

ORAL MEDICATED JELLY: AN OVERVIEW

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ABSTRACT

Oral medicated jellies (OMJs) are a new way to deliver drugs, making it easier for patients, especially children and the elderly, to take their medication. These jellies are made from natural and synthetic materials like pectin, gelatin, and cellulose derivatives, which help to mask the bitter taste of drugs. OMJs dissolve quickly in the mouth, allowing the medicine to be absorbed rapidly through the oral mucosa. OMJs offer several benefits: they taste good, are easy to take without water, and provide a quick onset of action. They are ideal for medications like pain relievers, allergy treatments, diabetes medications, and drugs for gastrointestinal issues. However, OMJs also have challenges, including sensitivity to moisture, the need for special packaging, and higher production costs. To ensure quality, OMJs are evaluated for their physical appearance, viscosity, pH, content uniformity, stability, and microbial contamination. This new form of medication helps improve patient compliance and offers a convenient alternative to traditional tablets and capsules. OMJs represent a significant advancement in making drug administration easier and more effective.

KEY WORDS: medicated jelly, oral medicated jelly, jelly, gelling agent, oral route, heating and congealing, oral jelly. Oral medicated jellies, patients compliance, paediatric drug delivery, taste masking, formulation strategies.

1. INTRODUCTION

Jelly is a term used to describe transparent or translucent, non-greasy, semi-solid products designed for both external and internal use.⁽¹⁾ Jellies are created from natural substances such as tragacanth, pectin, alginates, and boro glycerine, as well as synthetic versions of these natural substances like cellulose, sodium carboxymethyl cellulose, methylcellulose, and sodium carboxymethylcellulose.⁽²⁾

Currently, jelly candies are popular among children who like chewing them. They can also be used as an alternative way to administer medications instead of pills or liquid forms. Hence, there is a potential for additional patient-friendly delivery methods, particularly through oral administration. In the field of Paediatric patients, designing a novel drug delivery system is significantly important when considering the ease of administration and the appeal of dosage forms.^(3,4)

ORAL MEDICATED JELLY

Oral medicinal jellies are solid medications that can be dissolved in the mouth or throat for both local or systemic effects and enjoyable taste. While oral medicated jellies offer several benefits compared to pharmaceutical formulations, they also come with notable disadvantages. Medicinal jellies for oral use are a practical choice for delivering medication through different areas of the mouth including buccal, labial, gingival, and sublingual routes. They might also contain a variety of medications for addressing chronic health issues. Oral medicated jellies are available in different flavours such as mango, pineapple, strawberry, and chocolate, and they are infused with medications for pain relief, erectile dysfunction, arthritis, high blood pressure, and throat discomfort.⁽⁷⁾

Oral medicated gels are a form of unit dosage that quickly dissolve and are absorbed through the oral mucosa, leading to fast onset of the drug's effects. Most pharmaceutical substances are characterized by having a bitter flavour, which is masked by using sweeteners such as sugar and different flavours. In this form of oral medication, the jelly is chewed without water, releasing the active ingredients which are then mixed with saliva, swallowed, and enter the gastrointestinal tract. While in storage, the jelly stays solid for stability, but becomes a very thick liquid when used. Jellies are made by raising the level of polymers like gelatin, guar gum, gellan gum, and pectin that are frequently used. By choosing the right gelling agent in the correct concentration, the medication is slowly released from the jelly foundation. The main objective is to develop a water-loving gel formulation for oral administration.^(8,9) The medicated gel is mainly used for both oral and systemic conditions. The paediatric patients benefit from this medication because it resembles candy. The attractive colour, sweet taste, and various shapes and sizes of the jelly make it easy for them to consume and enjoy chewing it. The group of patients that are considered as paediatrics includes newborns, kids from 2 to 11 years old, and teenagers from 12 to 16/18 years old.⁽⁵⁾

CATEGORIZATION OF JELLIES^(4,5)

Jellies are able to be categorized as

Medicated jelly: They are mainly used on mucous membranes and skin and possess spermicidal, local anaesthetic, and antiseptic properties. These gels contain enough water that, when evaporated, creates a cooling effect in the area, while the leftover film offers protection.

Lubricating jelly: These varieties of gels are utilized to lubricate diagnostic tools like medical gloves, urological scopes, urinary catheters, and more.

