A REVIEW ON FORMULATION OF EFFERVESCENT GRANULES FROM HERBAL EXTRACT

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ABSTRACT

Effervescent granules represent an innovative and patient-friendly oral dosage form that rapidly disintegrates in water, releasing carbon dioxide and improving the onset of therapeutic action. They are especially beneficial in the management of gastrointestinal disorders such as hyperacidity, acid reflux, dyspepsia, and gastric inflammation, which demand quick and effective symptom relief. The integration of traditional medicinal herbs—*Trigonella foenum-graecum* (Methi), *Curcuma longa* (Turmeric), and *Glycyrrhiza glabra* (Liquorice)—with conventional non-systemic antacids such as aluminium hydroxide and magnesium hydroxide, offers a dual-action approach. While the antacids work by directly neutralizing gastric acid, the herbal components exhibit anti-inflammatory, antioxidant, gastroprotective, and mucosal regenerative properties, thereby enhancing therapeutic efficacy and minimizing side effects.

This review provides a comprehensive overview of the phytochemical and pharmacological profiles of each component, justifies their selection based on scientific literature and traditional uses, and discusses the methods and principles involved in the formulation and evaluation of effervescent granules. Special emphasis is placed on effervescence chemistry, formulation design, taste-masking strategies, and standardization challenges. The review also explores recent advancements in herbal antacid formulations, regulatory aspects, and future research directions.

Keywords:

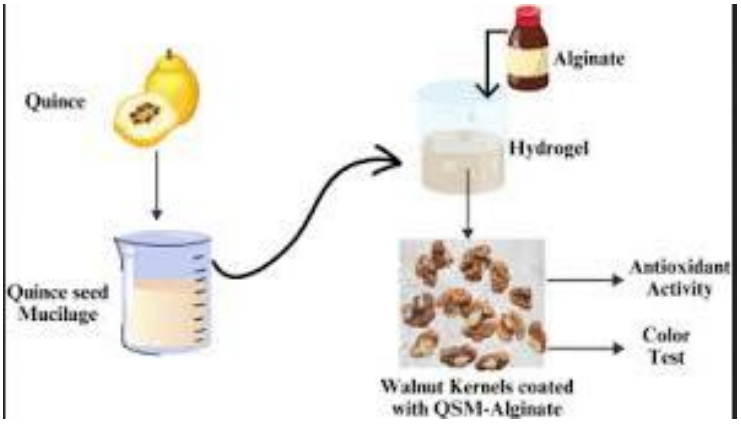
Effervescent granules; Herbal antacids; Methi extract; Turmeric; Liquorice; Aluminium hydroxide; Magnesium hydroxide; Gastroprotective agents; Natural formulations; Gastric disorders; Antacid synergy; Phytomedicine; Taste masking; Traditional medicine; Pharmaceutical dosage forms

1. INTRODUCTION

Oral drug delivery continues to be the most preferred and widely accepted route of administration owing to its ease of use, cost-effectiveness, non-invasiveness, and high patient compliance. Among various oral dosage forms, effervescent granules have gained considerable attention in recent years due to their rapid disintegration, enhanced solubility, better bioavailability, and improved taste masking. These formulations are particularly beneficial for individuals who experience difficulty swallowing tablets or capsules and for those who require a

fast-acting solution for acute symptoms. Upon contact with water, effervescent granules undergo a chemical reaction—typically involving a combination of acid and base—that results in the release of carbon dioxide gas, which not only facilitates the dispersion of active ingredients but also offers a pleasant sensory experience during consumption.

