

Development and Evaluation of a Novel Polyherbal Anti-Stress Effervescent Infusion Tablet

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❖ ABSTRACT

Stress significantly contributes to the development of various neuropsychiatric, metabolic, and immune-related disorders. Although many people use synthetic anxiety and depression medications to manage stress, their long-term use often leads to negative effects and lower acceptance among patients. As a result, more researchers are looking into herbal adaptogens as safer complementary options. Medicinal plants like Ashwagandha (*Withania somnifera*), Tulsi (*Ocimum sanctum*), and Chamomile (*Matricaria chamomilla*) have been widely recognized in both traditional medicine and modern studies for their ability to reduce stress, relieve anxiety, act as antioxidants, and protect the nervous system. These benefits mainly come from their effects on the hypothalamic-pituitary-adrenal axis, regulation of neurotransmitters, reduction of cortisol release, and lowering of oxidative and inflammatory stress markers. However, traditional herbal dosage forms often struggle with poor taste, inconsistent absorption, slow effects, and low patient compliance. Effervescent drug delivery systems offer an alternative by allowing for rapid dissolution, better taste masking, improved solubility, and easier administration. This review examines the scientific basis for selected anti-stress herbs and assesses how effervescent tablet technology can be applied to herbal infusion formulations. It highlights important elements such as formulation strategies, excipient compatibility, evaluation parameters, and quality considerations. Overall, combining herbal adaptogens with effervescent delivery systems provides a practical and patient-focused approach to managing stress. Current research suggests that herbal effervescent formulations could serve as effective and well-accepted options compared to traditional dosage forms, indicating the need for further clinical and stability studies.

KEYWORDS: Herbal Adaptogen, Stress Management, Neuroprotection, Effervescent Tablet.

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HISTORY

Stress has become one of the most common health issues in modern times, impacting physical, mental, and emotional health. Long before modern medicine, various cultures used herbal remedies to manage stress and encourage relaxation. Traditional medical systems like Ayurveda, Siddha, Traditional Chinese Medicine (TCM), and Western herbarium have documented plants such as Ashwagandha, Tulsi, and Chamomile for their stress-relieving, anxiety-reducing, and calming effects. These herbs helped maintain balance and regulate the body's response to stress, laying the groundwork for today's herbal nutraceutical products.

The Charaka Samhita and Sushruta Samhita, two ancient Ayurvedic classics, describe Rasayana herbs (rejuvenators) that help balance "Vata" and alleviate mental exhaustion. Ashwagandha (*Withania somnifera*) has been valued for centuries as a powerful herb that relieves stress and supports recovery. Tulsi (*Ocimum sanctum*) is traditionally regarded in Indian culture as a sacred plant that naturally combats anxiety, respiratory issues, and oxidative stress. In European and Egyptian traditional medicine, Chamomile (*Matricaria chamomilla*) was widely used in teas and infusions to promote calmness, reduce irritability, and support restful sleep.¹

Alongside the development of herbal stress remedies, pharmaceutical technology progressed, leading to the creation of effervescent formulations in the late 1600s. Originally made as medicinal "sherberts," effervescent powders and tablets became valued for their quick dissolution in water, improved taste, and enhanced absorption of active ingredients. By the 20th century, effervescent tablets were commonly used for vitamins, pain relievers, electrolyte supplements, and nutraceuticals because of their rapid effect and ease of use.²

In the past decade, there has been a significant global trend toward herbal wellness products, fueled by growing concerns about the side effects of synthetic anti-anxiety drugs and a preference for natural, plant-based treatments. The World Health Organization (WHO) also supports the development of safe and effective herbal products to

complement conventional medicine. Consequently, combining traditional herbal extracts with modern effervescent technology has become an innovative approach to managing lifestyle-related stress.

The anti-stress herbal infusion effervescent tablet concept integrates three established areas:

1. Herbal Medicine – scientifically supported adaptogens and anxiety-reducing herbs.
2. Infusion Therapy – water-based extraction and consumption of herbal active compounds.
3. Effervescent Technology – rapid tablet dissolution, improved flavour, stability, and better absorption. This product provides a modern solution for stress relief by offering a convenient, fast-dissolving tablet that delivers herbal actives in a pleasant, fizzy drink. It addresses common drawbacks of traditional herbal powders or capsules, such as poor solubility, bitter taste, and shows absorption in digestive system.

