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Design and Evaluation of Paracetamol Chewable Pediatric Oral Jelly

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Abstract: *Pediatric drug delivery systems require special consideration due to physiological, psychological, and developmental differences compared to adults. Conventional dosage forms risk of choking, and poor acceptability. Liquid formulations, although commonly used, suffer from issues such as dosing inaccuracies, stability concerns, and unpleasant taste. The present research work focuses on the design and evaluation of a chewable oral jelly formulation containing Paracetamol, a widely used analgesic and antipyretic agent in pediatric therapy. The objective was to develop a palatable, stable, and effective dosage form that enhances patient compliance and ensures accurate dosing.*

The formulation was developed using hydrophilic polymers such as pectin, gelatin, and sodium alginate, along with sweeteners, flavoring agents, and preservatives. Various formulations were prepared by altering polymer concentrations and evaluated for physicochemical parameters including pH, viscosity, drug content uniformity, syneresis, texture, and in vitro drug release profile.The optimized formulation demonstrated desirable characteristics such as acceptable taste, uniform drug distribution, minimal syneresis, and rapid drug release. Stability studies conducted as per ICH guidelines confirmed the formulation's stability.

The study concludes that chewable oral jelly is a promising and patient-friendly alternative to conventional pediatric dosage forms...

Keywords: Pediatric dosage form, Oral jelly, Paracetamol, Taste masking, Drug delivery system

I. INTRODUCTION

1.1 Overview of Pediatric Drug Delivery

Pediatric drug delivery represents one of the most sensitive and complex areas in pharmaceutical sciences. Unlike adult patients, children undergo continuous physiological and developmental changes that significantly influence drug absorption, distribution, metabolism, and excretion. These variations demand specially designed dosage forms that ensure both safety and therapeutic efficacy.

The pediatric population includes neonates, infants, toddlers, children, and adolescents, each group exhibiting distinct pharmacokinetic and pharmacodynamic characteristics. For instance, neonates have immature liver enzyme systems and reduced renal function, which affects drug metabolism and elimination. Similarly, gastric pH, intestinal motility, and enzyme activity vary significantly with age, thereby influencing drug absorption.

In addition to physiological differences, psychological factors also play a crucial role. Children are highly sensitive to taste, texture, color, and smell, which directly affects their willingness to take medications. Poor palatability often results in non-compliance, leading to therapeutic failure.

Therefore, the design of pediatric dosage forms must consider:

- Age-appropriate formulation
- Palatability
- Ease of administration
- Dose flexibility

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• Safety of excipients

1.2 Challenges in Pediatric Drug Delivery

Developing dosage forms for pediatric patients involves multiple challenges that are not typically encountered in adult formulations.

Fig. 1: Oral Jelly

1.5.2 Advantages

• Improved patient compliance
• Ease of administration
• Accurate dosing
• No risk of choking
• Enhanced palatability

1.5.3 Disadvantages

• Sensitivity to temperature and humidity
• Packaging requirements
• Limited drug loading capacity

1.6 Detailed Theory of Gel Formation

Gel formation is a critical aspect of oral jelly formulation. It involves the transformation of a liquid system into a semi-solid structure through the formation of a three-dimensional polymeric network.

1.6.1 Mechanism of Gel Formation

The process includes:
1. Hydration of Polymer Chains.
Polymers absorb water and swell.
2. Chain Entanglement.
Polymer chains interact and overlap.
3. Cross-Linking.
Physical or chemical bonds form between chains.
4. Network Formation.
A stable gel structure is formed that traps water and drug molecules.

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1.7 Types of Polymers Used in Oral Jellies

1.7.1 Natural Polymers

• Pectin

II. AIM AND OBJECTIVES

The present study focuses on designing a novel oral jelly formulation containing Paracetamol to overcome limitations associated with conventional dosage forms such as syrups and tablets.

2.1 Aim of the Study

The primary aim of this research work is:

• To design, formulate, and evaluate a chewable pediatric oral jelly of paracetamol with improved palatability, stability, and drug release characteristics.

2.2 Primary Objectives

The primary objectives of this study are:

- To develop oral jelly formulations using suitable polymers such as pectin, gelatin, and sodium alginate.
- To mask the bitter taste of paracetamol using sweeteners and flavoring agents. To ensure uniform distribution of drug within the jelly matrix.

2.3 Secondary Objectives

To evaluate parameters such as:

• pH
• Viscosity
• Texture
• Appearance

- To ensure accurate dosing in each unit of jelly.
- To study the release profile of paracetamol from the jelly formulation.
- To evaluate the stability of the formulation under different environmental conditions as per International Council for Harmonisation.

