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FORMULATION AND EVALUATION OF ORAL MEDICATED JELLY- AN REVIEW

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ABSTRACT

Jellies are semisolid dosage forms they are transparent and non-greasy can be used internally. Today, jelly candies are easily accepted by all patients due to the use of flavouring fruit juices andextracts like mango, lemon, orange and strawberry can make them to like the taste and chewing ability. Compared to conventional dosage forms, the patient-compliance form, especially in paediatrics and geriatrics, is advantageous. The unique feature of oral jelly is that it can be easily chewed, dissolves in saliva, and doesn't require water. Overall, oral medications have the potentialto revolutionize the way medications are administered. The review's objective is to provide a concise explanation of its advantages, disadvantages, and method for preparation. The oral medicated jelly is composed of gelling agent, preservatives, and flavouring agents. As a result, patients are more likely to be drawn to and accept it, contributing to poor patient compliance.

KEYWORDS: Semi-solid, Oral medicated jellies, Conventional, Patient compliance.

INTRODUCTION

"Jelly is defined as transparent or translucent non-greasy, semisolid preparation which is used for external as well as internal applications"

Traditional medications can often have a bitter or unpleasant taste, but oral jellies are usually flavored, making the medication more enjoyable to take. This is particularly helpful in

pediatric and geriatric care, where patient compliance can be a challenge. Flavor masking in these jellies helps ensure that patients complete their prescribed course of treatment without a version.[1] Medicated oral jelly is a unique pharmaceutical formulation used to deliver medications in a moreconvenient, palatable, and easy-to-administer format they are generally form administered in the oral cavity, to dissolve in mouth or pharynx.[2] It is typically a semi-solid form of medication, often flavored, making it more appealing for patients, especially those who may have difficultyswallowing tablets or capsules, such as children or the elderly and also especially those who haveno access to water.[3]

From a manufacturing stand point, oral jellies can be prepared in precise doses, ensuring consistent drug delivery. They can also be designed to release drugs in a controlled manner, ensuring a sustained therapeutic effect over time. This is particularly useful for medications that require consistent blood levels, such as those used for managing chronic conditions like hypertension or diabetes. In some cases, oral jellies can also be used for buccal absorption, where the medication is absorbed through the lining of the mouth, bypassing the digestive system and providing faster therapeutic action.[4]

Medicated oral jellies are often packed in sachets or tubes, making them portable and easy to use on the go. The packaging also enhances the stability of the product, protecting it from environmental factors such as moisture or air, which could degrade the active ingredient.

At present, medicated oral jellies are the only quick-dissolving dosage form recognized by FDA and listed in approved drug products with therapeutic equivalence evaluations. And also the 17th edition of the Japanese Pharmacopoeia defines jellies as non-flowable gelatinous compositions ofspecific size and shape, intended for oral administration.

TYPES OF JELLIES

Jellies are classified into three type, based on the ingredients, texture and intended use. Its classification are explained below in figure 1.

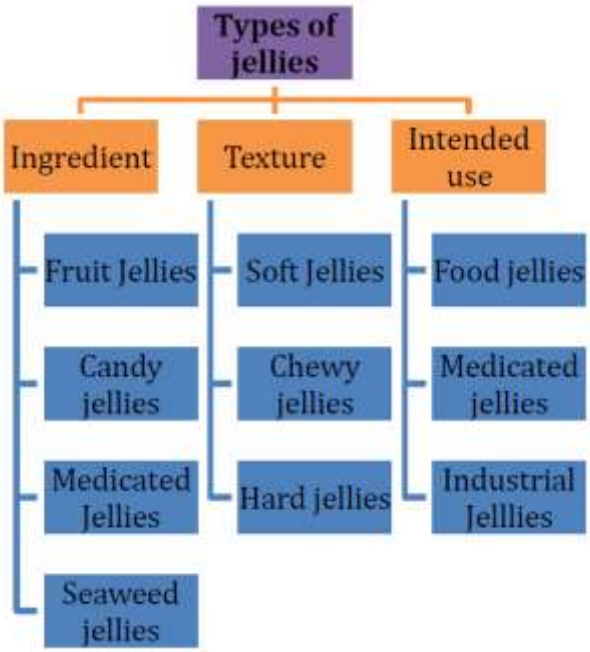

Fig. 1: Types of Jellies.