INTRODUCTION

Stress has become one of the most widespread health issues worldwide in today's society, impacting people of all ages, occupations, and lifestyles. Factors such as rising academic pressures, work-related demands, financial stress, insufficient sleep, and rapid modernization have made stress a leading cause of both physical and mental health problems. Prolonged stress is strongly linked to conditions like anxiety, depression, sleep disturbances, high blood pressure, metabolic diseases, and weakened immune responses. The World Health Organization (WHO) identifies stress as a significant risk factor for several non-communicable illnesses. Consequently, creating safe, effective, and easy-to-use anti-stress treatments holds significant scientific and therapeutic importance.⁴

Recently, herbal medicine has gained popularity due to its safety, compatibility with the body, minimal side effects, and comprehensive healing approach. Many therapeutic herbs, including

Tulsi (*Ocimum sanctum*), ashwagandha (*Withania somnifera*) and, Chamomile (*Matricaria chamomilla*)—have demonstrated clinically validated adaptogenic and anxiety-reducing properties. These herbs influence stress-related substances like cortisol, catecholamines, gamma-aminobutyric acid (GABA), nitric oxide, and inflammatory cytokines, making them Excellent Option for managing stress and related disorders. However traditional forms like decoctions, powders, and capsules often face challenges including unpleasant taste, incomplete dissolution, inconsistent absorption, and low patient adherence.

To address these issues, effervescent tablets have emerged as a highly advantageous alternative dosage form. These solid tablets dissolve quickly in water, containing organic acids (such as citric and tartaric acid) and bicarbonates (like sodium bicarbonate) that react to release carbon dioxide. This effervescent reaction leads to rapid tablet breakdown, faster dissolution, improved absorption, better taste masking, and enhanced bioavailability. When combined with herbal extracts, effervescent tablets provide an innovative method to deliver adaptogenic plant compounds in a fast-acting and user-friendly way. Therefore, the concept of an Anti-Stress Herbal Infusion Effervescent Tablet merges traditional herbal remedies with modern pharmaceutical technology to offer a

multifunctional, easy-to-use, and effective solution for stress relief.⁵

➤ Definition of Stress

Stress is described as the body's physiological and psychological reaction to internal or external stimuli (stressors) that disrupt homeostasis. It triggers adaptive behavioural, hormonal, and neural changes to help the body manage the challenge.

Types of Stress

1. Acute stress: A brief, sudden, immediate reaction.
2. Chronic stress: Long-lasting activation of the stress response system.
3. Psychological stress: Emotional or mental disturbances.
4. Physiological stress: Caused by illness, injury, dehydration, or excessive workload.

Causes of Stress: Stress arises from a combination of biological, psychological, and social factors:

1. Environmental Factors: Noise, pollution, overcrowding, extreme temperatures, accidents.
2. Lifestyle Factors: Lack of sleep, poor nutrition, insufficient exercise, substance misuse.
3. Psychological Factors: Academic pressure, job stress, relationship problems, financial difficulties.
4. Biological Factors: Hormonal imbalances, chronic diseases, genetic susceptibility.⁶

Mechanism of Stress

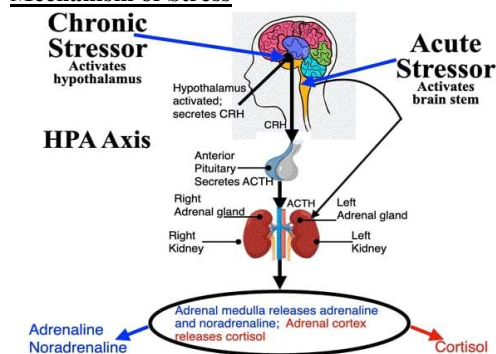


Fig No 01: Stress Pathophysiology.⁷

The stress response involves several neuroendocrine systems, including:

1. Activation of the Hypothalamic–Pituitary–Adrenal (HPA) Axis This is the main pathway for stress response.

Process:

- Stress stimulates the hypothalamus.
- The hypothalamus releases Corticotropin Releasing Hormone (CRH).
- CRH prompts the pituitary gland to secrete Adrenocorticotrophic Hormone (ACTH).
- ACTH stimulates the adrenal cortex.

- The adrenal cortex releases cortisol Elevated cortisol raises blood glucose, suppresses immune function, disrupts sleep patterns, heightens anxiety, and impairs memory.

2. Sympathetic–Adrenal–Medullary (SAM) System: The sympathetic nervous system is triggered by acute stress, which causes the adrenal medulla to produce adrenaline and noradrenaline Effects include increased heart rate, pupil dilation, sweating, heightened alertness, and muscle tension.

3. Neurotransmitter Imbalance; Stress alters levels of neurotransmitters such as: GABA (decreased during stress, leading to anxiety), Serotonin, Dopamine, Norepinephrine, Reduced inhibitory neurotransmission results in increased brain excitability.

4. Inflammation and Oxidative Stress: Stress elevates inflammatory cytokines (IL-6, TNF- α) and free radicals, causing neuronal inflammation, fatigue, and mood disturbances.

