

A Comprehensive Review on Formulation and Evaluation of Medicated Chewing Gum

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Abstract—Medicated chewing gum (MCG) is an advanced and innovative oral drug delivery system designed to release active pharmaceutical ingredients (APIs) during mastication for either local therapeutic action within the oral cavity or systemic absorption through the buccal mucosa. According to the European Pharmacopoeia, MCG is classified as a solid, single-dose preparation intended to be chewed but not swallowed. In recent years, MCG has gained substantial attention within pharmaceutical sciences due to its exceptional patient benefits, including improved patient compliance, ease of administration without water, rapid onset of action, and the critical ability to bypass hepatic first-pass metabolism and gastrointestinal degradation. MCG is currently successfully utilized across diverse clinical fields such as smoking cessation therapy, oral hygiene preservation, motion sickness management, acute pain relief, vitamin and nutritional supplementation, and the localized treatment of dental caries and oral infections. The formulation of MCG is sophisticated, universally involving an insoluble rubber-like gum base, plasticizers, softeners, fillers, intense and bulk sweeteners, flavoring agents, and the target active ingredients. This comprehensive review provides an in-depth examination of the historical perspective, fundamental release mechanisms, critical excipient selection, advanced manufacturing techniques (such as conventional melting, direct compression, and cryogenic freezing/grinding), stringent quality control evaluation parameters, and current therapeutic landscapes, while delineating future perspectives in this modern oral drug delivery field.

Index Terms—Medicated chewing gum, Buccal drug delivery, Gum base, Direct compression, Patient compliance, Drug release, Mastication.

I. INTRODUCTION

Oral drug delivery systems historically represent the most preferred, versatile, and commercialized route of drug administration within modern healthcare. Their enduring

preeminence is firmly rooted in their unmatched convenience of use, high inherent safety profiles, non-invasive nature, and robust patient acceptance levels [1, 2]. However, conventional oral solid dosage forms like tablets and capsules present distinct clinical and practical bottlenecks, most notably dysphagia (difficulty in swallowing) widely prevalent among pediatric and geriatric demographics, the strict requirement of clean drinking water for ingestion, and reduced systemic bioavailability driven by aggressive gastrointestinal degradation and robust hepatic first-pass metabolism. To comprehensively circumvent these limitations, pharmaceutical researchers have engineered advanced oral solid platforms, among which Medicated Chewing Gum (MCG) has emerged as an exceptionally effective, patient-centric, and therapeutically agile option. MCG is capable of delivering active pharmaceutical compounds via two distinct clinical pathways: locally within the tissues and fluids of the oral cavity, and systemically through rapid transmucosal absorption across the highly vascularized buccal epithelium [3, 4]. As rigorously defined by the regulatory guidelines of the European Pharmacopoeia, a medicated chewing gum is a solid, single-dose preparation formulated with one or more active pharmaceutical ingredients (APIs) tightly incorporated into an insoluble, rubber-like gum base, specifically engineered to be masticated for a prolonged period but explicitly intended not to be swallowed [5]. The ethno medical and cultural history of chewing gum extends back thousands of years, with ancient civilizations regularly masticating natural masticatory agents, such as chicle latex obtained from the Manilkara zapota tree in Mesoamerica or tree resins in Northern Europe, for oral cleansing, breath refreshment, and primitive teeth cleaning. However, its targeted transformation into a formal, validated pharmaceutical delivery system gained real clinical momentum in 1928 with the commercial launch of 'Aspergum®', an innovative aspirin-loaded chewing gum designed to provide rapid localized pain relief following tonsillectomies [6]. Decades later, the definitive breakthrough for this platform arrived with the global development and subsequent monumental commercial success of nicotine-loaded chewing gums (e.g., Nicorette®) used as an essential modality in smoking cessation Nicotine Replacement Therapy (NRT) [7]. This milestone profoundly demonstrated the capacity of MCG to deliver highly regulated doses of systemic medications across the buccal mucosal membrane, setting off a wave of extensive global academic and industrial R&D. During mastication, the mechanical action of the teeth and jaws systematically kneads the rubbery polymeric framework, sequentially releasing the embedded drug into the surrounding salivary fluid [8]. Once dissolved in saliva, the drug can exert immediate, high-concentration local action to treat oral ailments or undergo swift passive diffusion across the buccal epithelium into the systemic bloodstream, effectively avoiding the destructive environment of the stomach and the clearing effects of hepatic first-pass metabolism [9]. This results in a rapid onset of clinical action, lower therapeutic dose requirements, and a significantly maximized bioavailability profile [8, 10]. Furthermore, because the dosage form requires no water, boasts a pleasant, customizable taste, and is highly portable, it represents an ideal therapeutic vehicle for modern patient groups [1, 10].



