



(REVIEW ARTICLE)



## Science and Challenges in Formulating Gummies as a Novel Oral Dosage Form: A Review

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### Abstract

Medicated gummies represent a significant, patient-centric evolution in oral drug delivery, offering a palatable and easily administered alternative to traditional tablets and capsules. This comprehensive review synthesizes the current scientific literature to evaluate the viability of gummies as a novel oral solid dosage form. The review first highlights the primary advantages, focusing on enhanced patient adherence and acceptability across vulnerable populations, including pediatric, geriatric, and dysphagic patients. A detailed analysis is provided on the critical physicochemical properties of Active Pharmaceutical Ingredients (APIs) that govern their suitability for gummy formulation. Furthermore, the article explores the fundamental formulation science, contrasting key gelling agents like gelatin and pectin, and strategies for modifying drug release kinetics, from immediate to sustained profiles. The core challenges in manufacturing are thoroughly discussed, specifically addressing issues of chemical stability and the necessity of advanced taste-masking technologies. In conclusion, while medicated gummies offer substantial therapeutic benefits and market potential, their successful development hinges on overcoming complex formulation and manufacturing hurdles, positioning them as a rapidly evolving frontier in pharmaceutical technology.

**Keywords:** Medicated gummies; Patient-centric drug delivery; Oral solid dosage form; Formulation challenges; Gelling agents; Taste masking

### 1. Introduction

The concept of the gummy dosage form originates not in pharmaceuticals, but in the confectionery industry. The first gummy candies were introduced in Germany in the 1920s, leveraging gelatin's unique texture to create a palatable, chewable sweet[1]. The transition to a delivery system began in the nutraceutical and dietary supplement sector in the late 20th and early 21st centuries. This shift was driven by the need for more patient-friendly alternatives to large, chalky vitamin pills, particularly for children and the elderly. Vitamins (such as C, D, and B12) and minerals were the first active ingredients successfully incorporated into gummy matrices, targeting on the sensory appeal to improve patient compliance and adherence[2]. The emergence of medicated gummies into mainstream pharmacotherapy is a more recent development, driven by several factors: addressing Dysphagia( difficulty swallowing), Taste Masking and Technological advancements have allowed for better control over drug stability, dose uniformity, and release kinetics, making the form viable for pharmaceutical applications. Today, medicated gummies are recognized as an innovative and patient-centric Oral Solid Dosage (OSD) form, moving beyond simple supplements to deliver prescription and over-the-counter drugs [3].

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## 2. Literature Search Strategy

A comprehensive search of the scientific literature was conducted to identify relevant studies on the formulation, challenges, and applications of medicated gummy dosage forms. Databases including Science Directq, PubMed, and Helinet were systematically searched using key terms such as “medicated gummies,” “gelling agents,” “taste masking,” “content uniformity,” and “stability of APIs in gummies.” The search focused on articles, reviews, and regulatory guidelines published up to the present date. The identified literature was critically evaluated and synthesized by the authors to structure the review.

## 3. Discussion

### 3.1. Need for Gummies formulation

Gummy formulations have emerged as a patient-friendly alternative to conventional dosage forms by addressing several limitations associated with tablets, syrups, and capsules. Examples are as follows:

Drugs such as Lamotrigine and Risperidone, which suffer from poor pediatric compliance in traditional forms, showed improved palatability, acceptability, and adherence when formulated as gummies. Propranolol hydrochloride and drugs commonly administered as liquid such as cough suppressants or expectorants face stability issues, dosing inaccuracies, and inconvenience, which were mitigated through gummy formulations by offering enhanced stability and precise dosing.

For drugs like Paracetamol, Ibuprofen, Vitamins, and Minerals, gummies effectively overcame unpleasant taste, providing superior taste masking. Additionally, Isoniazid–Pyridoxine dual-drug therapy, typically associated with a high pill burden and poor palatability, benefited from gummy formulations by reducing pill burden.

