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Gummy-Based Drug Delivery Systems: A Novel Approach for Oral Formulations

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Abstract: Gummy-based drug delivery systems have emerged as an innovative and patient-centric alternative to conventional oral dosage forms. Their palatable taste, chewable form, and visual appeal enhance patient compliance, particularly among pediatric and geriatric populations. This review explores the evolution, advantages, formulation components, and techniques of gummy preparation, highlighting their potential in both nutraceutical and pharmaceutical applications. Evaluation methods and regulatory considerations are discussed, alongside current challenges such as dose uniformity, drug stability, and sugar-related health risks. Finally, future prospects such as 3D-printed personalized gummies and controlled-release systems underscore the growing relevance of this delivery platform in modern pharmaceutics.

Keywords: *Gummy-Based Delivery, Oral Dosage Forms, Patient Compliance, Gelatin, Pectin, Pediatric Drug Delivery, Controlled Release, Nutraceuticals, 3D Printing, Chewable Formulations.*

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I. INTRODUCTION

Oral drug delivery remains the most preferred and widely accepted route for the administration of therapeutic agents due to its convenience, safety, and high patient compliance. Conventional oral dosage forms such as tablets, capsules, and syrups have long dominated the pharmaceutical market. However, these forms may present challenges such as swallowing difficulties, poor palatability, and limited acceptability among specific patient populations like children, elderly individuals, and those with dysphagia. As a result, the pharmaceutical industry continues to explore innovative approaches to improve the effectiveness and acceptability of oral drug delivery systems.

One such advancement is the development of gummy-based drug delivery systems, which have gained significant attention in recent years. Originally designed as confectionery or nutraceutical supplements, gummies have now evolved into a promising platform for delivering both over-the-counter and prescription medications. Their chewable nature, attractive appearance, pleasant taste, and flexible formulation properties make them an ideal candidate for improving patient adherence to medication regimens.

Gummies are typically formulated using biocompatible gelling agents such as gelatin, pectin, and agar, which serve as the structural base. These gelling materials can be combined with active pharmaceutical ingredients (APIs), sweeteners, flavouring agents, and other excipients to create palatable and stable dosage forms. Moreover, gummy formulations offer the potential for dose flexibility, taste masking, and incorporation of multiple APIs, which are advantageous over traditional oral forms.

This review aims to explore the current advancements in gummy-based oral drug delivery systems by highlighting formulation strategies, types of gelling agents, evaluation techniques, advantages, challenges, and future prospects. The integration of pharmaceutical technology with consumer-centric design holds great promise in transforming gummies from simple supplements into mainstream therapeutic delivery systems.(1–3)

II. HISTORICAL BACKGROUND AND EVOLUTION

The evolution of gummy-based formulations can be traced back to the confectionery industry, where gelatin-based candies such as gummy bears were first introduced in the early 20th century. In 1922, Hans Riegel, the founder of Haribo, created the first gummy bear in Germany, marking the beginning of a revolution in chewable gelatin products. These early gummies were primarily consumed as sweets and gained popularity among children for their soft, chewy texture and vibrant appearance.

Over the decades, the gummy format was adapted by the nutraceutical industry for delivering dietary supplements such as multivitamins, omega-3 fatty acids, and minerals. This shift

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was primarily driven by the need to improve palatability and compliance, especially among pediatric and geriatric populations. Gummies quickly became a preferred alternative to conventional tablets and syrups, due to their ease of administration, flavour masking capabilities, and consumer-friendly design.

The success of nutraceutical gummies opened new avenues for their pharmaceutical application. Researchers and formulators began exploring the incorporation of active pharmaceutical ingredients (APIs) into gummy matrices, which led to the emergence of medicated gummies as a novel oral drug delivery platform. Unlike traditional dosage forms, gummies offer flexibility in design, taste, and texture, enabling personalized drug delivery with improved patient adherence.

