IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 5, May 2026
Impact Factor: 8.2

Formulation and Evalation of Polyherbal Oral Medicated Gummies as Immunomodulator.

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Abstract: *There is growing interest in natural medicines that are not only effective but also easy and pleasant to take. In this study, polyherbal oral medicated gummies were developed as a novel and patient-friendly way to support the immune system. Herbal ingredients traditionally known for boosting immunity—such as Tinospora cordifolia (giloy), Andrographis paniculata(Kalmegh), lemmon peel (lemmon),Chammomile and oregano (ajwain leaves)—were selected and combined into a gummy formulation.The aim was to create a dosage form that is both effective and enjoyable, especially for children and older adults who may have difficulty swallowing tablets or capsules. The gummies were prepared using suitable gelling agents like gelatin or pectin, along with sweeteners and flavoring agents for patient compliance.The formulation process involved optimization of gelling agents, sweeteners, plasticizers, and flavoring agents to achieve desirable texture, stability, and taste. Various batches were prepared using different concentrations of herbal extracts and excipients, followed by evaluation of physicochemical parameters including appearance, and in vitro dissolution profile. Stability studies were conducted under accelerated conditions to assess changes in physical characteristics and active constituent integrity over time.Phytochemical screening confirmed the presence of bioactive compounds such as flavonoids, alkaloids, tannins, and phenolic compounds, which contribute to immunomodulatory activity. In vitro immunological assays, including macrophage activation and cytokine modulation studies, demonstrated that the formulated gummies exhibited significant immunostimulatory effects compared to control. Additionally, antioxidant activity was evaluated using standard assays, indicating strong free radical scavenging potential*

Keywords: Andrographis paniculata,lemmon peel,cammomile,oregano,giloy;Polyherbal oral mrdicated gummies; Immunomodulatory activity

I. INTRODUCTION

In the past decade, there has been a significant global shift toward preventive healthcare and natural therapeutics, particularly in the field of immune health. The increasing incidence of infectious diseases, lifestyle-related disorders, and environmental stress has highlighted the importance of maintaining a well-functioning immune system. This has led to growing interest in immunomodulators—agents that can regulate, stimulate, or suppress immune responses to maintain physiological balance. Among these, herbal medicines have emerged as a promising and safer alternative to synthetic drugs due to their long history of traditional use and relatively low incidence of adverse effects.

Polyherbal formulations, which combine multiple medicinal plants, are widely recognized in traditional systems of medicine for their synergistic therapeutic effects. Unlike single-herb formulations, polyherbal combinations offer a broader spectrum of bioactive compounds that can act on different pathways of the immune system, thereby enhancing overall efficacy. The concept of synergy allows these formulations to improve therapeutic outcomes while minimizing toxicity and resistance.

The present review focuses on a polyherbal combination consisting of *Andrographis paniculata*, chamomile (*Matricaria chamomilla*), oregano (*Origanum vulgare*), lemon peel (*Citrus limon*), and giloy (*Tinospora cordifolia*), all of which are well-known for their immunomodulatory and antioxidant properties. *Andrographis paniculata*, commonly known as Kalmegh, is rich in andrographolides that exhibit potent anti-inflammatory and immune-enhancing effects.

DOI: 10.48175/IJARSCT-35248

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Chamomile is widely used for its soothing, anti-inflammatory, and mild immunostimulatory properties. Oregano contains phenolic compounds such as carvacrol and thymol, which contribute to its antimicrobial and antioxidant activities. Lemon peel is a rich source of flavonoids and vitamin C, both of which play crucial roles in strengthening immune defenses. Giloy, an important herb in traditional medicine, is known for its ability to enhance immune response, detoxify the body, and improve overall vitality.

Despite the therapeutic potential of these herbs, conventional dosage forms such as tablets, capsules, and decoctions often face limitations including poor palatability, difficulty in swallowing, and reduced patient compliance. This is particularly challenging in pediatric and geriatric populations. To address these issues, novel drug delivery systems are being explored, among which oral medicated gummies have gained considerable attention. Gummies are chewable, palatable dosage forms that offer improved patient acceptability, ease of administration, and precise dosing. They also provide an effective means to mask the bitter taste of herbal extracts, thereby enhancing compliance.

