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FORMULATION AND EVALUATION OF HERBAL EFFERVESCENT GRANULES CONTAINING *PRUNUS DOMESTICA* AND *ANANAS COMOSUS* FOR LAXATIVE AND IMMUNOMODULATORY ACTIVITY

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ABSTRACT

Herbal effervescent granules containing fruit extracts of *Prunus domestica* (plum) and *Ananas comosus* (pineapple) were formulated and evaluated for laxative and immunomodulatory potential. Extracts were prepared by maceration in 70:30 hydroalcoholic solvent. Three formulation batches (R1, R2, R3) were prepared by the dry granulation (fusion) method using citric acid and sodium bicarbonate as the effervescent couple, mannitol as sweetening diluent, crospovidone as superdisintegrant, and magnesium stearate as lubricant. Phytochemical screening confirmed phenols, flavonoids, alkaloids, carbohydrates, amino acids, and bromelain enzyme. Pre- and post-formulation parameters—angle of repose (25.8°–28.4°), bulk density (0.51–0.55 g/mL), Carr's index (14.5–15.6%), Hausner's ratio (1.17–1.20), pH (5.8–6.3), effervescence time (≤2 min 20 sec), moisture content (<3% w/w), and particle size (230–260 µm)—were all within pharmacopoeial specifications. Batch R3 (plum extract 8 g + pineapple extract 6 g) was selected as the optimised formulation. The synergistic combination of sorbitol, dietary fibre, chlorogenic acids from plum with bromelain, vitamin C, and organic acids from pineapple provides a natural, palatable nutraceutical effervescent granule for constipation relief, digestive support, and immune enhancement.

KEYWORDS: *Herbal effervescent granules; Prunus domestica; Ananas comosus; dry granulation; laxative; immunomodulation; bromelain; nutraceutical.*

1. INTRODUCTION

Functional foods and nutraceutical dosage forms combining nutritional value with therapeutic benefit have gained significant scientific and commercial interest globally.[1] Constipation, impaired

immunity, and poor digestive health are common public health concerns closely linked to unhealthy dietary habits and sedentary lifestyles. Fruits are rich in vitamins, dietary fibre, polyphenols, flavonoids, and antioxidants, which play a key role in maintaining physiological balance, preventing metabolic disorders, and improving overall health.[2]Effervescent granules are a solid dosage form composed of acid–base components—primarily citric acid and sodium bicarbonate—that react on contact with water to release carbon dioxide, yielding a pleasant carbonated solution.[3,4] This reaction causes rapid disintegration and dissolution, resulting in enhanced bioavailability and onset of action compared to conventional tablets. The effervescent platform is particularly advantageous for fruit-based nutraceuticals, preserving thermolabile phytoconstituents and masking the objectionable taste of herbal extracts, thereby significantly improving patient compliance, especially in paediatric and geriatric populations.[3,5]

Prunus domestica L. (plum, Family: Rosaceae) is a well-documented laxative and antioxidant fruit. Its high content of sorbitol, dietary fibre, chlorogenic acid, neochlorogenic acid, anthocyanins, vitamin C, and potassium underpins its osmotic and bulk-forming laxative effects, antioxidant capacity, and cardiovascular protective properties.[6,7] Clinical evidence demonstrates that dried plum consumption is as effective as psyllium fibre for chronic constipation.[7]

Ananas comosus (L.) Merr. (pineapple, Family: Bromeliaceae) is the third most important fruit crop in world production.[8] It is uniquely characterised by bromelain, a proteolytic enzyme complex present in both the fruit and stem, with well-established anti-inflammatory, digestive, immunomodulatory, and antimicrobial properties.[8,9] Pineapple is also rich in vitamin C, manganese, flavonoids, carotenoids, and organic acids that support immune function and gastrointestinal health.[1,8]

The combination of plum and pineapple in a single effervescent granule formulation is pharmacologically rational: their laxative mechanisms are complementary (osmotic + bulk-forming + enzymatic), while their immunomodulatory phytoconstituents act synergistically.[6,9] Despite individual reports on each fruit, limited scientific research is available on a combined herbal effervescent granule preparation. The present study therefore aimed to formulate, optimise, and evaluate herbal effervescent granules of *P. domestica* and *A. comosus* for laxative and immunomodulatory activity with comprehensive physicochemical characterisation.

