Novel Formulation and Evaluation of Health Immunity Booster Gummies

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***Abstract*—The increasing prevalence of lifestyle-related diseases has underscored the need for effective health supplements that can enhance immunity and overall well-being. The formulation process involved optimizing the ratios of the active ingredients to ensure maximum efficacy while maintaining desirable sensory attributes such as taste and texture. The gummies were subjected to a series of evaluations, including physicochemical analysis, stability testing, and sensory evaluation, to assess their quality and consumer acceptance. Furthermore, in vitro studies were conducted to evaluate the immunomodulatory effects of the formulated gummies, focusing on their ability to enhance immune cell activity and antioxidant capacity. Preliminary results indicate that the developed gummies not only possess a favorable sensory profile but also demonstrate significant potential in boosting immune responses. This innovative approach to health supplementation highlights the importance of integrating traditional herbal knowledge with modern formulation techniques, paving the way for a natural and effective solution to enhance immunity and prevent disease.**

***Index Terms*—Immunity enhancement, herbal gummies, immunomodulatory activity, antioxidant capacity, nutraceutical formulation**

I. INTRODUCTION

In recent years, there has been a growing interest in dietary supplements and functional foods that can enhance health and boost the immune system. The global pandemic has further accelerated this trend, prompting individuals to seek natural and effective ways to strengthen their immunity and prevent various diseases. Among the myriad of health supplements available, gummies have emerged as a popular choice due to their palatable taste, ease of consumption, and appealing texture, particularly among children and adults who may be reluctant to take traditional pills or powders[1].

The formulation and evaluation of a novel immunity booster gummy that incorporates a synergistic blend of natural ingredients known for their health-promoting properties: Clitoria ternatea (Butterfly Pea Flower), Ginger (Zingiber officinale), Ashwagandha (With ania somniferous), and Orange (Citrus sinensis)[2]. Each of these components has been traditionally recognized for their potential health benefits, particularly in enhancing immune function and overall well-being[3].

Clitoria ternatea, commonly known as Butterfly Pea Flower, is renowned for its antioxidant properties and its ability to reduce inflammation. Rich in anthocyanins, this vibrant blue flower has been shown to support cognitive function and may help in combating oxidative stress, which is a contributing factor in many chronic diseases[2].

Ginger, a well-known spice, has been utilized for centuries in traditional medicine for its anti-inflammatory and antioxidant effects. Its active compounds, such as gingerol, have been shown to enhance immune response and may help in the prevention of respiratory infections, making it a valuable addition to any immunity-boosting formulation[4].

Ashwagandha, an adaptogenic herb, is celebrated for its ability to help the body adapt to stress and promote overall vitality. Research indicates that Ashwagandha can enhance immune function by modulating the immune system and reducing cortisol levels, thereby supporting the body's natural defences against pathogens[5].

Orange, a rich source of vitamin C, is essential for the maintenance of a healthy immune system. Vitamin C is known for its role in stimulating the production of white blood cells, which are crucial for fighting infections. Additionally, the presence of flavonoids in oranges contributes to their antioxidant properties, further supporting immune health[6].

The combination of these four potent ingredients in a gummy formulation aims to create a holistic approach to immune support. This project will detail the formulation process, including the selection of appropriate excipients, the optimization of the gummy texture and flavour, and the evaluation of the final product for its physicochemical properties, stability, and consumer acceptability[6].

Through this innovative approach, aim to provide a convenient and enjoyable way for individuals to enhance their immunity and overall health, potentially reducing the risk of various diseases. The findings from this project could pave the way for further research and development of functional gummies that cater to the growing demand for natural health products in the wellness market[7].

The use of food colorant in food products is vital in increasing product appeal. Food colorants are divided into natural and synthetic food colors. Natural food color is derived from various sources such as seeds, fruits, vegetables, insects, and microorganisms without any chemical treatment. Synthetic food colorant is water-soluble substances that have been made in a factory and used in foods without any further processing. Artificial food colors are reliable and economical for restoring the original appearance of the foods compared to the natural colorants, which are expensive and less stable. However, in several cases, food colorants have been misused to conceal lousy quality. Studies linked the consumption of artificial dye to the harmful effect and hyperactivity in children. The synthetic food colorants showed an adverse effect on human health[8].