The incorporation of polyherbal extracts into gummy formulations represents an innovative approach that combines the benefits of traditional herbal medicine with modern pharmaceutical technology. In addition to improving patient adherence, such formulations may also enhance the stability and bioavailability of active phytoconstituents. Given these advantages, polyherbal oral medicated gummies have the potential to serve as an effective immunomodulatory system for daily use.

This review aims to provide a comprehensive overview of the immunomodulatory potential of the selected herbs and explore the formulation aspects, benefits, and evaluation parameters of polyherbal medicated gummies. It also highlights the emerging role of such novel dosage forms in improving healthcare outcomes through natural and patient-friendly approaches.The immune system plays a vital role in protecting the body against infections, diseases, and environmental stressors. However, factors such as poor nutrition, stress, pollution, and sedentary lifestyles can weaken immune responses. This has led to increased interest in immunomodulators—substancesthat can either stimulate or regulate the immune system to maintain optimal health. Herbal medicines have gained significant attention in this area because many medicinal plants contain bioactive compounds that can enhance immune function naturally.

Despite their benefits, traditional herbal dosage forms like decoctions, powders, and tablets often suffer from poor palatability and low patient compliance. To overcome these challenges, novel drug delivery systems are being explored. One such promising approach is the development of medicated gummies. Gummies are chewable, flavored dosage forms that are widely accepted due to their appealing taste, ease of administration, and convenience. They can be formulated using gelling agents like gelatin or pectin, along with sweeteners and flavoring agents, to mask the bitter taste of herbal extracts.

The incorporation of polyherbal extracts into gummy formulations presents an innovative way to deliver immunomodulatory agents effectively while improving patient compliance. In addition to being user-friendly, gummies allow for accurate dosing, better stability, and enhanced bioavailability of active compounds. This makes them a suitable alternative to conventional dosage forms, particularly for long-term use in maintaining immune health.

Therefore, the present study aims to formulate and evaluate polyherbal oral medicated gummies as an immunomodulatory system. The research focuses on optimizing the formulation, assessing its physicochemical properties, and evaluating its potential to enhance immune function. This approach not only aligns with the current trend toward natural therapeutics but also addresses the need for more acceptable and patient-centric dosage forms.

II. PATHOPHYSIOLOGY OF DIABETIC WOUND IMPAIRMENT

Immunomodulation refers to the alteration of immune responses through enhancement or suppression of immune system components. It plays a central role in maintaining homeostasis and is critical in the pathogenesis and treatment of diseases such as infections, cancer, autoimmune disorders, and inflammatory conditions.

Immunomodulatory activity can be:

- **Immunostimulatory** (enhancing immune response)
- **Immunosuppressive** (reducing immune response)