Recent years have witnessed significant advancements in the formulation of pharmaceutical gummies using various natural and synthetic gelling agents such as gelatin, pectin, agar, and carrageenan. Furthermore, technologies such as 3D printing, controlled-release systems, and functional ingredient incorporation have further expanded the scope of gummy formulations beyond simple chewables to advanced therapeutic carriers.

Today, gummy-based drug delivery systems are being explored not only for vitamins and supplements but also for prescription medications, including antihistamines, analgesics, cannabinoids, and pediatric formulations. This transformation from a candy-like treat to a scientifically sophisticated dosage form reflects the growing demand for innovative, patient-centric drug delivery solutions in modern pharmaceutics.

III. ADVANTAGES OF GUMMY-BASED DRUG DELIVERY

Gummy-based drug delivery systems offer several distinct advantages over traditional oral dosage forms such as tablets, capsules, and syrups. Their unique physicochemical and sensory properties make them highly suitable for populations with specific compliance challenges, including children, geriatrics, and patients with swallowing difficulties (dysphagia). The following are key advantages of gummy formulations:

- *Improved Patient Compliance and Acceptability*

One of the primary benefits of gummies is their enhanced palatability and chewable texture, which makes them more acceptable to patients, especially children. Unlike bitter tablets or unpalatable syrups, gummies can be flavoured and sweetened to mask the taste of active pharmaceutical ingredients (APIs), thereby improving medication adherence.

- *Ease of Administration*

Gummies do not require water for ingestion, which enhances convenience and makes them ideal for on-the-go administration. This is particularly useful in pediatric and geriatric care, where difficulty swallowing (dysphagia) or lack of access to clean drinking water may pose challenges.

- *Taste Masking and Sensory Appeal*

With the ability to incorporate natural or artificial flavours, sweeteners, and colours, gummies provide an appealing sensory experience. The ability to mask the bitterness of APIs through formulation techniques such as microencapsulation or pH modulation further increases their therapeutic acceptability.

- *Dose Flexibility and Customization*

Gummy formulations allow for precise dose control and can be easily adapted to contain multiple APIs or varying strengths. This flexibility supports personalized medicine, especially in pediatric formulations where exact dosing is critical and often weight-dependent.

- *Attractive Appearance and Texture*

The visual appeal, soft texture, and vibrant colours of gummies contribute to psychological acceptance, especially among pediatric patients. The resemblance to confectionery makes the medication experience more pleasant, reducing resistance and anxiety during administration.

- *High Marketability and Patient Preference*

Consumer surveys and pharmaceutical market data have consistently shown that patients prefer chewable and flavoured dosage forms over conventional ones. Gummy-based products thus offer commercial advantages and higher patient satisfaction, making them an increasingly preferred format for nutraceutical and pharmaceutical products alike.

- *Potential for Novel Technologies*

Gummies are compatible with advanced drug delivery technologies such as controlled release, mucoadhesion, and 3D printing. These features allow for further innovation in drug release profiles and therapeutic effectiveness.

The combination of functional, sensory, and psychological advantages makes gummy-based drug delivery systems a promising innovation in oral pharmaceutics. By enhancing patient compliance and offering formulation versatility, gummies align well with modern pharmaceutical goals of patient-centric therapy.

IV. FORMULATION COMPONENTS

- *Gelling Agents*

Gelling agents are the backbone of gummy formulations, providing the chewable texture and structural integrity. Commonly used gelling agents include gelatin, pectin, and agar. Gelatin, an animal-derived protein, offers elasticity and thermoreversibility. Pectin, a plant-based polysaccharide, is ideal for vegan-friendly and acidic formulations. Agar, obtained from seaweed, provides a firmer texture and is suitable for heat-stable gummies. The choice of gelling agent affects gel strength, mouthfeel, and drug release behavior.