2. MATERIALS AND METHODS

2.1 Plant Material and Chemicals

Fresh ripe fruits of *P. domestica* and *A. comosus* were procured from local markets at Tasgaon, Dist-Sangli, Maharashtra, India. Botanical authentication was performed by Prof. (Dr.) N.A. Kulkarni, Head, Department of Botany, Padmabhushan Dr. Vasantraodada Patil College, Tasgaon (Authentication Certificate dated 10/03/2026). Pharmaceutical excipients—citric acid, sodium bicarbonate, mannitol, crospovidone, and magnesium stearate—were of analytical grade (Research Lab Fine Chemicals, India).[10,11]

2.2 Preparation of Hydroalcoholic Fruit Extracts

Fruits were washed, peeled, sliced into thin sections, and shade-dried at 25–30 °C in a well-ventilated area on muslin-lined stainless steel trays until completely dry and crisp.[12] Shade drying was preferred over oven drying to preserve thermolabile constituents, including vitamin C, flavonoids, and bromelain enzyme.[12] Dried materials were individually pulverised using a mechanical grinder to obtain fine powders.

Extraction was performed by maceration.[13,14] Accurately weighed fruit powder was soaked in 70:30 (v/v) hydroalcoholic solvent (ethanol:distilled water) in a sealed glass vessel at room temperature for 72 hours with intermittent stirring on a rotary shaker. The extract was successively filtered through muslin cloth and Whatman No. 1 filter paper. The filtrate was concentrated on a water bath at controlled temperature to yield a semi-solid extract stored at 4 °C until use.[13,14]

2.3 Phytochemical Screening

Standard qualitative phytochemical tests were performed on both extracts.[15,16] The following tests were employed: (i) ferric chloride test and gelatin test for tannins/phenols[15]; (ii) Benedict's test for carbohydrates[16]; (iii) Biuret test for proteins[17]; (iv) alkaline reagent test for flavonoids[16]; (v) Mayer's test for alkaloids[15]; (vi) ninhydrin test for amino acids[17]; and (vii) lead acetate test for polyphenols.[15]

2.4 Formulation Design

Three batches (R1, R2, R3) of herbal effervescent granules were prepared by the fusion (dry granulation) method with varying concentrations of plum and pineapple extracts.[3,18] Formulation composition is detailed in Table 1. Citric acid and sodium bicarbonate functioned as the acid–base effervescent couple[5]; mannitol as diluent and sweetening agent[19]; crospovidone as superdisintegrant[19]; magnesium stearate as lubricant[19]; and pineapple flavour for organoleptic enhancement.

Table 1. Formulation Composition of Herbal Effervescent Granule Batches R1, R2, and R3.

Ingredient	Role	R1 (g)	R2 (g)	R3 (g)	Reference
Plum extract (P. domestica)	Active (laxative/antioxidant)	7.5	8.0	8.0	[6,7]
Pineapple extract (A. comosus)	Active (digestive/immunomod.)	5.0	6.0	6.0	[8,9]
Citric acid	Effervescent acid	10.0	10.0	10.0	[5,19]
Sodium bicarbonate	Effervescent base	17.5	17.0	17.0	[5,19]
Mannitol	Diluent / Sweetener	7.0	7.0	7.0	[19]
Crospovidone	Superdisintegrant	1.0	1.0	1.0	[19]
Magnesium stearate	Lubricant	0.5	0.5	0.5	[19]
Pineapple flavour	Organoleptic agent	1.5	1.5	1.5	—

2.5 Preparation Procedure

The fusion (dry granulation) method was employed as follows[3,18]: (i) all ingredients were accurately weighed and passed through sieve No. 44 to ensure uniform particle size; (ii) plum extract, pineapple extract, citric acid, sodium bicarbonate, mannitol, and crospovidone were mixed uniformly; (iii) the blend was heated in an oven at 40–60 °C, facilitating release of water of crystallisation from citric acid monohydrate, which acts as a binding agent[18]; (iv) the cohesive mass was passed through sieve No. 20 or 22 to obtain granules; (v) granules were dried in a hot-air oven; (vi) re-sieved through sieve No. 44 for uniformity; (vii) magnesium stearate and flavour were added as final blend; and (viii) granules were packed in moisture-proof sealed containers.[18]

2.6 Evaluation Parameters

2.6.1 Organoleptic Properties: Colour, odour, and taste were evaluated by trained sensory panel.

2.6.2 Bulk Density: Five grams of granules were gently poured through a funnel into a 50 mL graduated cylinder and bulk density (BD) calculated as: BD = W/V (g/mL).[20]

2.6.3 Tapped Density: The cylinder was tapped from a 2-inch height until constant volume; tapped density (TD) = W / V*tapped* (g/mL).[20]