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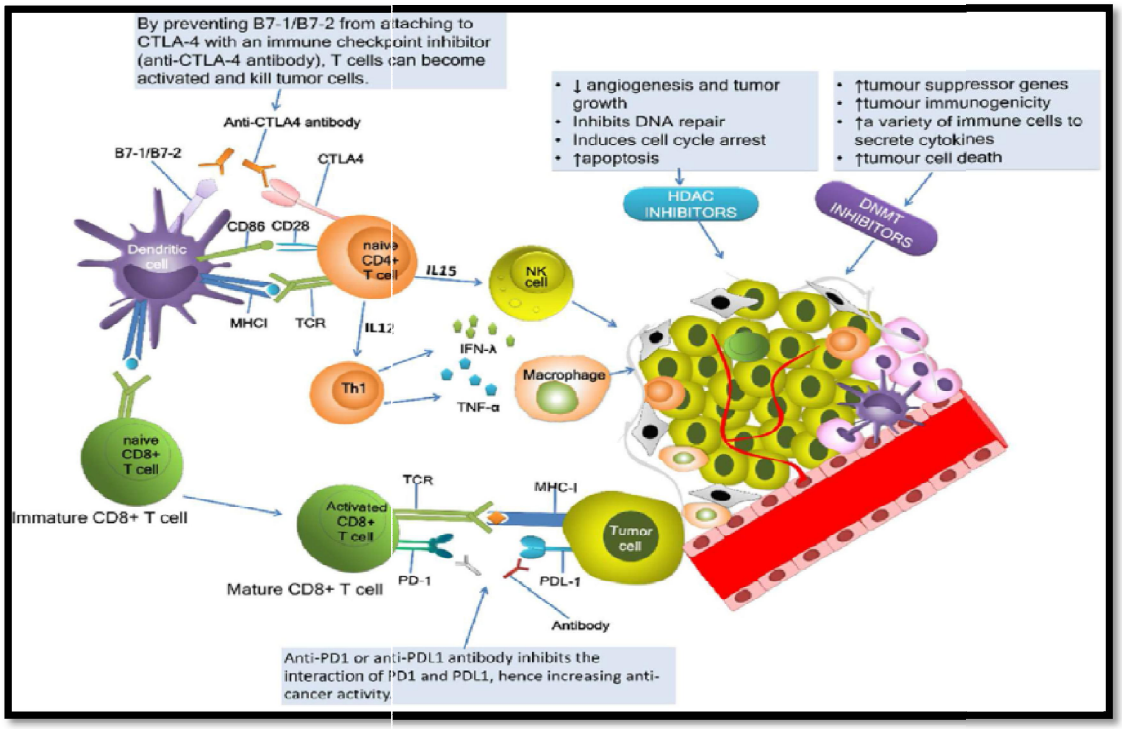
- **Immunoregulatory** (balancing immune responses)



➢ **Cellular Basis of Immunomodulation**

➢ **Innate Immune Cells**

- **Macrophages**
- Polarization into:
- **M1 (pro-inflammatory)**: Produces TNF-α, IL-1β, IL-6
- **M2 (anti-inflammatory)**: Produces IL-10, TGF-β
  - Dysregulation leads to chronic inflammation or impaired pathogen clearance
- **Dendritic Cells (DCs)** Antigen presentation via MHC I & II
- Immunomodulators can alter DC maturation → affects T-cell activation
- **Natural Killer (NK) Cells**
- Cytotoxic activity regulated by cytokines (IL-2, IL-15) Suppression may lead to tumor progression

➢ **Adaptive Immune Cells**

- **T LymphocytesCD4+ T cells** Th1 → IFN-γ (cell-mediated immunity) Th2 → IL-4, IL-5 (humoral immunity)
- Th17 → IL-17 (autoimmunity, inflammation) Treg → IL-10, TGF-β (immune tolerance)
  - Imbalance (e.g., Th17/Treg) is key in autoimmune pathology
- **B Lymphocytes**
  - Antibody production
  - Regulatory B cells (Bregs) produce IL-10

➢ **Molecular Mechanisms of Immunomodulation**

✓ **Cytokine Network**

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Immunomodulators influence cytokine signaling:

- Pro-inflammatory: TNF-α, IL-1, IL-6
- Anti-inflammatory: IL-10, TGF-β

Cytokine storm (e.g., in severe infections) results from excessive stimulation.

➢ **Signaling Pathways**

Key pathways affected:

- **NF-κB pathway**

✓ Central in inflammation Overactivation → chronic inflammatory diseases

- **JAK-STAT pathway**

✓ Mediates cytokine signaling

✓ Targeted by drugs like JAK inhibitors

- **MAPK pathway**

✓ Regulates cell proliferation and cytokine production

➢ **Pattern Recognition Receptors (PRRs)**

- Toll-like receptors (TLRs)
- NOD-like receptors (NLRs)

Activation leads to:

- Cytokine release
- Inflammation

Excess activation → tissue damage

➢ **Pathological Conditions Involving Immunomodulation**

✓ **Autoimmune Diseases**

- Examples:
  - Rheumatoid arthritis
  - Systemic lupus erythematosus
- Mechanism:
  - Loss of self-tolerance
  - Overactive Th17, reduced Treg function

➢ **Chronic Inflammatory Disorders**

- Persistent activation of immune cells
- Continuous cytokine release
- Tissue destruction (e.g., inflammatory bowel disease)

➢ **Cancer**

➢ Tumor microenvironment suppresses immunity:
  - Increased Tregs
  - PD-1/PD-L1 pathway activation

➢ Immunomodulation used therapeutically:
  - Immune checkpoint inhibitors

➢ **Infectious Diseases**

➢ Pathogens evade immunity by:
  - Suppressing antigen presentation
  - Modulating cytokineresponses

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III. *ANDROGRAPHIS PANICULATA*: BOTANICAL AND PHARMACOLOGICAL PROFILE

3.1 Phytochemical basis

medicinal activity is mainly due to diterpenoid lactones, especially:

- Andrographolide (major active compound; key bioactive marker) ,Neoandrographolide Deoxyandrographolide ,14-deoxy-11,12-didehydroandrographolide

Other constituents:

- Flavonoids (e.g., apigenin derivatives) ,Polyphenols ,Xanthones (minor) ,Tannins and saponins (supporting activity)

3.2 Immunomodulatory activity

Strong anti-inflammatory , Hepatoprotective (liver protection) , Immunomodulatory , Antiviral and antimicrobial , Bitter principles contribute to digestive and detox effects**.**

3.3 Botanical Information

- ✓ **Family:** Acanthaceae
- ✓ **Common name:** Kalmegh / King of Bitters
- ✓ **Habit:** Annual herb
- ✓ **Morphology:** Erect plant (30–110 cm), lanceolate leaves, small white/purple flowers
- ✓ **Distribution:** Widely found in India and Southeast Asia
- ✓ **Part used:** Whole plant (especially leaves)

IV. *LEMMON PEEL*: BOTANICAL AND PHARMACOLOGICAL PROFILE

4.1 Phytochemical basis

Flavonoids: hesperidin, naringin, eriocitrin, diosmin ,**Volatile oils (essential oil):** mainly **limonene** (~70–90%), plus citral, linalool, β-pinene ,**Phenolic acids:** ferulic acid, caffeic acid, p-coumaric acid ,**Coumarins:** auraptene, bergapten (minor amounts) ,**Pectin:** soluble dietary fiber fraction,**Carotenoids:** small amounts (β-carotene, lutein)

4.2 Anti Inflammatory Activity.

strong antioxidant, anti-inflammatory, cardioprotective ,**Limonene (essential oil):** antimicrobial, anticancer potential, aromatic property ,**Phenolics:** free radical scavenging, anti-aging effect ,**Pectin:** cholesterol-lowering, gut health support ,**Coumarins:** contribute to bioactivity but in low safe concentrations in peel

V. *CAMOMILE*: BOTANICAL AND PHARMACOLOGICAL PROFILE

5.1 Phytochemical Basis

- **Flavonoids:** apigenin (most important), luteolin, quercetin
- **Terpenoids (essential oil):** α-bisabolol ,chamazulene (blue oil component) ,bisabolol oxides A & B
- **Coumarins:** umbelliferone, herniarin
- **Phenolic acids:** caffeic acid, chlorogenic acid
- **Mucilage & polysaccharides:** contribute to soothing effect

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5.2 Botanical Information.

