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Review Article

Formulation And Evaluation of Paracetamol Chewable Pediatrics Jelly

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ABSTRACT

Pediatric population is a diverse group comprising of different subgroups. The use of unlicensed and off-label medicines for treating children is widespread due to the non-availability of suitable dosage forms for this age group. Oral medicated jellies are semisolid dosage forms that offer a convenient and palatable alternative to traditional oral medications. Developed in the 20th century, they gained regulatory approval in 2012 for use in osteoporosis treatment in Japan. Pharmaceutical jelly-based formulations represent a novel, emerging and patient-friendly approach in oral and mucosal drug delivery, contributing a palatable, semi-solid alternative to traditional tablets and capsules. Particularly advantageous for patient populations experiencing dysphagia, including pediatric and geriatric populations. There is a significant need for research and development into paediatric medicines. Only a small fraction of the drugs marketed and utilized as therapeutic agents in children have been clinically evaluated. The majority of marketed drugs are either not labelled, or inadequately labelled, for use in paediatric patients. Oral route is most commonly used for administration of medicament since they are economical, easy to administer, & high patient acceptance. Jellies are evaluated for further evaluations such as weight variation, spreadability, content uniformity, syneresis, palatability, dissolution etc.

INTRODUCTION

Paracetamol gummy candy is an innovative pharmaceutical confection designed to offer pain relief in a more enjoyable and palatable form. Typically, paracetamol is consumed in tablet or liquid form, but the gummy version provides a convenient alternative, especially for children or

adults who have difficulty swallowing pills.[1]. Patients are usually comfortable with oral drug delivery system since it is non-invasive and usually offers low cost of treatment. Oral drug delivery systems are the age-appropriate drug delivery systems that are explicitly designed to enhance the feasibility of drug administration in especially in children [2] Children have different taste habits and swallowing capacity than other

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subsets of the population, so this is a vital trait for the permissibility of medicines intended for them. In several cases, caregiver dependency affects medication acceptability and administration [3]. Dosage forms are essential in pharmaceutical sciences as they facilitate safe and effective drug delivery to patients. The development of new dosage forms aims to improve patient compliance, enhance drug stability, and optimize drug release profiles [4]. There are many ways of taking the drug into the body, such as oral, sub-mucosal (buccal and sublingual mucosal route), parenteral, transdermal and pulmonary applications [5]. To avoid injectable formulations, oral drug delivery is a more popular and convenient method [6]. However, oral drug intake causes local irritation and nausea at a higher rate compared to other drug delivery systems. This reduces the continuity of treatment in the geriatric population [7]. At the same time, the inability of infants and most children to use solid dosage forms limits the options in drug formulations that can be taken orally [8,9].

Jelly

According to the 17th edition of Japanese Pharmacopeia jellies meant for oral administration are non-flowable gelatinous preparations of definite size & shape, meant for oral administration.

"Jelly can be defined as transparent or translucent non-greasy, semisolid preparation meant for external as well as internal applications." [10]

Children & other age group may prefer medicated jelly compare to oral liquid or tablets due its eye catching appearance, pleasant taste, & is easy to handle. Medicated jelly can be used in local treatment of ailment related to oral cavity & also in the treatment of systemic condition. Compared to oral medicine administration, children may

prefer jelly as a drug delivery route as opposed to oral fluid or pill administration. The application of medicinal jelly is viable for both systematically and locally therapy of the mouth diseases. Jellies have enough water in them jelly with water provides an effect of local cooling after evaporation, and the leftover film offers protection [11]. To set oral medicated jellies apart from more typical dose forms, they should have certain desired qualities. Among the key benefits of these dosage forms is that they don't need water to swallow, however after just a few seconds, they melt or disintegrate in the mouth. [12]. At the same time, their long-term stay in the oral cavity due to how they are applied allows them to be used in treating mouth and throat diseases. Among the reasons for its preference is that it does not require water during use and can be applied whenever and wherever desired [13].

Recent market studies indicate that more than half of the patient population prefers Oral medicated jellies to other dosage forms and most consumers would ask their doctors for Oral medicated jellies (70%). Pharmaceutical jellies are now available as OTC medicaments in different flavours containing drugs for anesthetics arthritis

Classification of Jelly Dosage Forms

Jelly dosage forms can be classified based on several parameters, including route of administration, therapeutic application, and formulation characteristics.

