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FORMULATION AND DEVELOPMENT OF PARACETAMOL GUMMY CANDY

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ABSTRACT

Paracetamol (acetaminophen) gummy gel as an alternative dosage form for pain relief, aiming to improve patient compliance, particularly in children and individuals with difficulty swallowing tablets. The gummy gel was formulated using a combination of natural gelling agents, sweeteners, and paracetamol. The formulation was characterized in terms of its physical, chemical, and pharmacological properties. The study evaluates the gel's stability, release profile, and effectiveness compared to conventional tablet forms. Safety and user acceptance were also analyzed.

Keywords: Acetaminophen, gummy candy, pyrexia, endogenous

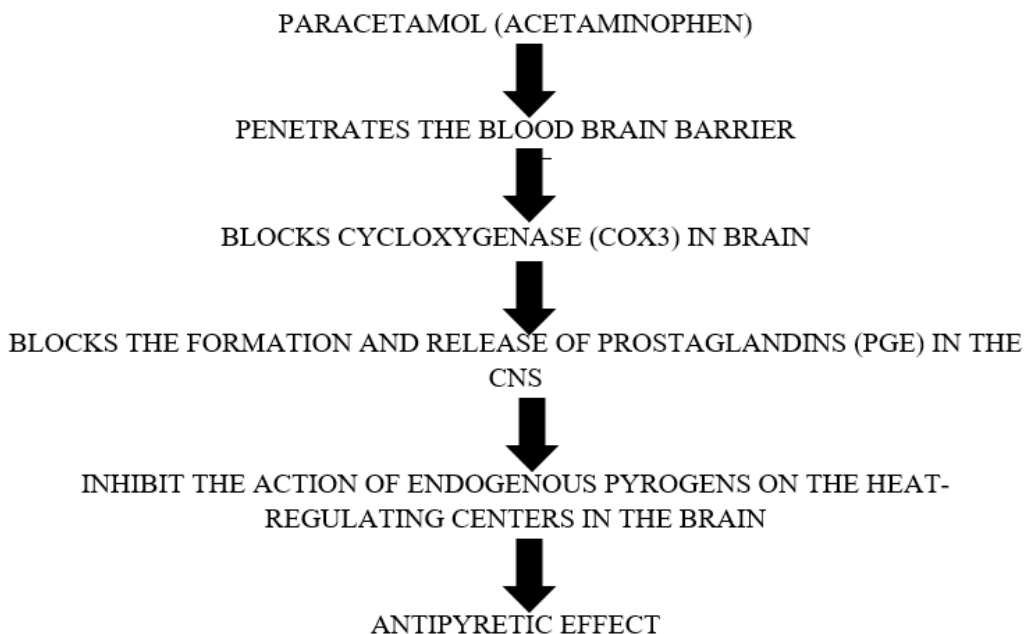
INTRODUCTION

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. These gummies combine the analgesic properties of paracetamol with the pleasant taste and chewable texture of a candy, making it easier to adhere to pain management regimens. The formulation of paracetamol gummies involves ensuring precise dosing while maintaining the stability of the active ingredient within the gummy matrix. The candy may contain other ingredients, such as sweeteners, Flavors, and coloring agents, which contribute to its overall appeal. In addition to their primary function as a pain reliever, these gummies can also serve as a more discreet and portable option for users. Jellies and gummies are popular with both children and adults. The base of a gummy bear is typically composed of a jellyifying agent (pectin, modified starch, gelatin, etc.) and sugars, in which water-soluble ingredients can be dissolved and insoluble ingredients are suspended in the viscous matrix. As a result, the application range of gummies is broad.

Special notes for Gummy form: -

- **Sugar content:** Might be a concern for people with diabetes or on sugar-restricted diets.
- **Children:** Risk of **accidental overdose** due to candy-like appearance.
- **Chewable additives:** Some gummies may include vitamins or herbal ingredients, which might have their own interactions.