Miscellaneous jelly: These are created for multiple purposes like electrocardiography, patch testing, and more.

IDEAL CHARACTERISTICS OF OMJS ^(10,11,12)

- It needs to break down rapidly in the mouth shortly after it is taken.
- It must be suitable and feel comfortable in the mouth.
- It must be suitable for masking taste.
- It must not be delicate or damaged during shipping.
- Economic considerations should be taken into account when determining production and packaging costs.
- It must remain stable when stored.
- Bitter-tasting drugs require the use of efficient taste masking technologies.
- Do not leave any residue in the mouth after being taken orally.
- Demonstrate minimal responsiveness to changed environmental factors like humidity and temperature.
- Enable high drug concentration.
- Capable of being modified and easily used with standard processing and packaging machinery at a low cost.
- The characteristics of the drug and excipient must not impact the orally dissolving tablet.
- In essence, bitter-tasting drugs should be masked with effective technologies in a moderate manner.
- Easily adaptable and suitable for standard processing and packaging equipment at a surprisingly low cost, despite common misconceptions.
- Expensive manufacturing procedure.

ADVANTAGES: ^(5,16)

- OMJ is appropriate for patients who struggle with swallowing pills or capsules, such as seniors, stroke victims, immobilized individuals, those with throat problems, and patients who refuse to swallow like kids, elderly individuals, and people with mental health disorders, resulting in improved compliance.
- Ideal for use while traveling in locations with limited access to water.
- Traditional manufacturing machinery.
- Economical.
- Decent chemical stability like traditional solid oral dosage form.
- Enable high drug capacity.
- Enables fast administration of drugs from medication formats.
- Quick start of effect.
- It is easy to use – can be used anywhere, anytime, without the need for water.
- Simple production using existing equipment.
- Enables high capacity for drug incorporation
- All medicated jellies possess a positive mouthfeel characteristic.
- The pleasant texture of jellies can alter how medicine is perceived.

DISADVANTAGES: ^(11,13,14,15)

- Because it is a liquid formulation, it needs appropriate packaging to ensure the safety and stability of the drugs.
- If not stated correctly, it can result in a bad aftertaste in the mouth.
- Expensive manufacturing process.
- Issues with how much of a substance can be absorbed and used by the body.
- Absence of physical durability in typical blister packaging.
- Oral jellies have a tendency to absorb moisture, therefore they should be stored in a dry location.
- Sterilizing oral jellies is difficult due to their tendency to melt easily at elevated temperatures.

LIMITATIONS OF ORAL MEDICATED JELLIES

- Expensive manufacturing process
- Special packaging is needed for oral medicated jellies to ensure the stability and safety of the highly stable product.

- It is also specifically demonstrating the delicate quality of effervescent granules, which is very important.
- Restricted capacity to include increased levels of potent medication.
- ODT has a tendency to absorb moisture so it should be stored in a dry environment.
- Absence of physical strength in traditional blister packaging.

THE IMPORTANCE OF CREATING ORAL MEDICATED JELLIES

The demand for non-invasive delivery systems persists due to patients' unwillingness to accept and follow current methods of delivery, as well as the expensive nature of disease management and the restricted market for drug companies and drug uses.

Factors affecting the patient:

Oral disintegrating formulations are perfect for people who struggle to swallow standard tablets and capsules with water for different reasons. The following items are as follows

- Children and elderly individuals who struggle with swallowing or chewing typically have trouble taking solid medication forms.
- Patients who decline to ingest solid medication due to fear of choking.
- Elderly individuals who are very old and may have difficulty swallowing a daily antidepressant dose.
- An eight-year-old, who has allergies, is looking for a more convenient method to consume antihistamine rather than syrup.
- A middle-aged woman undergoing radiation treatment for breast cancer may feel too unwell to ingest her H2-blocker medication.
- In a clinical environment, a schizophrenic individual might attempt to conceal a regular pill in their mouth to skip their daily intake of a different type of antipsychotic medication.⁽¹⁷⁾

DIFFICULTIES IN DEVELOPING MEDICATED JELLIES FOR ORAL ADMINISTRATION ⁽³⁴⁾

Palatability

Improving the taste of bitter medications and masking their flavour discreetly can positively influence how well patients stick to their treatment.