Today, one of the appropriate potential alternative oral dosage forms is gummies, similar to gelatinous food. The gummies can address swallowing problems, ensure patient safety, and ease of handle and taken without water. Thus, gummies can improve patient compliance in addition to their flavouring taste and pleasant appearance. Gummies have advantages of both solid and liquid preparations. Gummies have been a great way of delivering the active constituents for consumption by children. Their use for adults has gained acceptance as well. The gummies industry is expected to reach 4.17 million US dollars by 2025.[9]

Immune dysfunction can result in autoimmune diseases, immunodeficiency disorders, or hypersensitivity reactions. Immunity can be strengthened through vaccination, balanced nutrition, regular exercise, adequate sleep, stress management, hygiene, and avoidance of smoking and excessive alcohol consumption. Nutritional supplementation may further support immune function when dietary intake is inadequate.

Herbal immunity booster gummies represent an innovative nutraceutical approach that combines traditional herbal knowledge with modern dosage forms. Formulated with natural extracts such as *Clitoria ternatea*, ginger, ashwagandha, and orange extract, these gummies provide antioxidant, anti-inflammatory, adaptogenic, and immunomodulatory benefits. By enhancing immune cell activity, reducing oxidative stress, balancing inflammation, and supporting gut health, herbal gummies offer a palatable, convenient, and effective strategy for improving immunity and overall well-being.

II MATERIAL AND METHODS

Cultivation and collection of plant material: - All plant material were cultivated and collected form Central India College of Pharmacy Lonara, Nagpur

Clitoria ternatea (Butterfly pea) flowers were collected in the morning at full bloom and confirmed to be free from pesticides and contaminants. The flowers were shade-dried for 4–5 days until completely crisp, ground into a fine powder, and stored in airtight containers under cool and dry conditions.

Mature rhizomes of *Zingiber officinale* (ginger) were harvested 8–10 months after planting, thoroughly washed to remove adhering soil, sliced into thin pieces, and dried by sun-drying or oven-drying at 50–60 °C. The dried material was pulverized into a fine powder and stored in moisture-proof containers.

Roots of *Withania somnifera* (ashwagandha) were collected 6–8 months after planting when the aerial parts had dried. The roots were washed, cut into small pieces, dried under shade or in an oven at 40–50 °C,

pulverized into fine powder, and stored in airtight containers to prevent moisture absorption.

Fresh peels of ripe, organic oranges were collected, avoiding the bitter white pith. The peels were sun-dried or oven-dried at 40–50 °C until crisp, ground into fine powder, and stored in airtight, moisture-free containers.

IDENTIFICATION TESTS OF BIOACTIVE CONSTITUENTS

Plant Material	Target Compound	Test Used	Procedure Brief	Positive Indication
Ginger (Zingiber officinale)	Shogaol	Ferric chloride test	Add $FeCl_3$ solution to the extract	Greenish-blue or dark brown coloration
Clitoria ternatea	Anthocyanins	Ferric chloride test	Add $FeCl_3$ solution to the extract	Greenish or black coloration
Ashwagandha (Withania somnifera)	Withanine (alkaloid)	Mayer's test	Add Mayer's reagent to the extract	White or cream-colored precipitate
Orange peel powder (Citrus sinensis)	Ascorbic acid	Iodine test	Add iodine solution to the sample	Disappearance of brown iodine color

EXCIPIENT PROFILE

Ingredient	F1	F2	F3	F4
Clitoria ternatea (Butterflypea plant)	4g	5g	6g	7g
Ashwagandha powder	1g	1.5g	2g	2.5g
Ginger powder	1g	1.5g	2g	2.5g
Orange peel powder	1g	1.5g	2g	2.5g
Honey	7ml	15ml	21ml	30ml
Agar – Agar	5g	10g	15g	20g
Lemon Juice	1.5ml	2.5ml	3.5ml	5ml

EXTRACTION METHOD

PREPARATION OF GINGER EXTRACT:

Ginger was extracted with water by decoction process. 7 gm powder of Ginger was taken in conical flask and extracted with water four hours with occasional agitation. Then filtered. Ginger extract is obtained.

