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FORMULATION AND EVALUATION OF PARACETAMOLPEDIATRICCHEWABLE JELLIES/ GUMMIES

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ABSTRACT

Paracetamol (acetaminophen) is a commonly used analgesic and antipyretic drug; however, conventional tablets may reduce patient compliance, especially in children and individuals with swallowing difficulties. This study aimed to formulate and evaluate a paracetamol gummy gel as an alternative oral dosage form with improved palatability and ease of administration.The formulation was prepared using suitable gelling agents, sweeteners, and paracetamol, followed by evaluation of its physicochemical properties, drug content, stability, and in vitro drug release profile. Safety, effectiveness, and patient acceptability were also assessed in comparison with conventional tablet formulations.The findings suggested that paracetamol gummy gel provides a stable, effective, and patient-friendly alternative that may enhance compliance and therapeutic convenience.

KEYWORDS: Paracetamol, Acetaminophen, Gummy gel, Analgesic, Antipyretic, Patient compliance.

INTRODUCTION

Paracetamol Pediatric Gummies is a novel oral dosage form developed to provide pain and fever relief in a more palatable and convenient manner. Unlike conventional tablets or syrups, gummies offer a chewable alternative, making administration easier for children, elderly patients, and individuals with swallowing difficulties. Their pleasant taste and texture may also improve medication adherence.The formulation typically includes paracetamol incorporated into a gummy base containing gelling agents such as gelatin or pectin, along

with sweeteners, flavors, and coloring agents to enhance acceptability. These formulations are designed to ensure accurate dosing, stability, and ease of use.

Special Considerations

- **Sugar content:** May not be suitable for diabetic or sugar-restricted individuals.
- **Child safety:** Candy-like appearance can increase the risk of accidental overdose.
- **Additives:** Some formulations may contain vitamins or herbal ingredients that could affect compatibility.

Excipients Used

1. Paracetamol

Paracetamol is a widely used analgesic and antipyretic agent used to reduce fever and relieve mild to moderate pain in pediatric patients. It is commonly incorporated into chewable gummies and jellies for improved patient compliance.

2. Gelatin

Gelatin is a natural protein obtained from collagen and is used as a gelling agent in gummy formulations. It provides elasticity, softness, and chewable texture to pediatric jellies.

3. Sucrose

Sucrose is used as a sweetening agent to improve the taste and palatability of pediatric gummies. It also contributes to texture and stability of the formulation.

4. Citric Acid

Citric acid is added to gummies as an acidulant to enhance flavor and maintain the pH of the formulation. It provides a pleasant tart taste and improves product stability.

5. Sodium Benzoate

Sodium benzoate is a commonly used preservative that prevents microbial growth in gummy formulations. It helps improve the shelf life and safety of pediatric products.

Mechanishm of Action

1. Analgesic Mechanism of Paracetamol

Paracetamol (Acetaminophen)

↓

Crosses the Blood-Brain Barrier

↓

Acts Mainly in the Central Nervous System (CNS)

↓

Inhibits Prostaglandin Synthesis by Blocking Cyclooxygenase Activity in the Brain

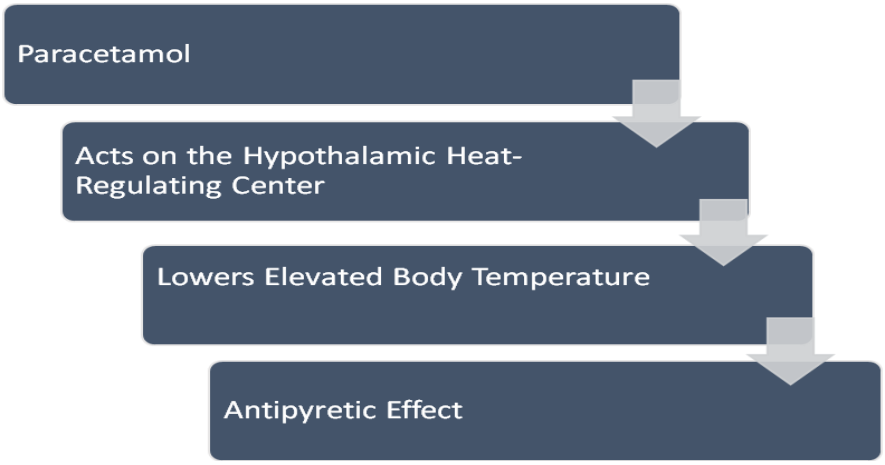
↓

Reduces Pain Signal Transmission and Sensitivity

↓

Produces Analgesic (Pain-Relieving) Effect

2. Antipyretic mechanism:



Pharmacokinetics

Parameter	Description
Absorption	Paracetamol is rapidly absorbed from the gastrointestinal tract, mainly in the small intestine, with good oral bioavailability.
Distribution	It is distributed uniformly throughout body fluids and shows low plasma protein binding at therapeutic doses.
Metabolism	The drug is primarily metabolized in the liver through glucuronidation and sulfation, while a small portion forms metabolites via cytochrome enzymes.
Excretion	Metabolites are mainly eliminated through urine, with only a small amount excreted unchanged.
Bioavailability	Oral bioavailability may increase at higher doses due to reduced first-pass metabolism.

Uses of Paracetamol Gummies/Jellies

Paracetamol gummies/jellies are commonly used for the relief of pain and fever in both children and adults. Their chewable form improves ease of administration and patient compliance.

