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“TO STUDY THE MEDICATED JELLIE”

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Abstract

The aim was to develop a patient-friendly, palatable, and effective oral dosage form suitable for paediatric and geriatric patients who experience difficulty swallowing conventional tablets and capsules. The drug was incorporated into the jelly matrix through a controlled heating and mixing process, followed by cooling to form a semisolid product with uniform consistency.

The study successfully demonstrated that natural gums can be effectively utilized for the formulation of medicated jellies as novel oral drug delivery systems.

Various natural gums such as guar gum, xanthan gum, acacia gum, and tragacanth gum were selected for jelly preparation because of their biocompatibility, biodegradability, non-toxicity, and ability to form stable gels.

The prepared medicated jellies exhibited desirable physicochemical characteristics, good patient acceptability, and uniform drug distribution.

Keywords,

Jelly, oral drug delivery systems, Adv.dis, classification, medicated jelly, First pass metabolism.

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INTRODUCTION

Oral drug delivery remains the most widely utilized and preferred method for administering medications due to its convenience, non-invasiveness, and cost-effectiveness.

Medicated jellies are versatile and can be designed to deliver a wide range of drugs, including those used for chronic diseases, pain management, and paediatric or geriatric care. Their formulation allows for controlled or sustained drug release, ensuring consistent therapeutic outcomes while improving patient adherence in long-term treatments.

Natural gums have gained prominence in pharmaceutical formulations due to their biocompatibility, biodegradability, and ability to modify drug release. These polymers influence the jelly's texture, viscosity, and stability, ultimately affecting the drug's bioavailability and overall performance. The incorporation of different types of natural gums, such as xanthan gum, guar gum, and acacia gum, can optimize the mechanical and rheological properties of the jelly, making it more effective as a drug delivery medium.

This study aims to develop and characterize medicated jellies using different gums to determine their impact on formulation properties and drug release profiles.

1.1 Oral Drug Delivery System

The oral drug delivery system is the most widely utilized route for administering pharmaceutical agents due to its ease of use, non-invasiveness, cost-effectiveness, and high patient compliance. It involves the ingestion of a drug formulation, which then undergoes absorption through the gastrointestinal (GI) tract before entering systemic circulation to exert its therapeutic effect.

Advantages of Oral Drug Delivery:19-22

- Oral administration is simple and convenient, making it easier for patients to adhere to prescribed therapies.
- Manufacturing and packaging of oral dosage forms are generally less expensive compared to other drug delivery systems.

Disadvantages of Oral Drug Delivery:23

- Drugs administered orally can undergo first-pass metabolism in the liver, which may reduce their bioavailability.

- Factors such as GI motility, pH, food interactions, and enzyme activity can affect drug absorption.

1.2 Classification of Routes of Drug Administration 24-30

Drug administration routes are classified based on the site of application and the intended effect. The oral, sublingual, and buccal routes are among the most commonly used methods for drug delivery due to their convenience and effectiveness. Each of these routes has distinct mechanisms of absorption, advantages, and limitations.

1. Oral Route

The oral route is the most commonly used method for drug administration, where drugs are ingested through the mouth and pass through the gastrointestinal (GI) tract before being absorbed into the bloodstream. This route is suitable for a wide range of drugs, including tablets, capsules, suspensions, and solutions.

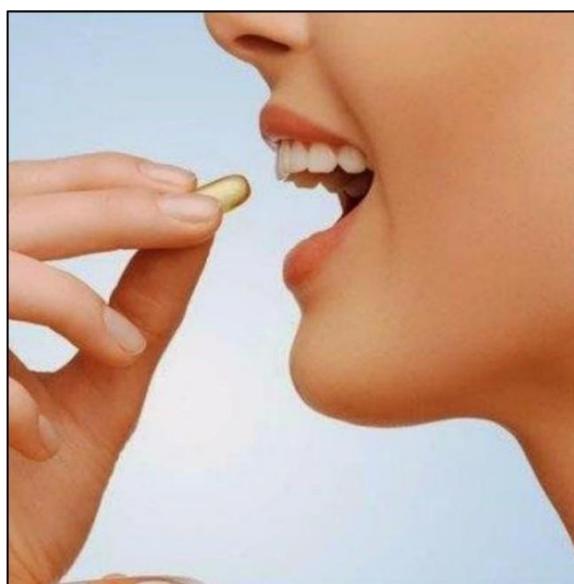


Figure 1: Oral Route

Advantages of the Oral Route:

- Non-invasive, convenient, and suitable for self-administration.
- Cost-effective and widely available in different dosage forms.

