

Chewable Healthcare: The Rising Impact of Gummy Supplements in Modern Medicine

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Abstract

Gummy supplements, a chewable dosage form historically associated with pediatric vitamin products, are increasingly recognized as a versatile platform for delivering a wide range of nutraceutical and pharmaceutical agents. Their consumer appeal lies in their palatability, convenience, and the ability to overcome swallowing difficulties – a significant barrier to adherence in multiple patient populations. Recent advances in formulation science have expanded the potential of gummy supplements beyond basic vitamin delivery to include probiotics, botanical extracts, functional lipids, and potentially even low-dose prescription therapeutics. This review provides a detailed analysis of evolution, formulation technologies, therapeutic applications, manufacturing processes, quality control considerations, regulatory frameworks, and prospects of gummy supplements in modern healthcare. By integrating insights from pharmaceuticals, food technology, and regulatory science, this paper highlights gummy supplements as a promising dosage form that bridges the gap between traditional pharmaceuticals and functional foods.

Keywords: Gummy supplements, chewable dosage forms, nutraceutical innovation, patient compliance, functional foods, drug delivery technology

INTRODUCTION

Medication adherence is a critical determinant of therapeutic efficacy, yet global estimates indicate that approximately 50% of patients do not take medications as prescribed, particularly in chronic disease management [1–3]. Among the contributing factors, swallowing difficulties (dysphagia), pill burden, and aversion to the taste or texture of traditional dosage forms are consistently reported. These challenges are magnified in pediatrics, geriatrics, and individuals with neurological or psychiatric conditions [4].

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Chewable dosage forms – including tablets, lozenges, and gummies – have emerged as a strategy to address these barriers. In recent years, gummies have transitioned from being a niche pediatric product to a mainstream delivery platform embraced by adults and seniors alike [5]. This shift has been fueled by the nutraceutical boom, advances in gelling agent technology, and growing functional food markets [6]. The gummy dosage form offers an organoleptically pleasing experience, masking unpleasant flavors while enabling accurate dosing of certain active ingredients. However, unlike simple confectionery, medicinal and nutraceutical gummies require rigorous formulation, stability testing, and regulatory compliance to ensure safety and efficacy [7].

HISTORICAL EVOLUTION OF GUMMY SUPPLEMENTS

Early Origins – Gummies as Confectionery

(Pre-1900s to Early 1900s) [8]

- *Invention of the Gummy Concept:*
 - Gummies originated as a form of candy.
 - The first gummy-like confection is traced to Turkish delight (Lokum) in the 18th century – a gelatinous, chewy sweet made from starch and sugar.
 - Gelatin-based jellies became popular in Europe in the 1800s when gelatin extraction from animal collagen became industrialized.
- *Pioneering Brands:*
 - In the early 1900s, companies, like Rowntree's (UK), introduced fruit pastilles and jellies.
 - Hans Riegel Sr. founded Haribo in Germany (1920) and invented the Gummibärchen (gummy bear) in 1922 – the precursor to modern gummy supplements.

From Candy to Functional Formulations (1970s–1980s) [7]

- *The Nutraceutical Shift:*
 - The concept of delivering health benefits in a palatable candy-like form emerged in the late 20th century.
 - Parents and health brands saw an opportunity to mask unpleasant tastes of vitamins for children.
- *Flintstones Chewables (1968):*
 - Not gummies yet but pioneered chewable vitamins for children – laying the groundwork for gummy vitamin formats.
- *First Actual Gummy Supplements:*
 - By the late 1970s, gelatin-based chewable supplements for kids entered niche markets in the US, though with limited flavors and nutritional variety.
- *Drivers of Adoption:*
 - Rising concern for child malnutrition and picky eating habits.
 - Growth of the dietary supplement industry after the US Dietary Supplement Health and Education Act (DSHEA) groundwork started in the 1980s.

Commercial Breakthrough & Mass Adoption (1990s–Early 2000s)

- *Gummy Vitamins for Kids Become Mainstream:*
 - *Early 1990s:* Brands, like Yummi Bears® (Hero Nutritionals, 1997), revolutionized the format with colorful, fruit-flavored, bear-shaped gummy vitamins for children.
 - This was the first brand marketed specifically as a gummy supplement, not candy.
- *Technology Improvements:*
 - Better flavor masking agents and non-clumping gelatin bases.
 - Stability in incorporation of vitamins A, C, D, and minerals like calcium.
- *Market Positioning:*
 - Parents preferred gummies because they avoided the “pill-swallowing” challenge for kids.
 - Marketing emphasized “fun nutrition”.

