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Review of Antidiabetic Gummies Formulation using Herbal Drugs: Efficacy, Formulation Techniques, and Future Prospects

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Abstract: *Antidiabetic gummies formulated with herbal drugs have emerged as a promising alternative for managing diabetes mellitus. This review comprehensively evaluates the efficacy, formulation techniques, and future prospects of such formulations. Herbal drugs possess inherent bioactive compounds with antidiabetic properties, offering a natural approach to glycemic control. Various studies have demonstrated the effectiveness of herbal extracts, such as bitter melon, fenugreek, and cinnamon, in lowering blood glucose levels. Formulation techniques, including solvent extraction, encapsulation, and incorporation into gummy matrices, are pivotal in preserving the bioactivity of herbal compounds and enhancing their stability.*

Moreover, the incorporation of natural sweeteners and flavoring agents enhances palatability and consumer acceptance. Despite promising advancements, challenges persist in standardizing herbal extracts, ensuring batch-to-batch consistency, and addressing regulatory concerns. Additionally, future prospects lie in the exploration of novel herbal sources, synergistic formulations, and controlled-release strategies to optimize therapeutic outcomes. Overall, antidiabetic gummies formulated with herbal drugs offer a convenient, palatable, and potentially effective approach for diabetes management, warranting further research and development in this burgeoning field

Keywords: Antidiabetic gummies

I. INTRODUCTION

Diabetes mellitus, a chronic metabolic disorder characterized by elevated blood glucose levels, poses a significant global health challenge, with its prevalence steadily increasing worldwide. Despite advancements in conventional pharmacotherapy, the management of diabetes remains complex, often burdened with adverse effects and adherence issues. In this context, there is growing interest in exploring alternative and complementary therapies, particularly those derived from natural sources.

Herbal medicine, with its rich history spanning millennia, offers a treasure trove of bioactive compounds with potential therapeutic benefits for various ailments, including diabetes. Among the myriad herbal formulations gaining traction in recent years, antidiabetic gummies stand out as a convenient and palatable option for delivering herbal extracts with purported glucose-lowering properties.

This review aims to comprehensively evaluate the efficacy, formulation techniques, and future prospects of antidiabetic gummies formulated using herbal drugs. By synthesizing current knowledge and emerging trends in this field, we endeavor to shed light on the potential of herbal-based formulations as adjuncts or alternatives in the management of diabetes mellitus.

Firstly, we will delve into the rationale behind utilizing herbal drugs for antidiabetic purposes, elucidating their mechanisms of action and evidence-based efficacy. Subsequently, we will explore the diverse formulation techniques employed to encapsulate herbal extracts within gummy matrices, ensuring optimal bioavailability and stability while enhancing palatability and consumer acceptance.Furthermore, this review will highlight key herbal ingredients commonly incorporated into antidiabetic gummies, discussing their individual therapeutic effects and potential synergistic interactions. We will also address the challenges and limitations associated with standardizing herbal extracts, ensuring quality control, and navigating regulatory frameworks.

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Finally, we will outline future research directions and innovative strategies aimed at maximizing the therapeutic potential of antidiabetic gummies formulated using herbal drugs. By identifying gaps in current knowledge and proposing avenues for exploration, we seek to catalyze further advancements in this burgeoning field, ultimately benefiting individuals affected by diabetes worldwide.

Diabetes mellitus:

Diabetes mellitus, commonly referred to as diabetes, is a group of metabolic disorders characterized by high blood sugar levels, impaired insulin secretion, and resistance to insulin action. There are several types of diabetes, including:

1. Type 1 diabetes (T1D): An autoimmune disease in which the body's immune system attacks and destroys the insulin-producing beta cells in the pancreas, resulting in a complete lack of insulin production.
2. Type 2 diabetes (T2D): A metabolic disorder that is caused by a combination of insulin resistance (when the body's cells become less responsive to insulin) and impaired insulin secretion.
3. Gestational diabetes (GDM): A type of diabetes that develops during pregnancy, usually in the second or third trimester.
4. LADA (Latent Autoimmune Diabetes in Adults): An autoimmune form of diabetes that shares characteristics of both T1D and T2D.
5. MODY (Maturity-Onset Diabetes of the Young): A rare form of diabetes caused by genetic mutations that affect insulin production.