Fig. Medicated Chewing Gum

II. MECHANISM OF ACTION AND DRUG RELEASE

The therapeutic efficacy of a medicated chewing gum relies entirely on a well-regulated, mastication-driven mechanical extraction process. Unlike standard solid dosage forms that undergo static disintegration and subsequent dissolution in stomach fluids, MCG acts as a dynamic mass that must be physically manipulated by the patient to initiate drug liberation [8, 11]. When a patient begins chewing the gum, the physical forces applied by the teeth squeeze, stretch, and deform the insoluble polymeric gum base. Simultaneously, the continuous influx of warm saliva (stimulated naturally by the chewing action and flavor excipients) begins to penetrate the outer matrix of the gum, hydrating the outermost layers. Soluble ingredients, including sweetening agents, crystalline bulking agents, and hydrophilic drugs, dissolve quickly in this advancing salivary front and are washed out into the oral cavity [8, 12]. For lipophilic or matrix-bound drugs, the release is heavily mediated by continuous mechanical kneading. The jaw action constantly re-exposes fresh, un-hydrated inner core layers of the gum base to the surface, allowing a continuous, step-wise extraction of the API over a standard 20 to 30-minute chewing cycle. The rate of drug release is therefore a direct function of the drug's partition coefficient between the hydrophobic gum core and the aqueous saliva, the total chewing frequency, and the specific composition of the gum base [11, 13].



Fig. MECHANISM FLOW DIAGRAM

Once the drug is fully released into the salivary fluid, it splits into two distinct operational pathways: 1) Local Action: The drug-loaded saliva coats the teeth, gums, and oral mucosal linings, exerting an immediate therapeutic effect for conditions like dental caries, oral candidiasis, or xerostomia [11]. 2) Systemic Action: A substantial portion of the dissolved drug, especially if non-ionized and lipophilic, undergoes rapid passive absorption through the stratified squamous epithelium of the buccal mucosa, entering the deep facial veins and draining directly into the superior vena cava. This systemic shortcut completely avoids first-pass hepatic clearance, resulting in rapid blood concentrations comparable to intravenous injection for specific molecular structures [4, 9].

III. IDEAL CHARACTERISTICS OF MEDICATED CHEWING GUM

To ensure complete patient compliance, precise therapeutic reproducibility, and industrial viability, an engineered MCG formulation must fulfill a strict set of organoleptic, mechanical, and biopharmaceutical criteria:

- Palatability and Taste Masking: Must possess an exceptionally pleasant taste, completely free of any gritty mouthfeel or chemical aftertaste, ensuring immediate willingness to chew, especially among pediatric and geriatric cohorts [1, 11].
- Texture and Chewability: The masticated mass must retain a cohesive, highly elastic, and smooth texture. It must explicitly be non-sticky, resisting any adhesion to natural teeth, crowns, fillings, or complex orthodontic dental work [13].
- Controlled Drug Release: The formulation must show a linear, controlled, and uniform release curve of the active drug over a standardized chewing window (typically 20-30 minutes), minimizing sudden dose dumping [8, 12].
- Mechanical Integrity: The gum must possess adequate initial hardness and physical strength to survive industrial compression or cutting without fracturing, and it should not crumble into fragments upon initial jaw impact [12].
- Storage Stability: The finished gum must exhibit chemical and physical stability, remaining entirely resistant to environmental moisture absorption, atmospheric oxidation, temperature-induced softening, or flavor loss during its shelf life [11].
- Safety and Biocompatibility: All structural polymers, softeners, sweeteners, and flavoring agents utilized must be fully non-toxic, non-cariogenic (preferably sugar-free), and completely free of any irritating effects on the delicate oral mucosa [1, 13].

IV. ADVANTAGES-

Medicated chewing gum balances unique physiological benefits with specific formulation and patient-dependent constraints. A clear understanding of these parameters is vital for selecting appropriate candidate drugs for this platform.