5. Disruption of the Sleep Wake Cycle: Increased cortisol interferes with melatonin production, leading to insomnia, irritability, and difficulty concentrating. Experience a natural method to relax with our Antistress Herbal Infusion Effervescent Tablets, a calming blend created to soothe the mind and restore harmony. Each tablet features the traditional benefits of Ashwagandha, Chamomile, and Tulsi (Holy Basil) three well-known adaptogenic and calming herbs recognized for aiding relaxation and reducing everyday stress. Just dissolve a tablet in water and serve a refreshing, aromatic infusion designed to faster inner calm, enhance mood, and support overall wellness. Whether after a busy day or during stressful moments, this gentle herbal formula provides an easy and pleasant way to unwind naturally and effectively.⁸

➤ **Effervescent Tablets:**

An effervescent tablet is a solid oral dosage form that dissolves rapidly in water and produces carbon dioxide through an acid-base interaction between a carbonate or bicarbonate salt (often sodium bicarbonate) and organic acids (such citric, tartaric, or fumaric acid). A sparkling, flavorful beverage is produced by the carbon dioxide emission, which also produces bubbles and froth.

Definition: Effervescent tablets are compressed solid dosage forms that, upon contact with water, disintegrate and dissolve while releasing carbon dioxide gas.

Main Ingredients:

1. Acid source: Citric acid or tartaric acid.
2. Alkaline source: Sodium bicarbonate.
3. Active ingredient or herbal extract.
4. Sweeteners: Stevia, sucrose, mannitol.
5. Flavouring agents: Orange, lemon, mint
6. Binders: Polyvinylpyrrolidone (PVP), gum acacia.
7. Lubricants: Magnesium stearate.
8. Fillers: Mannitol.⁹

Need and Significance of Effervescent Tablets:

Effervescent tablets are becoming increasingly favoured for nutraceutical and herbal products because of the following benefits:

1. Quick Dissolution and Rapid Onset of Effect: The effervescent process ensures the tablet fully dissolves within minutes, allowing faster absorption of plant-based compounds and a quicker therapeutic effect in relieving stress.
2. Improved Bioavailability: Dissolving the tablet in water minimizes stomach irritation, enhances the solubility of herbal ingredients, and avoids complications related to first-pass metabolism.
3. Better Taste and Consumer Acceptance: The added flavours and carbonation help mask unpleasant herbal flavours, making the product more palatable and acceptable to users.
4. Convenient Administration; particularly suitable for Elderly individuals, Children, People with difficulty swallowing (dysphagia).¹⁰

MATERIAL AND METHOD

➤ **Materials**

The components used to prepare the Anti-Stress Herbal Infusion Effervescent Tablets included extracts of Withania somnifera (Ashwagandha), Ocimum sanctum (Tulsi), and Matricaria chamomilla (Chamomile), all sourced from certified herbal suppliers. Effervescent agents comprised citric acid (extracted from lemon peel), tartaric acid, and sodium bicarbonate. Mannitol was utilized as a water-soluble filler, while gum acacia acted as a binder. Stevia was added as a natural sweetener, magnesium stearate served as a lubricant, and orange flavoring was included to improve taste. All chemicals employed were of analytical grade and kept in airtight containers to prevent moisture absorption.

INGREDIENTS	USE
Ashwagandha, Tulsi, chamomile	API
Citric acid and sodium biarbonate	Acid and base source
Orange flavour and stevia	Flavour and sweetner

Gum acacia and magnesium stearate	Binder & lubricant
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Table No 1: Ingredients & Uses

- **Drug profile**

- A. Herb Profile**

- **Ashwagandha (*Withania somnifera* Dunal)**

Synonyms:-Indian Ginseng, Withania root, Ashwagandha, Clustered Winter cherry

Biological Source: - *Withania somnifera* Dunal's dried roots and stem bases belonging to Family *Solanaceae*

Parts Used: Primarily the dried root; occasionally leaves and fruits for specific formulations.

Chemical Components: Alkaloids and withanolides (steroidal lactones) are the primary components of ashwagandha.¹¹

Pharmacological Properties: - Acts as an adaptogen and anti-stress agent by regulating the HPA axis and reducing cortisol levels. - Exhibits anxiolytic and mild sedative effects, with studies indicating GABAergic modulation. Provides neuroprotective benefits and enhances cognition, supported by preclinical and some clinical data.¹²

Withanolides

Traditional and Therapeutic Uses: Used in Ayurveda as a Rasayana tonic to strengthen the nervous system, boost vitality, and combat aging.

- Employed for managing stress, insomnia, weakness, low libido, and general debility.¹³

**Ashwagandha¹⁴****Fig No 02:**

- **Tulsi / Holy Basil**

Synonyms: Sacred basil, Kali-Tulsi, Veranda.

Biological source: Tulsi consists of the fresh and dried leaves of *Ocimum* species like *Ocimum sanctum* L. and *Ocimum basilicum*, Family *Lamiaceae* (mint family)

Parts Used: Leaves (fresh or dried), entire aerial parts, and essential oils extracted from leaves and flowers.