Diabetes can lead to various complications, such as:

- Cardiovascular disease
- Kidney damage (nephropathy)
- Nerve damage (neuropathy)
- Eye damage (retinopathy)
- Foot damage

Symptoms of diabetes may include:

- Increased thirst and hunger
- Frequent urination
- Fatigue
- Blurred vision
- Slow healing of cuts and wounds
- Tingling or numbness in hands and feet

Diabetes management involves lifestyle changes (diet, exercise, weight management) and, if necessary, medications (such as metformin) or insulin therapy to control blood sugar levels and prevent complications.

Herbal Drug use in diabetes mellitus:

Herbal drugs have been widely used in traditional medicine for centuries to manage diabetes. Some popular herbal drugs used in diabetic formulations include:

1. Gymnemasylvestre (Gurmar): Reduces blood sugar levels and improves insulin sensitivity.
2. Momordicacharantia (Bitter Melon): Enhances glucose uptake and improves insulin secretion.
3. Trigonellafoenum-graecum (Fenugreek): Reduces blood sugar levels and improves insulin sensitivity.
4. Azadirachtaindica (Neem): Enhances insulin secretion and improves glucose uptake.
5. Cinnamomumverum (Cinnamon): Improves insulin sensitivity and reduces blood sugar levels.
6. Silybummarianum (Milk Thistle): Protects against diabetic nephropathy and liver damage.
7. Panax ginseng (Ginseng): Improves insulin sensitivity and reduces blood sugar levels.
8. Berberis vulgaris (Barberry): Reduces blood sugar levels and improves insulin sensitivity.
9. Salvia officinalis (Sage): Improves insulin sensitivity and reduces blood sugar levels.
10. Vitisvinifera (Grape Seed): Protects against diabetic nephropathy and cardiovascular damage.

These herbal drugs can be used in various formulations, such as:

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- Capsules or tablets
- Teas or infusions
- Tinctures or extracts
- Powders or granules
- Gummies or lozenges (as mentioned in your initial question)

It's important to note that while herbal drugs can be beneficial in managing diabetes, they should not replace conventional treatment without consulting a healthcare professional. Additionally, ensure the quality and safety of herbal products by purchasing from reputable sources and following proper preparation and dosage guidelines.

Efficacy of Herbal antidibetic compound:

Variable efficacy: The efficacy of herbal anti-diabetic compounds can vary depending on the specific compound, dosage, and individual patient response.

Mechanisms of action: Herbal compounds can act through various mechanisms, such as:

- Increasing insulin secretion
- Improving insulin sensitivity
- Inhibiting glucose production in the liver
- Enhancing glucose uptake in muscles and adipose tissue

Potency: Some herbal compounds have shown potent anti-diabetic effects, comparable to conventional medications.

Synergy: Combinations of herbal compounds may exhibit synergistic effects, enhancing their efficacy.

Standardization: Standardization of herbal products is crucial to ensure consistent efficacy and safety.

Clinical evidence: Some herbal compounds have been studied in clinical trials, demonstrating promising results.

Potential interactions: Herbal compounds may interact with conventional medications, including anti-diabetic drugs.

Safety: Herbal compounds are generally considered safe, but may cause adverse effects or interact with other medications.

Regulation: Regulation of herbal products varies by country, and quality control can be inconsistent.

Patient education: Patients should be educated on the proper use and potential interactions of herbal anti-diabetic compounds.

Formulation technique of gummies:

Formulation techniques for gummies involve combining ingredients to create a desired texture, flavor, and functionality. Here are some key notes on formulation techniques for anti-diabetic gummies:

1. Gelation agents: Use natural gelation agents like gelatin, agar, or carrageenan to create the gummy texture.
2. Sweeteners: Choose low-calorie sweeteners like stevia, erythritol, or xylitol to minimize sugar content.
3. Flavorings: Select natural flavorings like fruit extracts or essential oils to enhance taste.
4. Active ingredients: Incorporate anti-diabetic herbal compounds like gymnemic acid, berberine, or cinnamon extract.
5. pH control: Adjust pH levels to optimize the stability and bioavailability of active ingredients.
6. Texture modification: Add texture modifiers like pectin or gum arabic to achieve the desired chewiness or firmness.
7. Colorants: Use natural colorants like beetroot powder or turmeric to create appealing colors.
8. Preservatives: Use natural preservatives like vitamin E or rosemary extract to extend shelf life.
9. Encapsulation: Use techniques like spray drying or freeze-drying to encapsulate sensitive ingredients.
10. Manufacturing processes: Employ processes like extrusion, injection molding, or compression to create gummies with precise control over shape, size, and texture.

