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A Concise Review on Formulation and Evaluation of Immediate Release Tablets of Papaya Pulp Powder Effective for Anti-Inflammatory Activity

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ABSTRACT:
The present work aimed on the formulation and evaluation of immediate-release tablets of papaya pulp powder for anti-inflammatory activity. Papaya (Carica papaya) is rich in bioactive compounds like papain, chymopapain, flavonoids, and vitamin C, which exhibit significant anti-inflammatory and immunomodulatory effects by inhibiting COX/LOX pathways and reducing pro-inflammatory cytokines. The immunostimulant properties of papaya also enhance the body's natural defence, making it a promising candidate for managing inflammation-linked immune responses. The objective is to summarize current approaches for converting papaya pulp powder into stable, fast-disintegrating tablets using suitable excipients and super disintegrants. Key evaluation parameters include disintegration time, dissolution profile, and in-vitro/in-vivo anti-inflammatory assays. This review highlights how immediate-release tablets can provide rapid onset of action for acute inflammatory conditions while preserving the activity of thermo-labile enzymes.

INTRODUCTION:

Inflammation is the body's natural defence response to harmful stimuli like pathogens, damaged cells, or irritants. It is meant to eliminate the cause of injury, clear dead cells, and start tissue repair. It triggers infection, trauma, toxins, or autoimmune reaction & released Mediators like histamine, prostaglandins, leukotrienes, cytokines like TNF-α, IL-1β, IL-6 which causes vascular changes like Blood vessels dilate Vessels [1]. So, tablets release anti-inflammatory agents from papaya pulp powder, like papain and flavonoids, work by blocking those mediators — mainly COX/LOX enzymes and pro-inflammatory cytokines. That reduces swelling, pain, and tissue damage. Connection to immunity: Short-term inflammation helps immunity by recruiting immune cells. But uncontrolled chronic inflammation damages tissue and weakens immune function. That is why papaya's dual anti-inflammatory + immunomodulatory role is valuable [2,3].

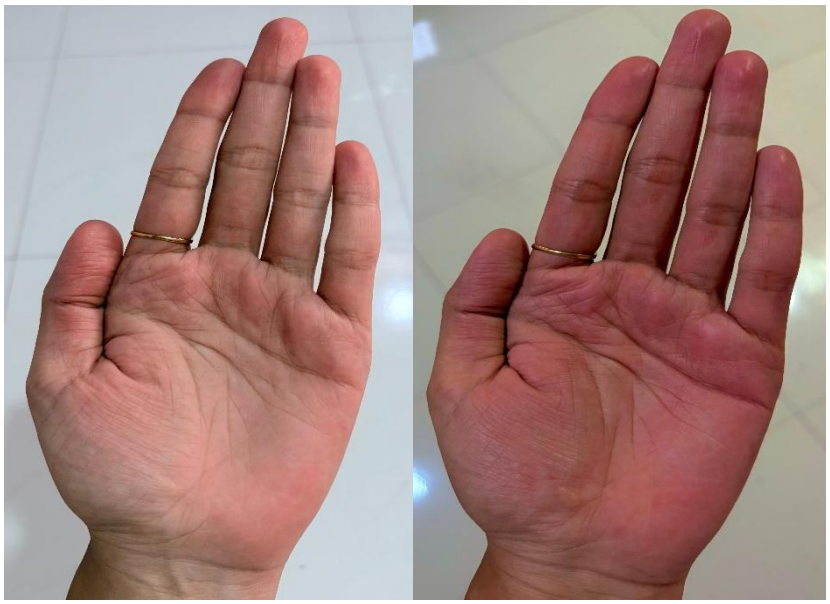

Fig 1. Normal VS Inflamed Hands

Fig 2. Papaya Pulp

Immediate-Release Tablet

An immediate-release (IR) tablet is a conventional oral solid dosage form that is designed and formulated to disintegrate and release its active pharmaceutical ingredient rapidly after oral administration, without any deliberate modification of the rate or site of drug release. It represents the most common type of tablet dosage form and is intended to provide prompt pharmacological action by making the drug available for absorption in the gastrointestinal tract as quickly as possible following ingestion [4].