- *Sweeteners*

Sweeteners enhance the palatability of gummies and help mask the taste of active pharmaceutical ingredients (APIs). Sucrose and glucose syrup are commonly used, while non-sugar alternatives like sorbitol, xylitol, and stevia are preferred

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for sugar-free or diabetic-friendly formulations. These not only improve taste but also contribute to the gummy's bulk and texture.

➢ *Plasticizers and Humectants*

Ingredients like glycerin and sorbitol serve as plasticizers and humectants. They help retain moisture, improve chewiness, and prevent the gummy from becoming hard or brittle over time. These components also play a role in extending the shelf-life and maintaining the flexibility of the product.

➢ *Active Pharmaceutical Ingredients (APIs)*

The selection of APIs depends on the intended therapeutic effect, target patient group, and physicochemical properties of the drug. APIs can be incorporated in soluble, dispersed, or encapsulated forms to enhance stability and bioavailability. Low-dose, highly stable drugs are preferred for gummy delivery due to limited volume capacity.

➢ *Flavouring and Colouring Agents*

To make the gummies more appealing, especially to children, various natural and synthetic flavours (e.g., orange, strawberry, lemon) and food-grade colorants are added. These enhance sensory appeal and improve patient compliance. The use of natural flavours and colours is increasing in demand due to consumer preferences for clean-label products.

➢ *Preservatives and Stabilizers*

Due to the high moisture content in gummies, preservatives like citric acid, sodium benzoate, or potassium sorbate are added to inhibit microbial growth and prolong shelf-life. Stabilizers such as antioxidants (e.g., ascorbic acid) and emulsifiers may also be included to maintain homogeneity and protect APIs from degradation.

➢ *Other Functional Additives*

Depending on the formulation goals, additives like emulsifiers, pH modifiers, binding agents, or coating agents may be incorporated. These enhance processability, improve appearance, and help in controlled or targeted drug release.(4–8)

V. TECHNIQUES OF GUMMY FORMULATION

➢ *Heat-Based Solubilization and Molding*

This is the most widely used conventional method for gummy formulation. In this technique, the gelling agent (such as gelatin, agar, or pectin) is hydrated and dissolved in hot water, typically at 60–80°C. Sweeteners, plasticizers (like glycerin), flavouring agents, colorants, and preservatives are then added to this hot mixture under continuous stirring. Once the solution is homogenous, heat-sensitive drugs are added after cooling the mixture to below 40°C to preserve drug stability. The final mixture is poured into molds and allowed to set at room temperature or under refrigeration. After setting (usually 12–24 hours), the gummies are de-molded and sometimes dried to reduce excess moisture and improve shelf-life.

➢ *Cold-Setting Method*

This method is ideal for heat-sensitive APIs or polymers that gel at low temperatures (like certain grades of pectin or carrageenan). In this process, the components are mixed at room temperature or slightly elevated temperatures (under 40°C), and gelling is initiated by pH changes or ionic crosslinking (e.g., calcium ions for low-methoxyl pectin). The formulation is then transferred into molds and allowed to set at low temperatures (refrigeration), avoiding exposure to heat altogether. This technique ensures better API stability but may require longer setting times.

➢ *Hot-Melt Extrusion (HME)*

Hot-melt extrusion is an advanced technique used for producing uniform gummy strips or shapes. All formulation components are blended and fed into an extruder, where they are heated and mixed under controlled shear and temperature conditions. The resulting semi-solid mass is shaped into strands or sheets and cut into required sizes. This method allows for continuous production and is useful for incorporating poorly soluble drugs using solubilizing agents or polymer matrices. However, it may not be suitable for highly heat-sensitive drugs.

➢ *3D Printing Technology*

3D printing is an emerging technique for producing personalized medicated gummies. Using digital formulation files and extrusion-based printers, gummy matrices containing APIs are deposited layer by layer in precise shapes, sizes, and doses. This method allows for on-demand production and customization of dose per patient requirement, making it promising for pediatric and geriatric populations. While still in experimental stages, this approach offers exceptional control over drug release and gummy morphology.