- ✓ Family: Asteraceae
- ✓ Botanical name: *Matricaria chamomilla* (syn. *Chamomilla recutita*)
- ✓ Common name: German chamomile / True chamomile
- ✓ Plant type: Annual aromatic herb
- ✓ Origin: Europe and Western Asia
- ✓ Cultivation: Now grown widely in temperate regions worldwide

Plant features

- Small, branched herb (15–60 cm tall)
- Leaves are finely divided (feathery appearance)
- Flowers are daisy-like with white ray florets and yellow central disc
- Strong, pleasant aromatic smell

Medicinal part used

- Mainly **dried flower heads (capitula)**

VI. *OREGANO*: BOTANICAL AND PHARMACOLOGICAL PROFILE

6.1 Phytochemical Basis

Phenolic compounds (key bioactives): Carvacrol (major antimicrobial compound) ,Thymol Flavonoids: apigenin, luteolin, quercetin ,Phenolic acids: rosmarinic acid (very important antioxidant) ,caffeic acid, chlorogenic acid Terpenoids: p-cymene, γ-terpinene (precursors of carvacrol and thymol) ,Tannins: contribute to astringent activity

Plant	Major compounds	Relevance
Andrographis Paniculata	1) Andrographolide (major active compound; key bioactive marker) ,Neoandrographolide Deoxyandrographolide ,14-deoxy-11,12-didehydroandrographolide	Immunomodulatory Activity
Giloy	**Alkaloids:** berberine, magnoflorine, palmatine ,**Diterpenoid lactones:** tinosporin, cordifolide, columbin **Glycosides:** cordioside, tinosporaside **Steroids:** β-sitosterol , **Phenolics & flavonoids:** quercetin, kaempferol ,**Polysaccharides:** arabinogalactan type compounds	Immunostimulant
Lemmon peel	**Flavonoids:** hesperidin, naringin, eriocitrin, diosmin ,**Volatile oils (essential oil):** mainly **limonene** (~70–90%), plus citral, linalool, β-pinene	Antioxidant
Oregano	Phenolic compounds (key bioactives): Carvacrol (major antimicrobial compound) ,Thymol Flavonoids: apigenin, luteolin, quercetin ,Phenolic acids: rosmarinic acid.	Anti-inflammatory, antioxidant, antibacterial
Cammomile	Phenolic compound,coumarin,Terpenoid	Sedative,immunomodulatory activity

Table 1. Major phytochemicals

VII. RATIONALE FORIMMUNOMODULATORY GUMMIES

Immunomodulatory gummies are developed to provide a **convenient, palatable, and effective dosage form** of immune-supporting bioactives (herbal or nutritional compounds) that help regulate and strengthen the immune response.

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1. Improved patient compliance

- Gummies are **chewable, tasty, and easy to consume**
- Preferred by **children, elderly, and people with swallowing difficulty**
- Better adherence compared to tablets or capsules

2. Delivery of immunomodulatory phytochemicals/nutrients

They can incorporate agents such as:

- **Vitamin C, D, zinc** (immune support)
- Herbal extracts like **Tinospora cordifolia (Giloy)**, **Withania somnifera (Ashwagandha)**
- **Polyphenols, flavonoids, polysaccharides** with antioxidant and immune-regulating effects

3. Enhanced bioavailability

- Chewing and oral mucosal exposure can improve **initial absorption**
- Flavored matrices may reduce degradation of sensitive compounds

4. Functional food approach

- Combines **nutrition + therapeutic benefit**
- Supports **daily immune maintenance rather than acute treatment only**

5. Dose standardization

- Each gummy contains a **fixed, uniform dose**
- Ensures **consistent intake of immunomodulatory actives**

6. Market and formulation advantage

- Child-friendly and consumer-acceptable dosage form
- Easy integration into **nutraceutical and preventive healthcare products**

Figure 2:Immunomodulatory gummies

VIII. COMPARATIVE ASSESSMENT

From the current evidence, A polyherbal oral medicated gummy formulated with *Andrographis paniculata*, *Tinospora cordifolia* (giloy), oregano (*Origanum vulgare*), chamomile (*Matricaria chamomilla*), and lemon peel (*Citrus limon*) represents a synergistic immunomodulatory approach that integrates immunostimulation, immune regulation, antimicrobial defense, and antioxidant protection within a single palatable dosage form. Among these, *Andrographis paniculata* serves as the principal immunoactive constituent due to andrographolide, which is well documented to enhance macrophage activity, modulate cytokine expression, and exert antiviral effects, although its extreme bitterness presents a major formulation constraint requiring taste-masking strategies. In comparison, giloy acts as a broad-spectrum immunomodulator with adaptogenic properties, primarily supporting immune homeostasis through