According to pharmacopeial definitions, including the United States Pharmacopeia (USP) and European Pharmacopoeia (Ph. Eur.), an immediate-release tablet is one that does not have special coatings or matrices intended to control, delay, or extend the release of the drug substance. The primary functional objective of an IR tablet is to break down into granules and then into fine particles within a short time after contact with gastrointestinal fluids, thereby allowing the drug to dissolve and become available for systemic absorption.

Regulatory guidelines generally specify that an uncoated immediate-release tablet should disintegrate within 15 minutes, and a film-coated IR tablet within 30 minutes, when tested under standard conditions. Furthermore, the dissolution requirement for most IR tablets is that not less than 85% of the labelled amount of the drug should be dissolved within 30 minutes in a suitable medium using USP Apparatus II at 50 rpm [5].

In clinical use, immediate-release tablets are selected when a rapid onset of therapeutic effect is desired, such as in the treatment of acute pain, fever, allergic reactions, or inflammatory conditions. For herbal actives like papaya pulp powder, the immediate-release design ensures that bioactive enzymes and phytochemicals are liberated quickly to exert anti-inflammatory action. Thus, the core definition of an immediate-release tablet centres on rapid, unmodified drug liberation intended for prompt absorption and fast therapeutic response [6].

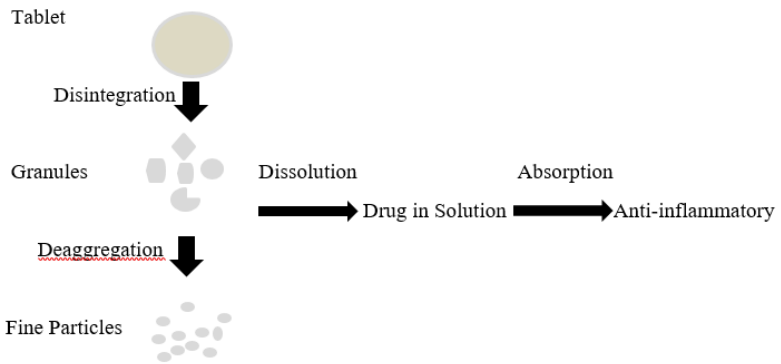

Fig 3. Mechanism of drug release from immediate release tablet

Advantages

- Rapid onset: Useful for acute inflammation, pain, fever
- High patient compliance: Easy to swallow, no special dosing technique
- Simple manufacturing: Direct compression possible, cost-effective
- Dose flexibility: Easy to split if scored
- Good stability: Less complex than SR/CR systems
- Fast relief: For papaya tablets, quick enzyme availability reduces edema fast

Disadvantages

- Frequent dosing: Short t½ drugs need 3-4 times/day → poor compliance
- Plasma fluctuation: Peak-trough profile, risk of side effects or sub-therapeutic levels
- Not for irritant drugs: Rapid release may cause gastric irritation
- Moisture sensitive: Papaya pulp powder is hygroscopic → stability issues

Limitations

- Unsuitable for sustained therapy: Chronic inflammation needs SR forms
- Enzyme degradation risk: Papain may lose activity due to gastric acid if not protected
- High dose drugs: Large tablets if dose >500 mg, swallowing difficulty
- Poor for drugs with narrow TI: Rapid input can cause toxicity
- Food effect: Fast dissolution can be affected by food, altering absorption

Various Approaches for Immediate-Release Tablets

Formulation of IR tablets relies on strategies that promote rapid disintegration and dissolution. The main approaches are:

1. Super disintegrant Approach
2. Direct Compression Approach
3. Wet Granulation Approach
4. Dry Granulation/Slugging Approach