1]Analgesic mechanism of paracetamol: -



2]Pharmacokinetic: -

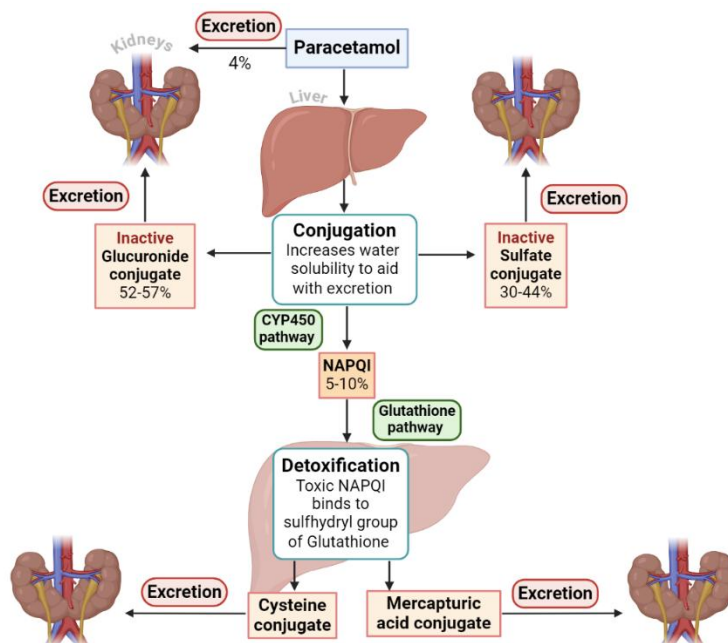


Fig.1 Pharmacokinetic

Table 1: Pharmacokinetic

	Action
Absorption	Paracetamol is well absorbed in the gastrointestinal tract. Oral paracetamol is absorbed, mainly from the small bowel, by passive transport, and has high, though variable, bioavailability.
Distribution	Paracetamol is distributed throughout the body fluids in a homogeneous way. Paracetamol given at therapeutic doses binds to plasma protein at less than 20%.
Metabolism	Paracetamol is essentially metabolized in the liver by conjugation with glucuronic acid (55%) and sulfuric acid (35%). Hepatotoxic metabolites are produced in small amounts by the cytochrome P450 (isoenzyme CYP2E1).
Excretion	Metabolites are excreted through the kidneys in the urine. Only 2-5% of the dose is excreted in an unchanged form in the urine. As a consequence of its short elimination half-life (1-3h), 24 hours after the ingestion of a single dose of paracetamol, 98% of the dose is eliminated.
Bioavailability	Oral Bioavailability is dose dependant: with larger doses, the hepatic first pass effect is reduced due to overwhelming of the liver enzymatic capacity; and therefore, bioavailability is increased.

3]Uses of Paracetamol Gummy candy: -

Paracetamol gummy candy is used for several conditions: -

- 1.Fever (Pyrexia):** -Helps reduce elevated body temperature caused by infections, vaccinations, or other illnesses.
- 2. Headaches:** -Effective in relieving tension headaches, mild migraines, and general head pain.
- 3. Toothache:** -Provides temporary relief from dental pain, teething (in children), or post-dental procedure discomfort.
- 4. Cold and Flu Symptoms**
 - Helps ease associated symptoms such as:
 - Fever
 - Body aches
 - Mild sore throat pain
- 5. Muscle Aches:** -Useful for mild muscle soreness due to overexertion, physical activity, or viral infections.
- 6. Back Pain:** -Provides relief from lower back pain or muscle strain.
- 7. Post-Vaccination Discomfort:** -Commonly used to manage mild fever and pain after vaccinations, especially in children.
- 8. Earache (Otalgia):** -Can help reduce pain and fever related to ear infections in children.

4]Advantages of preparation of medicated gummy candy for children: -

- **Kid-Friendly Format**
 - Easier for children to take than tablets or liquid medicines.
 - Pleasant taste masks the bitter taste of paracetamol.
- **Convenience**
 - No need for water or measuring spoons.
 - Great for on-the-go use.
- **Improved Compliance**

- Patients (especially children or elderly) are more likely to take medicine regularly if it's enjoyable and easy to consume

Precautions:

- **Dosage Control** is crucial—overdosing on paracetamol can cause liver damage.
- **Keep out of reach of children**—because they taste like candy, there's a risk of accidental overdose.
- Always check the exact paracetamol content per gummy and follow the dosing instructions from a healthcare provider or package insert.

