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Review Article Formulation, Development and Evaluation of Pediatric Medicated Jelly

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Abstract: *Oral medicated jellies are semi-solid pharmaceutical dosage forms characterised by their transparent appearance and non-greasy nature, and are suitable for internal use. In recent years, jelly-based formulations have gained popularity due to their palatable taste and ease of consumption. The incorporation of natural fruit flavours such as mango, lemon, orange, and strawberry enhances patient acceptance, especially by improving taste and chewability. Compared to traditional dosage forms like tablets and capsules, oral jellies offer improved patient compliance, particularly among pediatric and geriatric populations. One of their major advantages is that they can be easily chewed or allowed to dissolve in the mouth without water, making administration convenient.*
These formulations typically include gelling agents, preservatives, and flavouring agents, which collectively contribute to theirs tability and acceptability. Due to their patient-friendly properties, oral medicated jellies present a promising alternative in drug delivery systems and have the potential to transform conventional medication practices..

Keywords: medicated jelly ,Gelling agent, solid dosage form, oral medicated jelly, patient compliance, drug delivery system, palatability

I. INTRODUCTION

In simplest words, jelly consists of semisolid preparations that may be transparent or translucent without greasiness, meant for topical and internal uses.Jelly is a transparent or slightly translucent, non-greasy, semi-solid dosage form that may be used for both internal and external therapeutic applications. In the pharmaceutical sciences, jelly-based formulations have gained attention for their unique texture, appearance, and ease of administration. Conventional medicines often possess an unpleasant or bitter taste, which can reduce patient willingness to adhere to treatment. In contrast, oral medicated jellies are usually flavoured, making them more palatable and acceptable. This advantage is especially important in pediatric and geriatric populations, where maintaining patient compliance is often challenging.
Effective taste-masking strategies in jelly formulations help ensure that patients complete their prescribed therapy without resistance. Medicated oral jellies are a novel, patient-friendly drug delivery system for administration in the oral cavity. These formulations are intended to dissolve or disintegrate in the mouth or pharynx, eliminating the need for water during administration. Their semi-solid nature, combined with a pleasant taste and ease of swallowing, makes them particularly suitable for individuals who have difficulty consuming conventional solid dosage forms, such as tablets or capsules.
From a formulation and manufacturing perspective, oral jellies allow accurate dosing and uniform distribution of the active pharmaceutical ingredient. They can also be designed to provide modified or controlled drug release, ensuring prolonged action. This property is especially beneficial in the management of chronic conditions, where maintaining consistent drug levels in the bloodstream is essential. Furthermore, certain jelly formulations may facilitate buccal absorption, enabling the drug to be absorbed directly through the oral mucosa, thereby bypassing the gastrointestinal tract and producing a faster onset of action. In terms of packaging, medicated jellies are commonly supplied in unit-dose sachets or collapsible tubes, which enhance portability and convenience for patients. Such packaging also protects the

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formulation from environmental factors like moisture, oxygen, and contamination, thereby improving stability and shelf life.

Regulatory recognition of oral jellies further highlights their significance as a dosage form. They are acknowledged as fast-dissolving formulations in pharmaceutical standards, and official pharmacopoeias describe them as non-flowing, gelatinous preparations of defined size and shape intended for oral use.

II. AIM AND OBJECTIVES

Aim:

TO Formulation, Development And Evaluation Of Pediatric Medicated Jelly

Objective:

- To formulate a safe and palatable pediatric medicated jelly suitable for children.
- To develop a jelly dosage form that improves patient compliance and ease of admini
- stration in pediatric patients.
- To provide an effective alternative to conventional pediatric dosage forms like tablets and capsules.
- To formulate medicated jelly containing a suitable drug
- To enhance patient compliance through palatable dosage form
- To mask unpleasant taste of drug
- To evaluate physical and chemical properties of jelly
- To study drug release profile
- To develop a stable and effective formulation

III. LITRETURE REVIEW

Pediatric patients often experience difficulty in swallowing conventional dosage forms such as tablets and capsules, which may reduce patient compliance. To overcome this problem, pediatric medicated jelly has emerged as a novel and patient-friendly oraldosage form. Medicated jellies are soft, palatable, chewable, and easy to swallow, making them highly suitable for children. Pediatric medicated jellies are formulated using gelling agents such as gelatin, pectin, sodium alginate, and agaralong with sweeteners, flavors, colors, and preservatives to improve taste, texture, and stability. These formulations help in effective taste masking of bitter drugs and enhance acceptability among pediatric patients.