BASED ON INGREDIENTS

Fruit Jellies

These are the most common type, made from fruit juice, sugar, and pectin. They come in various flavors like strawberry, raspberry, apple, and grape[5] as shown in figure 2.

Fig. 2: Fruit Jellies.

Candy Jellies

These are typically made from sugar, corn syrup, gelatin, artificial flavors and colors. They oftenhave a chewy texture and are available in a wide range of shapes and flavors[6] as shown in figure3.

Fig. 3: Candy Jellies.

Medicated Jellies

These contain active ingredients for therapeutic purposes, such as pain relief or oral health. They may be made from gelatin, pectin, or other gelling agents. Figure 4 is an example of an medicatedjellies prepared by *Raja Manali M and Dhiren P.Shah, 2016.*

Fig. 4: Medicated Jellies.

https://wjpr.s3.ap-south-1.amazonaws.com/article_issue/1623046910.pdf

Seaweed Jellies

Seaweed jellies as shown in figure 5 are made from seaweed extract, such as agar or carrageenan.They are often used in Asian cuisine and have a unique texture and flavor.[7]

Fig. 5: Seaweed Jellies.

BASED ON TEXTURE

Soft Jellies

These jellies have a tender and delicate texture, often with a smooth surface as shown in figure 6.

Fig. 6 Soft Jellies.

Chewy Jellies

As shown in figure 7 these are firmer and require more effort to chew, with a gummy or rubberytexture.[8]

Fig. 7: Chewy Jellies.

Hard Jellies

These are the most solid type of jelly as shown in figure 8 are often with a brittle texture.

Fig. 8: Hardy Jellies.

BASED ON INTENDED USE

Food Jellies

These are typically consumed as a snack or dessert as shown in figure 9.

Fig. 9: Food Jellies.

Medicinal Jellies

These are used for therapeutic purposes, such as treating sore throats, hypertension or providing relief from pain. Below figure 10 is an example of an medicated jellies prepared by Ahmed HassenElshafeey and Rania Moataz El-Dahmy (2022) which is used for the treatment of hypertension.

Fig. 10: Medicated Jellies.

https://www.sciencedirect.com/science/article/pii/S1319016422001967

Industrial Jellies

These are used in various industries, such as food processing, cosmetics, and pharmaceuticals.[9] Few example are shown in figure 11.

Fig. 11: Industrial Jellies.

UNIQUE PROPERTIES OF MEDICATED ORAL JELLIES

Medicated oral jellies offer various unique properties in drug delivery. One of the key benefits is palatability, as these jellies are formulated with flavoring agents that provide a pleasant taste, making them especially appealing to children and the elderly who may have difficulty swallowing traditional medications. Additionally, the ease of administration is a major property; oral jellies are easy to swallow and do not require water, making them a convenient option for patients with swallowing difficulties or those unable to consume liquids. This combination of good taste and ease of use contributes to improved patient compliance, which can lead to better therapeutic outcomes. Furthermore, depending on their formulation, oral jellies can be designed for controlled release, allowing for sustained drug delivery and reducing the need for frequent dosing. Lastly, thejelly matrix provides protection of drug integrity, safeguarding sensitive drugs from degradation and ensuring their stability and efficacy throughout the treatment process.[10]

BENEFITS OF ORAL MEDICATED JELLIES

Enhanced Bioavailability: The unique properties of medicated oral jellies can improve the bioavailability of certain drugs, leading to increased therapeutic efficacy.

Reduced Side Effects: By providing controlled release, medicated oral jellies can help to reducethe occurrence of side effects associated with rapid drug absorption.

Improved Patient Quality of Life: Medicated oral jellies can enhance patient quality of life by reducing the inconvenience and discomfort associated with traditional drug delivery methods.

Potential for New Therapeutic Applications: The versatility of medicated oral jellies offers opportunities for the development of new drug delivery systems for a wide range of therapeutic indications.[11]

APPLICATION OF ORAL MEDICATED JELLIES

Medicated oral jellies have the potential to be used for a variety of therapeutic applications, including.

Pediatrics: For children who struggle with swallowing tablets or capsules.

Geriatrics: For elderly patients with swallowing difficulties or impaired cognitive function.