5]Side effect: -

1. Common (but rare at correct doses)

- Nausea
- Vomiting
- Stomach upset or pain
- Loss of appetite

2. Serious (usually from overdose or prolonged use)

- **Liver damage:** -The most dangerous side effect of paracetamol.
 - Symptoms of liver issues include:
 - Yellowing of skin or eyes (**jaundice**)
 - Dark urine
 - Fatigue
 - Pain in the upper right abdomen
- **Allergic reactions** (rare)
 - Rash
 - Itching or swelling (especially of the face, tongue, or throat)

Aim: To prepare and evaluate paracetamol gummy candy.

Objective of paracetamol gummy candy:

The objective of paracetamol gummy candy is to provide a convenient, palatable, and child-friendly way to deliver the therapeutic effects of paracetamol (acetaminophen).

Main Objectives:

- I. **Pain relief (analgesic):** Helps reduce mild to moderate pain such as:
 - Headaches
 - Toothaches
 - Muscle aches
 - Sore throat
 - Minor injuries
- II. **Fever reduction (antipyretic):** Lowers fever caused by:
 - Infections (like colds, flu)
 - Teething (in children)
 - Post-vaccination fever

Specific Goals for Gummy Form:

- **Ease of administration:** Especially for children or adults who have difficulty swallowing pills or dislike liquid medicine.
- **Improved compliance:** Tastes better, so users (especially kids) are more likely to take the correct dose.
- **Portability & convenience:** No need for water, easy to carry.

Ingredient used in formulation:

API: Paracetamol

Excipients: gelatine, agar, sucrose, citric acid, methylparaben

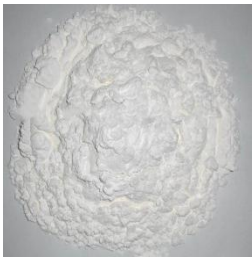
Table 2 Ingredients & Role

Ingredients	Role
Paracetamol	API
Sucrose	Sweetening agent
Gelatine	Gelling agent
Agar	Gelling Agent
Citric acid	Buffer {adjust pH}
Glycerine	Softening Agent, act as Humectant
Sorbitol	Sweetener
Sodium Benzoate	Preservative

Equipment Used During Formulation: -

1. Precision scale (for accurate drug dosage)
2. Beaker
3. Homogenizer or mixer
4. Molds (food-grade silicone)
5. Drying racks or controlled environment chamber

Chemical Used: -

		
Paracetamol	Gelatin	Citric acid
		
SORBITOL	SODIUM BENZOATE	SODIUM CITRATE

Apparatus Used: -



BEAKER

STIRRER

BURNER

Procedure

The method of gummy preparation includes preparation of two solutions, i.e., a solution of water and sugar and a solution of gelatin and water.



Weigh all the required ingredients of the formulation accurately.



Sucrose syrup was prepared by adding sucrose to water & is heated until it is dissolved, then citric acid is added to prevent crystallization of sugar.



In another beaker, Gelatine was soaked in the required quantity of water to facilitate its hydration, and then it is added to the above mixture & heated until completely dissolved.



Add the weighed Sorbitol and dissolve it completely.



Then drug complex is prepared, sodium benzoate was dissolved in an appropriate vehicle, & added to the above mixture with stirring.



After that sodium citrate was added with continuous stirring to maintain pH.



The solution is mixed thoroughly and uniformly and & heated until completely dissolved.



Then color, and flavoring agents were added to the above mixture & mixed thoroughly.



Add the mixture into mould.



Cool it at room temperature

Table 3 Batches

Sr.no	Ingredients	F1(10gm)	F2(20gm)	F3(30gm)	Role
1	Paracetamol	1gm	2gm	3gm	API
2	Sucrose	2.50gm	5gm	7.50gm	Sweetener
3	Gelatin	2.00gm	4gm	6gm	Gelling agent
4	Sorbital	1.50gm	3gm	4.50gm	Humectant
5	Citric Acid	0.10gm	0.20gm	03.0gm	
6	Sod.Citrate	0.10gm	0.20gm	0.30gm	Buffering agent
7	Sod.Benzoate	0.01gm	0.02gm	0.03gm	Preservative
8	Water	q. s	q. s	q. s	Solvent
9	Coloring Agent	0.01gm	0.02gm	0.03gm	Gives color
10	Flavoring Agent	0.03gm	0.06gm	0.09gm	Taste enhancer