Several research studies have shown that medicated jellies provide uniform drug distribution, better stability, rapid drug release, and improved bioavailability. Evaluation parameters such as pH, viscosity, syneresis, spreadability, drug content, and in-vitro drug release are important for determining the quality and effectiveness of the formulation.

Due to their attractive appearance, pleasant taste, ease of administration, and improved patient compliance, pediatric medicated jellies are considered a promising alternative to conventional pediatric dosage forms like tablets and syrups.

PLAN OF WORK

Literature Review
↓
Drug & Excipient Selection
↓
Pre-formulation Studies
↓
Formulation Development
↓
Preparation of Jelly
↓

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Evaluation
↓
Optimization
↓
Stability Studies
↓
Data Analysis
↓
Final Report

TYPES OF JELLY

Jellies are classified into three types based on ingredients, texture, and intended use. Its classification is shown in Figure 1 below

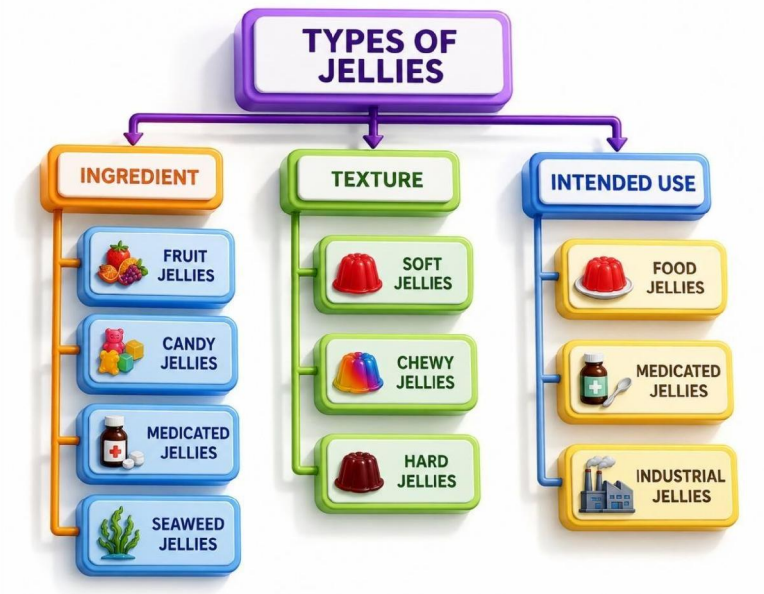

Fig. 1: Types of Jellies.

BASED ON INGREDIENTS

Fruit jellies

Fruit jellies represent one of the most widely used types of jelly formulations. They are primarily prepared by combining fruit juices with sugar and suitable gelling agents, such as pectin, which provides the characteristic gel-like consistency. These jellies are known for their pleasant taste, attractive appearance, and smooth texture.

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Fig. 2: Fruit Jellies.

Candy Jellies

Candy jellies are confectionery products made primarily from sugar, corn syrup, and gelling agents such as gelatin. They are often enhanced with artificial flavours and colouring agents to improve their taste and visual appeal

Fig. 3: Candy Jellies.

Medicated Jellies

Medicated jellies are pharmaceutical formulations that incorporate active drug substances intended for therapeutic use, such as relieving pain or improving oral health conditions. These preparations serve as an alternative drug delivery system, particularly for patients who have difficulty swallowing conventional dosage forms.

Fig. 4: Medicated Jellies.

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Seaweed Jellies

Seaweed jellies are prepared using extracts obtained from marine algae, commonly agar or carrageenan, which act as natural gelling agents. These substances provide a firm and stable gel structure without the need for synthetic additive.

Fig. 5: Seaweed Jellies

BASED ON TEXTURE

Soft Jellies

Soft jellies are characterised by their gentle, delicate consistency, offering a smooth, uniform surface. They have a tender gel structure that deforms easily under slight pressure, making them easy to chew and swallow.

Fig.6;Soft jellies

Chewy Jellies

Chewy jellies are characterised by a comparatively firm structure that requires greater masticatory effort. They exhibit an elastic, gummy, or rubbery consistency, providing a prolonged chewing experience.