III. PREFORMULATION STUDIES

3.1 Introduction

Preformulation studies constitute the initial phase in the development of any pharmaceutical dosage form. These studies provide detailed information about the physicochemical properties of the drug, which are essential for designing a stable, effective, and patient-friendly formulation.

In the present study, preformulation investigations were carried out for Paracetamol to assess its suitability for incorporation into a chewable pediatric oral jelly.

The data obtained from these studies help in:

• Selecting appropriate excipients
• Determining formulation strategy
• Predicting stability and compatibility

3.2 Objectives of Preformulation Studies

The main objectives include:

• To determine physicochemical properties of the drug
• To study solubility and dissolution characteristics

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• To evaluate drug-excipient compatibility
• To establish analytical methods for drug estimation
• To predict stability of the drug

3.3 Organoleptic Properties

3.3.1 Importance

Organoleptic properties are sensory characteristics such as color, odor, and taste. These are particularly important in pediatric formulations where patient acceptability is critical.

3.2.4 Preservatives

• Sodium Benzoate (0.1%)
Prevents microbial growth and increases shelf life.

3.2.5 Acidulant

• Citric Acid
Maintains pH and enhances taste.

3.2.6 Flavoring and Coloring Agents

• Fruit flavors (orange/strawberry)
• Approved food-grade colorants Enhance acceptability among pediatric patients.

3.2.7 Solvent

• Distilled Water
Used as a vehicle for preparation.

3.3 Equipment Used

The following instruments were used:
• Digital weighing balance
• Magnetic stirrer
• Hot plate
• pH meter
• Brookfield viscometer
• UV spectrophotometer
• Glassware (beakers, flasks)
• Molds for jelly formation

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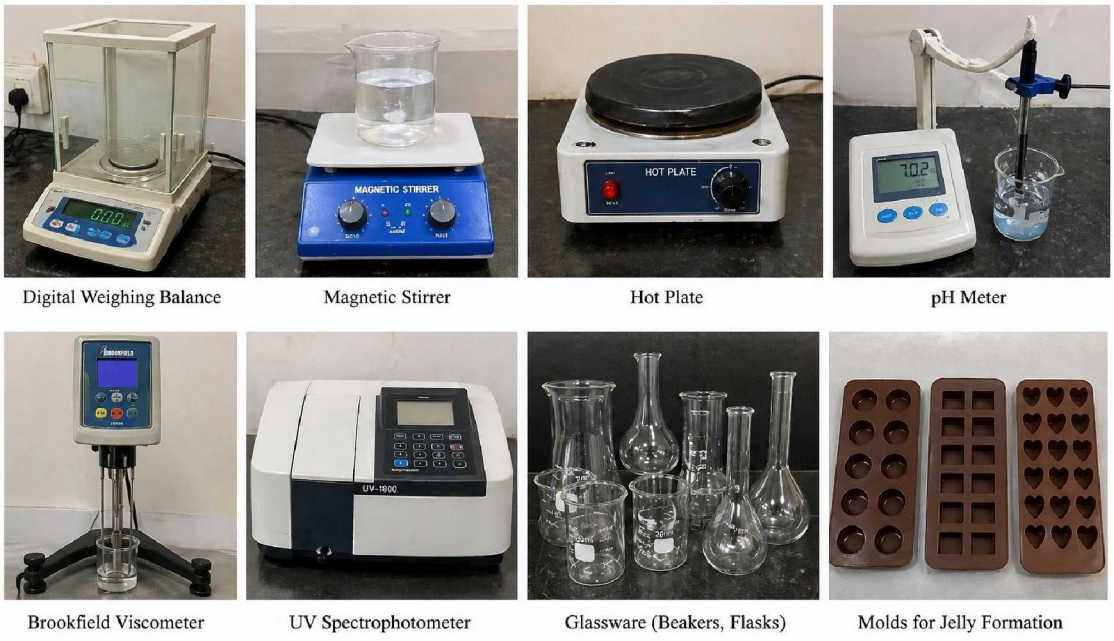

Fig. 3: Equipment Used

3.4 Method of Preparation

3.4.1 Principle

The formulation was prepared using the heating and congealing method, which involves dissolving polymers in water followed by incorporation of drug and excipients.