Based on the Route of Administration

1. Oral Jellies

These are the most common jelly formulations, designed for systemic drug delivery via the oral cavity. They are easy to ingest and do not require water, making them highly suitable for pediatric



and geriatric populations. Examples include antipyretic, antihistaminic, and multivitamin jellies.[14]



2. Topical Jellies

Topical jellies are semisolid formulations intended for external application on the skin or mucous membranes. Formulated for application on the skin or mucosal surfaces, these jellies serve as vehicles for local delivery of drugs such as analgesics, antiseptics, or antifungals.[15]

3. Vaginal and Rectal Jellies

These are used for local action within the vaginal or rectal cavity [16], often as carriers for antimicrobials, contraceptives, or anti-inflammatory agents.

Based on Therapeutic Purpose

1. Prescription Jellies

Formulated for the treatment of specific medical conditions, such as epilepsy (e.g., diazepam rectal jelly), allergic reactions, or chronic diseases.

2. Over-the-Counter (OTC) Jellies

Used for self-medication, these include jellies containing vitamins, herbal extracts, or minor analgesics. They are designed for safety, palatability, and ease of use.

3. Nutraceutical and Functional Jellies

These jellies contain dietary supplements, probiotics, or antioxidants and are aimed at enhancing general health and wellness rather than treating specific conditions[17].

Based on Formulation Characteristics

1. Sugar-Based Jellies



Contain high concentrations of sugars and gelling agents, providing a pleasant taste and texture. Common in pediatric preparations and nutraceuticals.

2.Sugar-Free or Diabetic-Friendly Jellies

Formulated with non-sugar sweeteners like sucralose or stevia, these are suitable for diabetic patients and calorie-conscious consumers [18].

3.Fast-Dissolving Jellies

Engineered to dissolve rapidly in the oral cavity, these are ideal for rapid onset of action and are often used for emergency medications [19].

4.Sustained or Controlled Release Jellies

Designed using polymers that allow the gradual release of the active drug over a prolonged period, improving therapeutic efficacy and reducing dosing frequency.

Advantages

- 1.Faster onset of action.
- 2.Convenience and portability.
- 3.Ease of absorption.
- 4.Lower chance of choking.
- 5.Accuracy of dosage. [20.21]

Disadvantages

1. As it is aqueous based preparation it needs appropriate packaging to maintain stability of drugs in various environment
2. It may lead to unpleasant taste if not formulated Appropriately.[22]

Challenges

1.Palatability

For formulation specialist, hiding the bitterness of the drugs used to make oral medicated jellies is a difficult task. Dissolving oral medication delivery method often contain the drug in a flavor -masked form due to the fact most medications are not appetizing.[23]

2.Hygroscopicity/Moisture sensitivity

A number of oral jelly dose they are hygroscopic, meaning they Become less physically stable in typically humidity and temperature ranges.[24]

3.Dosage / Quantity of drug

The quantity of medication that can be incorporated into every dosage unit. The creation of fast dissolving dosage forms is hampered by molecules that require high doses mostly because of three factors: a) the active ingredient's flavor is masking; b) mouth sensation; and c) jelly size. [25]

4.Water solubility

Water-soluble medications present a variety of formulation difficulties because of production of eutectic mixtures, which lower the freezing temperatures and produce a opaque substances that may crumble when dried because of sublimation process loss of structure that support it.

6.The size of jelly's

The jelly's size determines how easy it is to take. According to reports, jelly larger than 8 mm was the simplest to manage, while 78 mm was the simplest to swallow. It is therefore difficult to get a jelly that is both manageable and simple to take.[26]

7.The medication characteristics



The performance of jellies might impact by a variety of pharmacological features. For instance, a medication solubility, crystal structure, particle size, and bulk density can all have an impact on the final jelly's power and dissolve ability.

8. Mouth Sensation

In mouth, the OMJs shouldn't break up into bigger pieces.[27]

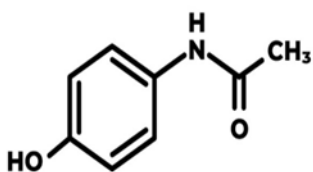
9. Environmental Sensitivity

When assessing the sensitivity of jelly (such as fruit or Gelatin-based jelly) to environmental conditions, the goal is to understand how factors like temperature, humidity, and light impact its texture, flavour, colour, and shelf stability.