Expansion to Adult Markets (Mid-2000s–2010s)

- *Adult Gummies Emerge:*
 - Gummy supplements began targeting millennials and adults reluctant to take pills.
 - Brands, like Vitafusion (US), launched multi-vitamins and specialized gummies (Omega-3, Vitamin D, Biotin).
- *Diversification in Formulations:*
 - Inclusion of herbal extracts (echinacea, elderberry), collagen peptides, probiotics.
 - Sugar-free options developed using pectin, isomalt, or stevia.
- *Shift in Perception:*
 - Once seen as “kids’ vitamins,” gummies became part of functional wellness lifestyles.

- *Regulatory Push:*
 - Post-DSHEA (1994) in the US, supplement makers had more freedom in formulation and marketing – boosting innovation.

Modern Era – Specialized Nutrition & Global Dominance (2015–Present)

- *Premium and Functional Positioning:*
 - Gummies now address beauty-from-within, sports nutrition, immunity, sleep aids, and gut health.
 - *Examples:* Collagen gummies, CBD gummies, melatonin gummies.
- *Technological Advances:*
 - Microencapsulation for *heat- and light-sensitive nutrients* (e.g., CoQ10, probiotics).
 - Vegan-friendly pectin-based gummies replacing gelatin to meet plant-based trends.
- *Global Market Boom:*
 - Asia-Pacific and European markets expanding with local flavor profiles and fortified traditional confectionery.
- *Consumer Trends Driving Growth:*
 - Convenience (no water or swallowing required).
 - Compliance (better adherence rates compared to pills).
 - Lifestyle branding (Instagram-worthy health products).
- *Sustainability Focus:*
 - Shift toward biodegradable packaging, reduced sugar content, and clean-label formulations.

Outlook

- Integration of personalized nutrition (DNA-based or lifestyle-based gummy formulations).
- Sugar-free, functional blends targeting metabolic health, cognition, and longevity.
- Expansion in pharma-grade nutraceutical gummies with precise dosing and clinical validation.
- Wider adoption of 3D printing technology to create multi-layered gummies delivering different nutrients in one bite [9].

COMPOSITION AND FORMULATION SCIENCE

While gummies look like a playful snack, their pharmaceutical or nutraceutical formulation demands precision, stability, and bioavailability control. Unlike standard confectionery, gummy supplements must consistently deliver an exact dose of active ingredients (AIs) with minimal degradation over their shelf life [1, 10–12].

Active Ingredients (AIs)

The choice and handling of the active ingredients are central to formulation design.

- *Common Actives:*
 - *Vitamins:* C, D, E, A, B-complex, biotin.
 - *Minerals:* Calcium, zinc, magnesium, iron (often in chelated or microencapsulated form to prevent metallic taste).
 - *Botanicals:* Elderberry, echinacea, ginseng, green tea extract.
 - *Specialty ingredients:* Collagen peptides, probiotics, omega-3 fatty acids, melatonin, CBD.
- *Formulation Challenges:*
 - *Stability:* Many vitamins (e.g., Vitamin C) are heat- and light-sensitive.
 - *Taste masking:* Minerals and botanicals may impart bitterness or metallic notes.
 - *Solubility:* Fat-soluble vitamins require emulsifiers or carriers for uniform distribution.

Gelling Agents (Base Structure)

Determine texture, chewability, and release profile (Table 1) [10, 13].

Selection Criteria

- Active ingredient compatibility (gelatin may bind some actives).

- Market positioning (vegan vs. conventional).
- Desired mouthfeel and shelf stability.

Table 1. Gelling agent's key properties and their impact on gummies.