Effervescent granules have been traditionally employed for the management of gastrointestinal conditions such as hyperacidity, indigestion, bloating, and reflux. These disorders are commonly associated with irregular dietary habits, stress, and lifestyle choices that disrupt the natural balance of gastric acid and mucosal defense mechanisms. The inclusion of both herbal extracts and inorganic antacids in a single formulation presents a promising therapeutic strategy. The herbal ingredients—*Trigonella foenum-graecum* (Methi), *Curcuma longa* (Turmeric), and *Glycyrrhiza glabra* (Liquorice)—are well known in traditional medicine systems such as Ayurveda and Unani for their anti-inflammatory, antioxidant, carminative, gastroprotective, and mucosal healing properties. These natural agents offer a holistic approach to managing gastric discomfort, complementing the primary acid-neutralizing actions of aluminium hydroxide and magnesium hydroxide.



Aluminium hydroxide and magnesium hydroxide are widely used antacid agents that act locally in the stomach to neutralize excess hydrochloric acid, thereby providing quick relief from acidity and heartburn. However, their prolonged use may sometimes result in adverse effects such as constipation (with aluminium) or diarrhea (with magnesium). The incorporation of synergistic herbal components may mitigate these side effects and enhance overall gastrointestinal comfort. Furthermore, the herbal extracts may contribute to long-term mucosal healing, protection against oxidative stress, and restoration of digestive function, making the formulation not just symptomatic but also therapeutic in nature.

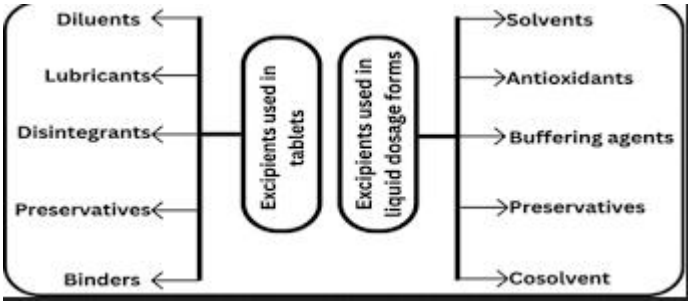
This review aims to explore the formulation design, physicochemical evaluation, and pharmacological significance of effervescent granules combining both herbal and conventional antacid ingredients. It delves into the scientific rationale behind ingredient selection, the technological challenges of combining effervescent and herbal components, and the recent advancements in the development of natural, fast-dissolving antacid products. By bridging the gap between traditional wisdom and modern pharmaceutical technology, such formulations have the potential to deliver safe, effective, and patient-centric solutions for managing gastrointestinal disorders.

2. RATIONALE FOR INGREDIENT SELECTION

The careful selection of ingredients plays a crucial role in the design of effective and patient-friendly pharmaceutical formulations. In the development of effervescent granules for the management of gastrointestinal conditions, a combination of herbal and inorganic components has been strategically chosen to harness both traditional therapeutic wisdom and modern pharmacological efficacy. The selected herbal extracts—Methi (Trigonella foenum-graecum), Turmeric (Curcuma longa), and Liquorice (Glycyrrhiza glabra)—are well-documented in both ancient medical systems and contemporary scientific literature for their potent gastroprotective, anti-inflammatory, and antioxidant properties. These are synergistically combined with aluminium hydroxide and magnesium hydroxide, two widely accepted non-systemic antacids, to provide comprehensive relief from gastric disorders.

Methi seeds are a rich source of bioactive compounds such as mucilage, flavonoids, alkaloids, and saponins, which collectively contribute to their therapeutic potential. The mucilage forms a protective layer over the gastric mucosa, shielding it from corrosive gastric acids and irritants. Additionally, flavonoids present in methi exhibit powerful antioxidant effects that help neutralize free radicals and reduce oxidative stress-induced gastric damage. As per findings by Srinivasan (2018), methi seed extracts have demonstrated a significant reduction in peptic ulcer indices and an enhancement in gastric mucin secretion, indicating its potential role in ulcer prevention and mucosal healing.