➢ *Vacuum Drying and Dehydration Techniques*

After molding, some gummy formulations undergo vacuum drying or dehydration to remove excess moisture and enhance stability. These techniques are used especially when a long shelf life is desired or when the gummy matrix is sensitive to environmental humidity. Drying also helps concentrate the flavour and improve texture but must be carefully controlled to avoid hardening or degradation of heat-sensitive drugs.(9–13)

VI. EVALUATION AND QUALITY CONTROL OF GUMMIES

Evaluation and quality control are essential in ensuring the safety, efficacy, and acceptability of gummy-based drug delivery systems. A comprehensive set of tests is performed to assess the physicochemical properties, drug content, release profile, and stability of the gummy formulations.

➢ *Physical Appearance and Organoleptic Properties*

Gummies should possess a uniform colour, shape, and surface texture, free from bubbles, cracks, or stickiness. Organoleptic properties such as taste, colour, odour, and mouthfeel are critical, especially for pediatric and geriatric patients. These attributes are usually evaluated through visual inspection and sensory panels.

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➢ *Weight Variation*

Uniformity in gummy weight is important to ensure consistent dosage. A sample of 20 gummies is weighed individually and compared with the average weight. Deviations must comply with pharmacopeial limits (±5–10%).

➢ *pH Measurement*

The pH of the gummy formulation should be within an acceptable range (typically 4–6) to maintain drug stability and prevent irritation in the oral cavity. It is measured by dissolving the gummy in distilled water and using a calibrated pH meter.

➢ *Moisture Content*

Moisture content directly affects the microbial stability and texture of gummies. It is determined by drying the sample in a hot air oven or using moisture analyzers. The acceptable moisture level usually ranges between 10–20%.

➢ *Drug Content Uniformity*

Assay of the active pharmaceutical ingredient (API) is performed using UV spectrophotometry or HPLC. Gummies are dissolved in suitable solvents and analyzed to ensure uniform drug distribution across the batch.

➢ *In Vitro Drug Release (Dissolution Study)*

To evaluate the release pattern of the drug, dissolution studies are conducted using USP Type I (basket) or Type II (paddle) apparatus in simulated gastric fluid or phosphate buffer (pH 6.8). Samples are withdrawn at regular intervals and analyzed to determine the cumulative percentage drug release.

➢ *Texture Analysis (Hardness/Chewing Resistance)*

Texture profiling is done to measure the firmness, chewiness, and elasticity of the gummy. A texture analyzer or penetrometer is used to determine resistance to mechanical stress, which reflects consumer acceptability and shelf-life.

➢ *Stability Studies*

Stability testing under ICH guidelines (temperature and humidity conditions) is performed to predict the shelf life and assess changes in physical appearance, drug content, moisture, and drug release profile over time.(14–17)

VII. APPLICATION AND MARKET PRODUCTS

➢ *Nutraceutical Applications*

Gummies are widely used in the nutraceutical industry for delivering essential nutrients such as vitamins (A, C, D, E, B-complex), minerals (zinc, iron, calcium), and omega-3 fatty acids. Their ease of administration and appealing taste make them particularly effective for populations that require supplementation but struggle with traditional tablets, such as children and the elderly. Nutraceutical gummies are commonly marketed for immune support, bone health, metabolic balance, and overall wellness.

➢ *Pharmaceutical Applications*

Pharmaceutical research is increasingly focusing on formulating APIs into gummy matrices. Active ingredients such as paracetamol, melatonin, loratadine, and diphenhydramine have been successfully incorporated into gummies to treat conditions like pain, allergies, and sleep disorders. These formulations provide an alternative to conventional oral solid dosage forms, improving compliance and reducing the risk of choking in vulnerable populations.

