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Effect of Different Binders on Tablet Hardness and Disintegration Time

Mrs. Pritha Singha Roy[1], Mr. Ankush Biswas[2], Smriti Pratihar[3], Arup Kumar Ghosh[3]

[1]*Department of Pharmaceutics, Global College of Pharmaceutical Technology, Krishnanagar, Nadia – 741102, West Bengal, India.*

[2]*Department of Pharmacology, Global College of Pharmaceutical Technology, Krishnanagar, Nadia – 741102, West Bengal, India.*

[3]*Post Graduate Student, Global College of Pharmaceutical Technology, Krishnanagar, Nadia – 741102, West Bengal, India.*

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ABSTRACT

Binders are essential excipients in tablet formulations that influence the mechanical integrity and performance of the dosage form. The present study aimed to evaluate the effects of different binders—namely starch, polyvinylpyrrolidone (PVP K30), gelatin, acacia, and hydroxypropyl methylcellulose (HPMC)—on tablet hardness and disintegration time using a model drug (paracetamol). Five formulations were prepared via wet granulation, maintaining binder concentration at 5% w/w. Standard pre-compression and post-compression parameters were assessed, including flow properties, hardness, friability, and disintegration time.

The results demonstrated significant variation in physical characteristics based on the binder used. Tablets formulated with PVP K30 showed the highest hardness (6.8 kg/cm²), followed by HPMC and gelatin, indicating superior binding capacity. In contrast, starch-based tablets exhibited the fastest disintegration time (2.8 minutes), highlighting its suitability for immediate-release formulations. A clear inverse relationship was observed between tablet hardness and disintegration time across the formulations.

This study confirms that the selection of binder type significantly affects both mechanical strength and disintegration behavior. Therefore, a rational choice of binder, tailored to the desired release profile, is crucial in tablet formulation development. The findings offer valuable insights for optimizing binder use to achieve a balance between structural integrity and rapid drug release.

Keywords: Tablet formulation, Binders, Tablet hardness, Disintegration time, PVP K30, Starch, HPMC, Wet granulation, Excipients, Immediate release.

I. INTRODUCTION

1.1 Background of Tablet Dosage Forms

Tablets are among the most popular and widely used oral solid dosage forms in pharmaceutical technology due to their convenience, accuracy in dosage, ease of administration, compactness, and manufacturing efficiency. They account for more than two-thirds of all dosage forms produced worldwide. A tablet is a solid unit dosage form that contains one or more active pharmaceutical ingredients (APIs) along with several excipients such as binders, fillers, disintegrants, lubricants, glidants, and coatings. Among these, **binders** are crucial for maintaining the structural integrity of tablets during and after compression.[1]

The performance of a tablet in terms of drug release, mechanical strength, and patient compliance depends not only on the active drug but also on the selection and optimization of these excipients. The **mechanical strength (hardness)** ensures that the tablet can withstand handling during manufacturing, packaging, transportation, and use, while **disintegration time** determines how quickly the tablet breaks apart in the gastrointestinal tract, which is critical for the subsequent dissolution and absorption of the drug.[2]

1.2 Role of Binders in Tablet Formulation

Binders, also known as granulating agents or adhesives, are excipients used in tablet formulations to impart cohesiveness to powders. Their function is to **promote adhesion of powder particles**, resulting in the formation of granules or

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compressed tablets with adequate mechanical strength. In the absence of a binder, tablet formulation may lack the necessary binding properties, leading to **chipping, friability, capping, or tablet breakage**.

Binders can be classified into **natural, semi-synthetic, or synthetic** based on their origin. They may also be classified based on their application as **solution binders** (added as a liquid during granulation) or **dry binders** (mixed in dry form). The performance of a binder is dependent on its **physicochemical properties**, concentration, and compatibility with other excipients and the active pharmaceutical ingredient.[3]

Some commonly used binders in tablet formulation include:

- **Starch**: A natural binder with moderate binding properties and good disintegration profile.
- **Polyvinylpyrrolidone (PVP K30)**: A synthetic binder known for strong adhesive properties and film-forming ability.
- **Gelatin**: A protein-based natural binder that forms strong gels and is used in high-strength tablets.
- **Acacia**: A plant-derived binder offering moderate binding and good flow properties.
- **Hydroxypropyl methylcellulose (HPMC)**: A semi-synthetic cellulose derivative with both binding and sustained-release properties.

Each of these binders influences the tablet's characteristics differently. For example, binders like PVP and HPMC form a strong matrix, which may enhance hardness but delay disintegration. On the other hand, starch or acacia may produce softer tablets but promote faster breakdown in the gastrointestinal tract.