### 3.2. Physicochemical Properties

All the drugs cannot be formulated as gummies. Certain Physicochemical properties of drug make it suitable to be formulated as gummies. They are as follows:

**Table 1** Impact of Key Drug Properties on Gummy Formulation

| Drug Property                    | Ideal Characteristic for Gummies  | Rationale & Challenge   |
|----------------------------------|---|---|
| Thermal Stability                | Stable at temperatures up to 70°C [1]   | Must withstand the hot-melt process during manufacturing.   |
| Compatibility with Hydrocolloids | The API must be compatible with gelling agent.[1]   | Incompatibility lead to decreased efficacy or stability over the product's shelf life .             |
| pKa                              | pKa such that drug is unionized in acidic gel (pH ~3-4)[15]. Because drug is known to better absorb in unionized form as per P <sup>H</sup> – partition Hypothesis. | Prevents instability, undesirable taste, and interaction with gel matrix.                           |
| Onset of action                  | Drugs intended for slightly delayed onset are ideal [16]  | chewing may allow minimal buccal absorption hence they are not designed for rapid sublingual onset  |
| Half-life (t <sub>1/2</sub> )    | Moderate to Long (>6 hours) [16][17]  | Supports once- or twice-daily dosing whereas Short t <sub>1/2</sub> drugs requires frequent dosing. |
| Dose                             | Low to Moderate (e.g., < 500 mg) [16][18]   | High dose is Limited by physical size and volume of a palatable gummy unit.                         |
| Taste                            | Drug must be Amenable to masking (or inherently tasteless) [19]   | Critical for patient acceptance. Bitter drugs require complex masking.                              |
| Solubility                       | The drug must solubilize in a solution of gelling agent [19]  | Critical for content uniformity and dose accuracy   |

## 4. Mechanism of Drug Release

Drug release from gummy dosage forms occurs through a sequential process involving mastication, which increases surface area, followed by hydration and dissolution of the hydrophilic gel matrix in saliva and gastrointestinal fluids, leading to drug liberation and subsequent absorption in the stomach and intestine[ 20,21].

### 4.1. Kinetics of gummies

Most commonly follow first-order kinetics, as drug release is largely governed by rapid dissolution or erosion of gelatin- or pectin-based matrices. In certain formulations designed to exhibit significant swelling, diffusion-controlled mechanisms may contribute to the initial release phase, where models such as Higuchi or Korsmeyer–Peppas can partially describe drug diffusion through the swollen polymer network [16,21,22].

### 4.2. Modification of Drug Release Rate in Gummies

The ability to control the drug release rate from a gummy is achieved by modifying the properties of its hydrogel matrix.

#### 4.2.1. To Speed Up Drug Release (immediate release)

The goal here is to make it easier for water to enter the gummy and for the drug to diffuse out.

- **Decrease Polymer Concentration** creates a less dense, more porous matrix. This allows water to penetrate faster and provides wider channels for the drug to escape, leading to a quicker release[23].
- **Use a Lower Bloom Strength Gelatin** (e.g., 150 Bloom) forms a softer, weaker gel network offers less resistance to drug diffusion, speeding up release [23].
- **Incorporate Disintegrants:**(e.g., croscarmellose sodium or sodium starch glycolate) can cause the gummy matrix to swell and break apart more quickly when it comes into contact with fluid. This releases the drug much faster than diffusion alone [24].

#### 4.2.2. To Slow Down Drug Release (Sustained or Controlled Release)

- The objective here is to create a more tortuous and restrictive path for the drug to travel, thereby slowing its diffusion out of the matrix.
- **Increase Polymer Concentration:** results in a denser, more entangled polymer network. This creates smaller pores and a more difficult path for the drug to navigate, significantly slowing down its release rate [23].
- **Use High Molecular Weight Polymers:** creates a more robust and viscous gel layer upon hydration. This viscous barrier slows down both water penetration into the gummy and drug diffusion out of it [23].
- **Increase Cross-linking Density** Intentionally adding cross-linking agents (e.g., transglutaminase for gelatin) strengthens the hydrogel matrix. A more heavily cross-linked matrix swells less and has smaller pores, which effectively traps the drug for a longer period, leading to sustained release [25].
- **Incorporate Hydrophobic Materials:** like certain waxes or lipids into the formulation can slow down the penetration of water into the gummy. This delays the dissolution of the drug and its subsequent diffusion out of the matrix, prolonging the release profile [26].

## 5. Gummy Composition [23,27,28]

A gummy is a flavored and sweetened hydrogel composed of Hydrophilic Polymeric Matrix that Provides structural integrity and controls drug release. The formulation typically includes following components to ensure optimal texture, Palatability and stability.