Absorption of moisture / Sensitivity to moisture

Certain oral jelly formulations are somewhat hygroscopic and require protection from moisture, thus necessitating specialized packaging.

Dose /Amount of drug

If the drug is bitter, extra ingredients are needed to cover the taste, causing the dosage form to become larger.⁽³³⁾

Aqueous solubility

Different ingredients in jelly give structure and firmness to water-soluble medications, creating eutectic mixtures that are typically quite important.

Size of jelly

The ease of consuming a jelly is determined by its size. Reports suggest that the most swallowable jelly size is 78mm, with the most manageable size being slightly above 8mm. Hence, achieving a jelly size that is convenient to take and manage is a challenging task.

The Drug Characteristic

The ultimate qualities of jelly are determined by the solubility, crystal shape, particle size, and bulk density of a drug, as originally thought.

Mouth feels

The oral mucin hydrogel particles must remain intact in the mouth and not break apart into bigger pieces. The particles produced following the breakdown of the OMJ need to be minimized in size. OMJ should not leave behind any remnants or only a minimal amount in the mouth after being taken orally. Moreover, adding flavours and cooling agents like menthol amplifies the sensation in the mouth.

Sensitivity towards environmental factors

Oral medicated jellies typically have a minimal sensitivity to environmental factors like humidity and temperature because the ingredients are designed to dissolve with very little water.

KEY INGREDIENTS USED IN FORMULATION OF JELLY:

- **GELLING AGENT USE IN FORMULATION:**

Typically, hydrocolloids are commonly used for creating gel-like matrices. Some instances of them include:

Sodium Alginate: Sodium Alginate is used in various oral and topical pharmaceutical formulations. Frequently used in topical products to increase viscosity and stabilize different pastes, creams, and gels. It is also used in cosmetics and food products.

Pectin: Pectin has been used as an adsorbent and bulking agent, as well as being evaluated in gel formulations for extended oral drug release.

Tragacanth: Tragacanth gum is used in many pharmaceutical formulas as a substance for suspending and emulsifying. It is mixed into creams, gels, and emulsions.

Gelatin: Gelatin is commonly used in different medicinal formulations, such as acting as a biodegradable material in an implantable drug delivery system. Gelatin is frequently used in both food products and photographic emulsions.

Xanthan Gum: Xanthan gum is frequently used in topical, pharmaceutical, cosmetic, and food products for its functions as a suspending agent, stabilizing agent, thickening agent, and emulsifying agent. In the food industry, it is used as a hydrocolloid, while in beauty products, it serves as a thickening agent in shampoo.

Cellulose Derivatives: Types of cellulose derivatives consist of methyl cellulose and sodium carboxymethyl cellulose.

- **PRESERVATIVES USE IN FORMULATION:**

Because jellies are a liquid preparation, they may provide a favourable environment for microbial growth. Although cellulose derivatives and clay are able to resist microbial attack. Preservation is necessary to avoid potential clashes with the thickening agents that may affect the shelf life of the product. Here are a few instances of them.

- Methyl Paraben
- Propyl Paraben
- Benzoic Acid
- Benzalkonium Chloride
- Chlorhexidine acetate ⁽¹⁸⁾

- **UTILIZATION OF STABILIZERS IN FORMULATING.**

Certain stabilizing additives are included in formulations to prevent the jellies from drying out. Here are several instances of them:

- Propylene glycol
- Sorbitol
- EDTA, such as chelating agent, is included to avoid the reactivity of bases and medicines with heavy metals. ⁽³⁰⁾

- **SOLUBILIZERS:**

Solubilizer excipients, like surfactants, are added to pharmaceutical formulas to enhance the solubility of drugs with low solubility, thereby increasing the bioavailability of the active pharmaceutical ingredient (API).

Example: Cremophore RH40, Polyethylene glycol 400, Propanediol, Sorbitol. ⁽¹⁹⁾

- **SWEETENERS**

Sweetening are substances added to formulations with the purpose of covering up bitterness and improving patient adherence.

Examples; sucrose, mannitol, sorbitol, saccharin, and Sucralose are all types of sweeteners. ⁽²⁰⁾

- **FLAVOURING AGENTS:**

Flavouring agents are used in pharmaceutical products such as oral syrup, oral suspension, elixirs, emulsion, lozenges, chewable tablets, effervescent tablets, dispersible tablets, and jellies to improve taste and give a pleasant flavour. They are utilized to increase patient compliance or improve the appeal of medication presentations.