3.4.2 Step-by-Step Procedure

1. Accurately weigh all ingredients
2. Dissolve polymer in distilled water with continuous stirring
3. Heat the mixture gently (avoid excessive heating)
4. Add sweeteners and preservatives
5. Dissolve Paracetamol separately and incorporate into the mixture
6. Add citric acid to adjust pH
7. Add flavor and color
8. Pour the mixture into molds
9. Allow to cool and solidify at room temperature
10. Remove formed jellies and store in airtight containers

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Diagram: Jelly Formation Mechanism

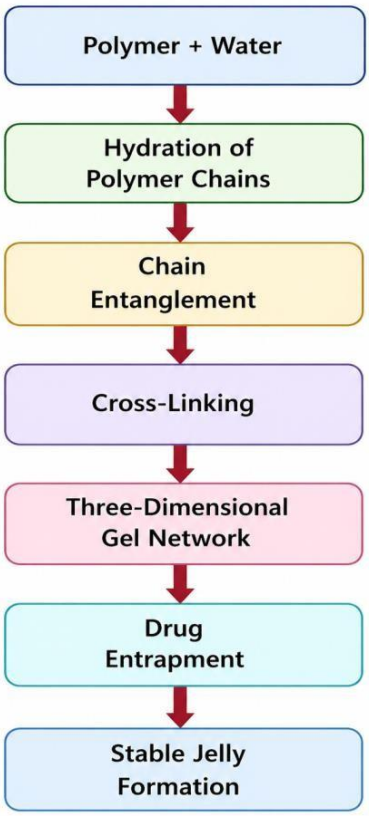

Fig. 5: Flow Diagram of Jelly Formation Mechanism

Gelatin
- Protein-based polymer
- Thermoreversible gel

Advantages:
- Excellent elasticity
- Smooth mouthfeel

Limitations:
- Sensitive to temperature
- May soften at high temperatures

Sodium Alginate
- Anionic polymer
- Forms strong gels

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Advantages:
• High viscosity
• Good stability

Limitations:
• Requires cross-linking for strong gel

Role of Excipients in Formulation
Each excipient plays a specific role:
• Sweeteners: Mask bitterness
• Flavoring agents: Improve taste
• Preservatives: Prevent microbial growth
• Acidulants: Maintain pH

Optimization of pH
pH influences:
• Gel formation
• Drug stability
• Taste
Ideal pH range: 5.5 – 6.5

Drug Incorporation and Uniformity
Uniform distribution of Paracetamol is essential.
Factors affecting uniformity:
• Mixing speed
• Temperature
• Viscosity
Proper mixing ensures consistent drug content.

Selection of Optimized Formulation
Based on evaluation, F2 (Pectin 1.5%) was selected. Reasons
• Ideal texture
• Good taste
• No syneresis
• Uniform drug content
• Rapid drug release

Conclusion
Indicates proper formulation and processing.
pH Measurement
Importance pH affects:
• Drug stability
• Taste
• Oral compatibility

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Method
• Jelly dissolved in distilled water
• Measured using calibrated digital pH meter

Result
pH range: 5.5 – 6.5

Interpretation
• Suitable for oral cavity
• Prevents irritation
• Maintains drug stability

Viscosity Measurement
Importance
Viscosity influences:
• Mouthfeel
• Drug release
• Stability

Conclusion
Polymer concentration affects texture.

In Vitro Drug Release Study
Importance
Determines release behavior of drug.

Apparatus
USP Dissolution Apparatus Type II

Medium
Phosphate buffer pH 6.8

Procedure
1. Place jelly in dissolution medium
2. Maintain temperature at 37°C
3. Withdraw samples at intervals
4. Analyze spectrophotometrically

Results

Time (min)	% Drug Release
5	30
10	55
20	75
30	92

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Interpretation

- Rapid initial release
- Suitable for quick therapeutic action

IV. RESULTS AND DISCUSSION

Physical Appearance Observations

All prepared formulations were evaluated for physical characteristics such as color, clarity, texture, and uniformity.

Formulation	Appearance
F1	Soft, slightly sticky
F2	Smooth, transparent
F3	Hard and rigid
F4	Soft and elastic
F5	Slightly firm
F6	Very firm

Discussion

The physical appearance of oral jelly plays a significant role in patient acceptance. The optimized formulation (F2) exhibited a smooth and transparent structure with no air bubbles, indicating proper mixing and gel formation.

Higher polymer concentrations resulted in increased firmness, while lower concentrations produced softer gels. This demonstrates the direct relationship between polymer concentration and gel consistency.

pH Analysis

Results

Formulation	pH
F1	6.3
F2	6.2
F3	6.1
F4	6.4
F5	6.3
F6	6.0

Discussion

All formulations showed drug content within acceptable limits (95–105%), indicating uniform distribution of Paracetamol.

The optimized formulation (F2) showed the highest drug content uniformity, suggesting efficient mixing and formulation technique.

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Texture Analysis

Observations

Formulation	Texture
F1	Very soft
F2	Ideal
F3	Hard
F4	Elastic
F5	Moderately firm
F6	Very hard

Discussion

Texture is crucial for chewability and patient acceptance. The optimized formulation provided a soft yet firm texture, making it easy to chew and swallow.