Gelling Agent	Source	Key Properties	Impact on Gummies
Gelatin	Animal collagen	Thermo-reversible gel, elastic, chewy texture	Creates classic gummy bear feel; not vegan; sensitive to heat
Pectin	Citrus peel, apple pomace	Plant-based, heat-stable, softer bite	Vegan-friendly; sets at low pH; preferred in functional gummies with fruit flavors
Carrageenan	Red seaweed	Firm, elastic gel	Stable in heat; vegan; can give a firmer bite
Agar	Seaweed extract	Brittle gel, high setting temperature	Suitable for heat-stable formulations; less elastic texture

Sweeteners

- *Purpose:*
 - Improves palatability and consumer compliance.
 - Balances acidity from active ingredients or flavorants.
 - May act as a humectant to retain moisture.
- *Types:*
 - Conventional Sugars*
 - *Sucrose:* primary sweetener for bulk and flavor.
 - *Glucose syrup (corn syrup):* adds chewiness, prevents crystallization.
 - Sugar-free Alternatives*
 - Polyols (maltitol, xylitol, sorbitol, isomalt) – lower glycemic impact; may have a cooling effect.
 - High-intensity sweeteners (stevia, sucralose, monk fruit extract) – minimal calories; often paired with bulk fillers.
- *Formulation Considerations:*
 - Sugar-free versions require adjustments in *water activity* (a_w) to prevent microbial growth.
 - Polyols may cause digestive discomfort in high doses—regulatory labeling required (Figure 1).

**Figure 1.** Types of sweeteners.

FUNCTIONAL EXCIPIENTS

Excipient's role in gummies has been described in Table 2.

Table 2. Excipient's role in gummies.

Function	Example Excipients	Role in Gummies
Emulsifiers	Lecithin, mono- & diglycerides	Aid dispersion of fat-soluble vitamins, omega-3 oils.
Stabilizers	Glycerin, sorbitol	Prevent drying or crystallization; maintain soft texture.
Antioxidants	Ascorbyl palmitate, tocopherols	Protect oxidation-prone nutrients (e.g., fish oil, vitamin E).
Acidulants	Citric acid, malic acid, tartaric acid	Provide tartness; adjust pH for pectin setting; help taste masking.
Preservatives	Potassium sorbate, sodium benzoate	Inhibit mold/yeast growth in high-moisture gummies.

Taste Masking Techniques

Taste masking is critical for consumer acceptability

- *Microencapsulation:*
 - Actives coated with lipids, starches, or polymers to shield from taste buds and oxygen.
 - Prevents interaction with gelling agents and moisture.
- *Flavor-Active Balancing:*
 - Using strong fruit or citrus profiles to overpower bitterness.
- *pH Modulation:*
 - Acidulants can suppress certain bitter notes.
- *Use of Sweetness Enhancers:*
 - Combining sugars with high-intensity sweeteners to give a clean, lasting sweetness.

Manufacturing Considerations

The formulation science must integrate with production processes.

- *Cooking temperature:* High heat can degrade heat-sensitive actives – necessitating post-cook dosing via cold addition.
- *Mixing uniformity:* Essential for dose consistency; often achieved via high-shear mixers.
- *Water activity control:* Too high → microbial spoilage; too low → hard, brittle gummies.
- *Setting and curing:* Gelatin requires cooling; pectin requires acid-induced setting at elevated temperatures.

Stability and Shelf Life

- Influenced by *moisture migration*, oxidation, and vitamin degradation.
- *Packaging:*
 - Moisture-barrier bottles or blister packs.
 - Light-protective materials for light-sensitive vitamins.
- *Shelf-life testing:*
 - Conducted under ICH stability guidelines (e.g., 25°C/60% RH, 40°C/75% RH).

Quality Control Parameters

Importance of Quality Control parameters have been shown in Table 3.

Table 3. Importance of parameters used in QC.

Parameter	Test Method	Importance
Active ingredient content	HPLC, spectrophotometry	Ensures correct dosing.
Microbial safety	Plate count, yeast/mold testing	Compliance with pharmacopeial limits.
Texture analysis	Texture profile analysis (TPA)	Consistent mouthfeel.
Water activity (a _w)	Hygrometer	Prevents microbial spoilage.
Sensory evaluation	Taste panel	Flavor and texture acceptance.

ADVANTAGES OVER CONVENTIONAL DOSAGE FORMS

Gummy supplements have rapidly gained popularity in the nutraceutical and pharmaceutical sectors due to their unique blend of sensory appeal, convenience, and formulation flexibility, offering several benefits over tablets, capsules, and powders [14, 15].