Fig.7;Chewy jellies

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Hard Jellies

Hard jellies represent the firmest category among jelly formulations, exhibiting a rigid and compact structure. They are characterised by a relatively brittle texture, which may break or fracture rather than deform when pressure is applied.

Fig. 8: Hard Jellies

Medicinal Jellies

Medicinal jellies are formulated with active pharmaceutical ingredients for therapeutic applications. These preparations are designed to deliver drugs effectively for the management or treatment of various conditions, such as sore throat, hypertension, or pain relief

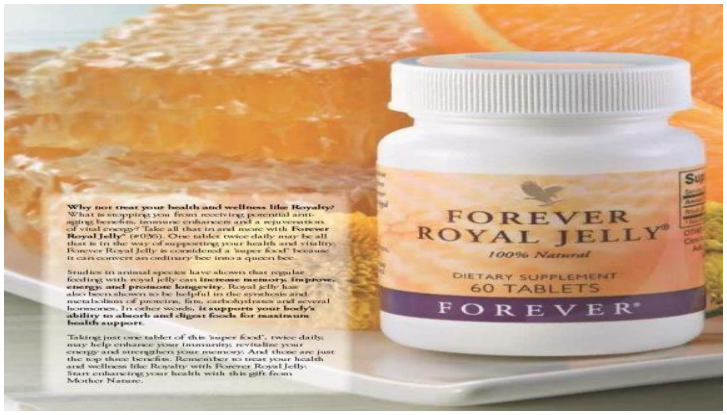

Fig. 9;Medicinal jellies .

Industrial Jellies

Industrial jellies are specialised formulations utilised across multiple sectors, including food processing, cosmetics, and the pharmaceutical industries. Unlike edible or medicinal jellies intended for direct consumption, these are primarily developed for functional and technical applications.

Fig.10; Industrial Jellies

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Friut jellies

These are typically consumed as a snack or dessert as shown in figure .11

Fig.11; Friut Jellies

ADVANTAGES AND DISADVANTAGES OF JELLY

ADVANTAGES OF JELLIES

1. Convenient Administration:

Jellies can be administered easily at any place and time without the need for water.

2. Improved Drug Delivery:

They help overcome difficulties associated with conventional dosage forms by providing better drug release and retention in the oral cavity.

3. Reduced Dosing Frequency:

Due to their efficient drug release and absorption, jellies may require less frequent dosing than To formulate jelly for other categories of drugs.

4. Easy Termination of Therapy:

Treatment can be discontinued easily whenever required, providing better control over drug administration.

5. Enhanced Bioavailability:

Drugs in jelly form can dissolve or remain suspended in saliva, making them readily available for absorption or for swallowing into the gastrointestinal tract.

6. Formulation Flexibility:

Jellies offer versatility in formulation design, allowing modification of taste, texture, and drug release characteristics.

7. Better Patient Compliance:

Their pleasant taste and ease of use improve adherence to medication, especially in sensitive Gpatient groups.

8. Suitable for Localised Treatment:

Medicated jellies can be used effectively to treat conditions of the oral cavity and for certain systemic therapies.

9. High Patient Acceptability:

They are widely accepted by children, elderly individuals, and patients with swallowing difficulties (dysphagia).

10. Rapid Action:

Jellies are suitable for situations requiring quick onset of action, including emergency treatments.

DISADVANTAGES OF MEDICATED JELLIES

1. Stability Issues:

Being aqueous in nature, jelly formulations are more prone to microbial growth and chemical instability, requiring appropriate packaging and storage conditions.

2. Taste Variability:

Improper formulation or inadequate flavour masking may result in an unpleasant taste, reducing patient acceptability.