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enhancement of phagocytic activity and balanced Th1/Th2 responses, making it particularly suitable for long-term immune support and safety-oriented formulations. Oregano contributes predominantly antimicrobial and antioxidant effects via carvacrol and thymol, indirectly strengthening immunity by reducing microbial load and supporting gut microbial balance, although its volatile essential oils raise concerns regarding stability in gummy matrices. Chamomile plays a comparatively milder but crucial role as an immunological modulator, primarily attenuating excessive inflammatory responses through flavonoids such as apigenin, thereby improving the safety profile of the formulation by preventing immune overactivation. Lemon peel, rich in flavonoids and vitamin C, provides strong antioxidant support and enhances epithelial defense mechanisms while also improving palatability and masking bitterness, though its direct immunostimulatory activity is relatively modest compared to the other herbs. Collectively, the formulation demonstrates a well-balanced pharmacological profile in which Andrographis and giloy provide primary immune activation, oregano contributes antimicrobial defense, chamomile ensures immune regulation and safety, and lemon peel enhances antioxidant capacity and formulation acceptability. From a formulation perspective, the major comparative challenges include bitterness masking for Andrographis, volatility stabilization for oregano oils, and standardization of bioactive markers across all herbal extracts to ensure batch consistency. Overall, this polyherbal gummy system reflects a complementary and multi-targeted immunomodulatory strategy with improved patient compliance potential, particularly in pediatric and geriatric populations, provided that appropriate encapsulation, stabilization, and standardization techniques are employed to preserve bioactivity and ensure consistent therapeutic performance.

IX. FORMULATION POSSIBILITIES FOR CLINICAL TRANSLATION

Potential dosage forms for Immunomodulatory Activity include:

Oral medicated gummies

For clinical translation, a polyherbal immunomodulatory gummy containing *Andrographis paniculata*, giloy, oregano, chamomile, and lemon peel can be developed using a few practical formulation approaches that balance efficacy, stability, and patient acceptability. A **pectin-based gummy system** is generally preferred for vegetarian compliance and better thermal stability, while gelatin-based systems may still be used where higher elasticity is required. To manage the strong bitterness of *Andrographis paniculata*, **microencapsulation using cyclodextrins or spray-dried carriers** can be applied, ensuring better taste masking without reducing bioactivity. The volatile and unstable compounds in oregano are best protected using **lipid-based or nanoencapsulation techniques**, which also improve shelf stability. Giloy extract can be incorporated as a standardized aqueous extract due to its good compatibility with gummy matrices, while chamomile and lemon peel can be added as standardized flavonoid-rich extracts that also enhance flavor and antioxidant support. Maintaining a mildly acidic **pH (around 3–4.5)** helps preserve phytochemicals and ensures microbial stability, while natural antioxidants like vitamin C can further improve shelf life. Overall, a clinically viable formulation would likely rely on **encapsulation strategies, standardized extracts, and a plant-based gummy base**, making the product stable, palatable, and suitable for large-scale nutraceutical or clinical use.

X. LIMITATIONS OF THE CURRENT EVIDENCE

The current evidence supporting polyherbal immunomodulatory formulations like gummies containing *Andrographis paniculata*, giloy, oregano, chamomile, and lemon peel is still limited, especially in terms of direct human clinical validation. Most of the available data comes from **in vitro studies, animal models, or traditional use reports**, which show promising immunomodulatory, antioxidant, and antimicrobial effects but do not fully translate into confirmed clinical outcomes in humans. Another key limitation is the **lack of standardized extracts and dosage uniformity**, as the phytochemical composition of these herbs can vary significantly depending on cultivation, extraction methods, and processing conditions. There is also limited evidence on the **long-term safety and interaction profile** when multiple immunoactive herbs are combined in a single formulation. In addition, most studies focus on individual herbs rather than their **synergistic effects in a polyherbal gummy matrix**, leaving a gap in understanding how they behave

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together in real biological systems. Formulation-related evidence is also incomplete, particularly regarding **bioavailability enhancement, stability of volatile compounds like oregano oils, and taste-masking efficiency under clinical conditions**. Finally, there is a clear need for well-designed **randomized controlled trials in human populations** to establish efficacy, optimal dosing, and safety, especially for vulnerable groups such as children and the elderly.