Improved Patient Compliance

- Palatable taste and pleasant texture make gummies particularly appealing to children, elderly patients, and individuals with pill-swallowing difficulties (dysphagia).
- Positive user perception – they are perceived as a “treat” rather than medication, reducing resistance to supplementation.
- Studies show higher adherence rates for gummy vitamins compared to equivalent tablet forms.

Reduction in Pill Burden

- Beneficial for individuals on polypharmacy or multiple daily supplements.
- Allows combination formulations (e.g., multivitamin + omega-3 + probiotics in one gummy) to reduce the number of separate products needed.

No Need for Water or Special Administration

- Convenience factor – ideal for on-the-go consumption without requiring water.
- Can be taken discreetly in public or workplace settings without the stigma sometimes associated with pill-taking.

Customizable Flavors, Colors, and Textures

- *Flavors*: From traditional fruit flavors (strawberry, orange) to exotic options (acai, passionfruit, lychee) for market differentiation.
- *Colors*: Can be naturally derived (e.g., beetroot, turmeric) or artificial, aligning with brand identity.
- *Textures*: From soft chew to firmer jelly, adjusted by varying gelling agent type and concentration.
- Allows regional customization to suit local taste preferences.

Multi-Nutrient and Functional Integration

- Capable of delivering *multiple active ingredients in one dose*
 - Vitamins + minerals.
 - Botanical extracts + antioxidants.
 - Specialty nutrients (collagen, coenzyme Q10, omega-3s, melatonin, probiotics).
- Advanced microencapsulation and multilayer gummy technologies enable inclusion of incompatible actives in the same product by separating them into distinct layers or microcapsules.

Enhanced Sensory Experience

- Combines chewability, aroma, and sweetness to create a multi-sensory consumption experience.
- Encourages consistent daily use, especially in pediatric and geriatric populations.

Branding and Consumer Appeal

- Premium lifestyle positioning – easily marketed as a “fun, tasty, healthy” product.
- Attractive packaging formats (bottles, pouches, blister packs) increase shelf appeal.
- High social media shareability, aiding organic brand promotion.

Broader Demographic Reach

- Appeals equally to children, adults, and seniors, unlike certain dosage forms (e.g., syrups targeted mainly at children).
- Particularly useful for nutritional intervention in special populations – such as patients undergoing chemotherapy who may have swallowing difficulties.

THERAPEUTIC AND NUTRACEUTICAL APPLICATIONS

Gummy supplements serve as an effective delivery platform for a wide spectrum of bioactive compounds. Their ability to integrate multiple active ingredients in a palatable, chewable matrix has broadened their applications in both preventive health and mild therapeutic support (Table 2) [5, 10, 16].

Vitamins and Minerals

- *Applications:*
 - *General wellness:* Multivitamin gummies for daily nutritional support.
 - *Targeted supplementation:* Vitamin D for bone health, Vitamin C for immunity, Iron for anemia prevention.
- *Formulation Challenges:*
 - *Stability:* Water- and heat-sensitive vitamins (e.g., Vitamin C, B12) require post-cook addition or microencapsulation.
 - *Taste masking:* Metallic taste of iron and zinc mitigated via flavor masking and encapsulation.
- *Examples:*
 - Vitamin C + Zinc immunity gummies.
 - Calcium + Vitamin D3 bone health gummies.

Probiotics

- *Applications:*
 - Gut health, digestive support, immune modulation.
- *Formulation Considerations:*
 - *Viability:* Probiotics are sensitive to moisture, oxygen, and heat—require controlled water activity and incorporation at low processing temperatures.
 - Use of freeze-dried cultures and protective carriers (e.g., inulin, resistant starch).
- *Examples:*
 - Lactobacillus and Bifidobacterium gummies for gut microbiota balance.
 - Symbiotic gummies combining probiotics and prebiotics.

Botanical Extracts

- *Applications:*
 - Immune support (Elderberry, Echinacea).
 - Cognitive function (Ginkgo biloba, Bacopa monnieri).
 - Stress relief (Ashwagandha, Chamomile).
- *Formulation Challenges:*
 - Bitter or astringent taste—requires flavor masking with fruit acids and sweeteners.
 - Variability in botanical potency—necessitates standardized extracts.
- *Examples:*
 - Elderberry + Vitamin C immunity gummies.
 - Ashwagandha stress-relief gummies.