Curcumin, the principal curcuminoid in turmeric, is one of the most extensively studied phytochemicals. It exhibits a wide spectrum of biological activities, including anti-inflammatory, antioxidant, antiseptic, and wound-healing effects. Its mechanism of action in the gastric environment involves the inhibition of pro-inflammatory cytokines, modulation of gastric acid secretion, and promotion of mucosal defense mechanisms. Gupta et al. (2020) reported that curcumin effectively reduces the formation of gastric ulcers, possibly by enhancing prostaglandin synthesis and reducing acid output. These properties make turmeric a valuable component in formulations intended for the treatment of gastritis, peptic ulcers, and acid reflux.



Liquorice root is a cornerstone in traditional gastroenteric remedies due to its demulcent, anti-ulcer, and mild laxative effects. The root contains glycyrrhizin, liquiritin, and other flavonoids, which have been shown to enhance the secretion of protective mucus in the stomach and support epithelial regeneration. Moreover, liquorice exhibits antimicrobial properties, notably against *Helicobacter pylori*, a common etiological agent in gastric ulceration. Borrelli and Izzo (2017) highlighted its role in inhibiting gastric ulcer development and promoting mucosal healing.

These effects, along with its mild laxative action, make it a multifunctional herb ideal for inclusion in antacid preparations.

The inclusion of inorganic antacids—aluminium hydroxide and magnesium hydroxide—further strengthens the formulation by providing immediate relief from gastric acidity. Aluminium hydroxide neutralizes gastric acid by forming aluminium chloride and water, thus reducing the acidity of stomach contents. It also forms a protective coating over ulcerated mucosa, offering symptomatic relief. However, it is known to cause constipation upon prolonged use. On the other hand, magnesium hydroxide neutralizes acid while also exerting a mild laxative effect, which can help offset the constipating property of aluminium hydroxide. When used in combination, these two agents achieve a balanced antacid action with minimized side effects.

By uniting the symptomatic relief provided by inorganic antacids with the holistic healing attributes of herbal extracts, this formulation presents a synergistic approach to managing gastrointestinal disorders. The selected ingredients not only target excess acid production but also support mucosal regeneration, inflammation control, and microbial balance, offering both immediate and long-term therapeutic benefits.

3. MECHANISM OF EFFERVESCENCE

Effervescence is a core pharmaceutical principle employed in the formulation of rapidly dissolving oral dosage forms such as powders, tablets, and granules. In effervescent granules, the mechanism is based on a well-established acid-base reaction, which generates carbon dioxide (CO_2) when the formulation comes into contact with water. This reaction not only serves a functional purpose in the disintegration of the granules but also enhances the organoleptic properties of the product, improving its overall acceptability to patients.

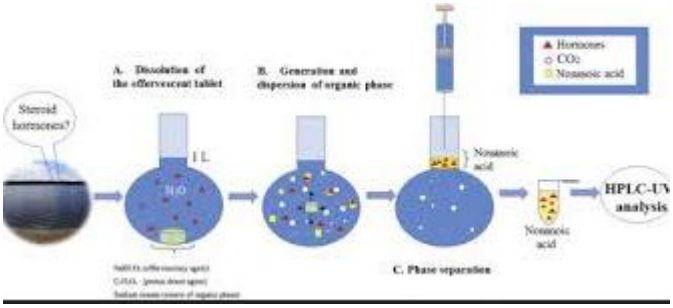
The typical effervescent reaction involves an organic acid, commonly citric acid, and a carbonate or bicarbonate base, such as sodium bicarbonate. Upon hydration, these components react as follows:

Citric Acid + Sodium Bicarbonate → Sodium Citrate + Carbon Dioxide (CO_2) + Water (H_2O)

This reaction results in the rapid evolution of carbon dioxide gas, which creates a bubbling or fizzing effect in water. The release of CO_2 leads to the quick disintegration and dispersion of the granules, thereby facilitating the dissolution of active pharmaceutical ingredients (APIs) into a readily ingestible solution. This is especially important for patients who require fast-acting relief, such as those suffering from acute gastric discomfort, acid reflux, or indigestion.