**Table 2** Key ingredients of gummies

| Component Category | Examples  | Purpose in the Formulation                   |
|--------------------|---|--|
| Gelling Agent(s)   | Gelatin, Pectin, Carrageenan, Modified Starch, Gellan Gum       | Forms the structure and defines the texture. |
| Sweeteners (Bulk)  | Sucrose (table sugar), Glucose Syrup (corn syrup), Invert Sugar | Provides sweetness, adds bulk                |

|                         |  |   |
|-------------------------|--|---|
| Acidulants              | Citric Acid, Malic Acid, Tartaric Acid   | Provides tartness to balance sweetness and enhances fruit flavors.      |
| Flavors & Colors        | Citrus, strawberry & FDA approved colors | Provides the taste and appearance                                       |
| Water                   | Purified Water                           | Acts as the solvent.  |
| Humectants              | Sorbitol, Glycerin                       | Helps to retain moisture  |
| Coating/Polishing Agent | Carnauba Wax, Beeswax, Mineral Oil       | Applied to the finished gummies to prevent them from sticking together. |

### 5.1. Key Gelling Agents

The choice of gelling agent is the most critical decision, dictating texture, stability, and consumer suitability.

**The two primary agents are gelatin and pectin.** Gelatin, derived from animal collagen, provides an elastic, chewy texture and is thermo-reversible (melts when heated). Pectin, a plant-based alternative, yields a tender, “short” bite and is thermo-stable once set, making it suitable for vegan and vegetarian formulations [27] [28] [29].

Starch and Other Hydrocolloids

**Starch** is another common plant-based hydrocolloid, often used in combination with other gelling agents to modify texture and consistency [30].

### 5.2. Sweeteners and Sugar Replacers

In traditional gummies, a combination of sucrose and liquid glucose/corn syrup is used which is not suitable for health conscious or diabetic population because they have high calories approximately 4 kcal/gram., high glycemic index that contribute to significant spike in blood sugar and tooth decay

The best approach for modern, health-focused gummies is often a **synergistic blend** of Erythritol, soluble corn fiber and stevia

- **Erythritol:** A zero-calorie polyol with the highest digestive tolerance [31].
- **Soluble Corn Fiber:** Prevents erythritol from crystallizing and is great for “Natural” and “High Fiber” claims [32].
- **Stevia or Monk Fruit:** Natural, Plant based, zero-calorie high-intensity sweeteners to achieve the desired taste [33].

This combination supports claims like “sugar free” and “reduced sugar” [34].

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## 6. Method of manufacturing [35]

The method of manufacturing medicated gummies involves controlled heating, mixing, and molding steps to obtain a uniform, palatable, and stable dosage form. Each step is designed to ensure proper dissolution of gelling agents, uniform drug distribution, and desired texture. Careful control of processing parameters is essential to achieve consistent quality and therapeutic performance.

- **Solution Preparation:** Active Pharmaceutical Ingredient (API) is dissolved /dispersed in a heated aqueous solution containing gelatin or pectin, plasticizers (glycerin, sorbitol), sweeteners, flavors, and colors.
- **Degassing:** Vacuum is applied to remove air bubbles.
- **Molding:** The hot, viscous solution is deposited into molds.
- **Cooling & Setting:** Molds are cooled to set the gel network.
- **Demolding & Polishing:** The gummies are removed from the molds and often dusted with a mild lubricant (e.g., vegetable oil) to prevent them from sticking together.
- **Drying/Curing:** Optional step to reduce moisture content and alter texture.

**The Most Commonly Used Method is Starch Molding** the industry standard where a tray of corn starch is imprinted with cavities. The hot gel solution is deposited into these cavities. The starch absorbs excess moisture and aids in setting. It is cost-effective for large-scale production and allows for intricate shape [36]

## 7. Challenges of Incorporating Active Pharmaceutical Ingredients (APIs)

Adding an API transforms a gummy from a confection to a complex drug delivery system, introduce numerous challenges owing to chemical properties, during manufacturing etc. the problems encountered and strategies used to overcome those are discussed below:

### 7.1. Chemical instability

- **Heat Degradation:** API degrades during high-temperature cooking. Therefore use a low-temperature process or add API late in the process.
- **pH Degradation:** API is unstable in the low pH which is required for pectin gels. So Optimize pH or microencapsulate the API to protect it from pH degradation.