Chemical constituents: Linalol, eugenol, methylchavicol, methylcinnamat, linolen, ocimene, pinene, cineol, anethol, estragol, thymol, citral, and camphor are the main chemical elements.¹⁵

Eugenol

Pharmacological Properties:

- Exhibits broad-spectrum antimicrobial effects against bacteria and fungi in vitro, along with antiviral activity.

- Acts as an antioxidant and anti-inflammatory agent.¹⁶

Traditional and Therapeutic Uses:

- Commonly used to treat respiratory issues such as cough and bronchitis, fever, common cold, digestive problems, stress relief, and holds significance as a sacred plant in religious practices.¹⁷

**Fig**

No 03: Tulsi

➤ **Chamomile (*Matricaria chamomilla* / *Matricaria recutita* or *Chamaemelum nobile* for Roman chamomile)**

Synonyms: Chamomile, German chamomile (*Matricaria chamomilla*), Roman chamomile (*Chamaemelum nobile*) Family *Asteraceae* (*Compositae*)

Parts Used: Dried flower heads (capitula) and essential oil extracted from the flowers.

Chemical Constituents: Essential oil contains α -bisabolol, chamazulene (a blue oil component produced during steam distillation), matricin (a precursor), along with other sesquiterpenes and esters. Flavonoids include apigenin, luteolin, quercetin, and patuletin glycosides. Also contains coumarins, polyacetylenes, and tannins.¹⁸

α -bisabolol

Pharmacological Properties:

Acts as an anxiolytic, mild sedative, and sleep aid, possibly through apigenin's interaction with benzodiazepine receptors. Exhibits anti-inflammatory, antispasmodic (helpful for gastrointestinal spasms), and mild pain-relieving properties.¹⁹

Has topical wound-healing, anti-inflammatory, and anti-irritant effects, making it useful in skin care products. Demonstrates antimicrobial activity in laboratory studies.²⁰



Fig No

04: Chamomile.²¹

Traditional and Therapeutic Uses: Used to alleviate mild anxiety, sleep problems, digestive disturbances, colic, and as a topical agent for reducing inflammation and soothing the skin.



Fig No 05: Powder Extract of Ashwagandha, Tulsi, Chamomile

B. Synthetic Drug Profile

➤ Citric Acid (Extracted from Lemon Peel)

Category: Acidulant, effervescent agent, flavour enhancer, chelating agent.

Source: Naturally derived from lemon peel through processes of extraction, concentration, and crystallization. Contains natural citrates, ensuring eco-friendly and sustainable sourcing.

Description: It appears as white or colourless crystalline powder is odourless and has a pleasant sour test.

Role in Formulation:

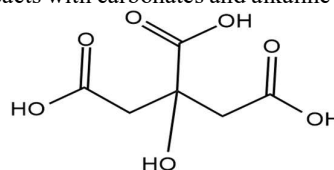
- Reacts with sodium bicarbonate to produce effervescence (carbon dioxide release).
- Enhances tablet disintegration and mouthfeel.

Benefits:

- Natural and biodegradable,
- Provides strong effervescence
- Improves taste appeal.
- Functions as a mild preservative.

Limitations:

- Sensitive to moisture.
- Reacts with carbonates and alkaline substances.



Citric acid

➤ Sodium Bicarbonate

Category: Effervescent and alkalizing agent.

Description: White crystalline powder.

- Slightly alkaline taste, Water-soluble.

Role in Formulation:

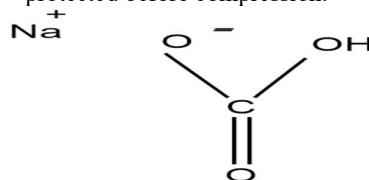
- Reacts with citric acid to release CO₂ bubbles, promoting rapid tablet disintegration.
- Maintains pH balance in the final beverage.
- Provides smooth effervescence and aids dispersion of herbal extracts.

Benefits:

- Safe and widely accepted.
- Delivers quick effervescent action.
- Helps mask bitterness of herbal ingredients.

Limitations:

- Sensitive to moisture.
- Can react prematurely with acids if not properly protected before compression.



Sodium Bicarbonate

➤ Orange Flavour (Natural or Artificial)

Category: Flavouring agent

Description: Sweet, citrus aroma

- Available as liquid or spray-dried powder

Role in Formulation:

- Masks unpleasant or bitter flavours of herbs like ashwagandha, tulsi, and chamomile
- Offers a refreshing and consumer-friendly taste
- Enhances patient acceptance and marketability

Benefits:

- Improves sensory appeal.
- Boosts compliance.
- Complements the lemon-citric flavour profile of effervescent tablets.