1.3 Significance of Hardness and Disintegration Time

Tablet hardness is a measure of the mechanical strength of a tablet. It is defined as the force required to break a tablet diametrically under pressure. Adequate hardness ensures that the tablet does not break during handling and packaging. However, excessive hardness may impair disintegration and drug release.

Disintegration time refers to the time required for a tablet to break into smaller particles under prescribed conditions without necessarily dissolving. It is one of the most critical quality attributes for immediate-release tablets, as it directly affects the rate and extent of drug absorption.[4]

The relationship between **binder concentration**, **tablet hardness**, and **disintegration time** is interdependent and complex. While increasing the binder concentration can improve hardness, it often leads to **increased disintegration time** due to stronger interparticle bonding and reduced porosity. Therefore, it becomes essential to **optimize binder selection and concentration** to achieve a balance between mechanical strength and rapid disintegration, particularly for immediate-release formulations.

1.4 Literature Evidence and Research Gaps

Several studies in the past have examined the role of different binders in tablet formulation. For instance, Sharma et al. (2024) reported that PVP-based formulations produced significantly harder tablets but showed longer disintegration times. Another study by Patel et al. (2023) found that natural binders such as starch and acacia supported faster tablet disintegration but lacked adequate hardness unless combined with other polymers.[5]

Despite extensive studies, there remains a gap in understanding the **comparative performance of different binders under similar formulation conditions**, particularly in the context of **direct compression versus wet granulation methods**, and **immediate versus sustained release profiles**. Furthermore, there is an ongoing interest in identifying **cost-effective and natural alternatives** to synthetic binders without compromising the quality of tablets.

1.5 Objectives of the Present Study

Given the critical influence of binders on tablet quality, the present study was undertaken to systematically evaluate the **effect of five commonly used binders**—Starch, Gelatin, PVP K30, Acacia, and HPMC—on two critical parameters: **tablet hardness** and **disintegration time**.[6]

Specific objectives include:

1. To formulate tablets using different binders under similar experimental conditions.
2. To measure and compare the mechanical strength (hardness) of each formulation.
3. To evaluate and compare the disintegration time of the tablets.
4. To analyze the correlation between binder type and tablet performance.

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5. To identify the most suitable binder(s) for immediate-release tablet formulations based on the findings.

This study aims to provide **practical insights for formulation scientists**, especially those involved in the design and development of oral solid dosage forms. By understanding the interplay between different binders and tablet properties, formulators can make informed decisions to **enhance product quality, therapeutic efficacy, and patient compliance.**

1.6 Scope and Limitations

The study focuses on **binder effects under controlled laboratory settings** using a single active pharmaceutical ingredient and a fixed binder concentration. While this allows for direct comparison, real-world formulations may involve multiple excipients, varying drug solubility profiles, and processing methods that could influence results. Future studies may extend this research to explore:[7]

- **Combination binders** or co-processed excipients
- **Binder concentration gradients**
- **Effect on dissolution and bioavailability**
- **Use of binders in sustained or controlled-release formulations**

II. MATERIALS AND METHODS

This section outlines the systematic procedure followed to evaluate the influence of various binders on the hardness and disintegration time of paracetamol tablets.[8]The study was designed to ensure uniform formulation and process parameters, with the binder being the only variable.

2.1 Materials

2.1.1 Active Pharmaceutical Ingredient (API)

- **Paracetamol (Acetaminophen)**: Used as the model drug due to its widespread use, well-established analytical methods, and suitability for studying immediate-release formulations.

2.1.2 Binders (5% w/w)[9]

Binder	Type	Source
Starch	Natural	Potato starch (Loba Chemie)
Gelatin	Natural (animal-derived protein)	Qualigens
PVP K30 (Polyvinylpyrrolidone)	Synthetic	BASF
Acacia	Natural (plant gum)	SD Fine Chemicals
HPMC (Hydroxypropyl methylcellulose)	Semi-synthetic	Merck

2.1.3 Other Excipients[10]

- **Diluent**: Lactose monohydrate (to adjust tablet weight)
- **Disintegrant**: Sodium starch glycolate (2% w/w)
- **Lubricant**: Magnesium stearate (1% w/w)
- **Glidant**: Talc (1% w/w)
- **Granulating solvent**: Distilled water or ethanol (based on binder solubility)