Disadvantages of the Oral Route:

- Subject to first-pass metabolism, reducing the active drug concentration.
- Drug absorption is influenced by food, gastric pH, and motility.
- Not suitable for patients with nausea, vomiting, or swallowing difficulties.

- Some drugs can cause gastric irritation or degradation in the acidic environment.

2. Sublingual Route

The sublingual route involves placing the drug under the tongue, where it dissolves and is absorbed directly into the bloodstream through the mucous membrane. This bypasses the digestive system and first-pass metabolism, leading to faster drug action. Common sublingual dosage forms include tablets, films, and sprays.

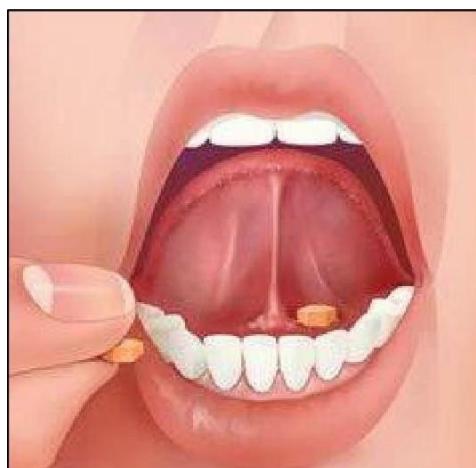


Figure 2: Sublingual Route

Advantages of the Sublingual Route:

- Rapid absorption and faster onset of action compared to oral administration.
- Bypasses first-pass metabolism, enhancing drug bioavailability.

Disadvantages of the Sublingual Route:

- Only small doses of drugs can be administered due to limited absorption surface.
- Unpleasant taste or irritation may affect patient compliance.

3. Buccal Route

The buccal route involves placing the drug between the gum and the inner cheek, where it dissolves and is absorbed through the buccal mucosa into the bloodstream. Like the sublingual route, this method avoids first-pass metabolism, leading to improved bioavailability.

Advantages of the Buccal Route:

- Bypasses first-pass metabolism, improving drug bioavailability.
- Provides controlled and prolonged drug release for sustained effects.
- Non-invasive and suitable for patients with difficulty swallowing.

- Can be used for both local and systemic effects.