MATERIALS AND METHODS:

Medicated jellies are a form of pharmaceutical dosage, which combine the basic principles of jelly chemistry with the addition of active medicinal ingredients.

1. Paracetamol-



Paracetamol

- Molecular Formula: C₈H₉NO₂
- Molecular weight: 151.165 g·mol⁻¹
- IUPAC Name: N-(4-hydroxyphenyl) acetamide, N-(4-hydroxyphenyl) ethanamide

- Bioavailability: 70-90% absorbed from the gastrointestinal tract following oral Administration.

- Half-Life: 1.5 to 2.5 Hrs

- Protein Binding: Bind to serum albumin about 10–25%.

- Solubility: Soluble in water and insoluble in diethyl ether.

- Category: Analgesics and antipyretics

- Storage: Preserved in tight, light-resistant containers stored at room temperature and protected from moisture and heat.

- Dose: 250 mg, 3times/day

- Use: Treat mild to moderate pain, treat fever (high temperature)

2. Sodium Alginate

- Molecular formula: (C₆H₇NaO₆)_n.

- Molecular weight: 198.11 g/mol.

- Category: Gelling agent

- Melting point: 99 °C.

3. Sucrose

- Molecular formula: C₁₂H₂₂O₁₁.

- Molecular weight: 342.29 g/mol.

- Constituents: Glucose and fructose.

- Category: Sweetening agent.

- Melting point: 186–188 °C.

4. Citric Acid



- Molecular formula: C₆H₈O₇.
- Molecular weight: 192.12 g/mol.
- Category: Flavouring agent.
- Melting point: 153–159°C.
- Category: Preservative.
- Melting point: 95–99°C[28]

5. Propyl Paraben

- Molecular formula: C₁₀H₁₂O₃.
- Molecular weight: 180.20 g/mol.

Method

Heating,

Molding

Cooling Method

Formulation tablet [29]

Sr no	Ingredients	Given quantity (10gm)	Given quantity (20gm)	Given quantity (30gm)	Role
1	Paracetamol	1	2	3	API
2	Sucrose	2.50	5	7.50	Sweetener
3	Citric acid	0.10	0.20	0.30	Flavouring agent
4	Gelatin	2.00	4.00	6.00	Gelatin agent
5	Sorbitol	1.50	3.00	4.50	Humey
6	Sodium citrate	0.10	0.20	0.30	Buffering agent
7	Sodium benzoate	0.01	0.02	0.03	Preservative
8	Water	q.s	q.s	q.s	Solvent
9	Colouring agent	0.01	0.02	0.03	Given colour
10	Flavouring agent	0.03	0.06	0.09	Taste enhance

Evaluation test

1. Physical Examination

The medicated jelly will be examined physically for appearance like texture, transparency and consistency, gumminess and grittiness. Grittiness is determined by rubbing. [30]

2. pH:

The pH of the jelly can be determined using digital pH meter. 0.5 gm of the weighed formulation was

dispersed in 50 ml of distilled water and the pH was noted.

3. Syneresis:

Syneresis is defined as contraction & separation of water from the gel upon storage. One of the major causes for it is using lesser concentration of gelling agent. [31]

4. Drug content

The primary goal of a drug content test is to ensure that each dose of a pharmaceutical product



contains the specified amount of the active ingredient, as stated on the product label. [32]

offering a pleasingly smooth texture and consistency.

5. Stickiness and Grittiness

The jelly is rubbed between two fingers to determine its stickiness and grittiness, which are then visually assessed.

6. Weight variation

It is calculated by weighing ten jellies on average after they are removed from molds, weighed separately, then combined in a beaker.

7. Viscosity

The Brookfield viscometer was used to test viscosity. Since the system is not Newtonian, spindle number four was employed. Viscosity in centipoise = Dial reading x factor. [33]

8. Stability studies

The prepared jelly can be used to assess stability studies, which are determined in accordance with ICH recommendations.

CONCLUSION

The development of oral medication jelly provides a promising alternative to traditional oral dosage forms. Its distinct features, such as ease of use, improved taste, and suitability for individuals with swallowing difficulties (e.g., children and the elderly), make it a versatile option in modern medicine. It has many advantages in comparison to other dosage forms such as patient compliance, does not require water for administration, & it remains stable. Medicated jelly, emerges as an optimal choice for improving patient compliance. Moreover, it provides advantages in concealing the bitter taste and disagreeable odour of drugs,

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