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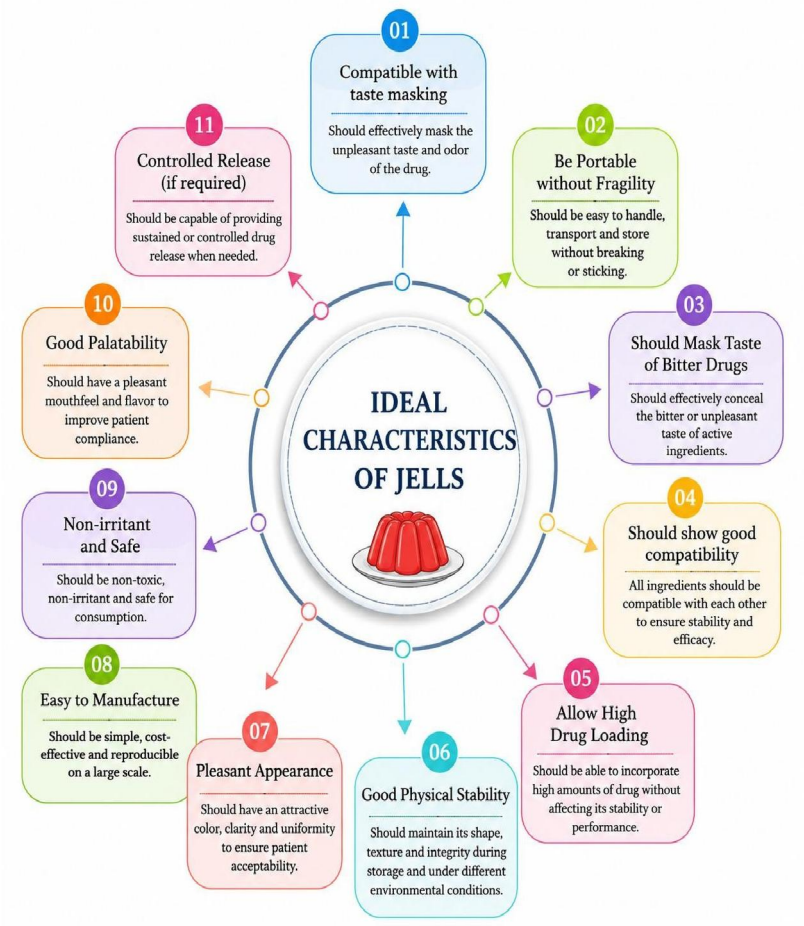
3. Fragility:
Jellies may possess a soft and delicate structure, making them susceptible to deformation or damage during handling and transportation.
4. Low Mechanical Strength of Packaging:
Conventional packaging materials such as blister packs may not provide sufficient protection, increasing the risk of product damage.
5. Hygroscopic Nature:
Oralmedicated jellies tend to absorb moisture from the environment, which can affect their texture, stability, and shelf life.
6. Need for Specialized Packaging:
To maintain product quality and safety, jellies often require specially designed packaging that protects them from moisture, air, and contamination.

IDEAL CHARACTERISTICS OF JELLIES

- Jelly is compatible with pleasing feel of mouth and after sometime it does not leave any residue in oral cavity. It has capable of loading high amount of drug.
- Jellies are compatible with bitter drug and they are able to mask its taste.
- In altered environmental conditions they have low sensitivity for example in case of change in temperature as well as humidity



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PERIODIC MEDICATED JILLY FORMULATION

- Gelling agent:Sodium alginate, pectin, gelatin,gum acasia
- Sweetners: Sucrose, dextrose, saccharin, sucralose,mannitol
- Colouring agent:Natural colours (beta carotene) Mineral colour (red & yellow ferric oxides
- Flavouring agent:Orange, lemon, chocolate, mint, grape, honey
- Preservatives: Methyl paraben, proyl paraben, benzoic acid
- Stabilizers: Propylene glycol, sorbitol

1. Instruments Used in Formulation

Dr.No	Instrument	Purpose
1	Digital Weighing Balance	Accurate measurement of ingredients
2	Magnetic Stirrer with Hot Plate	Uniform mixing and heating
3	Water Bath	Maintains constant temperature
4	Homogenizer	Ensures smooth gel consistency
5	pH Meter	Maintains vaginal pH (3.5-4.5)

2. Instruments Used in Evaluation

Sr.No	Category	Instruments
1	Physical	Brookfield Viscometer, Texture Analyzer, Spreadability apparatus
2	Chemical	UV Spectrophotometer, pH Meter
3	Drug Release	Franz Diffusion Cell
4	Microbiological	Incubator, Autoclave
5	Stability	Stability Chamber

NEED FOR JELLY DEVELOPMENT

The basic purpose for non invasive delivery of active chemical moiety is patient's poor acceptance and compliance with, already approved conventional forms, limited market size of active pharmaceutical ingredient companies and active chemical entity usage can be related to the more cost of management of disease. The development of oral medicated jelly as an novelty in effective delivery of active chemical entity, aims to improve the safety as well as effectiveness of administered chemical moiety as well as patient compliance and convenience.