F1 Batch

Preparation of two solution



Solution of water and 2.50gm sugar, Solution of water & 2.00gm gelatin



Add 0.10gm citric acid in sucrose solution to prevent crystallization of sugar



Add above solution in solution of gelatin and then 1.50gm Sorbital and dissolve completely



Add 1gm Drug (paracetamol) & 0.01gm Na. Benzoate dissolve in appropriate vehicle and add above mixture and stir



0.10gm Na. Citrate was add during stirring to maintain pH



Solution is mixed thoroughly, Heat until completely dissolved



Then add 0.01gm coloring and 0.03gm flavoring agent to above mixture & mixed thoroughly



Add mixture in mould



Cool in room temperature



F2 Batch
Preparation of two solution



Solution of water and 5gm sugar, Solution of water and 4gm gelatine



Add 0.20gm citric acid in sucrose solution to prevent crystallization of sugar



Add above solution in solution of gelatin and then 3 gm Sorbital and dissolve completely



Add 2gm Drug (paracetamol) & 0.02gm Na. Benzoate dissolve in appropriate vehicle and add above mixture and stir



0.20gm Na. Citrate was add during stirring to maintain pH



Solution is mixed thoroughly, Heat until completely dissolved





Then add 0.02gm coloring and 0.06gm flavoring agent to above mixture & mixed thoroughly



Add mixture in mould



Cool in room temperature



F3 Batch

Preparation of two solution



Solution of water and 7.50gm sugar, Solution of water and 6gm gelatin



Add 0.10gm citric acid in sucrose solution to prevent crystallization of sugar



Add above solution in solution of gelatin and then 03.0gm Sorbital and dissolve completely



Add 3gm Drug (paracetamol) & 0.03gm Na. Benzoate dissolve in appropriate vehicle and add above mixture and stir



0.30gm Na. Citrate was add during stirring to maintain pH



Solution is mixed thoroughly, Heat until completely dissolved



Then add 0.03gm coloring and 0.09gm flavoring agent to above mixture & mixed thoroughly



Add mixture in mould



Cool in room temperature



Result:

Evaluation Test of Gummies:

- 1) Physical Appearance
 - a) Colour b) Odour c) Shape d) State e) Taste f) Texture
- 2) weight variation
- 3) Thickness

- 4) Drug content
- 5) pH of gummy
- 6) Stability testing

1. Physical Appearance: -

All the prepared gummies are visually observed for their colour, shape, odour, texture, and clarity of gummies. Taste and odor should be pleasant and acceptable. No visible defects like air bubbles, cracks, or discoloration.

2. Thickness: -

The thickness of a gummy was measured using Vernier Calliper. The thickness of 5 gummies were checked. To measure the consistency of thickness among gummy units, which impacts packaging, dosage uniformity, and consumer experience.

Procedure: -

- **Sample Size:** Randomly select **5 to 10 gummies** from a production batch.
- **Measurement Procedure:**

- a) Place the gummy flat on a clean, firm surface.
- b) Measure the **maximum vertical height (thickness)** at the center.



Figure: Vernier calliper

3. Calculate Average Weight: Add the 10 weights and divide by 10 to get the **mean weight**.

Determine Deviation: Calculate the **percentage deviation** of each gummy from the mean weight:

Deviation	Individual Weight – average Weight	x100
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Figure: Weighing balance

4. pH Determination:

- a. Dissolve gummy in distilled water.
- b. Measure pH using a digital pH meter
- c. Ideal pH: around 4.0–7.0 for oral dosage safety.



Figure: pH meter

5. Weight uniformity test:

The **weight variation test of gummies** is commonly used in **pharmaceutical and nutraceutical** settings to ensure **uniformity in dosage** (e.g., when gummies contain vitamins, minerals, or other active ingredients).

Purpose: To verify that each gummy contains the correct amount of the active ingredient by confirming uniformity in weight.

Procedure:

1) **Sample Size:** Select **10 randomly chosen gummies** from a batch.

2) **Weigh Individually:**

- a) Weigh each gummy **separately** using a **precision balance**.
- b) Record the individual weights.