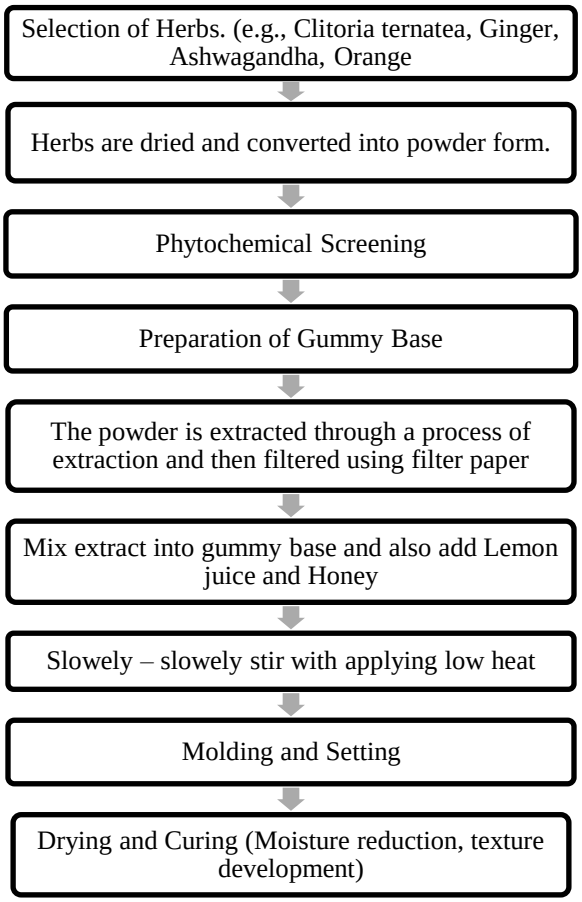
PREPARATION OF ORANGE PEEL POWDER EXTRACT: - Orange Peel Powder was extracted with water by decoction process. Use about 7g of orange peel powder per 50ml of water. Add the powder to a pot and pour in the corresponding amount of distilled water. Let the mixture soak for 30–60 minutes to allow the powder to absorb water and soften (helps improve extraction). Bring the mixture to a gentle boil. Continue boiling for 30–45 minutes on medium-low heat. Let the decoction cool to room temperature. Filter through Filter paper to remove residue

PREPARATION OF ORANGE PEEL POWDER EXTRACT: -

Ashwagandha was extracted with water by decoction process. Measure the Ashwagandha powder and water. That is about 10 g powder to 100 ml water.Add both to a pot and stir to mix. Heat the mixture on medium heat and bring to a gentle boil. Simmer the mixture on low heat for 20–30 minutes, or until the volume is reduced by half (e.g., from 100 ml to 50 ml). Cool slightly, then strain through a fine sieve by uising filter paper to remove the solid residues. Collect the liquid extract (the decoction) in a clean container.

PREPARATION OF CLITORIA TERNATEA EXTRACT: - Clitoria Ternatea was extracted with water by decoction process. Use about 10 g of Clitoria ternatea powder per 100 mL of distilled water. Place the powder in a pot and add distilled water. Bring the mixture to a boil and then simmer gently for 15–30 minutes and keep the pot covered. Allow the decoction to cool to room temperature naturally. Filter the mixture through fine sieve with the help of filter paper to remove the plant residue.

