FORMULATION AND EVALUATION OF ORAL MEDICATED PARACETAMOL JELLY FOR PEDIATRICS

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Abstract

The aim of this research was to develop and evaluate an oral medicated jelly formulation of paracetamol tailored for pediatric use. Oral jellies provide an attractive alternative to traditional solid and liquid dosage forms, especially for children who often experience difficulty swallowing tablets or dislike the taste of syrups. In this study, paracetamol jellies were prepared using natural and synthetic gelling agents such as pectin, sodium alginate, and gelatin, in combination with sweeteners and flavoring agents to enhance palatability. The formulations were evaluated for physical appearance, viscosity, pH, drug content uniformity, in vitro drug release, and stability under various conditions. Among the various formulations, the jelly prepared using pectin exhibited optimal characteristics including pleasant taste, uniform drug distribution, and a controlled release profile suitable for pediatric administration. Stability studies confirmed that the jelly remained physically and chemically stable over a 3-month period. The results suggest that oral medicated jelly is a promising and patient-friendly dosage form for delivering paracetamol to children, improving compliance and therapeutic effectiveness.

Keywords: Paracetamol, pediatric formulation, oral jelly, drug delivery, patient compliance, taste masking, controlled release.

I. INTRODUCTION:

Introduction of this paracetamol jelly formulation for pediatrics stems from a critical need to address the challenges associated with administering oral medications to children. Traditional dosage forms often encounter issues such as taste aversion and difficulty in swallowing, leading to non-compliance and compromised therapeutic outcomes in pediatric patients.

This study aims to bridge this gap by exploring an innovative gel-based delivery system for paracetamol specifically designed for children.

The formulation process involves a meticulous balance of key parameters like viscosity, taste masking, and palatability, with the primary goal of creating a medication that is not only effective but also readily accepted by its young recipients.

The motivation behind this research lies in enhancing the overall patient experience for children requiring paracetamol treatment. By introducing a jelly formulation, we anticipate improved medication adherence, reduced resistance from pediatric patients, and ultimately better therapeutic outcomes.

This approach aligns with the growing emphasis on patient-centric healthcare and tailoring pharmaceuticals to meet the unique needs of different demographics.

As we delve into the development and evaluation of this paracetamol jelly, we anticipate that the findings will not only contribute to the field of pediatric pharmaceuticals but also set a precedent for exploring novel formulations that prioritize both efficacy and patient acceptability.

Advantages of Paracetamol Jelly

The Paracetamol jelly formulation for pediatrics offers several advantages:

- **Palatability**: The jelly formulation addresses the common issue of taste aversion in pediatric patients, making it more palatable and increasing the likelihood of compliance.
- **Ease of Administration:** The gel-based nature of the formulation provides a userfriendly alternative, especially for children who may struggle with swallowing conventional tablets or liquids.
- **Accurate Dosage**: The jelly allows for precise dosing, reducing the risk of dosage errors common in pediatric medicine and ensuring the child receives the correct amount of paracetamol.
- **Improved Patient Compliance:** The appealing texture and taste contribute to better acceptance by pediatric patients, promoting adherence to the prescribed medication regimen.
- **Rapid Dissolution:** The jelly formulation may facilitate faster drug dissolution, potentially leading to quicker onset of action compared to traditional oral dosage forms.
- **Reduced Gastrointestinal Irritation**: Gel-based formulations may be gentler on the gastrointestinal tract, minimizing the likelihood of irritation, which can be particularly beneficial for pediatric patients.
- **Innovative Drug Delivery Approach:** The use of a jelly formulation represents an innovative approach to pediatric drug delivery, opening avenues for similar formulations for other medications.
- **Potential for Customization:** The formulation process allows for customization of factors such as viscosity and taste, enabling tailoring to individual preferences and needs. In summary, the

paracetamoljelly offers a child-friendly, easy-to-administer, and potentially more effective alternative for delivering paracetamol to pediatric patients, addressing some of the challenges associated with conventional forms of medication in this demographic.

Ideal Characteristics of Oral Medicated Jelly

I t should leave minimal or no residue in mouth after oral administration, compatible with pleasing mouth feel.

- Be compatible with taste masking.
- Allow high drug loading.
- Effective taste masking technologies should be adopted for bitter taste of drugs.The drug and excipients property should not affect the orally disintegrating tablet.
- Variations towards changes in environmental conditions should be less.

Dominence of Jelly

It can be administered easily i.e, anywhere, anytime.

It is ideal method of drug delivery for dysphasia patients.