4.1. Structural and Clinical Advantages-

MCG offers a series of distinct biopharmaceutical and practical clinical benefits over conventional oral tablets [1, 4, 11]:

1. **Avoidance of First-Pass Metabolism:** By enabling direct absorption through the highly vascularized buccal mucosa, the active drug directly enters systemic circulation. This protects susceptible molecules from aggressive stomach acids, intestinal enzymes, and heavy hepatic first-pass metabolism, directly boosting oral bioavailability [4, 9].
2. **Rapid Onset of Action:** Buccal absorption bypasses the lengthy gastrointestinal transit, disintegration, and intestinal absorption steps, leading to rapid blood concentrations and a fast onset of clinical action, ideal for treating acute breakthroughs like migraines, nausea, or breakthrough pain [3, 8].
3. **Administration Without Water:** The formulation entirely removes the need for clean drinking water and the physical act of swallowing, providing a highly discreet, convenient, and easy-to-use dosage form suitable for active, traveling individuals, and patients suffering from dysphagia [1, 10].
4. **Immediate Therapy Cessation:** If a patient experiences an unexpected adverse reaction or wishes to stop therapy immediately, they can simply spit out the gum mass, instantly halting further drug release and systemic absorption [1, 11].
5. **High Patient Acceptance and Compliance:** The pleasant sweet taste, chewing action, and refreshing flavors make MCG highly acceptable, reducing the emotional and physical resistance often seen with taking tablets or injections in pediatric and geriatric care [1, 10].

4.2. Disadvantages-

Despite its exceptional clinical utility, the MCG platform presents specific manufacturing and patient-centered drawbacks [1, 11, 13]:

1. **Variable Chewing Behavior:** The total dose of drug delivered and its rate of release are deeply dependent on individual patient chewing mechanics, including total chewing force, frequency (strokes per minute), and individual salivary flow rates, which can introduce dosing variability [11, 13].
2. **Salivary Dilution and Swallowing:** A high percentage of the released drug dissolves into saliva and is inevitably swallowed into the stomach, where it faces standard GI breakdown or undergoes regular intestinal absorption, potentially diluting the target buccal effect [8].
3. **Taste Masking Bottlenecks:** Formulating drugs with highly bitter, metallic, or localized irritating tastes requires advanced taste-masking technologies. High-dose drugs are particularly challenging to incorporate without ruining the texture or flavor profiles of the product [1, 11].
4. **Risk of Jaw Fatigue and Choking:** Continuous mastication for extended periods can induce physical jaw fatigue, muscle soreness, or exacerbate pre-existing Temporomandibular Joint (TMJ) disorders in susceptible patients [13].
5. **Sensitivity to Moisture and Storage:** The open polymeric matrices of chewing gums are highly sensitive to ambient humidity and oxidation, requiring advanced, specialized, and

moisture-resistant blister packaging to preserve quality over time [11, 12].

V. NEED FOR DEVELOPMENT OF MEDICATED CHEWING GUM-

The ongoing industrial push to develop and market innovative medicated chewing gums is driven by a clear clinical need to fix the historical, biopharmaceutical, and patient-centered shortcomings of standard tablets, capsules, and oral liquids [1, 3].

Conventional oral therapies are fundamentally limited when treating patients with physical constraints. For instance, pediatric and geriatric cohorts frequently experience psychological resistance or severe physical difficulty (dysphagia) when tasked with swallowing large solid oral doses [1, 10]. Oral liquid suspensions, while easier to swallow, often fail to mask bitter tastes and suffer from chemical instability in water, leading to rapid degradation and short shelf lives. MCG cleanly resolves these issues by delivering active medications in a highly palatable, familiar, and chewable format that turns taking medicine into a comfortable, stress-free routine [10, 11].

Furthermore, modern lifestyles demand mobile, fast-acting, and highly convenient medical therapies. MCG provides an ideal option, requiring no access to clean water or measuring spoons, making it perfect for rapid use during travel, working hours, or acute medical situations (e.g., sudden motion sickness, acute panic attacks, allergic reactions, or severe breakthrough pain) [1, 10]. From a biological perspective, for drugs that are heavily degraded by gastrointestinal fluids or extensively cleared by hepatic enzymes, MCG offers a non-invasive, highly effective alternative to painful injections by delivering the drug straight into systemic circulation via the buccal mucosa, significantly improving clinical performance while lowering the required dose and minimizing systemic side effects [4, 9].

VI. FORMULATION COMPOSITION AND EXCIPIENT SELECTION-

Formulating a stable, therapeutically effective, and pleasant medicated chewing gum requires balancing hydrophobic and hydrophilic excipients. Every component must be carefully selected to optimize drug release kinetics, structural texture, and taste-masking efficiency [8, 11].

Table 1 provides a detailed breakdown of the standard excipients, their specific functional roles, and commonly used pharmaceutical examples:

Excipient Category	Primary Functional Role	Common Examples Used
Gum Base (20–60%)	Forms the structural, insoluble masticatory matrix; regulates drug release.	Polyvinyl acetate (PVA), Polyisobutylene, Butyl rubber, Chicle, Jelutong [11, 13].
Plasticizers / Softeners	Improves elasticity and flexibility; prevents matrix brittleness; retains moisture.	Glycerin, Propylene glycol, Lecithin, Hydrogenated vegetable oils [11, 12].