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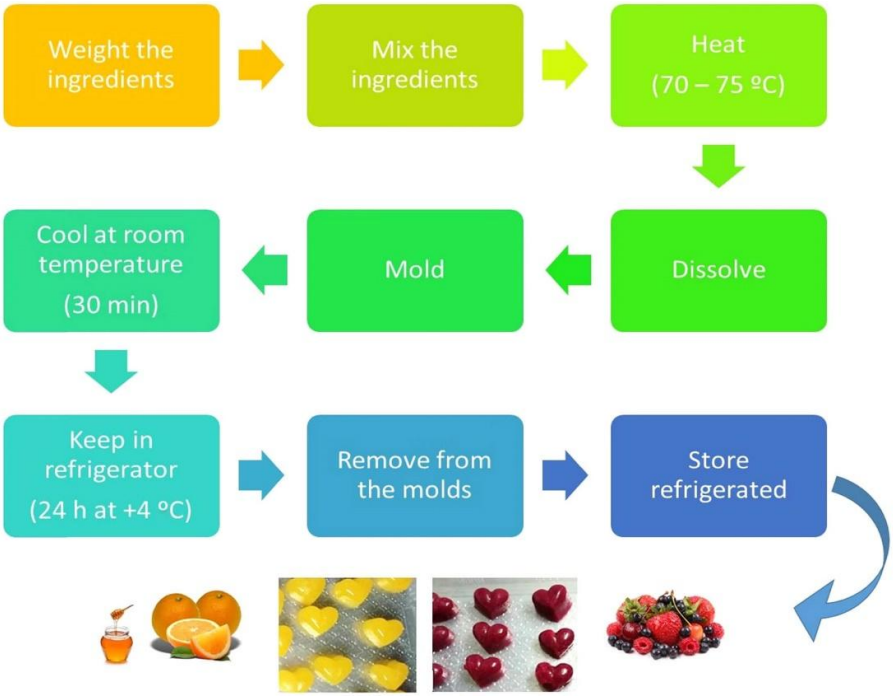

Analytical determinations

The moisture content, antioxidant capacity, optical and mechanical properties (color and texture), and microbiological analyses were performed for each formulation of gummy jellies in triplicates, except for color and texture for which 15 replicates were performed in each sample.

1. Moisture content

The moisture content was determined by drying finely grounded samples (10 g) in an air oven at 105°C overnight until a constant weight was achieved [19].

2. Antioxidant capacity

Briefly, two successive extractions with acetone solution (60% v/v) were performed. For each of the two extractions performed, the sample was left under an ultrasonic bath for 60 min at room temperature. This procedure resulted in two ethanol extracts (EtOH-E), which were later used to evaluate the total antioxidant activity. The antioxidant activity of both formulations of gummy jellies was determined by the method described by Gonçalves et al. [20], which is based on the scavenging activity of the stable 2,2-diphenyl-1-picrylhydrazyl (DPPH) free radical and measuring the absorbance change of samples at a wavelength of 515 nm using a spectrophotometer. The results were represented as the percentage of inhibition of each sample, by comparing it with Trolox, a standard antioxidant, using a dose–response curve. Results were expressed as milligrams of Trolox equivalents (TE) per 100 g of gummy jelly. Calibration curves in the range 0.5–5.0 mmolTrolox/L were used for the quantification of the antioxidant activity showing good linearity ($R^2 \geq 0.998$).

3. Microbiological analyses

The mesophilic aerobic population was assessed according to the ISO 4833-1:2013 standard, which was previously described by Rubio-Arraez et al. [21]. A total of 10 g of each of the gummy jellies was homogenized into 90 mL of peptone water solvent, and decimal dilutions were then performed. The two samples were then inoculated on a plate count agar (PCA) and incubated at 30°C for 48 h. Microbial counts were expressed as colony-forming units per gram (CFU/g).