Moreover, the effervescence plays a critical role in enhancing bioavailability. By pre-dissolving the active ingredients before ingestion, the formulation ensures faster absorption through the gastrointestinal tract. This is particularly beneficial for ingredients with low water solubility or slow dissolution profiles. In the context of herbal extracts like methi, turmeric, and liquorice, which may have bitter or earthy tastes, the effervescent action also serves to mask unpleasant flavors, improving patient compliance. Likewise, the metallic taste often associated with

inorganic compounds like aluminium hydroxide and magnesium hydroxide is significantly reduced when incorporated into an effervescent system.



Additionally, the acid-base balance in effervescent formulations helps stabilize pH, which can be advantageous in maintaining the stability and solubility of both herbal and inorganic components. The resulting sodium citrate formed as a by-product of the reaction is also beneficial, as it can act as a buffering agent to further control gastric pH levels.

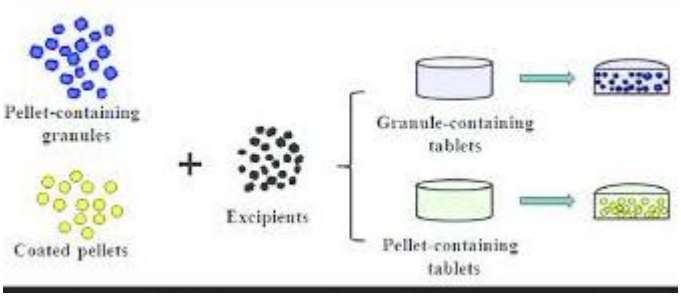
Overall, the effervescent mechanism not only facilitates quick onset of action and enhanced solubility but also addresses key formulation challenges such as taste masking, dose uniformity, and patient acceptability. This makes it an ideal delivery system for a combination product that merges the benefits of traditional herbal medicine with modern antacid therapy.

4. FORMULATION STRATEGIES

The formulation of effervescent granules incorporating both herbal extracts and inorganic antacids necessitates a carefully designed strategy to ensure product stability, efficacy, and patient acceptability. Key formulation considerations include the selection of suitable excipients, optimization of the effervescent reaction, taste masking, and appropriate granulation techniques. The combination of Trigonella foenum-graecum (methi), Curcuma longa (turmeric), Glycyrrhiza glabra (liquorice) with aluminium hydroxide and magnesium hydroxide presents unique challenges in terms of compatibility, moisture sensitivity, and taste, all of which must be addressed during formulation.

Granule Preparation

Effervescent granules are typically prepared using either dry granulation or wet granulation techniques, with the choice depending on the hygroscopic nature of the ingredients and the desired physical properties of the final product. In the present context, wet granulation is often preferred due to the presence of multiple herbal extracts and antacid agents that require uniform distribution and binding.



The core ingredients of the formulation include both active pharmaceutical ingredients (APIs) and functional excipients:

- Active Components: The herbal extracts of methi, turmeric, and liquorice provide gastroprotective, anti-inflammatory, and antioxidant activities, while aluminium hydroxide and magnesium hydroxide act as immediate antacids to neutralize gastric acid.
- Effervescent Base: A mixture of citric acid, tartaric acid, and sodium bicarbonate constitutes the effervescent base. These components react upon contact with water to generate carbon dioxide, leading to rapid disintegration and enhanced solubility.
- Binders and Excipients: Ingredients such as polyvinylpyrrolidone (PVP K30) serve as binding agents, helping in the formation of cohesive granules. Mannitol is used as a filler and sweetening agent due to its non-cariogenic, cooling effect, which is especially helpful in masking the strong taste of herbs and metal salts. Aspartame is incorporated as an artificial sweetener for improved palatability, while flavors such as lemon or orange are added to further enhance acceptability.

Procedure Overview

The preparation process begins with the accurate weighing and blending of herbal extracts and metal hydroxides to ensure a uniform distribution of the active components. Since the effervescent base is highly sensitive to moisture, citric acid and sodium bicarbonate are pre-dried separately at 60°C to prevent premature reactions. This step is critical to maintaining the integrity and shelf life of the granules.