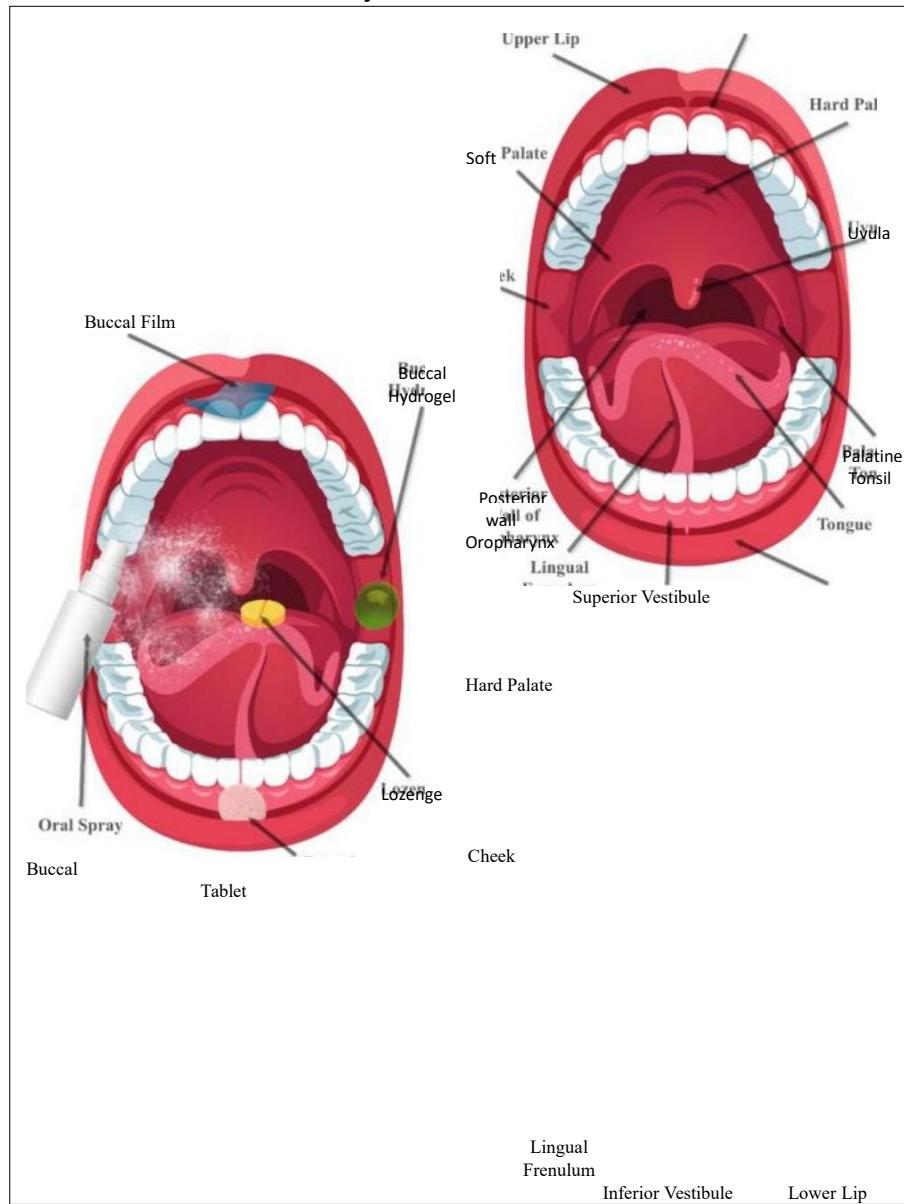


Figure 3: Buccal Route

Disadvantages of the Buccal Route:

- Absorption is slower compared to the sublingual route.
- Limited to small doses due to space constraints in the buccal cavity.

1.3 PHYSIOLOGY OF THE ORAL CAVITY 31-33

For a long time, the mouth cavity was considered as a site of absorption. Ponchel discovered that nitro-glycerine can be absorbed from the mouths. Since subsequently, other active chemicals have been researched for local or systemic usage. When a delivery system can be left in situ in a given area for an extended period of time, bioavailability improves significantly. Both local and systemic medication absorption will improve. Drugs are administered sublingually, passing through the mucosal barrier.

- Using a buccal delivery system to treat oral diseases. The buccal mucosa is optimal for attaching the retentive delivery system.

Components or Structural Aspects of the Oral Cavity:

The oral cavity includes the lips, cheeks, hard and soft palates, as well as the mouth's surface.

The oral cavity's total surface area is 170 cm². The oral cavity consists of two parts:

- The outer oral vestibule
- The actual oral cavity.

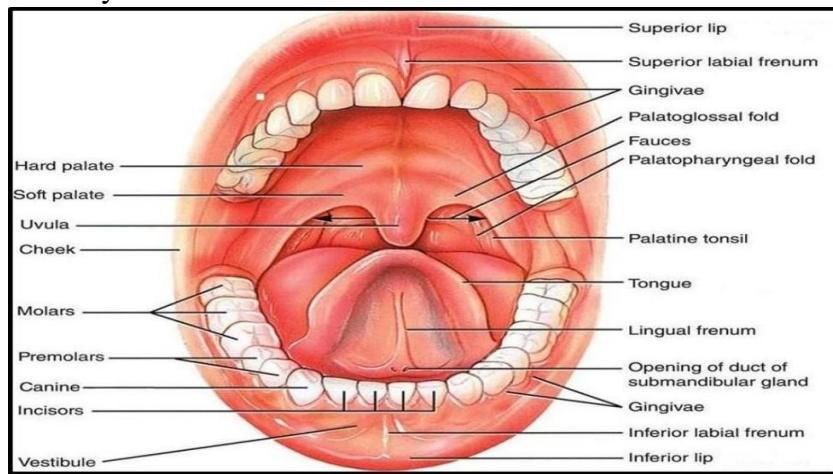


Figure 4: Structure of Oral Cavity

Anatomical Characteristics:

- Masticatory mucosa is found on the hard palate and gingiva.
- The lips, cheeks, floor of the mouth, underside of the tongue, and soft palate are lined with lining mucosa in the upper part of the tongue and certain areas of the lips, there is particular mucosa.
- there exists distinct mucosa.

● Secretions in the oral cavity:

Include saliva, reticular fluid, and mucus. Saliva is a complex fluid containing organic and inorganic components.

Saliva's physiological functions are as follows:

- Mineral salts are used to demineralize teeth.
- Modulation of oral flora microorganisms.
- Lubricating and cleansing the oral and pharyngeal mucosa

mucoadhesive materials to maintain contact with it for an extended time. However, this mucous layer may hinder the absorption of drug.

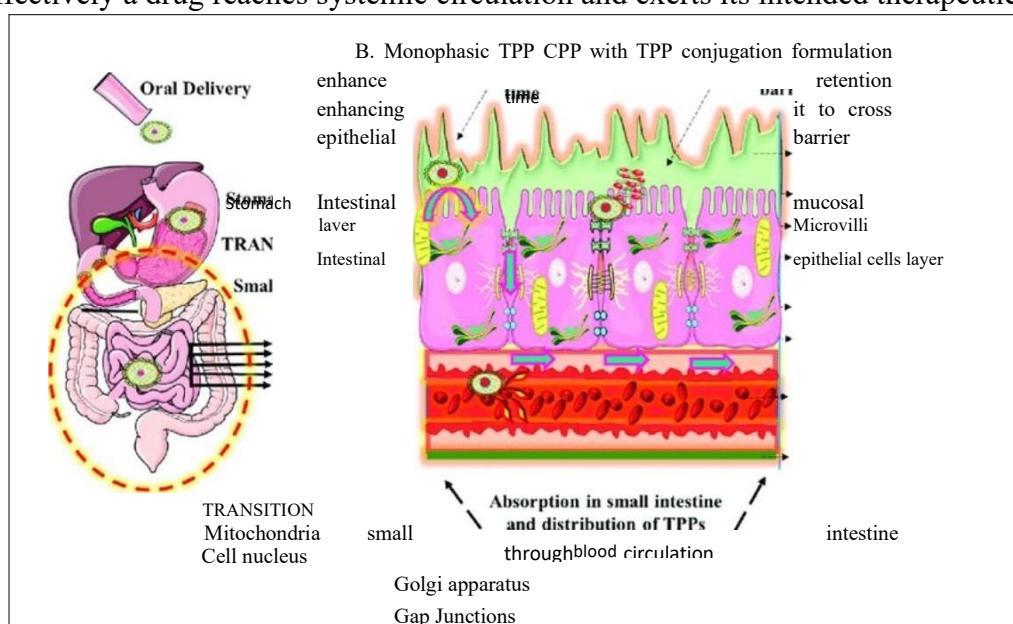
Functions of the oral cavity:

- It serves as the entrance for water and food consumption.
- It involves chewing and mixing of food components.
- It aids in lubricating food and beverages and forming a bolus.

1.4 Key Aspects of Oral Drug Delivery

a. Mechanism of Drug Absorption

Oral drug delivery is a complex process involving multiple physiological and biochemical interactions that determine the drug's bioavailability and therapeutic efficacy. The pathway of drug absorption consists of several key stages, including drug release, gastrointestinal transit, absorption, and first-pass metabolism. Each of these steps plays a critical role in influencing how effectively a drug reaches systemic circulation and exerts its intended therapeutic effects.