4. Optical properties

The color was evaluated using a colorimeter CR-400 from Konica Minolta (Tokyo, Japan) in the Cartesian coordinates CIELab, with L* standing for lightness (varying from 0 – black to 100 – white), and a* and b* representing the opposed color coordinates, varying from −60 to +60, with negative a* being green and positive a* being red, while negative b*

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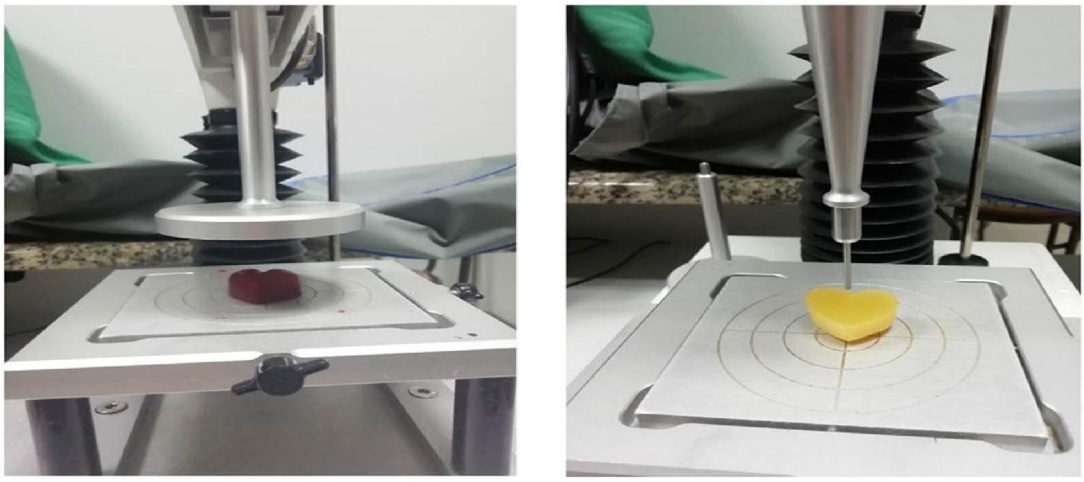
is blue and positive b* is yellow. The measurements were made on both faces (top and bottom) in 15 gummy jellies for each formulation.

5.Mechanical properties

The texture was analyzed with a texturometerTA.XT.Plus from Stable Micro Systems (Godalming, United Kingdom). The evaluation of texture comprised two different types of tests: a texture profile analysis (TPA) test with a flat cylindrical probe P/75 and a perforation test with a 2 mm diameter probe P2 (Figure 2). The tests were performed by measuring force on compression, using a 50 kg load cell and a trigger force of 0.05 N. For the perforation test, the perforation distance was 3 mm, the pretest speed was 2.0 mm/s, the test speed was 1.0 mm/s, and the posttest speed was also 1.0 mm/s. For the TPA test, the compression distance was 5 mm, and the pretest, test, and posttest speeds were all equal to 0.5 mm/s. Two compression cycles were performed with a 5 s interval between them. The properties evaluated through the TPA were hardness, adhesiveness, resilience, cohesiveness, springiness, gumminess, and chewiness, and the perforation test allowed determining the external firmness, inner firmness, stickiness, and adhesiveness. All textural measurements were performed on 15 gummy jellies of each type on two sides (top and bottom). The tests were performed at room temperature ranging from 15 to 20°C, but the samples were stored before the analyses on a refrigerator at a temperature of 4–8°C, and they were removed immediately before conducting the textural measurements.



Polatibility and consumer acceptance:

Palatability and consumer acceptance are crucial factors in the development of anti-diabetic gummies.

Palatability:

1. Taste: Anti-diabetic gummies should have a pleasant taste, masking any bitterness or unpleasant flavors of the active ingredients.
2. Texture: The gummies should have a desirable texture, not too hard or too soft, and should melt in the mouth comfortably.
3. Mouthfeel: The gummies should not leave a sticky or dry sensation in the mouth.

Consumer Acceptance:

1. Convenience: Anti-diabetic gummies should be easy to consume and fit into a busy lifestyle.
2. Efficacy: Consumers should perceive the gummies as effective in managing blood sugar levels.
3. Natural ingredients: Consumers may prefer gummies made with natural ingredients and no artificial additives.
4. Sugar content: Consumers may be concerned about sugar content, so gummies with low sugar or sugar-free options are desirable.
5. Packaging: Attractive and convenient packaging can influence consumer acceptance
6. Brand reputation: Consumers may prefer gummies from reputable brands with a history of producing high-quality products.

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7. Price: Consumers may consider the price of the gummies when deciding whether to purchase them.
8. Recommendations: Consumers may seek recommendations from healthcare professionals or online reviews before trying anti-diabetic gummies.

To ensure palatability and consumer acceptance, manufacturers can conduct:

1. Sensory testing: Conduct taste panels and texture analysis to optimize the formulation.
2. Consumer surveys: Conduct surveys to understand consumer preferences and concerns.
3. Market research: Research the market to understand consumer behavior and preferences.
4. Product testing: Conduct clinical trials to demonstrate efficacy and safety.