Functional Lipids

- *Applications:*
 - Heart health (Omega-3 fatty acids from fish oil or algal oil).
 - Skin and joint support (Evening primrose oil, flaxseed oil).
- *Formulation Considerations:*
 - Oxidation prevention – antioxidants, like tocopherols or ascorbyl palmitate, are essential.
 - Use of emulsifiers (e.g., lecithin, mono- and diglycerides) for even dispersion in aqueous gummy base.
- *Examples:*
 - Omega-3 DHA + EPA gummies.

- *Vegan algal oil gummies for plant-based consumers.*

Specialty and Functional Actives

- *Collagen Peptides:*
 - *Supports skin elasticity, hair, nails, and joint health.*
 - *Hydrolyzed collagen is more soluble and easier to incorporate.*
- *Melatonin:*
 - *Sleep aid gummies for circadian rhythm regulation.*
 - *Requires precise low-dose incorporation for safety.*
- *Coenzyme Q10:*
 - *Antioxidant and cardiovascular health support.*
 - *Fat-soluble; requires solubilization or emulsification.*

Low-Dose Over-the-Counter (OTC) Medications

- *Examples:*
 - *Low-dose acetaminophen for mild pain relief.*
 - *Antacids in chewable gummy format.*
- *Regulatory Considerations:*
 - *Strict dosage control and clear labeling.*
 - *Stability testing under pharmaceutical GMP conditions (Figure 2).*



Figure 2. Applications in both preventive health and mild therapeutic support.

Key Formulation Principles for Each Application

Various functional ingredients face unique formulation challenges in food applications (Table 4).

Table 4. Challenges and their solution for various applications.

Application	Main Challenge	Solution Strategies
Vitamins & minerals	Stability, taste masking	Microencapsulation, antioxidant protection.
Probiotics	Heat & moisture sensitivity	Cold addition, protective carriers, low water activity.
Botanicals	Bitter taste, potency variation	Flavor masking, standardization of extracts.
Functional lipids	Oxidation, dispersion	Antioxidants, emulsifiers.
Collagen/melatonin	Solubility, dosing	Hydrolyzed form, precision weighing.
OTC drugs	Dose accuracy, regulatory compliance	GMP manufacturing, uniform mixing.

MANUFACTURING TECHNOLOGIES

The manufacturing of gummy supplements requires the integration of confectionery processing techniques with pharmaceutical-level precision to ensure dose uniformity, stability, and sensory quality. The technology employed directly affects nutrient integrity, product quality, and scalability.

Conventional Manufacturing Process

The standard method is adapted from confectionery production, with additional controls to ensure active ingredient stability and homogeneity [17].

Cooking

- *Objective:* Dissolve gelling agents, sweeteners, and syrups; reduce moisture content to desired solids level (~78–82% for gummies).
- *Typical Process:*
 - Ingredients (gelatin, pectin, sugars) heated with water to controlled temperatures.
 - For pectin-based gummies, cooking may occur at 110–125°C, followed by acid-induced setting.
- *Considerations:*
 - High temperatures may degrade heat-sensitive actives – requiring post-cook addition.

Blending/Active Ingredient Incorporation

- After cooling the base to an optimal temperature (often <70°C for gelatin, <90°C for pectin), actives are added.
- High-shear or planetary mixers ensure uniform distribution.
- Emulsifiers help disperse fat-soluble actives.

Depositing

- Heated slurry is deposited into starch molds, silicone molds, or steel trays using automated depositing lines.
- Precision dosing ensures each gummy contains the correct amount of active ingredients.

Cooling/Setting

- *Gelatin gummies:* cooled gradually to 10–20°C for several hours to form elastic gels.
- *Pectin gummies:* set via acid/temperature control within minutes.

Demolding and Post-Processing

- Gummies are released from mold.
- *Optional surface treatment:*
 - Oil coating to prevent sticking.
 - Sugar sanding for texture and flavor.

- Wax coating for shining and moisture barrier.

Low-Temperature Processing

- Developed for heat-sensitive actives (probiotics, vitamin C, enzymes) [18].
- Uses vacuum cooking or cold mixing to minimize thermal degradation.
- Actives are added at much lower temperatures (below their degradation threshold).
- *Benefits:*
 - Higher nutrient retention.
 - Expanded range of activities possible.