- Good mouth feel property of gellies helps to change the perception of medication.Allow high drug loading.
- Jelly is most convenient for disabled, bedridden patients, travellers and busy people, who do not always have access to water.
- Good chemical stability as conventional liquid dosage form.
- Suitable during travelling where water may not be available

Rationalae

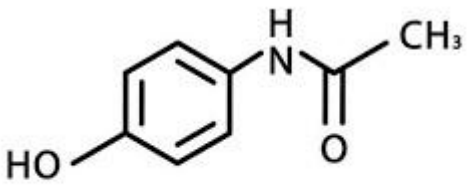
- The ratinalae behind the use of oral medicated jelly in international market as one of most favoured dosage form for children,paediatrics, geriatric and dysphagia patients.
- Controlled release jellies are also practical by controlling the viscosity of polymers.
- For chronic illness treatment multiple drugs can be incorporated in them.
- Patients for whom chewing is difficult, painful or lower jaw is paralysed can use medicated jelly easily.
- Jellies formulation was found to be very stable over durations of days with no significant

Limits;

As it is aqueous base preparation it needs appropriate packaging to maintain stability of drugs in various environment

It may lead to unpleasant taste if not formulated appropriately

II. DRUG PROFILE



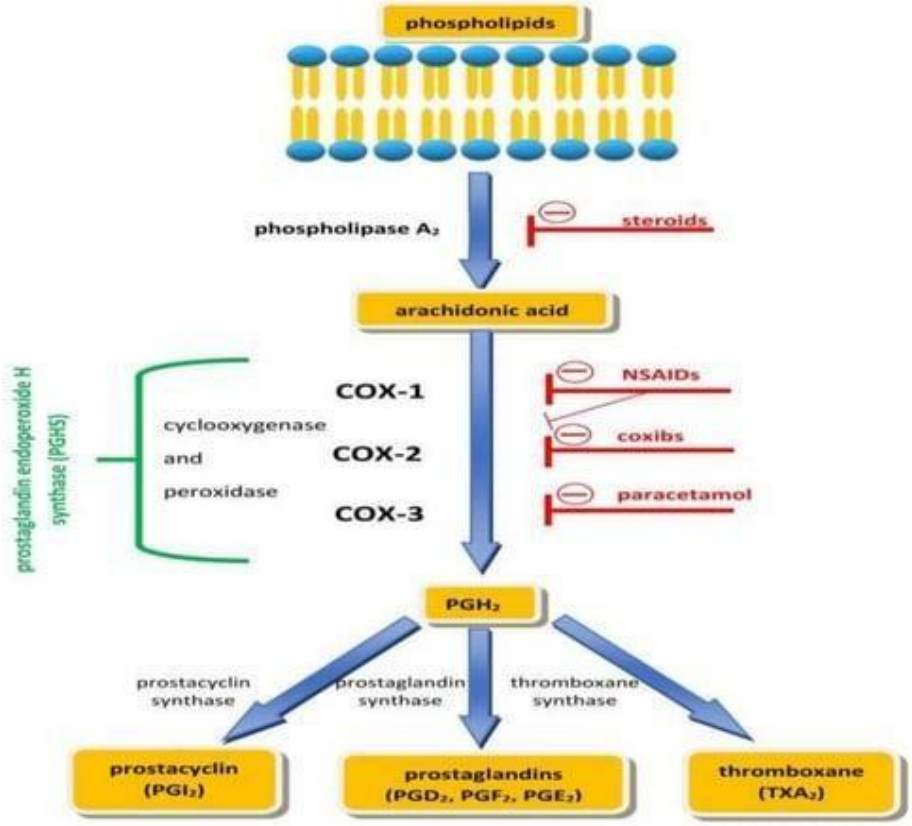
Paracetamol

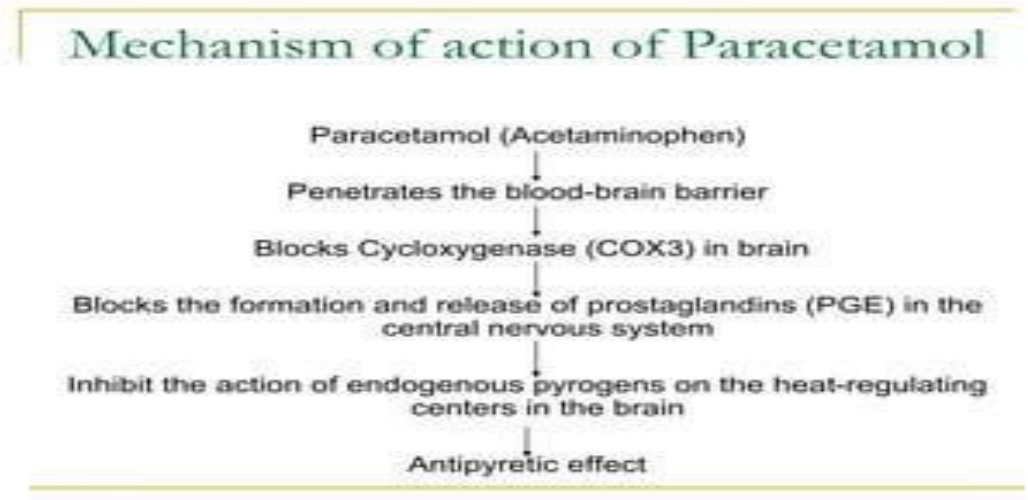
$C_8H_9NO_2$

Paracetamol

- Synonym - Acetaminophen
- Mol. Wt. 151.2 gm/mol
- Molecular Formula :- C8H9NO2
- Category- Analgesic and antipyretics
- Description- white crystals or white crystalline powder.
- Storage- Store protected frim light and moisture.
- Half Life :-100-240 minutes
- Route :- Oral
- Metabolism :- Liver

III. Mechanism of Action Paracetamol





IV. MATERIAL AND METHODS

□ Gelling Agent

- **Sodium aginate:** Alginate was obtained from the cell wall of brown algae. It is used as a gelling agent, thickening agent in pharmaceutical formulations alginates bind with water and forms thick gum . It is used in various oral formulations.
- **Carrageenans:** It is obtained from extract pf red edible seaweeds, & are liner sulfated poly-saccharides. They are mainly used as gelling agents. carrageenan is vegetarian & is used as substitute for gelatin.