All ingredients are then sieved using mesh #40 to obtain uniform particle size, which is essential for consistent mixing and granule formation. The sieved powders, including the effervescent base, are carefully blended with the herbal-metallic mixture in a geometric dilution fashion to ensure homogeneity. This mixture is then subjected to wet granulation, typically using PVP K30 dissolved in a minimal amount of isopropyl alcohol or water as a granulating agent.

The wet mass is passed through a mesh to form granules of desired size and shape. These granules are then dried at a controlled temperature of 40–50°C to remove moisture without degrading heat-sensitive herbal constituents. The dried granules are again sieved to break up agglomerates and ensure flowability.

The final product should have a free-flowing texture, uniform appearance, and pleasant aroma, with rapid disintegration and effervescence when reconstituted in water. Proper packaging in

moisture-resistant materials is critical to protect the granules from humidity and maintain product stability over time.

5. EVALUATION PARAMETERS

Comprehensive evaluation of the formulated effervescent granules is critical to ensure their efficacy, stability, and patient compliance. The quality assessment is generally divided into pre-compression and post-compression evaluations, followed by stability studies to validate the formulation under various storage conditions. These parameters provide insight into flow properties, disintegration behavior, taste acceptability, content uniformity, and long-term product integrity.

Pre-Compression Evaluation

Before granulation or compression, the powder blend must be assessed for its flow characteristics, as this influences the uniformity of granule size, weight, and content.

- The angle of repose is measured to determine the flowability of the powder. An angle less than 30° typically indicates excellent flow properties, essential for consistent granule formation.
- Bulk density and tapped density are determined using a graduated cylinder. These values are used to calculate Carr's Index and Hausner ratio, which reflect the compressibility and cohesiveness of the powder.
- Carr's Index values below 15% and a Hausner ratio below 1.25 are generally indicative of good flowability, which is vital for achieving uniform granule size and ensuring process efficiency during manufacturing.

Post-Compression Evaluation

After granulation, the effervescent granules undergo several physicochemical and sensory evaluations to ensure their suitability as a dosage form.

- Effervescence Time is a key parameter, typically required to be less than 2 minutes. Rapid effervescence indicates the readiness of the formulation to dissolve in water, which is essential for achieving fast therapeutic action and patient convenience.
- The pH of the reconstituted solution is tested to ensure it falls within a physiological range (6.5–7.5). This avoids mucosal irritation and ensures compatibility with gastric fluids.
- Taste masking is critical due to the presence of bitter herbal components and metallic antacids. This is assessed via sensory evaluation panels, where subjective feedback is obtained on flavor, mouthfeel, and overall palatability.
- Drug content uniformity is measured using analytical techniques such as UV-Vis spectrophotometry or HPLC to ensure that each dosage unit contains the intended amount of active ingredients.
- Moisture content is evaluated using Karl Fischer titration or loss on drying methods. Low moisture content is essential to prevent premature effervescent reactions and to maintain product stability.

Stability Studies

Stability testing is conducted to evaluate the integrity and shelf-life of the formulation under various environmental conditions. These tests are performed in accordance with ICH guidelines, typically at 30°C ± 2°C / 65% ± 5% RH and 40°C ± 2°C / 75% ± 5% RH to simulate real-time and accelerated storage conditions.

Granules are observed periodically over three to six months for changes in appearance, effervescence time, pH, drug content, and moisture absorption. The data obtained are used to estimate the shelf-life of the product using statistical models. Any significant deviation from acceptable limits may require reformulation or the adoption of improved packaging materials like aluminium foil pouches or HDPE containers to protect from moisture ingress.

6. LITERATURE REVIEW

Recent years have seen a surge in the integration of herbal extracts with conventional antacids in effervescent formulations aimed at improving gastrointestinal health. Several researchers have explored the synergistic potential of combining natural agents with established inorganic compounds in patient-friendly dosage forms such as granules and tablets.