➢ *Cosmeceutical and Beauty Applications*

Gummies have also found applications in the beauty and skincare sector, commonly known as cosmeceuticals. Formulations containing biotin, collagen, hyaluronic acid, zinc, and vitamin E are marketed to support healthy skin, hair, and nails. These beauty-focused gummies are especially popular among young adults and are often presented in attractive packaging to encourage consistent use.

➢ *Targeted and Controlled Drug Delivery*

Advancements in formulation science have allowed the development of gummies with controlled or sustained drug release. By modifying the gelling agents or incorporating encapsulation technologies (like lipid or polymeric carriers), gummies can be designed to release the drug at a specific site or over an extended period. This approach is being explored for more complex therapeutic categories, including hormonal therapies and anti-inflammatory drugs.

➢ *Commercially Available Gummy Products*

Several popular gummy brands have successfully established themselves in global markets. Examples include Vitafusion®, Goli® Nutrition, Olly®, SmartyPants®, and Nature's Bounty®. These companies offer a wide variety of functional gummies addressing health concerns such as immunity, sleep support, digestive health, and energy enhancement. Their success highlights the growing consumer preference for chewable, flavourful, and convenient supplements.

➢ *Market Growth and Future Potential*

The global gummy supplement market has shown exponential growth over the last decade, with increasing consumer awareness and demand for health products. Market trends indicate a shift toward vegan, sugar-free, and organic gummy formulations, with rising interest in gummies as delivery systems for personalized medicine and lifestyle-specific supplementation (e.g., for athletes, pregnant women, or the elderly).(18–21)

VIII. CHALLENGES AND LIMITATIONS

➢ *Drug Loading and Dose Uniformity*

One of the primary limitations in gummy-based drug delivery systems is achieving adequate drug loading while maintaining the organoleptic properties (taste, texture, and appearance). Many APIs have a bitter or unpleasant taste, and incorporating higher doses may require masking agents or flavour enhancers, which can complicate the formulation. Additionally, ensuring uniform distribution of the active pharmaceutical ingredient (API) throughout the gummy

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matrix is critical but often challenging, especially at larger production scales.

➢ *Stability and Shelf-Life Issues*

Gummies are sensitive to environmental factors such as temperature, humidity, and light, which can significantly affect the chemical stability of incorporated drugs. Hygroscopic ingredients and the water-based nature of gummies can lead to microbial growth or degradation of APIs over time. Preservatives may be needed, but their compatibility with the formulation and patient safety must be carefully considered.

➢ *Sugar Content and Health Concerns*

Traditional gummy formulations often contain high levels of sugar and glucose syrup to ensure palatability and proper gelation. However, excessive sugar intake can lead to dental issues, childhood obesity, and metabolic disorders. While sugar-free or low-sugar options are being developed using substitutes like sorbitol, xylitol, or stevia, these may alter the texture or flavour and require reformulation strategies.

➢ *Limited Suitability for All Drugs*

Gummy systems are best suited for low-dose, highly potent, and water-soluble drugs. They are not ideal for drugs requiring high doses, poor solubility, or those unstable in aqueous environments. Additionally, not all APIs can withstand the heating or processing involved in gummy production, limiting the versatility of this delivery platform.

➢ *Regulatory and Quality Control Challenges*

As gummies blur the line between food and pharmaceutical products, regulatory classification can vary across countries. This can lead to inconsistencies in quality control standards, labeling requirements, and clinical evaluation. Moreover, ensuring batch-to-batch consistency, microbial safety, and content uniformity in a chewable matrix is more complex than in traditional tablets or capsules.

➢ *Risk of Accidental Overconsumption*

Due to their candy-like appearance and taste, gummies pose a significant risk of overdose, particularly in children, who may mistakenly consume them as sweets. This has been a growing concern with gummy-based supplements like melatonin and vitamins, with reported cases of emergency room visits due to unintentional ingestion.(22–24)

IX. FUTURE PROSPECTS AND INNOVATIONS

➢ *Personalized Medicine through Gummy Delivery*

With advancements in pharmacogenomics and 3D printing, the future of gummy-based drug delivery may shift toward personalized dosing. Using technologies like semi-solid extrusion 3D printing, gummies can be manufactured with precise drug doses tailored to an individual's genetic profile, weight, or therapeutic needs. This will greatly benefit populations such as pediatrics and geriatrics, where dose adjustment is critical.