### 7.2. Challenges during Manufacturing [28]:

- **Gelling Interference:** API ions disrupt the gelling agent network. use a different pectin type or blend.
- **Content Uniformity:** when API is not evenly distributed in the viscous slurry due to low dose, sticky ingredients (Sweeteners and flavors). The strategy is to Control slurry viscosity; ensure efficient mixing; control API particle size

### 7.3. Sensory/Palatability challenges [38][39]

Undissolved API creates unacceptable mouth feel. Reduce particle size to dissolve API

Bitter taste: employ Taste masking technology. Some of them are

- **Complexation[40]:** The API molecule is trapped inside a host molecule (e.g.,cyclodextrin), hiding the bitter part.
- **Ion – exchange resins [41]:** The charged API is electrostatically bound to an insoluble, tasteless polymer resin
- **Bitter Blockers[42]:** Specialized molecules that block the bitter taste receptors on the tongue or the nerve signal to the brain.

## 8. Challenges of Moisture and microbial Control in Gummy Manufacturing [43]

Gummy formulations are particularly susceptible to moisture uptake and Microbial contamination due to their high water activity and sugar content, necessitating stringent control during manufacturing and storage. Following are the key challenges encountered at different stages of manufacturing and their consequences.

**Table 3** Challenges of moisture and microbial control in manufacturing

| Manufacturing Stage             | Key Challenge   | Consequence of Too Much Moisture (Under-Processing)   | Consequence of Too Little Moisture (Over-Processing)  |
|---------------------------------|---|---|---|
| <b>Cooking</b>                  | Achieving the solid content (typically 75-82% Brix) by evaporating a precise amount of water. | - Soft, sticky, runny texture. - High water activity ( $a_w$ ), leading to mold and yeast growth. - May fail to set properly. | - Extremely viscous slurry that is difficult to pump and deposit. - Final gummy is hard, tough, and rubbery. - Risk of premature gelling in the cooking vessel. |
| <b>Depositing &amp; Setting</b> | Preventing the hygroscopic gummy mass from absorbing moisture from its                        | - Sticky surfaces that are difficult to demold. - Prevents a proper "skin" from forming on the gummy. - Increased risk of     | - Hard outer shell or crust forms on the gummy. - Can lead to a non-uniform texture.  |

|   |  |   |  |
|---|--|---|--|
|   | surroundings (air or molds).   | microbial contamination on the surface.   |  |
| <b>Drying, Packaging &amp; Storage[53,55]</b> | Reaching the final target water activity ( $a_w$ ) and maintaining it throughout the product's shelf-life. | -Syneresis ("weeping"): Water droplets form on the surface, causing stickiness. - Clumping and sticking together in the package. - High water activity allows for microbial spoilage. | - Gummy becomes dry, hard, and brittle over time. - Loss of desirable chewy texture. - Potential for cracking. |

Mitigation strategy for moisture control and microbial control: Manufacturers don't just rely on final product testing. They ensure these limits are met through:

Maintaining Low Water Activity ( $a_w$ ) (typically below 0.75) creates a self-preserving system where most microbes cannot grow, Raw Material Testing, Good Manufacturing Practices (GMP), In-Process Monitoring, Proper packaging and storage etc.

- **Storage Conditions:** Typically stored in sealed containers at controlled room temperature (15-25°C), protected from light and moisture [53].
- **Shelf Life:** Generally 18-24 months, depending on formulation and packaging [45][54]
- **Packaging Requirements for Gummies:** To overcome the above challenges, high-barrier packaging materials such as Mylar or polyethylene films or Cold-formed blister packs for each individual dose can be employed along with a Desiccant within the primary packaging[ 56]

## 9. Evaluation of gummies

Several quality control tests applied to conventional solid and oral dosage forms are also relevant for gummies to ensure safety, efficacy and uniformity. They are organoleptic evaluation, weight variation/content uniformity, drug content assay, In- vitro Dissolution/ drug release studies, PH test, Moisture content (typically less than 2%) and stability studies(as per ICH Q1A(R2) guidelines)[44 -52]

In case of gummies, due to their gel-based, high moisture matrix, gummies require additional specialized tests not typically applied to conventional solid dosage forms. They are as follows:

### 9.1. Texture Analysis

It is done using Texture analyzer[46].