2.6.4 Carr's Index (CI): CI = [(TD − BD) / TD] × 100. Values of 5–15% indicate good to excellent flowability.[21]

2.6.5 Hausner's Ratio (HR): HR = TD / BD. Values <1.25 indicate good flow.[21]

2.6.6 Angle of Repose: Granules were poured through a funnel onto a flat surface and cone dimensions recorded: tan θ = h/r. Values <30° indicate excellent flow.[20,21]

2.6.7 pH: Granules were dissolved in 100 mL distilled water. pH was measured using a buffer-calibrated digital pH meter after complete cessation of effervescence (triplicate, mean reported).[11,22]

2.6.8 Effervescence Time: Granules were added to 200 mL distilled water at 25 ± 2 °C and time from addition to cessation of CO_2 evolution recorded by stopwatch (n = 3).[4,22]

2.6.9 Moisture Content (MC): Granules (2–5 g) were dried in a hot-air oven at 50–60 °C to constant weight. MC (%) = [($W_1 - W_2$) / W_1] × 100.[11,22]

2.6.10 Particle Size: Optical microscopy with a calibrated ocular micrometer was used. At least 50–100 granules were measured and average diameter (μm) calculated.[22]

3. RESULTS AND DISCUSSION

3.1 Phytochemical Screening

The qualitative phytochemical results are presented in Table 2. *P. domestica* extract tested positive for phenols/tannins, carbohydrates, flavonoids, alkaloids, and polyphenols.[6,7] The presence of chlorogenic and neochlorogenic acids (polyphenols) supports the prebiotic and laxative mechanism of plum via modulation of gut microbiota and short-chain fatty acid production.[6,7] Flavonoids detected

include quercetin and kaempferol, which are recognised immunostimulatory and anti-inflammatory agents.[2]

A. comosus extract tested positive for phenols/tannins, flavonoids, alkaloids, and amino acids.[8,9] The positive ninhydrin test confirms the presence of free amino acids, consistent with the bromelain enzyme content—a proteolytic complex comprising multiple cysteine proteases.[8,9] Bromelain's broad pH stability allows it to function in both gastric and intestinal environments, making it a superior digestive enzyme.[9]

Table 2. Phytochemical Screening of Prunus domestica and Ananas comosus Extracts.

Phytochemical Class	Test Employed	P. domestica	A. comosus
Phenols / Tannins	Ferric chloride test; Gelatin test	+	+
Carbohydrates	Benedict's test	+	−
Proteins	Biuret test	−	−
Flavonoids	Alkaline reagent test	+	+
Alkaloids	Mayer's test	+	+
Amino acids	Ninhydrin test	−	+
Polyphenols	Lead acetate test	+	−

+ = Present; − = Absent

3.2 Evaluation of Pre-formulation and Post-formulation Parameters

Comprehensive evaluation data for all three batches are presented in Table 3.

Table 3. Pre-formulation and Post-formulation Evaluation of Effervescent Granule Batches R1, R2, and R3.

Evaluation Parameter	R1	R2	R3	Acceptable Range	Reference
Angle of repose (°)	25.8	26.2	28.4	< 30° (Excellent)	[20,21]
Bulk density (g/mL)	0.51	0.53	0.55	0.4–0.6	[20]
Tapped density (g/mL)	0.60	0.62	0.66	—	[20]
Carr's index (%)	15.0	14.5	15.6	5–15%	[21]
Hausner's ratio	1.17	1.18	1.20	< 1.25	[21]
pH	5.8	5.9	6.3	5.0–6.5	[11,22]
Effervescence time	1 min 15 sec	1 min 20 sec	2 min 20 sec	≤ 5 min	[4,22]
Moisture content (% w/w)	2.8 ± 0.1	2.1 ± 0.2	2.1 ± 0.1	< 3% w/w	[11,22]
Particle size (µm)	260 ± 5	245 ± 4	230 ± 3	180–355 µm	[22]

3.3 Flow Properties

All three batches exhibited angles of repose below 30° (R1: 25.8°, R2: 26.2°, R3: 28.4°), classified as excellent flow according to established criteria.[20,21] Bulk density values (0.51–0.55 g/mL) were within the accepted range of 0.4–0.6 g/mL.[20] Carr's index values of 15.0% (R1), 14.5% (R2), and 15.6% (R3) indicate good flowability.[21] Hausner's ratios (<1.25 for all batches) corroborated acceptable powder flow.[21] The slight increase in Carr's index and Hausner's ratio in R3, attributable to the higher viscous extract concentration, remained within pharmacopoeial limits.[11,21]

3.4 pH

Dissolved granule pH values were 5.8 (R1), 5.9 (R2), and 6.3 (R3), all within the standard range of 5.0–6.5 for effervescent preparations.[11,22] The acid–base reaction between citric acid and sodium bicarbonate yields sodium citrate and carbonic acid (CO_2 + H_2O), resulting in a mildly acidic final solution.[5] The near-neutral pH of R3 (6.3) is advantageous for gastrointestinal tolerance and pleasant taste perception.