Microencapsulation Technology

- *Purpose:*
 - Protects unstable actives from oxygen, light, and heat.
 - Masks unpleasant flavors and odors (e.g., iron, fish oil).
- *Encapsulation Methods:*
 - Spray drying (lipid or polymer coating).
 - Coacervation (gelatin/gum Arabic microcapsules) [10].
 - Fluid-bed coating.
- *Advantages:*
 - Improves shelf-life.
 - Enables controlled release of actives during digestion.
 - Allows incorporation of otherwise incompatible ingredients in a single gummy.

EMERGING MANUFACTURING INNOVATIONS

3D Printing of Gummies

- Allows precise, personalized dosing based on individual nutritional needs (age, health status, DNA profile).
- Can print multi-layer gummies containing separate active zones to prevent interaction.
- Enables custom shapes, textures, and nutrient combinations [9, 15, 19].

Layered Gummy Technology

- Two or more gummy layers, each with different actives or flavors.
- Prevents cross-reaction between incompatible nutrients [19].

Continuous Manufacturing Systems

- Fully automated lines from ingredient feeding to packaging.
- Reduces batch variability and increases production efficiency.

Quality and Regulatory Controls

- *Critical Parameters:*
 - Moisture content and water activity (to prevent microbial growth).
 - Active ingredient assay for dose verification.
 - Texture profile analysis for consistent chew.
- *Regulatory Compliance:*
 - Adherence to *Good Manufacturing Practices (GMP)*.
 - Labeling requirements for dosage accuracy and allergen declaration [20].

CHALLENGES AND LIMITATIONS

While gummy supplements offer superior consumer appeal and compliance, their formulation and market positioning present technical, safety, and regulatory hurdles. These challenges must be addressed during product design, manufacturing, and marketing to ensure safety, efficacy, and consumer trust [17, 20, 21].

Dose Restrictions

- *Low Dose Capacity:*
 - Gummies typically weigh 2–5 g, limiting the amount of active ingredient they can carry.
 - High-dose actives (e.g., calcium carbonate, magnesium) require multiple gummies, increasing sugar/calorie intake.
- *Formulation Constraints:*
 - Limited space for actives due to bulk of gelling agents, sweeteners, and flavoring agents.
- *Impact:*
 - Not suitable for drugs or nutrients requiring large daily doses unless consumers take many pieces.

Stability Concerns

- *Heat and Moisture Sensitivity:*
 - Vitamins, such as C, B12, and folic acid, degrade rapidly in high-moisture environments.
- *Interaction Between Actives:*
 - Certain minerals (iron, calcium) may react with vitamins, reducing potency.
- *Storage Requirements:*
 - May require desiccants, refrigeration, or opaque packaging to protect from humidity, oxygen, and light.
- *Shelf Life:*
 - Shorter compared to tablets or capsules due to higher water activity.

High Sugar Content

- *Nutritional Impact:*
 - Many gummies contain 2–4 g of sugar per piece, contributing to daily sugar load.
- *Health Risks:*
 - Frequent use can promote dental care, contribute to weight gain, and be unsuitable for diabetic individuals.
- *Formulation Trade-off:*
 - Sugar-free alternatives (polyols, stevia) may alter texture, cause gastrointestinal discomfort, or be costlier.

Regulatory Ambiguity

- *Classification Challenges:*
 - In some regions, gummies fall into a gray zone between food, dietary supplements, and pharmaceutical categories.
- *Inconsistent Global Regulations:*
 - Nutrient fortification limits, labeling requirements, and health claim approvals vary widely by country.
- *Quality Control:*
 - In markets with lax oversight, mislabeling or underdosing of actives is a risk.

Risk of Overconsumption

- *High Palatability:*
 - Candy-like taste and appearance may lead to excessive intake, especially among children.
- *Toxicity Concerns:*
 - Fat-soluble vitamins (A, D, E, K), iron, and certain botanicals can cause adverse effects if overdosed.
- *Mitigation:*
 - Child-resistant packaging and clear dosage labeling are essential.

Manufacturing Complexity

- *Specialized Processing:*
 - Need for low-temperature or microencapsulation techniques increases cost and complexity.
- *Shelf-life Optimization:*
 - Balancing water activity, texture, and nutrient stability is technically challenging.
- *Scale-up Risks:*
 - Maintaining uniformity of actives during large-scale production is harder than with solid-dose tablets.