- **Gelatin:** Gelatin is generally used as gelling agent in pharmaceutical preparation, vitamin capsule.
- **Agar:** Agar-agar is vegetarian product & substitute to gelatin.It is obtained from algae & is white and semi-translucent.

Agar

Gelati

□ Sweetners

- **Sucrose:** Sucrose was most preferred sweetening agent because it is soluble in water , it is economical i.e, its highest purified form can be obtained at reasonable price, physically and chemically stable in different PH.
- **Mannitol:**Mannitol is a white , crystalline polyol obtained by hydrogenation of fructose .It imparts a mild cooling sensation.
- **Sucralose:** It is an artificial sweetners. It is tharmo-stable and also remains stable in wide PH range. It can be used in products that need a longer shelf life. **Coloring agent**
- **FD& C colors:** Natural colors (It is extracted from natural sources or chemically synthesized such as beta-carotene).

- **Mineral colors:** Example of mineral color include mixture of red& yellow ferric oxides.**Flavoring agents**

Flavors Used As Per Taste:

- **Acidic**-Orange, lemon, cherry.
- **Alkaline**-Vanilla, chocolate, mint.
- **Bitter-** orange , lemon, anise.
- **Metallic**- grape , berry.
- **Sweet**- honey, chocolate, raspberry.

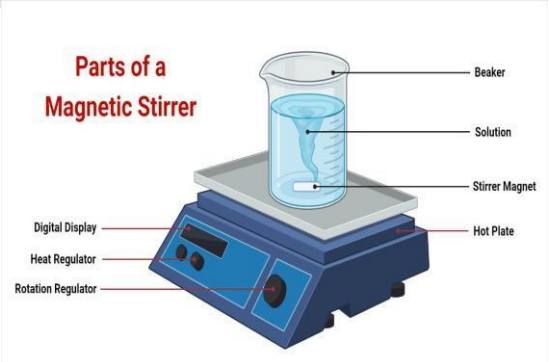
- **Preservatives**

  Eg. Methyl paraben, propyl paraben, Benzoic acid, Benzalkonium chloride, chlorhexidine acetate

- **Stabilizers**

- Stabilizers are used to maintain desirable properties of product. It is used to prevent the drying of jellies.
- Examples: propylene glycol and sorbitol.
- Chelating agent are used to avoid any reactivity between base or medicament with heavy e.g EDTA

Instruments



- Magnetic stirrer
- Weighing balance
- Viscometer
- Digital PH meter
- UV spectrophotometer

Formula :

- Gelling agent- Sodium alginate ,or carrageenan Drug- Paracetamol (250)mg.
- PH modifier- citric acid
- Preservatives- propyl paraben, methyl paraben.
- Sweetner- sucrose, dextrose
- Purified water- (q.s)
- Coloring agent- (q.s).
- Cross linkers- Calcium chloride.