5. Sublimation Approach
6. Effervescent Approach
7. Liquisolid Compact Approach
8. Use of Highly Soluble Excipients

Pre-formulation Parameters

Before developing any formulation, conducting pre-formulation studies is essential to assess changes in drug characteristics and the suitability of the drug candidate. Preformulation testing investigates the physical and chemical properties of the drug substance both individually and in combination with excipients. This process is crucial as it lays the groundwork for rational dosage form development. By identifying potential issues early, researchers can make informed decisions about formulation strategies and optimize drug delivery. The results of Preformulation studies can influence various factors, including stability, solubility, and bioavailability. Ultimately, these findings ensure a more efficient and effective development process for pharmaceutical products. Carr's index, Hausner's ratio, and angle of repose are used to describe the flow characteristics of powder (prior to compression) [7]. Following that, in order to ascertain:

Angle of repose:

Angle of repose carried out by fixed funnel method. The powder poured through a funnel that raised vertically until a maximum cone height (h) obtained. Radius of the heap (r) and the angle of repose (θ) obtained.

Following formula used to determine angle of repose,

$\theta = \tan 1\ (h/r)$

Where, θ = angle of repose

h = height

r = radius

Table 1: USP range for angle of repose

Sr. No	Angle of repose	Flow property
1	25-30	Excellent
2	31-35	Good
3	36-40	Fair
4	41-45	Passable
5	46-55	Poor
6	56-65	Very Poor
7	>66	Very Very Poor

Bulk density:

Bulk density determined by filling powder into a graduated cylinder. The bulk volume (V) and weight of the powder (M) determined.

$$\text{Bulk density} = \frac{\text{Weight of powder}}{\text{Bulk Volume of Powder}}$$

Tapped density:

The measuring cylinder containing a known weight of powder tapped for a fixed time.

$$\text{Tapped density} = \frac{\text{Weight of powder}}{\text{Tapped volume of powder}}$$

Carr's index:

Both bulk as well as tapped densities used for determined the powders compressibility by Carr's index.

$$\text{Carr's index} = \frac{\text{Tapped density - Bulk density}}{\text{Bulk density}} \times 100$$

Hausner's ratio:

It determines the interparticle friction and used to predict flow property of powder.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Table 2: USP ranges for Hausner's ratio

Sr. No	Hausner's ratio	Flow property
1	1.00-1.11	Excellent
2	1.12-1.18	Good
3	1.19-1.25	Fair
4	1.26-1.34	Passable
5	1.35-1.45	Poor
6	1.46-1.59	Very Poor
7	>1.60	Very very poor

Methodology

Preparation of Immediate Release Tablet of Papaya Pulp Powder

1) Firstly, Papaya fruits purchased from the local market which are fully ripe with a soft texture and sweet aroma.
2) Then extract the pulp: Cut the Papaya in half and scoop out the pulp using a spoon Remove any seeds or fibrous parts from the pulp.
3) Dehydrate the pulp: Spread the Papaya pulp evenly on a tray dryer. Set the tray dryer to a low temperature (around 50-60°C or 120-140°F) and allow the pulp to dry for several hours until it becomes dry and brittle.
4) Grind into a fine powder: Once the pulp is completely dehydrated, transfer it to a blender. Grind the dried pulp into a fine powder.
5) Sieve and store: Pass the powdered pulp through a fine mesh sieve to remove any larger particles or lumps. Store the Papaya pulp powder in an airtight container in a cool, dry place away from direct sunlight.
6) Then check the solubility of fruit extract powder in the phosphate buffer.
7) The melting point of extract was checked by capillary method.
8) After that, checked the λ max of fruit extract, it was found to be 324 nm.
9) Physiological properties of extract were also checked.
10) Then prepared the formula for papaya pulp powder tablet compatible with other excipients in 6 batches and maintain the weight of tablet at 250 mg.
11) After making batches, pre-formulation of tablet was done.
12) Then tablets were punched by the direct compression method using tablet punch machine.
13) After the tablet preparation, post-compression evaluation done.
14) Dissolution rate checked in 25 min after the 5 min interval.
15) FTIR study of the fruit extract and most compatible batch done [7] [8].