Oral Health: For treating mouth ulcers, gingivitis, or periodontal disease.

Systemic Drug Delivery: For controlled release of certain medications, such as antihypertensives, anti-diabetic agents, or anti-inflammatory drugs.

Targeted Drug Delivery: For delivering drugs to specific sites within the gastrointestinal tract, such as the small intestine or colon.[12]

CHALLENGES AND LIMITATION OF MEDICATED ORAL JELLIES

Despite their numerous advantages, medicated oral jellies also face certain challenges and limitations.

Formulation Complexity: Developing stable and effective medicated oral jellies can be complex, requiring careful consideration of factors such as drug solubility, gelling agent properties, and compatibility with other excipients.

Manufacturing Challenges: The production of medicated oral jellies may involve specializedmanufacturing techniques and equipment, which can increase production costs.

Regulatory Hurdles: Obtaining regulatory approval for new medicated oral jelly formulationscan be time-consuming and expensive.

Limited Shelf Life: The stability of medicated oral jellies may be limited, especially if theycontain sensitive drugs or are exposed to unfavorable storage conditions.[13]

ADVANTAGES OF MEDICATED JELLIES

1. Convenient administration: They can be easily taken anywhere, anytime, without requiringwater.
2. Controlled drug delivery: The therapeutic effect can be halted by spitting out the jelly before it'sfully ingested.
3. Ideal for dysphagia patients: Medicated jellies reduce the risk of aspiration, making them asuitable option for patients with swallowing difficulties.
4. Enhanced patient compliance: The pleasant mouthfeel of jellies can alter patients' perceptionsof medication, making it more acceptable.
5. Fast-acting relief: Medicated jellies provide rapid onset of action.[14]

6. Flexible treatment: Treatment can be terminated at any time, if needed.

DISADVANTAGES OF MEDICATED JELLIES

The aqueous nature of medicated jellies necessitates specialized packaging to preserve drug stability across diverse environmental conditions. Moreover, improper formulation can compromise palatability, yielding an unpleasant taste.

IDEAL CHARACTERISTICS OF ORAL MEDICATED JELLIES

Be able to mask your taste. Drugs with a bitter taste should use efficient taste masking technology. After oral administration, leave little to no residue in the mouth. Show minimal response to temperature and humidity changes in the environment. Permit a high level of drug loading. Flexible and compatible with standard processing and packaging machinery at a reasonable cost. The properties of the medication and excipient shouldn't have an impact on the oral disintegrating.[15]

HISTORY OF JELLIES

The origins of oral medicated jellies date back to ancient times, with early civilizations utilizing them for medicinal purposes.

In the beginning of Ancient Greece and Rome (500 BCE - 500 CE): Medicinal jellies were made from honey, fruit, and herbs to treat various ailments.

Later during Medieval Europe (500 - 1500 CE): Apothecaries created medicinal jellies using sugar, honey, and fruit to administer medicines.

In 19th century (1800s): The development of gelatin and pectin allowed for the creation of morestable and consistent medicinal jellies.

1867: Japanese pharmacists developed various medicinal preparations, including jellies, to administer traditional Chinese medicines.

In the 20th century (1900s): Pharmaceutical companies began mass-producing medicinal jelliesusing modern manufacturing techniques.[16]

1925: 4th edition of the Japanese Pharmacopeia introduced a new standard for medicated jellies, specified the requirements for the jelly base, active ingredients, and packaging.

In Mid-20th century (1950s-1960s): The development of new gelling agents, such as carrageenanand xanthan gum, expanded the range of medicinal jellies.

1961: 7th edition of the Japanese Pharmacopeia introduced a new monograph for medicated jellies also provide a detailed standards for the preparation, quality control, and labeling of medicated jellies.

1996: 13th edition of the Japanese Pharmacopeia introduced a new standard for medicated jellies, which specified the requirements for the use of preservatives, antioxidants, and other additives.[17]

EXCEPIENTS USED IN ORAL JELLY

Gelling agent: Pectin, Tragacanth, Gelatine, Xanthan gum, Gellan gum, Carrageenan, Guar gumSodium alginate, Cellulose derivative.

Stabilizers: Propylene glycol, Sorbitol.