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PREPARATION PROCEDURE OF JELLY

Step 1: Selection of Drug and Excipients

Select a suitable pediatric drug (e.g., Vitamin C) along with a gelling agent (gelatin/pectin), sweetener, flavour, preservative, and purified water.

Step 2: Weighing of Ingredients

Accurately weigh all ingredients according to the required formulation.

Step 3: Preparation of Gelling Base

Soak the gelling agent (e.g., gelatin) in a small quantity of water and allow it to swell. Then heat gently with continuous stirring until it dissolves completely to form a clear solution.

Step 4: Preparation of Drug Solution

Dissolve the drug in a small quantity of purified water separately. If the drug is poorly soluble, it can be uniformly dispersed.

Step 5: Addition of Sweetener and Preservative

Add sweetening agents (such as sucrose or sorbitol) and preservatives (methyl paraben/propyl paraben) to the gelling solution and mix thoroughly.

Step 6: Incorporation of Drug

Add the prepared drug solution into the gelling base with continuous stirring to ensure uniform distribution.

Step 7: Flavor and Color Addition

Add suitable flavour (e.g., strawberry/orange) and colour at a lower temperature to enhance palatability and appearance.

Step 8: Mixing and Homogenization

Stir the entire mixture continuously to obtain a smooth, uniform, and lump-free jelly mass.

Step G: Filling/Moulding

Pour the prepared jelly into molds, sachets, or suitable containers while still in liquid form.

Step 10: Cooling and Setting

Allow the filled containers to cool at room temperature to form a gel and achieve proper setting.

Step 11: Packaging and Storage

Pack the prepared jellies in suitable packaging (sachets or containers) and store in a cool, dry place.

EVALUCATION OF PARAMETER

1) Physical Appearance

The physical appearance of medicated jellies is evaluated by visual inspection to assess important characteristics such as clarity, transparency, texture, and overall consistency. This examination helps in determining the uniformity and aesthetic quality of the formulation. A well-prepared jelly should exhibit a clear or slightly translucent appearance, smooth texture, and uniform consistency without the presence of air bubbles, lumps, or phase separation.

2) pH Test

The pH of the medicated jelly is determined using a calibrated digital pH meter at room temperature. For this analysis, an accurately weighed quantity of jelly (approximately 0.5 g) is dissolved in a suitable volume of distilled water to prepare about a 1% solution.The solution is mixed thoroughly to ensure uniform dispersion, and the pH is then measured.

The pH of the formulation plays a crucial role in maintaining its stability, drug integrity, and palatability. An appropriate pH ensures better shelf life and improves the overall acceptability of the jelly.

2)Stickiness and Grittiness

The stickiness and grittiness of the jelly formulation are evaluated by gently rubbing a small quantity of the sample between two fingers. This simple tactile assessment helps in determining the smoothness and uniformity of the preparation. An ideal jelly should feel smooth and non- gritty, indicating proper dispersion of ingredients, while excessive stickiness or the presence of coarse particles may suggest poor formulation quality.

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4) Pourability of the Mixture

The pourability of the jelly formulation is an important parameter that determines how easily the prepared mixture can be transferred into molds or containers before setting. The formulation should possess adequate fluidity in its hot state to allow smooth and uniform pouring without premature gel formation.

Buffering agents such as trisodium citrate play a key role in controlling this property.These agents act as retarders by temporarily preventing the interaction of pectin molecules during the heating stage. They also help in maintaining a higher pH before the addition of acid, thereby delaying the gelation process .An increase in the concentration of such retarders results in a longer setting time and a lower gelation temperature, which provides sufficient time for proper pouring and shaping of the jelly before it solidifies.

5) Taste Evaluation (Rewritten – Original Version)

The taste of the jelly formulation is assessed using a panel of human volunteers. For this evaluation, a small quantity oftheoptimizedjelly formulation(approximately 5 g) is given to each participant. The volunteers are instructed to place the sample in their mouth for a few seconds and then report their perception of taste, including sweetness, flavor, and overall acceptability.This test helps in determining the palatability of the formulation, which is an important factor for patient compliance, especially in pediatric preparations.