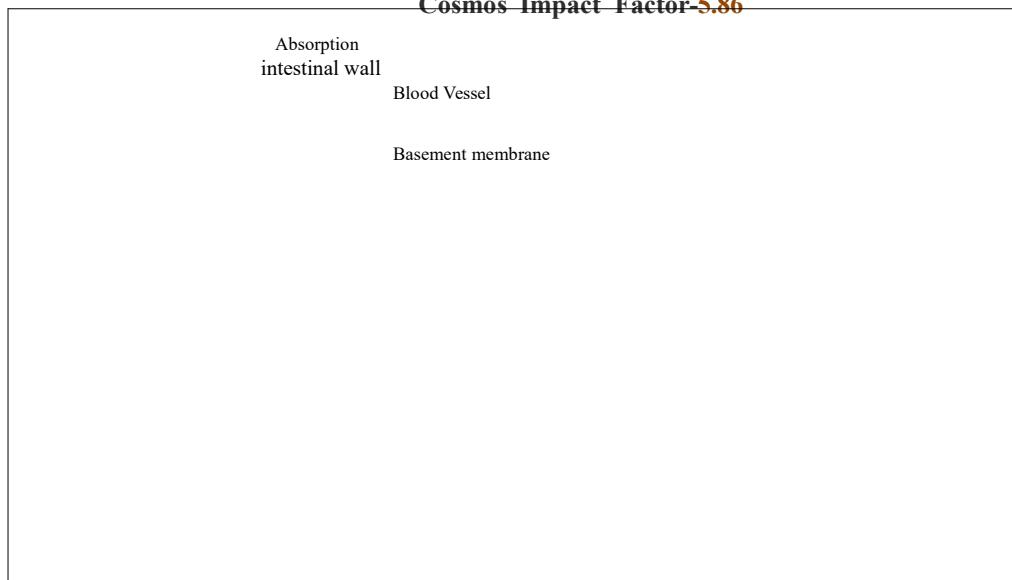


Figure 5: Oral delivery of drugs and their absorption into the bloodstream. (A): Path of orally administered therapeutic peptide and proteins (TPP) through the digestive system; (B): key components and pathways for absorption through the intestinal epithelial barrier.

b. Drug Release

The first step in oral drug absorption is the release of the active pharmaceutical ingredient (API) from its dosage form. When a drug is ingested in the form of a tablet, capsule, or medicated jelly, it undergoes disintegration and dissolution in the gastrointestinal (GI) fluids.

c. Gastrointestinal Transit

After dissolution, the drug must travel through different sections of the GI tract, including the stomach, small intestine, and large intestine. The stomach serves as a temporary reservoir where the drug remains for varying durations, depending on factors such as gastric emptying time, food intake, and pH levels.

d. Absorption

Drug absorption primarily occurs in the small intestine through various mechanisms, including passive diffusion, facilitated diffusion, active transport, and endocytosis. The majority of drugs are absorbed via passive diffusion, where they move from an area of high concentration (intestinal lumen) to an area of lower concentration (bloodstream) without requiring energy.



e. First-Pass Metabolism

Before reaching systemic circulation, orally administered drugs undergo a metabolic process known as the first-pass effect. Once absorbed in the intestine, the drug is transported via the portal vein to the liver, where it undergoes enzymatic metabolism.

1.5 Types of Oral Drug Delivery Systems34—40

Oral drug delivery systems encompass a wide range of formulations designed to optimize drug absorption, efficacy, and patient compliance. These systems are developed based on the pharmacokinetic and therapeutic requirements of specific drugs and patient populations. Below are the key types of oral drug delivery systems, each with unique characteristics and advantages.

1. Immediate-Release Tablets and Capsules

Immediate-release (IR) formulations are designed to disintegrate and dissolve rapidly after ingestion, allowing for quick absorption of the active pharmaceutical ingredient (API). These formulations are commonly used for drugs that require a rapid onset of action, such as pain relievers, antipyretics, and certain antibiotics.

2. Extended-Release Formulations

Extended-release (ER) formulations are designed to release the drug gradually over an extended period, maintaining steady therapeutic levels in the bloodstream. This controlled drug release reduces the frequency of dosing, improving patient adherence and minimizing fluctuations in drug concentration, which can lead to side effects.