Evaluation of Immediate Release Tablet of Papaya Pulp Powder

Physical appearance

The overall appearance of the tablet was visually examined in shape, colour, texture and odour [7] [8].

Weight Variation

20 tablets are weighed in order to conduct the weight variation test. separately, figuring out the mean weight and contrasting the weight of each tablet with the average. The weight variation test would be an effective way to figure out the tablets' uniform drug content.

Hardness

Another name for hardness is "tablet crushing strength." A Monsanto hardness tester was used to measure the tablet's hardness. The tablet was positioned between the upper and lower plungers, and a threaded bolt was turned to apply force until the tablet broke, and the tablet's hardness was expressed in kg/cm.

Friability

The Roche friabilator determines it by using a plastic chamber that rotates at 25 rpm, dropping tablets from inches away, and running for 100 revolutions to subject a number of tablets to the combined effects of abrasion and shock. Friability should be less than 1%, according to the standard limit, after preweighed tablets are dusted and reweighed. The following formula used to determine the % friability:

$$\% \text{ Friability} = \frac{\text{Initial weight of the tablets} - \text{Final weight of the tablets} \times 100}{\text{Initial weight of the tablets}}$$

Tablet Thickness
Vernier callipers were used to determine the thickness of the tablet. The tablet was positioned vertically between two jaws and for this test, six tablets were used and the thickness was measured and given in millimetres.

Wetting Time & Water Absorption Ratio
A piece of double-folded tissue paper was placed in a small Petri dish filled with six millilitres of water. After a tablet was placed on the paper, the time it took to get it completely wet was measured. Water absorption ratio 'R' was determined using following equation:

$$R = 100 \times (Wa - Wb/Wb)$$

Where, Wa = weight of tablet before water absorption,
Wb = weight of tablet after water absorption

In vitro disintegration time
Ten millilitres of phosphate buffer solution (pH 6.8) at 37±0.5 °C were mixed with the tablet. The amount of time needed for a tablet to completely disperse was measured.

In Vitro dissolution study
USP XXI examined the in vitro dissolution of fast-dissolving papaya pulp powder tablets. I use a paddle stirrer in an Electro Lab USP TDT-06T type II dissolution apparatus. The dissolution medium was 900 millilitres of phosphate buffer, pH 6.8. The stirrer's rotation speed was set to 50 rpm. The dissolution media was preheated to 37±0.5°C, and this temperature was maintained during the experiment. Each test used a single tablet; five millilitres of the dissolution medium sample were extracted using a syringe equipped with a pre-filter at predetermined intervals, and the absorbance at 324 nm was used to measure the amount of drug released. A new amount of dissolving medium was added to replace the volume that was removed at each time interval [9,10,11].

CONCLUSION:

The present review highlights the potential of papaya pulp powder as a natural anti-inflammatory agent and the suitability of immediate-release tablets as a dosage form for delivering its therapeutic benefits. Immediate-release tablets offer a practical and patient-compliant platform for this phytoconstituent, ensuring rapid disintegration and dissolution for quick onset of action in acute inflammatory conditions. Various formulation approaches including direct compression, dry granulation, and incorporation of super disintegrants like Cross- Carmellose sodium or cross povidone can be employed to achieve the desired disintegration time of less than 15 minutes and dissolution of ≥85% in 30 minutes, as per pharmacopeial standards. However, formulation challenges such as hygroscopicity, poor flow, and the thermolabile nature of papain must be addressed through appropriate excipient selection, moisture protection, and processing techniques that avoid heat and water. In conclusion, immediate-release tablets of papaya pulp powder represent a promising, cost-effective, and natural alternative for managing inflammation. With optimized formulation and stability strategies, these tablets can provide fast, safe, and effective relief, bridging traditional herbal knowledge with modern pharmaceutical technology. Future research should focus on scale-up studies, stability under ICH conditions, and clinical evaluation to establish their therapeutic potential in inflammatory disorders.

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