Cost Implications

- *Gummies Often Require:*
 - Premium raw materials (gelling agents, flavors, encapsulated actives).
 - More complex production lines than tablets/capsules.
- *Result:* Higher retail prices, which may limit accessibility in certain markets.

REGULATORY CONSIDERATIONS

The regulatory classification of gummy supplements varies significantly across jurisdictions, influencing their formulation, labeling, marketing, and manufacturing requirements. These differences are critical for companies aiming to launch products in multiple markets [22, 23].

United States

- *Regulatory Authority:*
 - Food and Drug Administration (FDA) oversees dietary supplements under the Dietary Supplement Health and Education Act (DSHEA, 1994).
- *Classification:*
 - Gummies without active pharmaceutical ingredients (APIs) are classified as dietary supplements.
- *Key Requirements:*
 - Good Manufacturing Practices (cGMPs) for dietary supplements (21 CFR Part 111).
 - Labeling must include:
- *Supplement Facts Panel.*
- *List of Ingredients.*
- Suggested use and serving size.
- FDA disclaimer for structure/function claims (e.g., “*This statement has not been evaluated by the FDA...*”).
 - Prohibited from making disease treatment claims unless approved as a drug.
- *Medicinal Gummies Containing APIs:*
 - Must comply with 21 CFR Parts 210/211 (drug GMPs).
 - Require New Drug Application (NDA) or Over-the-Counter (OTC) monograph compliance.
 - Clinical validation of safety and efficacy.

European Union

- *Regulatory Authority:*
 - European Food Safety Authority (EFSA).
- *Classification:*
 - Gummies are categorized as food supplements under Directive 2002/46/EC.
- *Key Requirements:*
 - Labeling
- Nutrition/health claims must be pre-approved by EFSA under Regulation (EC) No 1924/2006.
- Must state daily dosage and warnings for excessive consumption.
 - Novel ingredients

- Require approval under the Novel Food Regulation (EU) 2015/2283 if not widely consumed before May 15, 1997.
 - Additives and colorants
- Must comply with Regulation (EC) No 1333/2008.
- *Medicinal Classification:*
 - If therapeutic claims are made, product is regulated as a medicinal product under Directive 2001/83/EC and must meet GMP and marketing authorization requirements.

India

- *Regulatory Authorities:*
 - FSSAI (Food Safety and Standards Authority of India) – for food supplements.
 - AYUSH – for traditional/herbal products based on Ayurveda, Unani, Siddha, or Homeopathy systems.
- *Classification:*
 - Gummies with vitamins, minerals, or botanical extracts marketed as supplements fall under FSSAI's Nutraceutical Regulations (FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016).
- *Key Requirements:*
 - Compliance with ingredient limits as per the FSSAI schedule.
 - Pre-approval of novel or non-specified ingredients.
 - Mandatory labeling: nutritional information, recommended dosage, cautionary notes.
- *Medicinal Gummies:*
 - If containing APIs (e.g., paracetamol, ibuprofen), must be registered under the Drugs and Cosmetics Act, 1940 and manufactured in GMP-certified facilities.
 - Clinical validation and state licensing are required.

Common Global Compliance Elements

- *Child Safety:*
 - Child-resistant packaging is encouraged in many regions due to overdose risk.
- *Claims:*
 - Structure/function claims are generally permitted; disease prevention/treatment claims trigger drug classification.
- *Testing:*
 - Mandatory quality checks for microbial load, heavy metals, and active ingredient assay.
- *Label Transparency:*
 - Accurate declaration of sugar content, allergens, and possible side effects.

Regulatory Challenges

- *Cross-jurisdictional Variation:*
 - Same product may require different labeling, allowable ingredient levels, or even reclassification in different markets.
- *Novel Ingredient Approval Timelines:*
 - Can delay product launches.
- *Evolving Standards:*
 - Growing global focuses on sugar limits, clean-label claims, and plant-based certifications.

MARKET TRENDS AND FUTURE PROSPECTS

The gummy supplement sector has transitioned from a niche product category to a mainstream delivery format in the nutraceutical industry. Driven by consumer preference for convenience, palatability, and functional wellness, the market shows strong growth potential in both developed and emerging economies [24–26].