V. FORMULATION

Ingredient	F1	F2	F3	F4	F5
Sodium alginate/carrageenan (gm)	7	10	8	8.5	10
Citric acid (ml)	5	5	5	5	5
Propyl paraben/ methyl paraben (gm)	0.02	0.18	0.02	0.15	0.2
Calcium chloride/glutaaldehyade (gm)	2	2	2	2	2
Sucrose (mg)	60	65	60	55	60
Paracetamol (mg)	250	250	250	250	250
Purified water (q.s)	100	100	100	100	100
Coloring agent	Q.S	Q.S	Q.S	Q S	Q.S

VI. Methods of preparation:

Accurately weigh polymer powders were dispersed in purified water

⇩

Maintained at 90 °C.

⇩

Stir for 20 min.by magnetic stirrer. add sweetening agent, citric acid & Preservatives with stirring

⇩

Add paracetamol ⇩ drug with dissolved in water .

Final weight adjusted with purified water, mixed and transferred to Molds and allow to cool.

VII. Methods of Preparation No :-2

Preparation of beads for bead formation, 100 mL of a 1-1.5% w/v aqueous solution of sodium alginate was introduced dropwise from a glass syringe with a size-22 needle into 100 mL of an aqueous calcium chloride solution being stirred at 400 rpm. The concentration of CaCl2 in the solution ranged from 1% w/v to 3% w/v. The stirring was continued for one hour and the calcium alginate beads were harvested by filtration, washed with distilled water, and air dried overnight

- **Method Of Prepration Paracetamol Jelly**

Preparation of paracetamol jelly several jelly formulations were prepared using heating and congealing method. Three gelling agents (pectin, HPMC and SodCMC) were used .Each of the polymers was dispersed in a small volume of warm distilled water and stirred using a magnetic stirrer to facilitate the hydration of hydrophilic polymer. Then, the required amount of sucrose will add to the polymer solution with continuous stirring; after that, paracetam0l and all the remaining excipients are added under stirring.

The final weight was adjusted to 25 g with distilled water.

Then was poured into molds to be stored as separate unit doses (the weight of each dose is

2.5g and contains 250 mg paracetamol) and allowed to cold at room temperature.

VIII. EVALUATION PARAMETERS

- **Physical appearance:** Physical examinations are important regarding patient compliance and acceptance. The prepared jellies were examined visually for color, texture, clarity and consistency.

- **Stickiness and grittiness:** Stickiness and grittiness should be examined by visual inspections of the formulations by slowly rubbing the jelly sample by two fingers.

- **PH:** The pH of the jellies were examined using digital pH meter at room temperature. For this, 0.5 g of jelly should mixed in 50 ml of distilled water to make 1% solution and the pH was noted. The pH of the final jelly have influence on not only stability but also on the taste.

- **Pourability of the mixture:** The jelly formulation mixture should be easily pourable in the molds. The buffer salts (retarders) like trisodium citrate play an important role in this process, which approaching of the pectin molecules during the hot phase is interfered sterically and also raise the pH-value before the acid addition, thus preventing pre-gelation. The higher the buffer salt, i.e. retarder, concentration, the lower the setting temperature and the longer the setting time which provides sufficient time for pouring and setting of the jelly.

- **Taste Evaluation:** Taste evaluation was done bythe volunteers. Five grams of optimized formulation should kept at taste panel experts and for 5 seconds have told to place the gel in their mouth. They were asked to comment on the taste.

- **Content Uniformity:**At first, jelly from the each formulation were taken, crushed and mixed. Drug equivalent of mixture was extracted by suitable media from the mixture. The absorbance of each solution should measure by UV-visible spectrophotometer at suitable wavelength or the quantity of drug contain in each extract was examined using suitable analytical method. This test is to ensure that each dosage forms contains equal amount of drug substances i.e. active pharmaceutical ingredients within the batch.

In-vitro dissolution study: The USP paddle type apparatus used for in-vitro dissolution study by using dissolution medium (900ml) was kept at 370C ± 0.50C and 50 rpm.

IX. RESULT

EVALUTION PARAMETERS	OBSERVATIONS	RESULT
COLOR	ORANGE	PASS
TASTE	SWEET	PASS
TEXTURE	SMOOTH	PASS
PH	7.5	PASS
DRUG UNIFORMITY	250MG \ JELLY	PASS
STABILITY	STABLE	PASS

X. CONCLUSION

Jelly as an oral dosage form for pediatrics is being explored. It has high potential due to several advantages over liquid formulation in term of patient acceptance, suitability for controlled release applications, stability and other aspects. More studies are needed to further explore this new.

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