Examples: Strawberry, Vanilla, and Orange are all flavours commonly used in desserts. ^(37,38)

SOME MEDICATIONS COMMONLY USED IN ORAL JELLY

PAINKILLERS	Ibuprofen, Paracetamol, and Diclofenac
ANTI-PARASITIC MEDICATIONS	Albendazole and Mebendazole
EMESIS INHIBITORS	Domperidone, Ondansetron
HISTAMINE INHIBITORS	Cetirizine and Cinnarizine
LEUKOTRIENE BLOCKER	Zafirlukast, Montelukast

2. METHOD OF PREPARATION ^(23,24)

- Each ingredient will be precisely weighed.
- Jellies were made by heating up and solidifying process.
- The appropriate quantity of sugar syrup is made ready.
- The thickening agents are stirred continuously into the sugar syrup and heated until fully dissolved.
- After the gelling agents have fully dissolved, the stabilizers and solubilizers are added.
- Preservatives are included to the mixture with continuous stirring once it is completely dissolved.
- After that, the drug was mixed in with constant stirring, followed by the addition of colour and flavour, allowing the jellies to settle and mix thoroughly.
- The ultimate mass was modified using distilled water.
- The entire solution was poured into moulds and left to cool and settle without any disturbance, ensuring the moulds were properly covered to prevent exposure to the outside environment.

EVALUATION PARAMETERS FOR ORAL JELLY

Physical appearance:

The clarity, texture, and consistency of the medicated jelly were examined for its outward appearance.

Stickiness and grittiness:

The texture of the medicated jelly was evaluated by visually examining it after cupping it between two fingers. ⁽²⁵⁾

Spreadability:

Measuring Spreadability involved sandwiching the jelly sample between two glass slides and pressing it to a consistent thickness with a 1000gm weight. The amount of time it took to separate the two sliding movements on the bottom slide was recorded as Spreadability.

$$S=m*L/T$$

Were,

m= weight tide to slide

L= length moved on glass slide

T= time taken ⁽²⁸⁾

Viscosity:

The Brookfield viscometer is utilized to gauge the viscosity of a new sample on each occasion.

Viscosity in centipoise = Dial reading × factor ⁽²⁷⁾

pH level:

The acidity level of the entire jelly was measured with a digital pH meter. The weight formulation of 0.5gm was dispersed in 50ml of distilled water and the pH was recorded. ⁽²⁶⁾

Consistency of content:

This assessment is carried out for all types of dosage forms to ensure the consistency of drug substance content. The process involves crushing and combining the jelly before extracting the mixture using appropriate means, with the quantity of the drug being measured through analytical techniques. ⁽²¹⁾

Stability

Stability evaluations are conducted according to ICH guidelines, which include keeping the jelly at room temperature for 90 days to monitor any alterations in its physical appearance.

Syneresis

The liquid is separated by the gel contraction, and the jelly preparation is assessed at room temperature after 24 hours.

Microbial studies

These researches serve as a crucial factor in identifying the microbial composition of jellies, which are susceptible to microbial growth because of the water content. The jellies were assessed for growing harmful microorganisms on a specific substance for E. coli, S. aureus, and P. aeruginosa. ⁽²²⁾

Invitro Taste analysis

A 5ml pH simulated saliva was utilized to evaluate the taste ability of the jelly that was prepared. One jelly is placed into a 50ml beaker along with 5ml of solution from each batch, and then filtered for a duration of 60 to 120 seconds. UV was used to analyze drug content in the filtrates.

Dissolution Studies:

The dissolution study in vitro was performed with a USP type 2 paddle device rotating at 50 rotations per minute. The amount of solvent used was 900ml at a temperature of 37°C with a precision of ± 0.5 ⁽³⁷⁾

3. CONCLUSION

Oral medicated jellies (OMJs) are a patient-friendly drug delivery system that improves medication compliance, particularly for paediatric and geriatric patients. They use natural and synthetic polymers to mask the taste of drugs, providing a more pleasant experience for patients. Despite challenges like moisture sensitivity and higher manufacturing costs, the benefits of OMJs outweigh these drawbacks. They offer a promising alternative to traditional oral dosage forms, addressing issues related to patient compliance and providing an effective method for drug administration.

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