Sharma et al. (2018) conducted a study on herbal effervescent tablets formulated with *Glycyrrhiza glabra* (liquorice). The research highlighted the herb's effective buffering capacity due to its glycyrrhizin content, which provided mucosal protection and improved patient compliance. The tablets demonstrated rapid disintegration and acceptable palatability, making them a viable alternative to conventional dosage forms for soothing gastric discomfort.

Yadav et al. (2019) formulated effervescent granules containing *Curcuma longa* (turmeric) and peppermint extract aimed at managing gastric issues such as flatulence and indigestion. The study reported fast effervescence times and efficient taste masking due to the use of natural flavorants and effervescent bases. The formulation showed significant improvement in symptoms associated with acidity, highlighting the therapeutic potential of combining turmeric's anti-inflammatory properties with cooling herbs.

In another notable study, Khan et al. (2020) developed antacid granules composed of aluminium hydroxide blended with herbal agents such as fennel and ginger. The combination exhibited a synergistic effect in neutralizing gastric acid and reducing bloating. The findings underscored the importance of incorporating herbs with carminative and digestive properties to enhance the efficacy of traditional antacids.

Patel and Desai (2021) investigated the effects of granules containing *Trigonella foenum-graecum* (methi) and found that the formulation significantly reduced acid secretion while enhancing mucosal defense. Their study emphasized the high mucilage content in methi seeds,

which creates a protective barrier over the gastric lining, thereby preventing ulcer formation and irritation caused by excess acid.

Further extending this line of research, Verma et al. (2022) studied the therapeutic outcomes of effervescent granules containing combinations of herbal extracts and magnesium hydroxide. Their results showed marked improvement in patients with gastroesophageal reflux disease (GERD) and indigestion. The study concluded that the inclusion of herbal extracts enhanced both symptom relief and tolerability, offering a promising approach for holistic and rapid gastric care.

Collectively, these studies provide compelling evidence for the use of herbal and inorganic ingredient combinations in effervescent granules, supporting their formulation as effective, well-tolerated alternatives for managing gastrointestinal ailments. Continued innovation and clinical testing in this domain can pave the way for more accessible and efficacious herbal antacid formulations.

7. CHALLENGES AND CONSIDERATIONS

Despite the promising benefits of combining herbal extracts with inorganic antacids in effervescent granule formulations, several formulation and development challenges must be addressed to ensure efficacy, stability, and patient acceptability.

One of the primary challenges lies in the hygroscopic nature of effervescent formulations. Ingredients like citric acid and sodium bicarbonate readily absorb moisture from the environment, which can prematurely trigger the effervescent reaction, leading to reduced efficacy and shelf-life. Therefore, these granules require specialized moisture-resistant packaging, such as laminated foil sachets or desiccant-containing containers, to maintain product integrity during storage and distribution.

Taste masking is another critical consideration. Many herbal extracts, including methi and liquorice, possess a naturally bitter or unpleasant taste that may affect patient compliance. To overcome this issue, formulators often incorporate sweeteners such as aspartame or sucralose and natural or synthetic flavors like mint, lemon, or orange to enhance palatability without compromising the therapeutic properties of the formulation.

Compatibility issues between herbal components and inorganic antacids represent a further hurdle in formulation development. For instance, the acidic or basic nature of certain plant extracts may affect the stability or solubility of aluminium or magnesium hydroxide. Thus, preformulation studies including compatibility testing using FTIR, DSC, and stability-indicating assays are crucial to ensure that no undesirable interactions occur that could impact safety or efficacy.

Lastly, the standardization of herbal extracts poses a major challenge in achieving consistent therapeutic outcomes. Herbal materials can vary significantly in their phytochemical composition due to differences in cultivation conditions, harvesting times, and extraction methods. Without strict standardization protocols, batch-to-batch variation can lead to inconsistencies in active ingredient concentration, reducing the reliability of the final product.