Limitations:

- Volatile; requires protection from heat.
- Sensitive to oxidation.²²

➤ **Gum Acacia (Acacia Gum / Gum Arabic)**

Category: Binder, suspending agent, stabilizer.

Description: Dried gummy exudate from Acacia Senegal.

- Pale off-white powder.
- Water-soluble, forming a viscous solution.

Role in Formulation:

- Assists granule formation during wet granulation.
- Enhances tablet hardness.
- Reduces dust and improves compressibility.
- Improves mouthfeel and stabilizes herbal particles in solution.

Benefits:

- Natural and non-toxic.
- Provides excellent binding without affecting effervescence.
- Enhances powder flow.

Limitations:

- Prone to microbial growth; requires dry storage

➤ **Magnesium Stearate**

Category: Lubricant.

Description: Fine white hydrophobic powder.

- Magnesium salt of stearic acid.

Role in Formulation:

- Prevents powder from sticking to dies and punches.
- Improves flow during compression, Facilitates smooth tablet ejection.

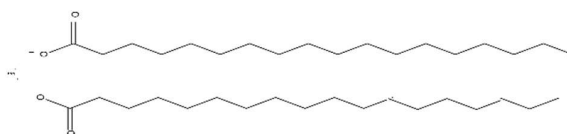
Benefits:

- Highly effective lubricant.
- Used in small amounts (<1%)

Chemical Structure:

Magnesium Stearate

Limitations:



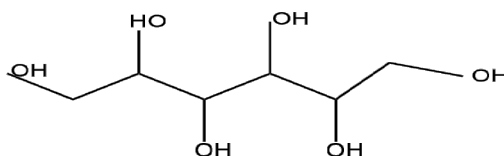
- Excessive use can reduce tablet hardness and dissolution due to hydrophobic nature.

➤ **Mannitol**

Category: Diluent, sweetener, cooling agent

Description: White crystalline powder

- Sweet taste with cooling effect
- Non-hygroscopic



Role in Formulation:

- Increases tablet bulk, Enhances sweetness and mouth feel.
- Provides cooling sensation to improve taste and palatability.
- Aids rapid dissolution of effervescent tablets.

Benefits:

- Suitable for diabetics (low glycaemic index).
- Non-cariogenic, Stable and moisture-resistant.

Limitations:

- Excessive amounts may slightly slow dissolution.

➤ **Stevia (Steviol Glycosides)**

Category: Natural sweetener

Description: Extracted from *Stevia rebaudiana* leaves.

- 200–300 times sweeter than sugar, Zero-calorie, herbal, heat-stable.

Role in Formulation:

- Adds sweetness without calories.
- Masks bitterness of herbal extracts, Enhances palatability of effervescent drinks.

Benefits:

- Natural and safe for diabetics.
- Stable in acidic environments (ideal for effervescent formulations).
- Effective in very small quantities.

Limitations:

- ❖ May leave a slight after taste.²³**Extraction of Herbal Ingredients (Hydroalcoholic Method):**

The anti-stress effects of ashwagandha, tulsi, and chamomile were extracted hydroalcoholically using 70% ethanol, which was chosen for its ability to extract both polar and non-polar phytochemicals such as flavonoids, alkaloids, glycosides, and terpenoids. After being coarsely crushed, the dry plant materials were sieved using a #40 mesh screen. For 48 hours, each plant (50 g) was steeped in 500 mL of 70% ethanol while being shaken periodically. Whatman No. 1 filter paper was used after muslin cloth was used to filter the mixture. After removing the ethanol from the filtrate using a rotary evaporator at 40–45°C, the semi-solid extract was dried in a hot-air oven at 45°C. Until they were needed again, the dried extracts were kept in sealed amber bottles.^{24,9}

❖ **Phytochemical Test**

Test	Reagent used	Procedure	Observation	Inference
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Alkaloids	Mayer's/Wagner's/ Dragendorff's	Extract table with dilute acid-filter-add reagent	Creamy (may be) or reddish-brown ppt (wagner / dragendorff)	Alkaloids present (mainly from Ashwagandha & Tulsi)
Flavonoids	Shinoda test (Mg ⁺ HCl)/Alkaline reagent	Add Mg ribbon + cons. HCl or add NaOH and acidify	Pink (shinoda) or yellow (disappearing on acid/alkaline)	Flavonoids present (from chamomile & tulsi)
Tannins / Phenol	5% Ferric chloride	Add FeCl ₃ to aqueous tablet extract	Blue-black or green coloration	Phenolic compounds present
Saponins	Foam test	Shake aqueous extract for 30 sec-	Persistent stable foam	Saponins present (from Ashwagandha)

		stand 10 min		
Terpenoids/Steroids	Salkowski test	Add chloroform extract + conc. H ₂ SO ₄	Reddish-brown or greenish ring	Terpenoids/steroid present (withanolides essential oils)
Glycosides	Keller-Kiliani test	Add glacial acetic acid + FeCl ₃ - layer with H ₂ SO ₄	Reddish-brown ring at interface	Cardiac/steroidal glycosides present in traces
Coumarins	105 NaOH = UV light	Add NaOH – observe under UV 365nm	Yellow fluorescence	Coumarins present (from chamomile)