Preservative: Methylparaben, Propyl paraben, Benzalkonium chloride, Sodium benzoate

Solubilizers: Cremophore RH40, PEG 400.

pH modifers: Citric acid.

Sweetners: Simple syrup, Acesulfame potassium**Flavours:** Strawberry, Vanilla, Orange.[18]

METHODS OF PREPARATION[19]

1. Oral medicated jellies were prepared by using different polymer using different ratio.
2. Initially an sugar syrup is prepared by using sucrose and water at the required ratio.
3. To this syrup gelling agent of the required quantity and heating until it gets dissolved.
4. To this solution stabilize and solubilizer are added and stirred to dissolved.
5. To the above mixture preservative is added.
6. Once completely dissolved it is brought to an room temperature then, drug along with colourand flavours is added
7. This solution is paired into the required shape and size mold and is allow to settled down toform an jelly.

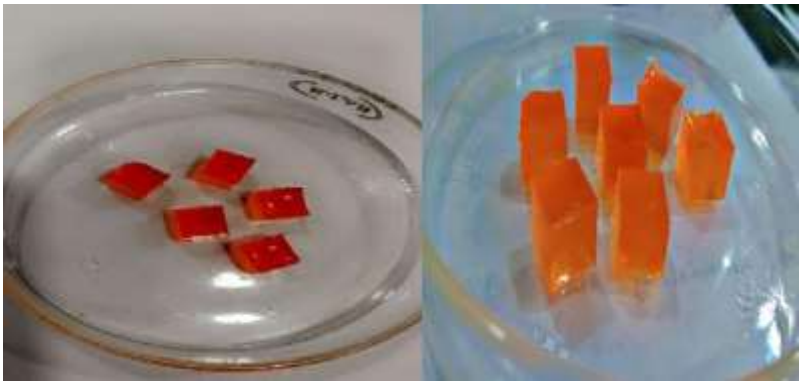

Fig. 12: Example of some formulated oral jellies.

QUALITY CONTROL TEST FOR OMJS

Quality control for oral medicated jellies is a critical aspect of ensuring their safety, efficacy, andpatient acceptability. Here's a comprehensive overview, incorporating relevant references.

1. **Physical Properties**

a) **Viscosity:** Measures the jelly's thickness and flowability. This is crucial for ensuring the product has the right consistency for application and absorption.

b) **Spreadability:** Assesses how easily the jelly can be spread on the skin. This test ensures the product is comfortable to apply and doesn't require excessive force.

c) **Appearance:** Evaluates the jelly's color, clarity, and texture. This test ensures the product meets visual quality standards and is free from defects.

2. **Chemical Properties**

a) **pH:** Measures the jelly's acidity or alkalinity. This is essential for ensuring the product doesn't irritate the skin or compromise its natural pH balance.

b) **Drug content:** Verifies the amount of active pharmaceutical ingredients (APIs) present in the jelly. This test ensures the product contains the correct amount of APIs to deliver the intended therapeutic effect.

c) **Release profile:** Assesses how the APIs are released from the jelly over time. This test ensures the product delivers the APIs consistently and predictably.

3. **Microbiological Testing**

a) **Microbial contamination:** Detects the presence of microorganisms, such as bacteria, yeast, or mold, in the jelly. This test ensures the product is free from microbial contamination and safe for use.

4. **Stability Testing**

a) **Storage conditions:** Evaluates the jelly's stability under different storage conditions, such as temperature, humidity, and light exposure.

b) **Shelf-life determination:** Determines the jelly's shelf-life by assessing its physical, chemical, and microbiological properties over time.

c) **Packaging compatibility:** Verifies that the packaging materials don't interact with the jelly or affect its stability.

By carefully considering these factors and following rigorous quality control procedures, it

ispossible to develop safe, effective, and patient-friendly oral medicated jellies.[20]

Marketed Oral medicated jelly

Oral medicated jelly products are available over-the-counter (OTC) or by prescription, dependingon the medication and country regulations. Always consult a healthcare professional before takingany medication.

Table 1: Examples of the marketed oral medicated jellies.

s.no	Active ingredient	Application
1	Sildenafil	Erectile dysfunction
2	Tadafil	Erectile dysfunction
3	Alendronate	Osteoporosis
4	Aciclovir	Viral infection
5	Isosorbide	Hydrocephalus
6	Donepezil hydrochloride	Alzheimers dementia

Sildenafil oral jelly

Brand name: Kamagra oral jelly, Vigora jelly.