Bulk Sweeteners	Provides basic structural mass, uniform bulk texture, and pleasant sweetness.	Xylitol, Sorbitol, Mannitol, Maltitol, Sucrose, Dextrose [1, 11].
Intense Sweeteners	Provides high-power sweetness to mask highly bitter or metallic active drugs.	Sucralose, Aspartame, Saccharin Sodium, Acesulfame Potassium [11, 12].
Fillers / Bulking Agents	Adjusts final mechanical strength, reduces base stickiness, optimizes	Calcium carbonate, Talc, Magnesium carbonate, Dicalcium phosphate [12, 13].

processing.

6.1. Detailed Analysis of Crucial Excipients-

The gum base is the primary, water-insoluble component that acts as the vehicle for the medication. Synthetic elastomers like polyvinyl acetate (PVA) are highly preferred in modern manufacturing due to their consistent purity, excellent film-forming properties, and excellent compatibility with diverse active drug profiles [11, 13]. Plasticizers, primarily glycerin, are necessary to lower the glass transition temperature of these polymers, making the formulation easy to chew at standard body temperatures [12].

Flavoring agents (e.g., peppermint oil, spearmint oil, menthol, and citrus extracts) are heavily used to mask unpleasant tastes. Peppermint and menthol are particularly valuable because they provide a cooling, refreshing sensation that desensitizes oral taste receptors, helping mask bitter drug tastes [11, 12]. Among sweetening options, polyols like xylitol are highly favored because they are non-cariogenic, actively help prevent dental caries, and provide a pleasant cooling effect in the mouth [1, 11].

VII. ADVANCED INDUSTRIAL MANUFACTURING METHODOLOGY-

The industrial production of medicated chewing gum has evolved from standard confectionery processes to highly regulated, validated pharmaceutical techniques designed to maintain strict dose uniformity and drug stability [8, 12, 13].

7.1. Conventional Melting Method-

The conventional melting process is a well-established technique where the insoluble gum base is heated to a controlled temperature (typically between 50°C and 70°C) in a heavy-duty mixer until it becomes a soft, pliable, and workable molten mass. Once the base is melted, softeners and plasticizers like glycerin are mixed in to establish elasticity. The active pharmaceutical ingredient (API) is then added directly into the molten mass under continuous, high-shear mixing to ensure a completely uniform distribution. Finally, bulking fillers, sweeteners, and volatile flavors are added [12]. The homogeneous, warm dough is removed, rolled into uniform sheets using industrial rollers, cooled completely, and cut into specific unit sizes [12, 13]. While simple

and highly reliable for stable molecules, the prolonged heat exposure makes this method less suitable for heat-sensitive drugs or highly volatile flavoring agents [12].

7.2. Advanced Direct Compression Method-

The modern direct compression technique represents a major technological leap forward, utilizing specialized, free-flowing, directly compressible powdered gum bases (such as commercial Pharmagum®) [12, 13]. In this method, the powdered gum base is dry-blended with the micronized active drug, sweeteners, dry lubricants, and spray-dried flavors in a standard pharmaceutical blender until completely uniform. The resulting dry powder mix is then directly compressed into solid chewing gum tablets using standard rotary tablet press machinery [13].

This elegant process completely eliminates the need for thermal processing, making it ideal for heat-sensitive drugs. Furthermore, it utilizes standard, widely available tablet compression machinery, resulting in exceptional manufacturing efficiency, precise content uniformity, and minimized processing times [12, 13].

7.3. Cryogenic Freezing, Grinding, and Tableting Technique-

Designed specifically to process tough, elastic elastomer masses without exposing them to high temperatures, this method involves freezing the gum base using liquid nitrogen or solid carbon dioxide (dry ice) until it falls well below its glass transition temperature and becomes highly brittle. The frozen, brittle gum base is immediately ground into a fine, uniform powder using a specialized cryogenic impact mill. This cold powder is then safely blended with the active drug and other excipients under temperature-controlled conditions, and the mixture is compressed into finished tablets [13]. This technique provides excellent content uniformity, safeguards heat-sensitive molecules, and allows large-scale production of highly technical formulations [12, 13].

VIII. EVALUATION PARAMETERS

To comply with rigorous international pharmaceutical standards, finished medicated chewing gums must undergo extensive physical, chemical, and specialized functional testing [12, 13].