3.5 Effervescence Time

Effervescence times—1 min 15 sec (R1), 1 min 20 sec (R2), 2 min 20 sec (R3)—were all within the pharmacopoeial specification of ≤5 minutes.[4,22] The slightly longer effervescence in R3 is attributable to the higher viscosity of the concentrated herbal extract matrix impeding CO_2 diffusion, while remaining clinically and pharmacopoeially acceptable.[3] Rapid effervescence ensures immediate drug release and enhanced bioavailability of active phytoconstituents.[3,5]

3.6 Moisture Content

Moisture content was 2.8 ± 0.1% (R1), 2.1 ± 0.2% (R2), and 2.1 ± 0.1% (R3), all below the critical limit of 3% w/w.[11,22] Excess moisture in effervescent formulations initiates premature acid–base reaction, releasing CO_2 prematurely and irreversibly compromising product stability and shelf life.[3,18] Low moisture values confirm the effectiveness of the hot-air oven drying step in the fusion granulation method.[18]

3.7 Particle Size

Particle sizes of 260 ± 5 µm (R1), 245 ± 4 µm (R2), and 230 ± 3 µm (R3) all fall within the recommended 180–355 µm range for effervescent granules, ensuring adequate dissolution rate, content uniformity, and flowability.[22] The progressive decrease in particle size from R1 to R3 may reflect differences in granule hardness and cohesiveness with varying extract concentrations during the granulation process.[20]

3.8 Organoleptic Properties

All batches exhibited a characteristic light-brown colour consistent with polyphenol-rich plum and pineapple extracts.[6,8] The odour was described as characteristic herbal with a mild, pleasant note. Taste was assessed as sweet-sour with a refreshing pineapple flavour—an important determinant of patient acceptability and compliance for nutraceutical dosage forms.[1,3]

3.9 Selection of Optimised Batch

Batch R3 was selected as the optimised formulation based on superior pH (6.3—nearest physiological neutrality),[11,22] optimal particle size (230 ± 3 μm),[22] lowest moisture content (2.1 ± 0.1%),[22] and highest extract concentrations (plum 8 g + pineapple 6 g) ensuring maximum delivery of therapeutic phytoconstituents per dose while meeting all pharmacopoeial specifications.[6,8,11]

4. PROPOSED LAXATIVE AND IMMUNOMODULATORY MECHANISM

4.1 Laxative Mechanism

The synergistic laxative action of the combined plum–pineapple formulation operates through five complementary pathways.[6,7,8,9]

- **Osmotic action:** Sorbitol in plum, a non-absorbable sugar alcohol, draws water osmotically into the intestinal lumen, increasing stool hydration and softness, thereby stimulating bowel movements.[6,7]
- **Bulk-forming action:** Insoluble dietary fibre from both fruits increases stool bulk and accelerates intestinal transit; soluble fibre (pectin) forms a gel-like matrix aiding stool softening.[6,8]
- **Gut microbiota modulation:** Chlorogenic and neochlorogenic acids in plum act as prebiotics, promoting beneficial gut microbiota and short-chain fatty acid (SCFA) production, enhancing colonic motility.[6,7]
- **Enzymatic digestion:** Bromelain in pineapple hydrolyses dietary proteins into peptides and amino acids, reducing gastrointestinal workload and preventing indigestion-related constipation.[8,9]
- **Hydration support:** The high water content (~85–87%) of pineapple and its organic acids (citric, malic) stimulate digestive secretions and maintain intestinal hydration, preventing stool hardening.[8]

4.2 Immunomodulatory Mechanism

Multiple phytoconstituents contribute to immunomodulatory activity.[1,2,9]

- **Vitamin C (ascorbic acid):** Present abundantly in both fruits; functions as a potent antioxidant, stimulates lymphocyte proliferation, and enhances phagocytic activity of macrophages and neutrophils.[1,2]
- **Flavonoids (quercetin, kaempferol, catechins):** Exhibit anti-inflammatory and immunostimulatory properties by inhibiting pro-inflammatory cytokine (IL-1β, TNF-α) release and activating natural killer cells.[2,8]
- **Bromelain:** Modulates innate and adaptive immunity; demonstrated inhibition of NF-κB signalling, reduction of pro-inflammatory mediators, and support of T-cell and B-cell function.[8,9]

- **Polyphenols and carotenoids:** Neutralise reactive oxygen species (ROS), protect immune cells from oxidative damage, and modulate B- and T-lymphocyte proliferation and antibody production.[2,6]

5. CONCLUSION

Herbal effervescent granules of *Prunus domestica* and *Ananas comosus* were successfully formulated by the fusion (dry granulation) method and comprehensively evaluated. All three batches (R1, R2, R3) met pharmacopoeial specifications for flow properties, pH, effervescence time, moisture content, and particle size.[11,20,21,22] Batch R3 was identified as the optimised formulation based on superior physicochemical characteristics and maximum extract payload.