PROCEDURE FOR GUMMIES PREPARATIONS



III. EVALUATION PARAMETER:

APPEARANCE: -
PROCEDURE: - They have Circular shape with a gear-like edge, resembling a cog or a flower. Edge: Evenly spaced ridges or fluting around the perimeter. Appears symmetrical and well-formed, indicating good mold quality

TEXTURE ANALYSIS: -
PROCEDURE: - Smooth and slightly matte with a uniform finish. Edges: Clearly defined ridges, not overly worn or smudged. Cleanliness: Free from foreign particles or air bubble.

PH TESTING: -
PROCEDURE: - A digital pH metre was used to measure the gummy's pH. Gummy was dissolved in distilled water and electrode of pH was dipped into dissolved gummy. The ideal pH range for herbal gummies, is typically between 3.0 and 5.0

ASH VALUE: -
PROCEDURE: - Three grams of the drug (gummies) were placed in a silica crucible and heated over a burner flame. The material was then transferred to a muffle furnace and heated at 500-550°C for about 1 hr. The resulting ash, free of carbon, was allowed to cool and then weighed using ashless filter paper.
The standard ash value for herbal gummies typically falls within a range of 4.0% to 8.0% by weight (m/m).

DISINTEGRATION TIME: -
PROCEDURE: - Evaluation of disintegration time was used to predict the speed of disintegration of gummies in aqueous media while ensuring the release of the active ingredients from the gel matrix. The disintegration test was performed using a magnetic stirrer in a flask with 50 mL of purified water at 37°C.The chronometer was used to monitor the dissolving process and determine the dissolution time. The experiment was carried out with gummy bears that had been maintained at room temperature.
The standard disintegration time for chewable herbal gummies is considered to be within 10-30 minutes

SWELLING RATIO: -
PROCEDURE: - The amount of liquid in the gummy structure that can be absorbed is determined by the swelling index. Next, at a regulated room temperature of 25°C to 30oC, gummy mixture was immersed in 100 milliliters of filtered water for 10 min. Following soaking, a chewable gummy is taken out and cleaned with filter paper to remove any remaining water that may have stuck to the gummy's surface.
Herbal chewable gummies, a swelling ratio of around 1 to 3 is frequently observed

SWELLING RATIO = WS/WD

Were,

Ws = weight of chewable gummy after soaking. Wd = weight of chewable gummy before soaking.

RESULT & DISCUSSION

Evolution Test	F1	F2	F3	F4
Appearance	Pine green	Pine green	Teal green	Pine green
Texture Analysis	Cog wheel shaped	Cog wheel shaped	Cog wheel shaped	Cog wheel shaped
Disintegration Time	26 min	24 min	26 min	25 min
Swelling Ratio	1.056	1.20	1.25	1.25
pH Testing	4.55	4.60	4.70	4.78
Ash value	5.11 %	5.27 %	4.581 %	4.581 %

REPRODUCIBILITY OF OPTIMIZED FORMULATIONS

F4 batch was selected for optimized, it was found that F4 batch having good in quality parameter

Evolution Test	F4A	F4B	F4C
Appearance	Pine green	Pine green	Pine green
Texture Analysis	Cog wheel shaped	Cog wheel shaped	Cog Wheel shaped
Disintegration Time	24 min	23 min	25 min
Swelling Ratio	1.53	1.64	1.69
pH Testing	4.50	4.51	4.58
Ash value	5.27 %	4.581 %	4.581 %

IV. CONCLUSION

The present study successfully formulated and evaluated immunity booster herbal gummies using *Clitoria ternatea*, *Zingiber officinale*, *Withania somnifera*, and *Citrus sinensis* peel. Among the four batches prepared, the formulations showed acceptable physicochemical properties, stability, and good organoleptic characteristics. Evaluation parameters such as ash value, pH, disintegration time, and solubility were within permissible limits, confirming the quality of the gummies. Sensory evaluation indicated good consumer acceptability. Overall, the study highlights herbal gummies as a promising, palatable, and user-friendly nutraceutical dosage form for effective delivery of herbal actives, improving compliance and suitability for both children and adults.

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