In Vitro Drug Release Study

Results

Time (min)	F1	F2	F3	F4	F5	F6
5	35	30	20	32	28	18
10	60	55	40	58	50	35
20	80	75	60	78	70	55
30	95	92	75	93	85	70

Discussion

The drug release study revealed:

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Graphical Representation

• Calibration curve

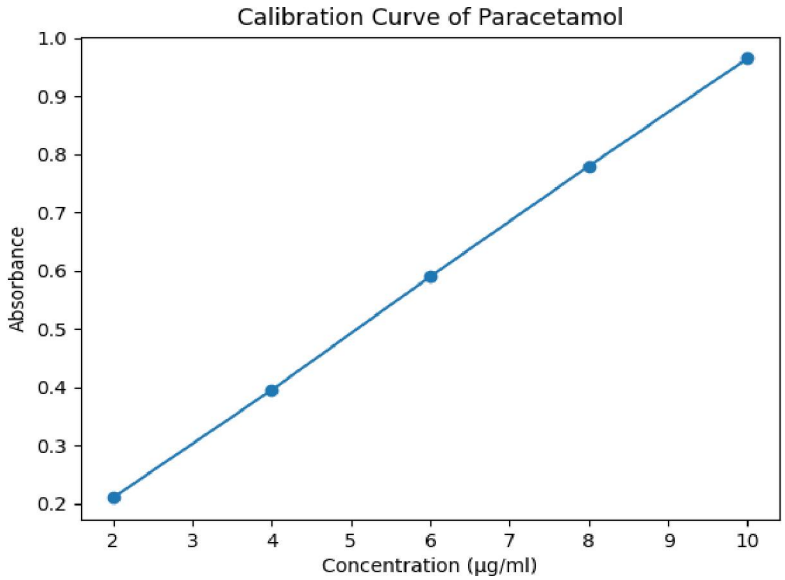

Fig. Calibration Curve of Paracetamol

• Dissolution profile graph

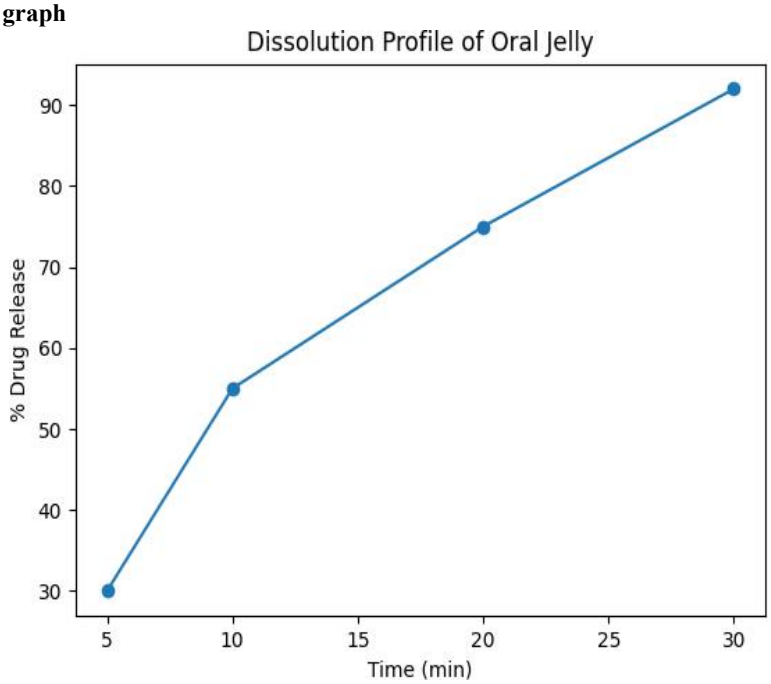

Fig. 9: Dissolution Profile of Oral Jelly

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III. SUMMARY AND CONCLUSION

Summary

The present study focused on the design and evaluation of a chewable pediatric oral jelly formulation of Paracetamol.

Key Steps in Study

1. Preformulation studies were conducted to evaluate drug properties
2. Various formulations were prepared using different polymers
3. Formulations were evaluated for physicochemical properties
4. Optimized formulation was selected
5. Stability studies were conducted

Key Findings

- Oral jelly formulation successfully developed
- Taste masking achieved effectively
- Optimized formulation (F2) showed:
  - o Ideal texture
  - o Uniform drug content
  - o Rapid drug release
  - o Stability under test conditions

Conclusion

The study concludes that chewable oral jelly is a promising dosage form for pediatric drug delivery. The formulation developed in this study provides:

- Improved patient compliance
- Accurate dosing
- Rapid therapeutic action

Thus, oral jelly can serve as an effective alternative to conventional dosage forms.

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