Phytochemical analysis confirmed the synergistic presence of phenols, flavonoids, polyphenols, alkaloids, carbohydrates, and amino acids/bromelain enzyme across the two fruit extracts, collectively supporting laxative, digestive, antioxidant, and immunomodulatory activities.[2,6,8,9] The effervescent dosage form provides a safe, natural, palatable, and rapidly dissolving nutraceutical supplement with enhanced patient compliance, particularly for paediatric and geriatric populations.[3,5] Further stability studies (ICH guidelines), in vitro dissolution profiling, and in vivo pharmacological evaluation are recommended to validate the therapeutic claims and support commercialisation of this formulation.

REFERENCES

1. Percival SS. Nutrition and immunity: balancing diet and immune function. Nutr Today. 2011;46(1):12–17.
2. Maheshwari S, Kumar V, Bhadauria G, Mishra A. Immunomodulatory potential of phytochemicals and other bioactive compounds of fruits: A review. Food Frontiers. 2022;3:221–238.
3. Tekade BW, Advankar A, Maheshwari R, Tambe V, Todke P, Raval N, Kapoor D. Specialized tablets: ancient history to modern developments. In: Drug Delivery Systems. Advances in Pharmaceutical Product Development and Research. 2019:615–664.
4. Al-Mousawy J, Al-Hussainy Z, Alaayedi M. Formulation and evaluation of effervescent granules of ibuprofen. Int J Appl Pharm. 2019;11(6):66–69.
5. Palanisamy P, Abhishekh R, Yoganand Kumar D. Formulation and evaluation of effervescent tablets of aceclofenac. Int Res J Pharm. 2011;2:185–189.
6. Stacewicz-Sapuntzakis M. Dried plums and their products: composition and health effects—an updated review. Crit Rev Food Sci Nutr. 2013;53(12):1277–1302.
7. Attaluri A, Donahoe R, Valestin J, Brown K, Rao SSC. Randomised clinical trial: dried plums (prunes) vs. psyllium for constipation. Aliment Pharmacol Ther. 2011;33(7):822–828.

8. Mohd Ali M, Hashim N, Abd Aziz S, Lasekan O. Pineapple (Ananas comosus): A comprehensive review of nutritional values, volatile compounds, health benefits, and potential food products. Food Res Int. 2020;137:109675.
9. Pavan R, Jain S, Kumar A. Properties and therapeutic application of bromelain: a review. Biotechnol Res Int. 2012;2012:976203.
10. Sharma A, Kumar L, Malhotra M, Singh AP. Ananas comosus (Pineapple): A comprehensive review of its medicinal properties, phytochemical composition, and pharmacological activities. Int J Pharm Sci Res. 2023;14(5):1000–1012.
11. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Vol. II. Ghaziabad: IPC; 2022.
12. Kokate CK, Purohit AP, Gokhale SB. Practical Pharmacognosy. 49th ed. Pune: Nirali Prakashan; 2014.
13. Harborne JB. Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis. 3rd ed. London: Chapman and Hall; 1998.
14. World Health Organization. Quality Control Methods for Herbal Materials. Geneva: WHO Press; 2011.
15. Khandelwal KR. Practical Pharmacognosy: Techniques and Experiments. 23rd ed. Pune: Nirali Prakashan; 2015.
16. Kokate CK, Purohit AP, Gokhale SB. Pharmacognosy. 49th ed. Pune: Nirali Prakashan; 2014.
17. Plummer DT. An Introduction to Practical Biochemistry. 5th ed. New Delhi: Tata McGraw-Hill; 2008.
18. CVS Subramanyam. Unit Operations Text Book. Effervescent Granules by Non-aqueous Method; p. 127.
19. Rowe RC, Sheskey PJ, Quinn ME, editors. Handbook of Pharmaceutical Excipients. 6th ed. London: Pharmaceutical Press; 2009.
20. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Mumbai: Varghese Publishing House; 2009.
21. Carr RL Jr. Evaluating flow properties of solids. Chem Eng. 1965;72(2):163–168.
22. United States Pharmacopeial Convention. United States Pharmacopeia and National Formulary (USP 43–NF 38). Rockville (MD): USP Convention; 2020.