8.1. Compendial and Physical Evaluation Tests

- **Organoleptic Screening:** The color, odor, overall taste, and mouthfeel are systematically assessed by human sensory panels or electronic tongue systems. The product must possess an appealing look and pleasant taste without causing any chemical irritation or burning sensations in the oral cavity [1, 11].
- **Weight Variation Testing:** Twenty individual units are randomly sampled and weighed to determine compliance with official pharmacopeial limits. This ensures excellent batch-to-batch weight consistency and uniform mass distribution [12].
- **Hardness and Texture Profile Analysis:** Using advanced texture analyzers, the formulation is tested for resistance to penetration and elasticity. The gum must balance mechanical

strength—avoiding both excessive hardness (which causes jaw fatigue) and excessive softness (which causes stickiness) [13, 14].

- **Friability Evaluation:** This test measures the product's ability to resist cracking, chipping, or breaking into fragments during high-speed packaging operations and commercial transport [12].
- **Cohesive Stickiness Assessment:** Specialized testing rigs measure the adhesive force of the chewed gum matrix against diverse surfaces. This ensures the gum stays cohesive and will not stick to teeth, dental crowns, or processing equipment [13, 14].
- **Drug Content Uniformity:** Individual gums are dissolved in appropriate solvents and quantified via UV-Vis Spectrophotometry or High-Performance Liquid Chromatography (HPLC). This confirms that every single unit contains the exact required dose of the active medication [12, 13].
- **In-Vitro Drug Release (Chewing Apparatus):** Because standard tablet dissolution testers cannot simulate the mechanical action of human chewing, specialized mastication apparatuses (such as the apparatus described in the European Pharmacopoeia) are used. The gum is placed in a small chamber filled with artificial saliva and mechanically chewed by a set of automated pistons. Samples of the fluid are withdrawn at regular intervals to map the precise drug release profile over time [12, 14].
- **Stability Profiles (ICH Guidelines):** The finished products are stored in environmental chambers under accelerated conditions (e.g., $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\% \text{ RH}$) according to official ICH guidelines. Researchers monitor parameters like drug content, matrix texture, flavor stability, and moisture absorption to determine the product's shelf life and ideal packaging [12].

IX. APPLICATIONS

The unique dual-delivery pathways (local and systemic) of medicated chewing gum allow it to be utilized across a wide variety of clinical indications, summary of which includes:

1. **Smoking Cessation Therapy:** The most globally recognized application of MCG. Formulations containing nicotine are used as an essential tool in Nicotine Replacement Therapy (NRT) to treat tobacco dependence, providing highly regulated buccal absorption that helps manage cravings [7, 11].
2. **Oral Health and Dental Care:** Perfect for delivering localized anti-plaque agents, chlorhexidine disinfectants, fluoride tooth-strengthening compounds, and breath-freshening essential oils directly into salivary fluids to treat dental caries, gingivitis, and bad breath (halitosis) [1, 11].
3. **Motion Sickness Management:** Loading fast-acting antihistamines or antiemetics (e.g., dimenhydrinate) into MCG allows rapid buccal absorption, providing swift protection against sudden motion sickness and nausea without needing water [11, 12].
4. **Acute Pain Management:** Useful for delivering rapid-acting analgesics like NSAIDs or triptans, bypassing the stomach to provide swift relief from acute migraines, tension headaches, or post-operative dental pain [6, 12].

5. Vitamin and Nutritional Supplementation: An excellent consumer-friendly option for delivering daily vitamins (e.g., Vitamin C, D, B12) and essential minerals, offering high bioavailability and excellent compliance, particularly among children [1, 11].
6. Saliva Stimulation and Xerostomia Relief: Chewing naturally triggers salivary reflex pathways, providing instant relief for patients suffering from severe dry mouth (xerostomia) caused by radiation therapy or Sjogren's syndrome [11, 13].

X. CONCLUSION

Medicated chewing gum represents a highly innovative, patient-friendly, and biopharmaceutically agile advancement in oral drug delivery technology, clearly moving beyond its traditional role in simple confectionery applications. By combining the advantages of rapid action, improved patient compliance, the ability to bypass first-pass hepatic metabolism, and administration without water, it provides an elegant alternative for delivering challenging small molecules [4, 8, 12].

While formulation challenges like moisture sensitivity, taste-masking of bitter drugs, and individual chewing variations require ongoing research, continuous advancements in polymer chemistry and manufacturing—such as the direct compression of powdered bases—are actively streamlining industrial production [12, 13]. Looking ahead, as industrial awareness grows and consumer demand for convenient, non-invasive therapies expands, medicated chewing gum is poised to capture a significantly larger share of the global pharmaceutical market, establishing itself as a core option for modern patient care [11, 14].

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