3. Delayed-Release Formulations

Delayed-release (DR) formulations are engineered to release the drug at a specific time after ingestion, often in response to changes in pH along the gastrointestinal (GI) tract. A common example is enteric-coated tablets, which are designed to bypass the acidic environment of the stomach and dissolve in the more neutral or alkaline conditions of the small intestine.

4. Orally Disintegrating Tablets (ODTs)

Orally disintegrating tablets (ODTs) are designed to dissolve rapidly in the mouth without the need for water, making them highly beneficial for patients with dysphagia (difficulty swallowing) and those who require on-the-go administration.

5. Chewable Tablets

Chewable tablets are solid dosage forms that are intended to be chewed before swallowing. They are particularly useful for paediatric and geriatric populations who may have difficulty



swallowing whole tablets. Chewable formulations are often flavoured to enhance palatability and encourage compliance, making them ideal for vitamins, antacids, and some pain relievers.

6. Oral Liquids

Oral liquid formulations include solutions, suspensions, syrups, and elixirs, providing an alternative to solid dosage forms, particularly for paediatric, elderly, and critically ill patients. Solutions contain drugs that are fully dissolved in a solvent, allowing for uniform dosing and rapid absorption.

7. Medicated Jellies

Medicated jellies are a novel semi-solid dosage form designed to improve patient compliance, particularly for individuals who struggle with swallowing traditional solid or liquid formulations. Additionally, natural gums used in these formulations contribute to the stability, viscosity, and mucoadhesive properties of the jelly,

1.6 Technological Advancements in Oral Drug Delivery

The field of oral drug delivery has witnessed significant technological advancements aimed at improving drug solubility, stability, bioavailability, and targeted delivery. These innovations address the limitations of conventional oral dosage forms and enhance therapeutic outcomes by optimizing drug release and absorption. Some of the key advancements include nanotechnology, microencapsulation, mucoadhesive systems, and smart polymers.

1. Nanotechnology in Oral Drug Delivery

Nanotechnology has revolutionized oral drug delivery by incorporating nanoparticles to improve drug solubility, stability, and bioavailability. Many drugs, particularly those belonging to the Biopharmaceutics Classification System (BCS) Class II and IV, exhibit poor aqueous solubility, which limits their absorption in the gastrointestinal (GI) tract.

2. Microencapsulation for Controlled and Targeted Release

Microencapsulation involves enclosing drug molecules within microscopic carriers, such as polymeric microspheres, liposomes, or lipid-based carriers. This technology enhances drug stability by protecting the active pharmaceutical ingredient (API) from environmental factors, such as pH changes and enzymatic degradation.

3. Mucoadhesive Drug Delivery Systems

Mucoadhesive drug delivery systems utilize bio adhesive polymers that adhere to the mucosal lining of the GI tract, enhancing drug retention time and improving absorption. These systems



take advantage of the natural mucus layer present in the stomach and intestines, allowing for prolonged contact between the drug and the absorption site.

4. Smart Polymers for Controlled Drug Release

Smart polymers are an emerging innovation in oral drug delivery that respond to specific environmental triggers, such as pH, temperature, or enzymes, to modulate drug release. These polymers enable precise and site-specific drug delivery by releasing the drug only when the



1.7 Introduction to Medicated Jelly:

Medicated jelly is a semi-solid, gel-like preparation that incorporates medicinal agents intended for therapeutic effects when applied to the skin, mucous membranes, or even ingested orally. The jelly formulation allows for easy administration, patient compliance, and targeted delivery of drugs. Medicated jellies are typically used for various purposes, such as topical treatments (e.g., antiseptic jellies),

g).

a. History of Medicated Jelly:

Medicated jellies trace their origins back to traditional preparations that were used to soothe and treat skin and mucous membranes. Historically, ointments, gels, and creams have been used for medicinal purposes, but the development of jelly-like formulations gained popularity in the 20th century, especially in oral and topical drug delivery systems.

- Early use of topical jellies: Initially, jelly formulations were developed for topical applications, such as lubricating jellies, antiseptic jellies, and aesthetic jellies, which were easy to apply and provided immediate relief on contact.

b. Types of Medicated Jellies

Medicated jellies are semi-solid formulations containing active pharmaceutical ingredients (APIs) dispersed within a gel-like matrix. They are designed for various applications, offering localized or systemic drug delivery through different routes of administration.