Current Market Landscape

- *Global Valuation:*
 - Estimated at USD 10–12 billion in 2024 and projected to surpass USD 20 billion by 2030, with a CAGR of ~8–10%.
- *Regional Leaders:*
 - North America: largest market due to established dietary supplement culture and strong retail presence.
 - Europe: growing demand for clean-label, vegan, and organic gummies.
 - Asia-Pacific: fastest-growing market, fueled by increasing middle-class income, preventive health awareness, and urban lifestyles.
- *Dominant Segments:*
 - Multivitamins and mineral gummies.
 - Immune support formulations (Vitamin C, Zinc, Elderberry).
 - Beauty-from-within products (collagen, biotin).

Key Consumer Trends

- *Vegan and Plant-Based Formulations:*
 - Growing consumers shift from gelatin to pectin, agar, or carrageenan bases.
 - Certification for vegan and halal/kosher gummies becoming a differentiating factor.
- *Sugar-Free and Low-Calorie Options:*
 - Use of polyols (maltitol, sorbitol), stevia, and monk fruit to address health-conscious and diabetic consumers.
 - “Keto-friendly” gummy lines entering niche segments.
- *Condition-Specific Formulations:*
 - Targeted health areas: sleep support (melatonin), gut health (probiotics), cognitive health (nootropics), joint care (glucosamine).
- *Clean Label and Transparency:*
 - Minimal additives, natural colors/flavors, non-GMO sourcing.
 - QR codes linking to lab test results for authenticity.

Technological and Product Innovation

- *Personalized Nutrition:*
 - DNA-based and lifestyle-based nutrient profiles, with tailored gummy packs for individuals.
 - Subscription services delivering monthly personalized formulations.
- *Pharma-Nutra Convergence:*
 - Low-dose over-the-counter medicines in gummy form (e.g., analgesics, antacids).
 - Medical nutrition gummies for targeted therapeutic areas.
- *Microencapsulation and Multi-Layer Gummies:*
 - Incorporation of incompatible actives by compartmentalization.
 - Prolonged shelf life and improved release profiles.
- *3D Printing and On-Demand Manufacturing:*
 - Customized shapes, doses, and nutrient blends.
 - Potential integration in pharmacies for point-of-sale personalized supplements.

FUTURE GROWTH DRIVERS

- Rising awareness of preventive healthcare in younger demographics.
- Increasing adoption in geriatrics and pediatric markets due to ease of administration.
- Expansion into functional food crossover products (e.g., fortified snacks).
- E-commerce growth enabling direct-to-consumer (D2C) brands to bypass traditional retail limitations.

CHALLENGES TO FUTURE EXPANSION

- Regulatory standardization for claims and allowable nutrient levels.
- Addressing sugar content while maintaining taste and texture.
- Managing production costs for premium formulations (vegan, organic, sugar-free).
- Consumer education to prevent overconsumption [27].

OUTLOOK

The next decade will likely see:

- Mainstream acceptance of gummies as a legitimate nutraceutical and pharmaceutical delivery form.
- High-value niches in personalized health, functional beauty, sports nutrition, and therapeutic gummies.
- Sustainability-driven innovation, including compostable packaging and upcycled plant-based ingredients.

CONCLUSIONS

Gummy supplements embody a convergence of food technology, pharmaceutical formulation science, and consumer-driven innovation. By combining palatable delivery formats with functional health benefits, they have redefined compliance strategies in both nutraceutical and, increasingly, pharmaceutical sectors. Their continued success will depend on:

- Advancements in formulation science to enhance stability, bioavailability, and taste masking.
- Adoption of low-sugar, vegan, and clean-label technologies to align with evolving consumer expectations.
- Rigorous clinical validation and quality assurance to substantiate health claims and build trust.
- Harmonization of global regulatory frameworks to ensure safety and streamline market entry.

While challenges, such as dose limitations, sugar content, and potential overconsumption remain, the sector's adaptability, driven by personalized nutrition, microencapsulation, and 3D printing, positions gummies as a sustainable, consumer-preferred dosage form. With strategic innovation and regulatory clarity, gummy supplements are poised to play a significant role in the next generation of functional foods and patient-friendly therapeutics.

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