1. **Fever (Pyrexia):** Helps lower raised body temperature caused by infections or immunization.
2. **Headache:** Provides relief from mild to moderate headaches, including tension-related pain.
3. **Toothache:** Useful in reducing dental pain and discomfort during teething or after dental procedures.
4. **Cold and Flu Symptoms:** Helps manage fever, body pain, and mild throat discomfort associated with colds and flu.
5. **Muscle Pain:** Effective for mild muscular aches caused by physical activity or illness.
6. **Back Pain:** May relieve mild lower back pain and muscle strain.

Advantages of Medicated Gummy Candy for Children

1. Child-Friendly Dosage Form

Gummies are easier to consume than tablets and help mask the unpleasant taste of medicines, improving acceptability in children.

2. Convenient Administration

They do not require water or measuring devices, making them suitable for travel and daily use.

3. Better Patient Compliance

The pleasant taste and chewable form encourage regular medicine intake, especially in children and elderly patients.

Side Effects of Paracetamol

1. Common Effects (Rare at Recommended Dose):

- Nausea
- Vomiting
- Stomach discomfort or abdominal pain
- Loss of appetite
- Mild dizziness
- Headache
- Fatigue or weakness

2. Serious Effects (Usually Due to Overdose or Prolonged Use):

Liver toxicity/hepatotoxicity: Jaundice, dark urine, nausea,abdominal pain, etc.

Kidney impairment: Prolonged or excessive use may affect kidney function.

Severe allergic reactions: Rash, itching, swelling, etc.

Skin reactions (rare): Serious conditions such as skin peeling, blistering, or redness.

- **Blood-related disorders (rare):** Changes in blood cell count leading to unusual bruising, etc.

Formulation Table

S. No.	Ingredient	F1 (10 g)	F2 (20 g)	F3 (30 g)	Function/Role
1	Paracetamol	1.0 g (10x100mg)	2.0 g (20x100mg)	3.0 g (30x100mg)	Active pharmaceutical ingredient (API)
2	Sucrose	2.5 g	5.0 g	7.5 g	Sweetening agent
3	Gelatin	2.0 g	4.0 g	6.0 g	Gelling/structuring agent
4	Sorbitol	1.5 g	3.0 g	4.5 g	Moisture-retaining agent (Humectant)
5	Citric Acid	0.10 g	0.20 g	0.30 g	Acidifying agent
6	Sodium Citrate	0.10 g	0.20 g	0.30 g	pH stabilizer / Buffering agent
7	Sodium Benzoate	0.01 g	0.02 g	0.03 g	Preservative
8	Purified Water	q.s.(~2.75ml)	q.s.(~5.5ml)	q.s.(~8.25ml)	Vehicle / Solvent
9	Coloring Agent	0.01 g	0.02 g	0.03 g	Improves visual appearance
10	Flavoring Agent	0.03 g	0.06 g	0.09 g	Enhances taste and acceptability

Evaluation Parameters

1. Physical Appearance

Physical appearance evaluation is carried out to examine the colour, odour, shape, taste, texture, and overall appearance of pediatric gummies/jellies. It ensures product acceptability, uniformity, and patient compliance.

2. Weight Variation Test

The weight variation test is performed to determine the uniformity of weight among individual gummies. It confirms proper distribution of ingredients and consistency in dosage.

3. Thickness Test

Thickness is measured using a vernier caliper or screw gauge to ensure uniform size and proper molding of gummies/jellies. Uniform thickness helps maintain consistent drug content and appearance.

4. Drug Content Uniformity

Drug content analysis is performed to determine the amount of drug present in each gummy/jelly formulation. It ensures accurate dosing and uniform distribution of the active ingredient.

5. pH Determination

The pH of gummies/jellies is measured to evaluate their acidity or alkalinity. Suitable pH improves stability, taste, and compatibility for pediatric administration.

6. Stability Study

Stability studies are conducted to assess the physical, chemical, and organoleptic stability of gummies during storage under different conditions. It helps determine shelf life and storage requirements.

7. Texture Evaluation

Texture evaluation determines the softness, elasticity, chewability, and stickiness of gummies/jellies. Proper texture improves patient acceptability and ease of consumption.

8. Organoleptic Evaluation

Organoleptic evaluation involves sensory assessment of taste, aroma, mouthfeel, and chewability. It is important for ensuring pediatric patient compliance and product palatability.

CONCLUSION

Paracetamol gummy candies offer a patient-friendly and innovative dosage form, especially for children and individuals who have difficulty swallowing conventional tablets. Their pleasant taste, chewable texture, and ease of administration improve patient acceptance and compliance in pain and fever management.Overall, paracetamol gummies provide a convenient and effective alternative to traditional oral dosage forms when used responsibly. With increasing interest in chewable and edible medications, maintaining product safety, quality, and patient awareness remains essential for their successful therapeutic use.Overall, paracetamol gummy candies represent a convenient, acceptable, and effective alternative to conventional oral dosage forms. With the growing demand for patient-centric drug delivery systems, medicated gummies have considerable potential in modern pharmaceutical formulations. Future research focusing on enhanced stability, controlled drug release, sugar-free formulations, and improved taste masking may further expand their therapeutic applications and clinical acceptance in pediatric and geriatric healthcare.

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