1. Topical Medicated Jelly

Topical medicated jellies are applied to the skin or mucous membranes for localized therapeutic effects. They provide rapid action and are commonly used for anaesthesia, antisepsis, and lubrication.

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2. Oral Medicated Jelly

Oral medicated jellies are designed for systemic drug delivery, offering an alternative to traditional oral dosage forms such as tablets and capsules. These formulations improve drug palatability and ease of administration, particularly for pediatric and geriatric patients.

- █ Systemic Drug Delivery: These jellies contain APIs that are absorbed through the gastrointestinal (GI) tract to exert systemic effects. Examples include acetaminophen jellies for fever and ibuprofen jellies for pain relief.



- **Pediatric and Geriatric Use:** Medicated jellies are particularly beneficial for children and elderly patients who have difficulty swallowing solid dosage forms. The jelly matrix enhances patient compliance by offering a pleasant taste and easy ingestion.
- **Nutraceutical Jellies:** These formulations deliver dietary supplements, vitamins, and minerals in a convenient jelly form. They provide a palatable and user-friendly alternative to traditional capsules and tablets.

3. Vaginal Medicated Jelly

Vaginal medicated jellies are used for contraceptive and therapeutic purposes, providing localized drug delivery for conditions affecting the female reproductive system.

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4. Rectal Medicated Jelly

Rectal medicated jellies are used for both local and systemic drug delivery. They provide an effective alternative for patients who cannot take oral medications due to nausea, vomiting, or swallowing difficulties.

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5. Nasal Medicated Jelly

Nasal medicated jellies provide localized drug delivery to the nasal mucosa, offering fast relief for respiratory conditions and potential antiviral protection.

- **Decongestant Jellies:** These formulations contain drugs like oxymetazoline, which reduce nasal congestion by constricting blood vessels in the nasal passages. They offer quick relief from conditions like the common cold and sinusitis.

Advantages of Medicated Jellies

- Medicated jellies offer an easy-to-swallow alternative, making them highly beneficial for children, elderly patients, and those with dysphagia.
- They ensure rapid drug release and absorption, leading to a faster onset of action compared to solid dosage forms.

Disadvantages of Medicated Jellies

- Medicated jellies have a shorter shelf life due to their high moisture content, making them prone to microbial contamination.
- Application can sometimes be messy, particularly in topical and vaginal formulations, leading to inconvenience and possible wastage.

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SUMMARY

The present study focuses on the design, development, and characterization of medicated jelly formulations using different natural gums as gelling agents. The aim was to develop a patient-friendly, palatable, and effective oral dosage form suitable for pediatric and geriatric patients who experience difficulty swallowing conventional tablets and capsules.

Various natural gums such as guar gum, xanthan gum, acacia gum, and tragacanth gum were selected for jelly preparation because of their biocompatibility, biodegradability, non-toxicity, and ability to form stable gels. The drug was incorporated into the jelly matrix through a controlled heating and mixing process, followed by cooling to form a semisolid product with uniform consistency.

The prepared medicated jellies were evaluated for their physicochemical properties including:

Appearance and texture

pH

Viscosity

Spreadability

Drug content uniformity

Syneresis (liquid separation)

In-vitro drug release

Stability studies

Among the formulations, those prepared with xanthan gum and guar gum exhibited optimal

CONCLUSION

The study successfully demonstrated that natural gums can be effectively utilized for the formulation of medicated jellies as novel oral drug delivery systems.

Key conclusions include:

1. Natural gums such as xanthan and guar gum serve as excellent gelling agents due to their biodegradability, non-toxicity, and good gel-forming ability.
2. The prepared medicated jellies exhibited desirable physicochemical characteristics, good patient acceptability, and uniform drug distribution.
3. Drug release behavior was influenced by the type and concentration of gum, with xanthan gum-based jellies providing the best controlled release profile.



4. Stability studies revealed that the optimized formulation remained physically and chemically stable under storage conditions.

5. This dosage form offers a promising alternative to conventional solid and liquid oral dosage forms, particularly for pediatric, geriatric, and dysphagic patient

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