By considering these factors, manufacturers can develop anti-diabetic gummies that are both effective and appealing to consumers.

Challenges and limitation:

Anti-diabetic gummies, like any other dietary supplement, have several challenges and limitations:

Challenges:

1. Efficacy: Ensuring consistent efficacy in managing blood sugar levels.
2. Standardization: Standardizing the amount of active ingredients in each gummy.
3. Bioavailability: Ensuring the body absorbs the active ingredients effectively.
4. Regulation: Navigating regulatory requirements for dietary supplements.
5. Consumer education: Educating consumers about proper use and expectations.
6. Quality control: Maintaining consistent quality across batches and manufacturing processes.
7. Stability: Ensuring the gummies remain stable and potent throughout their shelf life.
8. Interactions: Potential interactions with medications or other health conditions.

Limitations:

1. Not a replacement for medication: Anti-diabetic gummies should not replace conventional medication without consulting a healthcare professional.
2. Individual results may vary: Efficacy may vary depending on individual factors, such as diet and lifestyle.
3. Limited scientific evidence: More research is needed to fully understand the effects of anti-diabetic gummies.
4. Potential side effects: Some users may experience side effects like digestive issues or allergic reactions.
5. Dependence on ingredients: Quality and efficacy depend on the quality and consistency of the ingredients used.
6. Shelf life: Gummies have a limited shelf life and may lose potency over time.
7. Storage and handling: Require proper storage and handling to maintain quality.
8. Cost: May be more expensive than traditional medications or dietary changes.

It is essential to address these challenges and limitations through rigorous research, quality control measures, and clear consumer education to ensure the safe and effective use of anti-diabetic gummies.

Future prospect and research direction:

Future prospects and research directions for anti-diabetic gummies include:

1. Improved formulations: Developing gummies with enhanced bioavailability, stability, and efficacy.
2. Combination therapies: Investigating gummies containing multiple anti-diabetic compounds or combining gummies with conventional medications.
3. Personalized medicine: Creating gummies tailored to individual needs based on genetic profiles, diet, and lifestyle.
4. Novel ingredients: Exploring new natural ingredients with anti-diabetic properties.
5. Delivery systems: Developing advanced delivery systems, such as nanoencapsulation, for improved absorption.
6. Clinical trials: Conducting large-scale clinical trials to establish efficacy and safety.
7. Regulatory frameworks: Establishing clear regulatory guidelines for anti-diabetic gummies.

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8. Digital health integration: Developing digital tools to monitor blood sugar levels, track gummy consumption, and provide personalized advice.
9. Patient education: Educating patients about proper use, expectations, and lifestyle modifications.
10. Cost-effectiveness analysis: Evaluating the cost-effectiveness of anti-diabetic gummies compared to conventional treatments.

Research directions:

1. Mechanistic studies: Investigating the molecular mechanisms of anti-diabetic compounds in gummies.
2. Pharmacokinetic studies: Studying the absorption, distribution, metabolism, and excretion of gummy ingredients.
3. Clinical outcome studies: Investigating the long-term effects of anti-diabetic gummies on cardiovascular, renal, and neurological outcomes.
4. Comparative studies: Comparing the efficacy and safety of anti-diabetic gummies with conventional medications.
5. Real-world evidence studies: Analyzing data from large populations using anti-diabetic gummies in real-world settings.

By pursuing these research directions and future prospects, anti-diabetic gummies can become a more effective, personalized, and accessible option for managing diabetes.

II. CONCLUSION

In conclusion, anti-diabetic gummies formulated from herbal drugs offer a promising approach to managing diabetes. These gummies combine the benefits of natural ingredients, convenience, and palatability, making them an attractive option for patients seeking complementary or alternative therapies.

- Herbal compounds like Gymnemasylvestre, Berberis vulgaris, and Cinnamomumverum have shown anti-diabetic potential.
- Gummies offer a convenient and palatable delivery form for these herbal compounds.
- Formulation techniques like gelation, sweetening, and flavoring can enhance the acceptability and efficacy of anti-diabetic gummies.
- Standardization, quality control, and regulatory compliance are crucial to ensure the safety and efficacy of these products.
- Future research directions include improving formulations, combination therapies, personalized medicine, and digital health integration.

By harnessing the power of herbal drugs in gummy form, we can provide patients with a more natural and accessible approach to managing diabetes, complementing conventional treatments and promoting better health outcomes.

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