Table No 02: Phytochemical Test of Ashwagandha, Tulsi, Chamomile.^{25, 26, 27, and 28}

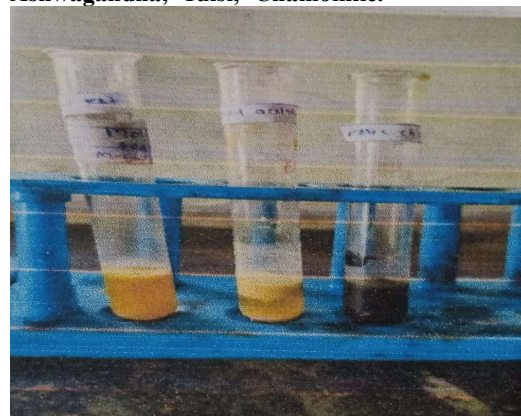


Fig No 07: Phytochemical Test of Ashwagandha, Tulsi, and Chamomile (keller-kilani, foam, salkowskitest etc)

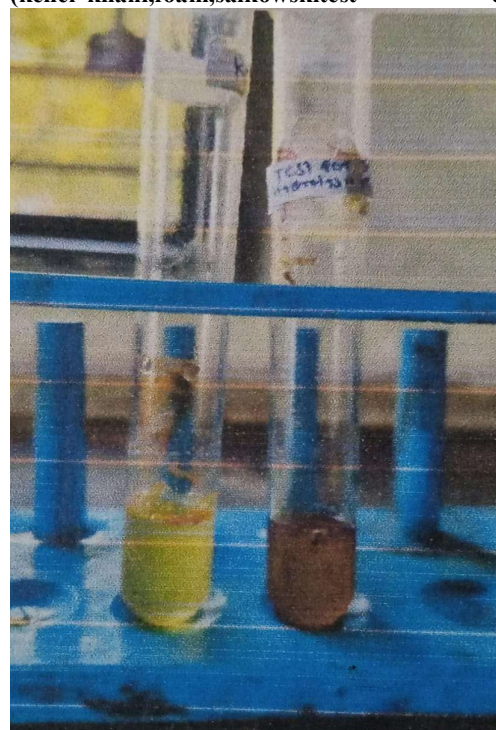


Fig No 08: Phytochemical Test of Ashwagandha, Tulsi, Chamomile (keller-kilani, foam, salkowskitest etc)

❖ **Formulation of Effervescent Tablet**

Preparation of Effervescent Granules

Effervescent granules were made using the fusion or dry granulation technique to avoid early effervescence. Citric acid and tartaric acid were pre-dried at 40°C for one hour to remove moisture. Sodium bicarbonate was dried separately to preserve its alkalinity. The dried acids, alkali, and herbal extracts were sieved through a #40 mesh and thoroughly mixed using geometric dilution. Gentle grinding was applied to partially fuse the citric acid, which serves as a binder, resulting in free-flowing granules. These granules were then passed through

a #20 sieve, dried again at 40°C for 30 minutes, and stored in a desiccator.²⁹

Fig No: 09 Effervescent Granules

❖ Preparation of Effervescent Tablets:

The dried granules were placed in a blender, and mannitol, gum acacia, stevia, orange flavour, and finally magnesium stearate were added and mixed evenly. The mixture was assessed for pre-compression properties including bulk density, tapped density, angle of repose, and Carr's index. The lubricated granules were compressed into tablets using a rotary tablet press under controlled humidity conditions (below 40% relative humidity) to prevent premature effervescence. The tablets were promptly sealed in moisture-proof containers and stored at room temperature.³⁰



Fig No 10: Effervescent Tablet Ingredients	F1(mg)	F2(mg)	F3(mg)	USE
Ashwagandha	60	90	100	API
Tulsi	90	80	70	API
Chamomile	100	110	120	API
Citic acid	650	600	700	Acid source
Sodium bicarbonate	860	900	810	Base source
Orange flavour	100	100	100	Flavouring agent
Gum acacia	70	50	30	binder
Magnesium stearate	30	20	10	lubricant
Mannitol	1000	100	1000	filler
Stevia	40	0	60	sweetener

Total weight	3000 mg	3000 mg	3000 mg	
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Table No 03: Formulation Table of Infusion Effervescent Tablet³¹

❖ Evaluation parameters

- Pre - Formulation parameter
Organoleptic -Colour, odour taste, appearance, Angle of repose, Carr's index, Hausner ratio
Bulk density, tapped density.
- Post -compression parameter
 1. General appearance
 2. Weight variation
 3. Hardness test
 4. Friability
 5. Effervescence time
 6. PH of solution
 7. Drug content uniformity

Pre-formulation study and Evaluation Parameters of Tablets

A) Preformulations study

The resulting granules were analyzed for micro meritrics properties, such as bulk density, tap density, angle of repose, Hausner's ratio, and carr's index, which were measured to ascertain the flow property and compressibility index.