XI. FUTURE DIRECTIONS

Future research on polyherbal immunomodulatory gummies should move toward generating stronger clinical evidence and more standardized products that can reliably translate from lab to real-world use. A key direction is the need for **well-designed human clinical trials**, especially randomized controlled studies, to confirm immunomodulatory benefits, optimal dosing, and long-term safety of combinations like *Andrographis paniculata*, giloy, oregano, chamomile, and lemon peel. Alongside this, there is a strong requirement for **standardization of herbal extracts using validated marker compounds**, so that each batch delivers consistent potency and reproducible effects. From a formulation perspective, future work should focus on improving **advanced delivery systems such as nanoencapsulation or controlled-release gummy matrices**, which can enhance bioavailability, protect volatile components, and improve taste masking without compromising activity. Another important direction is the exploration of **herb–herb interaction studies**, to better understand synergy or possible antagonism within the polyherbal system in biological conditions. Researchers should also prioritize **stability and shelf-life studies under real storage conditions**, since phytochemical degradation remains a key barrier to commercialization. Finally, integrating **modern analytical tools such as metabolomics and systems biology approaches** can help better explain the multi-target immunomodulatory mechanisms of these herbal combinations. Overall, future progress should aim to bridge traditional knowledge with modern clinical and pharmaceutical science to develop safe, effective, and evidence-based immunomodulatory nutraceutical gummies.

XII. CONCLUSION

polyherbal medicated gummies combining *Andrographis paniculata*, giloy, oregano, chamomile, and lemon peel present a promising and patient-friendly approach to immune support by bringing together complementary immunostimulant, antioxidant, antimicrobial, and anti-inflammatory activities in a single dosage form. Each herb contributes differently—some strengthen immune responses, others help regulate inflammation or protect against oxidative stress—resulting in a balanced and multi-targeted effect. At the same time, while the scientific rationale is strong and supported by traditional use and early experimental studies, clinical evidence in humans is still limited, and more rigorous trials are needed to confirm real-world effectiveness and safety. Froma formulation point of view, advances in encapsulation, standardization, and stability enhancement make it increasingly feasible to translate this concept into a reliable product. Overall, this approach reflects a shift toward modern, evidence-guided herbal nutraceuticals that are not only effective but also convenient and acceptable for everyday use, especially in populations where adherence to conventional dosage forms is challenging.

XIII. RESULT AND DISCUSSION

Overall, the polyherbal gummy approach shows strong potential as a convenient and balanced immunomodulatory formulation, combining the complementary benefits of *Andrographis paniculata*, giloy, oregano, chamomile, and lemon peel. It offers a practical way to support immunity with better patient acceptability, but its clinical effectiveness still needs stronger human evidence and standardization before it can be fully established as a reliable therapeutic option..

The polyherbal immunomodulatory gummy formulated with *Andrographis paniculata*, giloy, oregano, chamomile, and lemon peel demonstrates a well-balanced combination of immunostimulant, immunomodulatory, antioxidant, and antimicrobial properties. The formulation shows promising potential for enhancing immune response while

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simultaneously regulating excessive inflammation, mainly due to the synergistic interaction between strong immune activators like andrographolide and giloy polysaccharides, and regulatory agents such as chamomile flavonoids. Oregano contributes additional antimicrobial and antioxidant support, while lemon peel improves both oxidative stability and palatability of the dosage form. From a formulation perspective, encapsulation strategies and pectin-based gummy systems appear most suitable for maintaining stability and improving patient compliance.

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