6) Viscosity Study

The viscosity of the jelly formulation is determined using a suitable viscometer equipped with an appropriate spindle (commonly spindle no. 4) for semi-solid systems. Themeasurement is carried out at controlled temperature conditions (around 25 ± 5°C). The sample is allowed to rotate at a fixed speed (approximately 1.5 rpm), andthe viscosity is recorded after a specific time interval, typically 2 minutes.This evaluation helps in assessing the flow behavior and consistency of the jelly, ensuring that it possesses suitable thickness for easy handling, stability, and patient acceptability.

7) Texture Analysis

The texture of the jelly formulation is evaluated by assessing its resistance todeformation upon application of force. This can be performed manually by gently pressing the surface of the gel between fingers or instrumentally using a texture analyzer.This test helps in ensuring that the jelly possesses appropriate mechanical properties for easy handling and patient acceptability.

8) Content Uniformity

Content uniformity is evaluated to ensure that each jelly unit contains a consistent amount of the activepharmaceutical ingredient. Forthis test, individual jelly samples are collected, crushed, and mixed thoroughly to obtain a uniform mass. An accurately measured portion of this mixture, equivalent to the required drug quantity, is then extracted using a suitable solvent or medium

The prepared solution is filtered if necessary, and the drug content is analyzed using a UV-visible spectrophotometer at an appropriate wavelength or by any other suitable analytical method. The results obtained are compared to determine the uniform distribution of the drug within the formulation.

This test confirms that each dosage unit in the batch contains a consistent and accurate amount of the active ingredient, ensuring quality, safety, and therapeutic efficacy.

9) Spreadability Test

The spreadability of the jelly formulation is evaluated to determine its ease of application and uniform distribution. For this test, approximately 2.5 g of the jelly sample is placed between two glass slides. A specified weight (about 1000 g) is applied on the upper slide for a fixed duration of 5 minutes to obtain a uniform thickness.

After removing the applied weight, the time required for the two slides to separate under the influence of an applied force is recorded. The spreadability is then calculated using the formula:

$$S = \frac{W \times L}{T}$$

Where,

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S = Spreadability
W = Weight applied to the upper slide L = Length of the glass slide (7.5 cm) T = Time taken to separate the slides
A shorter separation time indicates better spreadability of the jelly formulatio

10) Syneresis

Syneresisrefers to thephenomenon in whichagelcontractsduringstorage, leadingto the separation and release of liquid from its structure. This effect is more prominent in formulations containing lower concentrations of gelling agents, resulting in reduced gel stability.

To evaluate syneresis, the prepared jelly samples are stored under different temperature conditions, typically at room temperature (25 ± 5 °C) and under refrigerated conditions (8 ± 1 °C). The samples are periodically observed for any signs of liquid separation or shrinkage of the gel.

III. RESULT

The pediatric medicated jelly was successfully formulated and evaluated. The prepared jelly showed good appearance, pleasant taste, smooth texture, and easy swallowability suitable for children. Evaluation studies confirmed acceptable pH, viscosity, spreadability, drug content uniformity, and minimum syneresis. The formulation also showed effective taste masking and good stability.

Stability studies indicated that the optimized jelly formulation remained stable during storage without significant changes in its properties. Thus, the developed pediatric medicated jelly was found to be safe, stable, palatable, and effective for pediatric drug delivery with improved patient compliance.The formulated pediatric medicated jelly showed good physical stability, uniform drug content,andacceptable pH suitable for oral use.It also demonstrated effective drug release and improved palatability, indicating better compliance in pediatric patients.

IV. CONCLUSION

Pediatric medicated jelly is an innovative and patient-friendly dosage form that improves palatability, ease of administration, and therapeutic effectiveness in children. Proper formulation and evaluation help in developing stable, safe, and effective medicated jelly formulations with enhanced patient compliance. due to several advantages over liquid formulations in term of patient acceptance, suitability for controlled release applications, stability and other aspects. More studies are needed to further explore this new dosage form.

Future Scope

- Formulating various formulations using different gelling agent in combination
- To formulate jelly for other categories of drugs.
- Thus, oral jellies have tremendous scope for being delivery system for most of drugs in future.
- Example: kamagra Oral Jelly.

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