➤ Bulk Density

The mass of a powder divided by the total volume it occupies—which includes the volume of the particles as well as the space between them—is known as bulk density.

Formula: Bulk density=Mass of powder (g) /bulk volume (ml)

Units: g/ml or g/cm³

Procedure:

1. Weigh 10 g of the granules.
2. Transfer into a 25 mL graduated cylinder.
3. Record the initial (loose) volume (V₀).

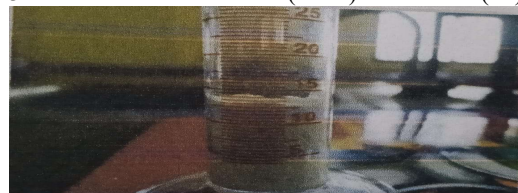


Fig No 11: Bulk Density

➤ Tapped Density:

Tapped density is the density obtained after the powder is subjected to mechanical tapping.

Procedure:

1. Weighing: Accurately weigh a known quantity of the powder sample.
2. Filling the Cylinder: Pour the powder into a graduated cylinder.
3. Tapping: Place the cylinder on a tapped density tester (also called a tapper or jolting volumeter)
4. Tapping Process: The tester taps the cylinder at a fixed rate (e.g., 300 taps per minute) for a set number

of taps (commonly 500, 750, or 1250 taps) until the volume stabilizes

5. Volume Measurement: Record the final volume (tapped volume)

6. Calculation: Use the formula to calculate tapped density.

Formula: Trapped Density = weight/ tapped volume

➤ Carr's Compressibility Index:

Indicates how compressible the powder is.

Formula: Carr's index (%) = $\frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} \times 100$

Significance

1. Powder Flow ability indicates whether the powder will flow freely or require flow enhancers.

2. Tableting and Capsule Filling Powders with low Carr's Index are easier to compress.

3. Blending Efficiency: Poorly flowing powders may segregate during Blending, affecting content uniformity.

4. Granulation Suitability: Higher Carr's Index values suggest a need for granulation to improve flow.

➤ Hausner Ratio:

Indicates flowability and cohesiveness of granules.

Formula: Tapped density/bulk density

Calculation: Use the formula to determine the angle of repose

Significance:

1. Powder Flowability directly indicates how easily a powder can move through processing equipment.

2. Blending Efficiency Powders with poor flow may require additional flow aids.

➤ Angle of Repose

Determines flow property of powder.

Formula: $\theta = \tan^{-1} (h/r)$

Procedure: Using fixed funnel method, Measurement.

1 Setup: Place a funnel at a fixed height above a flat surface.

2. Pouring the Powder: Allow the powder to flow freely from the funnel until a stable cone forms

3 Measurement: Measure the height (h) of the pile and the radius.³²

• Final Interpretation of Preformulation result

PARAMETER	RESULT	INTERPRETATION
Bulk Density	0.555g/ml	-
Tapped Density	0.689g/ml	-
Carr's Index	19.48%	Fair – Good flow
Hausner Ratio	1.24	Fair flow
Angle Of Repose	29.1	Good flow

Table no 4: Result of PreformulationB) POST-COMPRESSION EVALUATION PARAMETERS

➤ General appearance: The tablet's overall elegance, form, color, and surface textures make up its visual identity. All of these factors are necessary for customer approval.

Colour: Orange

Odour: Herbal and aromatic

Taste: Pleasant with citrus flavour

Mouthfeel: Smooth



Fig No 12: Tablet

➤ Weight Variation Test: The weight variation test is carried out in order to ensure Uniformity in the weight of tablets in a batch. The total weight of 20 tablets randomly from whole batch was determined and the average was calculated. The individual weights of the tablets were also determined accurately and the weight Variation was calculated.

Result: Average tablet weight = 1.52 g

Percentage deviation = $\pm 1.2\%$ (within acceptable limits.)

➤ Hardness Test: The hardness of tablet is an indication of its strength against Resistance of tablets to capping, abrasion or breakage under Conditions of storage, transportation and handling before Usage Measuring the force required to break the tablet across Tests it. Hardness of 10 tablets (randomly) in whole tablet Batch was determined by Monsanto hardness tester. Hardness Measured in kg/cm². Result: Hardness = 3.2 ± 0.4 kg/cm².