Active ingredient: Sildenafil Citrate.

Dosage form: Oral jelly, Typically 50 mg and 100 mg.

Effects of this medicine

Sildenafil oral jelly aids men with erectile dysfunction in maintaining an erection. The oral jelly can be easily swallowed, making it convenient for elderly individuals. This medication functions by enhancing blood flow to the penis. The medication works by blocking PDE inhibitors. The jelly we produce is available in five flavors: strawberry, cherry, banana, mango, lemon, and orange.

Side effects: Headache, diarrhea, stomach upset, dizziness.

Fig. 13: Sildenafil oral Jelly (Kamagra oral jelly).

Alendronate sodium hydrate Oral jelly

Brand name: Bonalon® Oral Jelly 35 mg.

Active ingredient: Alendronate sodium hydrate.

Dosage form: Clear and colorless to faint yellow jelly.

Effects of this medicine

This medication is absorbed by osteoclastic cells and hinders the activity of osteoclasts to reduce bone resorption, subsequently enhancing bone mass to avert fractures. It is commonly prescribedfor the treatment of osteoporosis.

Side effects: Gastric inflammation, indigestion (heartburn) and diarrhea.[21]

Fig. 14: Alendronate sodium hydrate oral jelly (Bonalon Oral Jelly).

Aciclovir Oral Jelly

Brand name: Aciclovir Oral Jelly 200mg "Nichiiko"

Active ingredient: Aciclovir

Dosage form: white to faintly yellowish white jelly

Effects of this medicine

This medication is an antiviral drug. It obstructs the DNA synthesis of the virus to hinder the proliferation of herpes simplex, varicella, and herpes zoster viruses. It is typically prescribed forthe treatment of herpes simplex, to prevent herpesvirus infections related to hematopoietic stem cell transplants, for managing herpes zoster, and to reduce the recurrence of genital herpes.

Side effects: Anemia, diarrhea, abdominal pain, erythema, fixed drug eruption.

Fig. 15 Aciclovir Oral Jelly (Nichiiko).

Isosorbide Oral Jelly

Brand name: Isosorbide Oral Jelly 70% divided pack 30mg

Active ingredient: Isosorbide

Dosage form: brown jelly

Effects of this medicine: This medication acts as a diuretic and effectively lowers brain pressure, intraocular pressure, and endolymphatic pressure by increasing plasma osmotic pressure. It is typically used to alleviate heightened intracranial pressure caused by brain tumors or head injuries, as well as to reduceintraocular pressure in glaucoma. Additionally, it serves as a diuretic for expelling kidney or urinary stones and is used in the treatment of Meniere's disease.

Side effects: Nausea, diarrhea, vomiting, rash and erythema.[22]

Fig. 16: Isosorbide Oral Jelly.

FUTURE SCOPE OF ORAL MEDICATED JELLIES

Oral medicated jellies have emerged as a promising dosage form, offering numerous benefits over conventional oral medications. They enhance patient adherence, being more palatable and easier to administer, particularly for pediatric and geriatric patients. Additionally, their unique formulation facilitates rapid drug dissolution and absorption, resulting in faster onset of action andenhance bioavailability.

Oral medicated jellies can also be engineered to release drugs in specific regions of the gastrointestinal tract, optimizing therapeutic efficacy, while safeguarding sensitive drugs from degradation. Furthermore, they can accommodate a broad range of drugs, including those with poor water solubility or stability issues, making them an attractive option for various therapeutic applications. Oral medicated jellies provide a pioneering, innovative, and user -friendly solution for medication administration. Oral medicated jellies have tremendous scope for being delivery system for most of drugs in future.[23]

CONCLUSION

Oral medicated jellies includes several advantages as a pharmaceutical dosage form,

including improved patient compliance, convenience, and rapid onset of action. They are particularly suitable for pediatric, geriatric, and dysphagic patients. However, their aqueous-based nature requires appropriate packaging to maintain drug stability. Overall, oral medicated jellies represent a promising advancement in drug delivery, offering a valuable alternative to conventional dosageforms.

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