The data from the Texture Profile Analysis (TPA) graph is used to calculate several key textural attributes:

**Table 4** Texture analysis

| Parameter                          | What It Measures  | Why It's Important for Gummies   |
|------------------------------------|---|--|
| <b>Hardness</b>                    | The peak force required during the first compression.   | This is the "bite force." The gummy must be soft enough for a child or elderly person to chew easily, but firm enough not to fall apart during handling. |
| <b>Cohesiveness</b>                | How well the gummy withstands the second compression compared to the first. It measures how well the internal structure holds together. | A highly cohesive gummy won't crumble in the mouth. Low cohesiveness means it breaks apart easily.   |
| <b>Springiness (or Elasticity)</b> | How well the gummy "springs back" to its original height after the first compression is removed.  | This relates to the "bouncy" or "rubbery" sensation. Too much springiness can make a gummy feel tough and difficult to break down.                       |
| <b>Chewiness</b>                   | The total energy required to chew the gummy until it's ready to be swallowed. It is   | This is the overall indicator of the effort needed to eat the gummy. It must be low enough to not  |

|                     |   |   |
|---------------------|---|---|
|                     | calculated from Hardness x Cohesiveness x Springiness.  | cause fatigue or difficulty for the intended patient population                                     |
| <b>Adhesiveness</b> | The force required to pull the probe away from the gummy after compression. This measures stickiness. | A highly adhesive gummy will stick to teeth, packaging, or fingers, which is generally undesirable. |

Strength (Bloom Value): Particularly important for Gelatin based gummies.. A standard cylindrical probe is allowed to penetrate the gummy surface to a defined depth. The force required to penetrate the gel is measured. Higher Bloom strength indicates a firmer gel matrix. This test ensures batch to batch consistency, mouth feel and affects drug release as discussed earlier

Microbial enumeration test : it is done to ensure the overall bio burden is below a safe threshold by plate count method / Pour Plate method. The acceptable limits are Total Aerobic Microbial Count(TAMC): Not more than 1,000 CFU/g and Total Yeast and Mold Count(TYMC): Not more than 100 CFU/g[51].

Release studies : The challenge is developing a method that accurately mimics the *in vivo* process i.e. chewing and dissolution. A robust method has to be developed to mimic mastication[49].

## 10. Labelling and Design

Regulations often prohibit the use of bright colors, cartoon imagery, or candy-like branding that could confuse children . Include warning labels like " keep out of reach of children" is mandatory[57].

## 11. Limitations of Gummies

- Dose Limitation [16][18], Sugar Content [31] and Overconsumption Risk [57]
- Stability Constraints [58], Manufacturing [18][55] and Regulatory Scrutiny [40][50]

## 12. Regulatory Guidelines:

U.S. FDA classify gummies as Drug (if therapeutic claim) and must comply with 21 CFR Parts 210/211 (cGMP). New Drug Application (NDA) or Abbreviated NDA (ANDA) is to be used for product approval.

## 13. Current research on Gummies

Goal is to formulate Drugs like Metformin, Cannabidiols, Amoxicillin, Albendazole etc. as Gummies using 3 D printed technology for improved patient adherence. [59,60,61,62]

## 14. Conclusion

Medicated gummies represent a highly promising and rapidly expanding segment of the oral solid dosage market, driven by their superior patient acceptability, particularly in vulnerable populations. The formulation science is complex, requiring careful consideration of the API's physicochemical properties, the choice of hydrocolloid (gelatin vs. pectin), and the method of drug release modification. While significant challenges exist, particularly concerning API stability under heat and low pH, and ensuring content uniformity during manufacturing, innovative solutions such as 3D printing, advanced taste-masking, and optimized continuous manufacturing processes are continually addressing these hurdles. The future of medicated gummies lies in their potential to deliver a wider range of APIs, including those requiring controlled release, thereby solidifying their role as a key patient-centric platform in modern pharmaceutical technology.

## Compliance with ethical standards

### *Disclosure of conflict of interest*

There is no conflict of interest by Fathima khadri\*, Dr. P. K . Kulkarni, Venkatesh, Dr. Hanumanthachar Joshi.

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