet.

Tablet Compression:

- Employ a tablet press to compress the mixture into effervescent tablets.
- Adjust tablet hardness and weight as needed for patient compliance.

Drying (if necessary):

- If moisture is introduced during the blending process, ensure adequate drying to prevent tablet degradation.

EVALUATION TEST

Weight variations

Twenty effervescent tablets are chosen at random and weighed one at a time. We compute the average weight and standard deviation for each of the twenty effervescent tablets.[26]

Hardness:

Monosanto hardness tester is used to determine how hard an effervescent tablet is.[26]



Figure 8: Hardness Testing

Friability:

Weighing twenty effervescent tablets, they are put inside a Roche friabilator. With each revolution, the effervescent tablet descends six inches as it spins at 25 rpm. The effervescent pills are reweighed after being dusted.[26]



Figure 9: Friability Testing

Disintegration time:

When a tablet is added to 200 ml of water in a beaker that is heated to 150–250°C, many gas bubbles start to form. when there is no longer any particle agglomeration and the effervescent tablet in the water stops producing gas. The examination is redone. using five more effervescent tablets.[27]



Figure 10: Disintegration Test

Effervescence Time:

A stopwatch was used to measure the amount of effervescence that occurred following the addition of three tablets to three water-filled beakers. The period of bubble time was set at when a clear solution was obtained.[27]



Figure 11: Effervescence Testing (formation and timing)

RESULTS AND DISCUSSION

Four different formulations table were developed with varying concentrations of excipients to achieve optimal outcomes, as detailed in Table 2. And 500mg effervescent tablets are formulated. Uniform tablet thickness was maintained by ensuring consistent die filling, favorable flow characteristics, suitable pressure, and controlled punch motion. All the formulations met the weight variation limit of $0.50 \pm 10g$, as shown in Table 3. The friability of each formulation was below 1%,

indicating tablet durability. Tablet firmness (hardness) was determined using a hardness testing instrument, with values ranging from 40 to 80 (N). The effervescence test, conducted with 200 ml of water, revealed effervescence times between 2.10 and 5.58 minutes for all formulations, as outlined in Table 3. Among all parameters, the F1

formulation emerged as the most favorable for a comprehensive evaluation.

All the testing of my own effervescent tablets, conducted according to IP standards, confirmed uniformity in the dosage form, ensuring consistency across all tablet batches.

Table 3: Evaluation table of herbal effervescent tablets for constipation

Formulation	Weight Variation (gm)	Hardness	Friability (%)	Effervescent Time (min)	Disintegration Time (min)
F1	0.49	5.8	0.8	2.10	2.46
F2	0.54	8.3	2.1	5.58	5.24
F3	0.51	7.1	1	4.3	4.52
F4	0.47	7.9	1.3	5.17	5.09

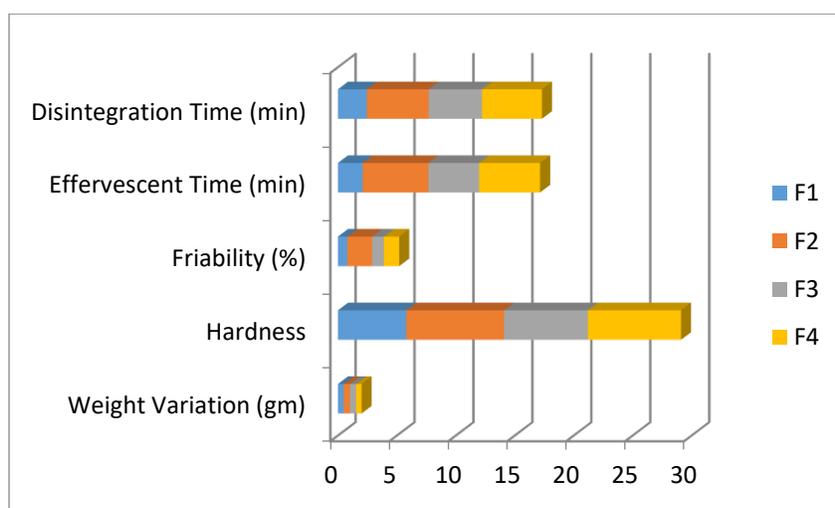


Fig 12: Graphical representation of Evaluation table of all formulations

CONCLUSION

In conclusion, constipation remains a prevalent gastrointestinal disorder affecting individuals across all age groups and demographics, significantly impacting their quality of life. The complexity of constipation calls for a comprehensive understanding of its causes, symptoms, and treatment modalities. Effervescent tablets present a promising approach for addressing constipation, offering benefits such as faster onset of action, improved taste, and enhanced gastrointestinal tolerance. The formulation and evaluation of herbal effervescent tablets for constipation represent a step towards

providing effective and accessible treatment options. Utilizing natural ingredients like Indian Senna, Psyllium husk, Bael fruit pulp, and Stevia, these tablets aim to harness the therapeutic properties of medicinal plants while minimizing adverse effects commonly associated with conventional medications. Through meticulous formulation processes and rigorous evaluation tests adhering to international standards, the efficacy and safety of these herbal effervescent tablets are ensured. The results demonstrate uniformity in dosage form, consistent tablet characteristics, and optimal effervescence properties across different formulations.

Effervescent tablets offer several advantages over traditional dosage forms, including faster absorption, increased patient compliance, and customizable dosing. However, it's essential to acknowledge the limitations, restrictions and hurdles connected with formulating effervescent tablet preparations, for example taste masking, cost-effectiveness, and stability concerns. Continued research and development efforts are necessary to overcome these obstacles and further optimize the efficacy and accessibility of herbal effervescent tablets for constipation management. In summary, the formulation and evaluation of herbal effervescent tablets for constipation represent a significant advancement in gastrointestinal healthcare, offering a safe, effective, and patient-friendly treatment option rooted in the rich tradition of herbal medicine. As we continue to explore innovative solutions for constipation management, collaboration between healthcare professionals, researchers, and pharmaceutical industries will be essential in driving progress and improving patient outcomes.

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