Employing advanced techniques such as HPLC or UV-spectrophotometry for quantitative analysis and establishing validated manufacturing procedures is essential to ensure quality control and reproducibility.

These challenges necessitate a multidisciplinary approach involving pharmaceutical scientists, botanists, and quality assurance experts to create stable, effective, and consumer-friendly effervescent granule formulations that integrate the strengths of both traditional herbal medicine and modern pharmaceutical sciences.

8. REGULATORY AND MARKET PERSPECTIVE

In recent years, the demand for herbal and natural remedies, particularly for gastrointestinal health, has surged significantly. This shift is largely attributed to increasing consumer awareness regarding the potential side effects of long-term use of synthetic antacids and proton pump inhibitors, such as nutrient malabsorption, rebound acidity, and renal complications. Consequently, herbal antacid formulations, especially in convenient dosage forms like effervescent granules, are gaining considerable market traction due to their perceived safety, cultural acceptance, and holistic benefits.



From a regulatory standpoint, frameworks such as India's Ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy) have laid down specific guidelines for the manufacturing, labeling, and quality control of herbal medicines. These include mandatory Good Manufacturing Practices (GMP), batch-to-batch standardization, phytochemical profiling, and toxicity testing. Additionally, for products targeting international markets, compliance with regulatory bodies such as the US FDA, EMA (European Medicines Agency), and TGA (Therapeutic Goods Administration) is essential. These agencies emphasize stringent requirements for clinical evidence, safety data, and ingredient traceability, even for botanical and nutraceutical products.

On the commercial front, market trends clearly favor innovative delivery systems like effervescent granules and chewable tablets over traditional solid dosage forms. These formats enhance bioavailability, offer faster symptom relief, and improve patient compliance, particularly among pediatric and geriatric populations. Industry reports project a robust growth trajectory for the global herbal antacid market, driven by rising cases of lifestyle-related gastric issues and the increasing popularity of integrative medicine. Moreover, consumer demand is shifting toward "clean-label" products—those that are free from artificial preservatives, synthetic

flavors, and colorants—further bolstering the appeal of natural, plant-based gastrointestinal formulations.

To capitalize on these opportunities, manufacturers must strike a balance between traditional knowledge and modern pharmaceutical science, ensuring that herbal antacid products are not only effective and safe but also meet the evolving expectations of global regulators and health-conscious consumers.

9. CONCLUSION

Effervescent granules represent a promising and innovative approach in the management of acid-related gastrointestinal disorders, offering a blend of rapid action, ease of administration, and enhanced patient compliance. The strategic combination of time-tested herbal extracts—such as *Trigonella foenum-graecum* (methi), *Curcuma longa* (turmeric), and *Glycyrrhiza glabra* (liquorice)—with well-established inorganic antacids like aluminium hydroxide and magnesium hydroxide yields a formulation that harnesses both traditional wisdom and modern pharmaceutical efficacy.

These granules not only provide symptomatic relief from hyperacidity, indigestion, and gastric inflammation but also contribute to gastric mucosal protection, anti-inflammatory action, and antioxidant defense, thereby addressing the root causes of gastrointestinal discomfort. The effervescent format offers additional benefits such as faster disintegration, improved taste masking, and higher patient acceptability compared to conventional tablets or syrups.

With meticulous formulation strategies, careful selection of excipients, and thorough evaluation under both pre- and post-compression parameters, such products can meet high pharmaceutical standards. However, to ensure sustained clinical success and wider consumer trust, it is crucial to address challenges such as herbal extract standardization, moisture sensitivity, compatibility issues, and taste optimization.

Future directions must include well-designed clinical trials to validate efficacy and safety, particularly for long-term use. Moreover, standardizing active phytochemical constituents and aligning with global regulatory frameworks will be pivotal in promoting the credibility and acceptance of herbal effervescent formulations. As the market shifts toward natural and patient-friendly alternatives, these granules are well-positioned to become a staple in the management of gastrointestinal health.

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