➢ *Sugar-Free and Nutraceutical Gummies*

Future innovations are focused on developing sugar-free or low-sugar gummy formulations using natural sweeteners like stevia, erythritol, or monk fruit extract. Additionally, the incorporation of nutraceuticals, probiotics, and plant-based actives is growing, allowing gummies to serve dual functions as both supplements and therapeutic agents. These functional gummies could revolutionize preventive healthcare and wellness.

➢ *Smart Gummies with Controlled Release*

Emerging research is exploring the formulation of controlled-release gummies using novel gelling systems and polymers such as pectin-chitosan, modified starches, and natural gums. These matrices can enable sustained or targeted release of APIs, extending their therapeutic effect and reducing dosing frequency. Smart gummies may also include stimuli-responsive materials that release drugs in response to pH or temperature.

➢ *Plant-Based and Vegan Gummy Innovations*

Traditional gelatin-based gummies face limitations for vegan, vegetarian, and religious dietary preferences. Future developments are centered on using plant-based gelling agents like pectin, agar-agar, carrageenan, and guar gum, making formulations more inclusive and sustainable. These alternatives also reduce the risk of animal-borne pathogens.

➢ *Global Expansion and Market Diversification*

The gummy pharmaceutical market is expected to grow substantially, especially in pediatric, geriatric, and women's health sectors. Companies are likely to expand into therapeutic areas beyond vitamins, including antihistamines, antibiotics, antipsychotics, and even vaccines. This will require innovation in drug stabilization, taste masking, and regulatory compliance to ensure safety and efficacy.

➢ *Integration with Digital Health*

Future gummy formulations may be integrated with digital health monitoring systems, such as ingestible sensors or RFID-embedded packaging. These tools can track compliance, dosing time, and location, making them especially useful in chronic disease management or clinical trials.(25–30).

X. CONCLUSION

Gummy-based drug delivery systems have emerged as a transformative advancement in the field of oral drug formulations, offering a unique combination of therapeutic efficiency and patient-centric design. Their soft, chewable form, combined with attractive colours and flavours, enhances the palatability and acceptability of medications, particularly among children, elderly individuals, and patients with swallowing difficulties. Unlike traditional solid dosage forms, gummies present a friendly and enjoyable experience, which significantly improves adherence to treatment regimens.

This review comprehensively highlights the historical development, advantages, formulation strategies, and applications of gummy drug delivery systems in both the

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pharmaceutical and nutraceutical sectors. Gelling agents such as gelatin, pectin, and agar play a pivotal role in determining the texture and release properties of the formulation. The inclusion of flavouring, sweetening, and stabilizing agents further enhances the sensory profile while maintaining product stability. Moreover, gummies have demonstrated versatility in carrying a variety of active pharmaceutical ingredients (APIs), including vitamins, minerals, herbal extracts, and over-the-counter medications like melatonin and paracetamol.

Despite their numerous benefits, gummy formulations are not without limitations. Challenges such as dose uniformity, API stability, sugar-related health risks, and regulatory classification remain critical areas of concern. There is also a need for more stringent quality control and child-proof packaging to prevent accidental overconsumption, especially in pediatric settings.

Looking ahead, innovations in drug delivery science, such as 3D printing, controlled-release hydrogels, and plant-based or sugar-free excipients, are opening new possibilities for advanced gummy systems. These next-generation formulations may support targeted therapy, personalized medicine, and broader patient inclusivity, including vegan and diabetic populations. With continued research, standardization, and technological integration, gummy-based drug delivery systems are poised to play a significant role in the future of oral therapeutics and preventive healthcare.

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