6. **Drug Content Uniformity (Assay):** is a critical quality control test used in **pharmaceuticals**, especially for dosage forms like **gummies, tablets, or capsules** that contain active pharmaceutical ingredients (APIs). Its goal is to ensure **each unit contains the correct amount of drug**, within an acceptable range.

Procedure:

- a. Crushed gummy samples are dissolved in a suitable solvent.
- b. Analyze using UV spectroscopy.
- c. Acceptable limit: 90–110% of the labeled amount of paracetamol.

Sample Size: Select **10 dosage units** (e.g., 10 gummies) at random from a batch.

Stability Studies: The gummies are stable in cool Temperature. stable at room temperature but increase the temperature gummies was melted.

7. In Vitro Drug Release (Dissolution Test):

- a) Performed using USP dissolution apparatus (Type I or II).
- b) Use buffer (pH 5.8 or 6.8), 37°C, 50–100 rpm.
- c) Analyze samples at regular intervals.
- d) At least 80% drug release should occur within 30–45 minutes.

8. Moisture Content:

- a) Determined using Karl Fischer titration or LOD (Loss on Drying) method.
- b) Excess moisture may affect stability and microbial growth.

RESULT

Result: Gummies was formulated and evaluated using the drug albendazole.

1. Physical appearance

S.No	PROPERTY	INFERENCE		
		Formula 1	Formula 2	Formula 3
1.	Colour	Pink	Yellow	Faint pink
2.	Shape	Rose shape	circular, square	Rose shape
3.	Odour	Strawberry like	Mangoes like	Strawberry like
4.	Taste	Sweet	Sweet	Sweet
5.	Texture	Smooth flexible	Smooth flexible	Smooth flexible

Table 4 Physical appearance

2. Thickness:

Formula 1		Formula2		Formula 3	
gummies	Thickness (cm)	gummies	Thickness	gummies	Thickness
1.	2	1.	2.4	1.	2.4
2.	2.3	2.	2.4	2.	2.4
3.	2.5	3.	2.4	3.	2.4

4.	2.4	4.	2.4	4.	2.4
5.	2.5	5.	2.4	5.	2.4

Table 5: Thickness

3. Weight variation:

Gummies	Weight (gm)
1.	5.00
2.	5.00
3.	5.01
4.	5.00
5.	5.10
6.	5.00
7.	5.00
8.	5.01
9.	5.00
10.	5.00

4. pH measurement:

pH	7.1
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5. Microbial testing:

- It is done by using streak plate method
- Result – No growth was found
- Prepare the Agar Plate
- Sterilize the Inoculating Loop
- Obtain the Sample
- Streaking the Plate
- Incubation



Figure: Streak Plate Method

CONCLUSION

Paracetamol gummy candies represent an innovative and more accessible way to take medication, particularly for those who struggle with traditional pill forms, like children or individuals who dislike swallowing tablets. Their taste appeal and ease of consumption make them a convenient alternative for both pain relief and fever reduction. However, their sweet, candy-like nature poses risks, especially when it comes to overconsumption, which could lead to serious health issues like liver damage.

While they are effective and generally safe when used properly, clear dosage instructions and careful packaging are essential to prevent accidental overdose. For children, they provide a more enjoyable experience, but supervision is important to ensure they take the correct amount.

Overall, paracetamol gummy candies can be a useful option for those who prefer or need alternative medication forms, but like any medication, they should be used responsibly and according to the recommended guidelines. As the market for edible medicines continues to grow, it's crucial that both manufacturers and consumers remain mindful of the potential risks while enjoying the convenience and accessibility that these products offer.

DISCUSSION

Paracetamol gummy candies are an interesting and increasingly popular form of medication delivery, especially for children or individuals who have difficulty swallowing pills. Paracetamol (also known as acetaminophen in some countries) is a common over-the-counter pain reliever and fever reducer. Typically, it comes in tablet, liquid, or capsule form, but the gummy candy version is a newer innovation. These gummies contain a specific dose of paracetamol are formulated to be more palatable, with a sweet, fruity taste, which makes them easier to ingest, especially for kids.

For Kids: Kids often struggle with swallowing pills, and liquid medicine can be unpleasant. Gummy versions make taking medicine feel like a treat.

For Adults: Even adults might prefer gummies over traditional pills, especially if they have a sensitive stomach or difficulty swallowing tablets

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