Fig No 13; Tablet hardness tester

➤ Friability Test: The Roche friabilator was used to determine the tablets' friability, which is defined as the weight loss of the tablet in the container as a result of tiny particles being removed from the surface during handling or transit. Take a sample of 6.5 g of

whole tablets for tablets weighing 0.65 g or less, and a sample of 10 entire tablets for tablets weighing more than 0.65 g. For 100 cycles, the Roche friabilator rotates at 25 rpm for four minutes. After dedusting, the pills were weighed once again. The algorithm was used to determine the percentage of weight reduction.³³

Instrument: Roche Friabilator.

Calculation: % Friability = $\frac{[(\text{Initial weight} - \text{Final weight}) / \text{Initial weight}] \times 100}{}$

Result: Friability = 0.62% (acceptable; should be less than 1%)



Fig No 14: Friability Test

➤ pH of Solution

Purpose: To determine the acidity or alkalinity after tablet dissolution.

Method: One tablet dissolved in 200 mL of water.

Importance: Ensures safety and palatability.

Result: pH = 5.8

➤ Effervescence Time

Purpose: To measure the time required for complete dissolution.

Method: Tablet placed in 200 mL water at room temperature.

Importance: Critical parameter for effervescent tablets.

Result: Effervescence time = 118 seconds (1 minute 58 seconds)



Fig No 15: Show Effervescence of Tablet

➤ Drug Content / Assay

Purpose: To quantify the amount of herbal active ingredients.

Method: UV spectrophotometric analysis.³⁴

Importance: Ensures accurate dosing.

Result: Ashwagandha content = 98.2, Tulsi content = 96.5%, Chamomile content = 97.4%

Result and Discussion:

Parameters	F1	F2	F3
Bulk density	0.45 g/ml	0.55g/ml	0.65g/ml
Tapped density	0.56g/ml	0.689 g/ml	0.70g/ml
Angle of repose	28.4	29.1	+30.2
-Hausner's ratio	1.23	1.24	1.25
Carr's index	19.64%	19.48%	20.00%

Table No 05: Preformulation Parameters

Evaluation Parameter	F1	F2	F3
General appearance	Yellowish -orange	Orange	Dark orange
Weight variation	pass	pass	pass
Hardness test (kg/cm²)	3.1 ±0.1 kg/cm ²	3.2±0.4 kg/cm ²	3.4±0.3 kg/cm ²
Friability test (%)	0.78%	0.62%	0.85%
Effervescence Time	140 second	118 second	135 second
Ph of solution	5.5	5.8	5.9
Drug content uniformity	98.2%	99.1%	97.8%

Table No 06: Evaluation Parameters Result

All three formulations (F1, F2, F3) showed good pre compression flow properties with acceptable bulk density, tapped density, angle of repose, hausner 's ratio and carr's index . Post compression parameter like hardness , friability, and effervescence time were within acceptable limit F2 has shown the best result with F2 is the best batch because: Lowest friability (0.62%),Fastest effervescence (115sec),Best drug content uniformity (99.1%),Good hardness (3.2 kg/cm²),Least moisture

uptake → best stability Acceptable effervescence time and higher dissolution rate. This F2 was found to be most optimize and successful formulations.

Conclusion

The present investigation successfully achieved the formulation and evaluation of an anti-stress herbal effervescent tablet incorporating extracts of *Withania somnifera* (Ashwagandha), *Ocimum sanctum* (Tulsi), and *Matricaria chamomilla* (Chamomile). The study effectively met its objective of developing a fast-acting, palatable, patient-compliant, and stable herbal dosage form with improved therapeutic convenience.

Pre-compression parameters confirmed that the granules exhibited satisfactory flow and compressibility characteristics, as evidenced by acceptable values of bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose. Post-compression evaluation demonstrated that the formulated tablets complied with pharmacopeial quality requirements, including uniformity of weight, adequate mechanical strength, low friability, consistent thickness, rapid effervescence time, and appropriate pH for oral administration. Drug content uniformity results further indicated efficient mixing and accurate dose distribution within the formulation.

The synergistic combination of adaptogenic and anxiolytic herbal extracts contributed to the potential anti-stress and relaxation-enhancing effects of the formulation. The effervescent delivery system improved dissolution, facilitated faster onset of action, and enhanced bioavailability, thereby offering superior patient acceptability when compared to conventional solid oral dosage forms or traditional herbal preparations.

In conclusion, the developed herbal effervescent tablet represents a promising and innovative approach for stress management, combining traditional herbal therapy with modern pharmaceutical formulation techniques. Further studies involving stability testing, scale-up feasibility, sensory evaluation, and in-vivo pharmacological assessment are recommended to substantiate its therapeutic efficacy and commercial applicability. This research highlights the potential of effervescent technology in advancing the modernization and clinical relevance of herbal medicines.

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