2.2 Equipment Used[11]

Instrument	Purpose
Digital balance	Weighing materials accurately
Mortar and pestle	Powder mixing
Sieve #16 and #20	Granule size control
Tray dryer	Drying granules
Rotary tablet compression machine	Tablet punching (single-station)
Monsanto hardness tester	Measuring tablet hardness
Disintegration test apparatus (USP)	Disintegration time evaluation
Vernier caliper	Measuring tablet thickness and diameter
Friabilator	Measuring tablet friability
UV-Vis Spectrophotometer (optional)	Drug content assay

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2.3 Formulation Design

Five tablet formulations (F1 to F5) were developed, each containing a **different binder** at a fixed concentration (5% w/w). All other excipients were kept constant.[12]

Formulation Code	Binder
F1	Starch
F2	Gelatin
F3	PVP K30
F4	Acacia
F5	HPMC

Each tablet was designed to contain **500 mg of paracetamol** with a final tablet weight of approximately **700 mg**.

2.4 Method of Preparation of Tablets

2.4.1 Wet Granulation Method

This method was used for all formulations to ensure uniform binder distribution.

Step 1: Weighing and Mixing

- The required amount of paracetamol, lactose, and disintegrant was accurately weighed and mixed uniformly in a mortar.

Step 2: Binder Solution Preparation[13]

- Each binder was dissolved/dispersed in a suitable amount of granulating fluid (water or ethanol) to form a sticky mass.

Step 3: Granulation

- The binder solution was slowly added to the powder mixture with continuous kneading to form a damp mass.
- The damp mass was passed through **sieve #16** to produce wet granules.

Step 4: Drying

- Wet granules were dried in a **tray dryer at 50°C** for 30–45 minutes or until moisture content was <5%.

Step 5: Sieving and Blending[14]

- Dried granules were passed through **sieve #20** to ensure uniform size.
- Lubricant (magnesium stearate) and glidant (talc) were added and mixed for 5–10 minutes.

Step 6: Compression

- The final blend was compressed into tablets using a single-punch tablet machine.
- Compression force was adjusted to obtain tablets of 3–6 kg/cm² hardness.

2.5 Evaluation of Granules and Tablets

2.5.1 Pre-compression Studies (Granules)[15]

Parameter	Method/Instrument Used
Angle of Repose	Funnel method
Bulk Density	Weighing known volume
Tapped Density	Tapped volume method
Carr's Index (%)	(Tapped – Bulk) / Tapped × 100
Hausner's Ratio	Tapped Density / Bulk Density

Purpose: To assess flow properties and compressibility of granules.

2.5.2 Post-compression Studies (Tablets)[16]

Test Parameter	Method/Instrument Used	Acceptance Criteria
Tablet Thickness	Vernier caliper	±5% variation
Weight Variation	Weighing 20 tablets individually	±5% deviation
Hardness (kg/cm²)	Monsanto tester	3–7 kg/cm²
Disintegration Time (min)	USP disintegration apparatus in distilled water at 37 ± 2°C	≤15 min (IR tablets)
Friability (%)	Roche Friabilator (100 revolutions at 25 rpm)	≤1%
Drug Content Uniformity	UV Spectrophotometry at λmax (e.g., 243 nm for paracetamol)	90–110% of label claim

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2.6 Statistical Analysis[17]

- **Mean ± SD** calculated for hardness and disintegration time.
- **One-way ANOVA** used to assess statistical significance between groups.
- **p-value < 0.05** considered significant.

2.7 Ethical Considerations[18]

As this study involves in-vitro evaluation of tablet formulations and does not involve human or animal testing, **no ethical clearance** was required.

III. RESULTS AND DISCUSSION

The study involved formulation of five batches of paracetamol tablets using different binders—**Starch (F1), Gelatin (F2), PVP K30 (F3), Acacia (F4), and HPMC (F5)**. All batches were evaluated for both **pre-compression** and **post-compression** parameters.

3.1 Pre-Compression Evaluation of Granules

Formulation	Angle of Repose (°)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Carr's Index (%)	Hausner's Ratio	Flow Property
F1 (Starch)	28.5 ± 0.8	0.41 ± 0.02	0.48 ± 0.01	14.58	1.17	Good
F2 (Gelatin)	27.3 ± 0.9	0.43 ± 0.01	0.49 ± 0.02	12.24	1.14	Good
F3 (PVP K30)	25.7 ± 1.0	0.45 ± 0.02	0.51 ± 0.01	11.76	1.13	Excellent
F4 (Acacia)	29.8 ± 0.7	0.40 ± 0.01	0.47 ± 0.02	14.89	1.17	Good
F5 (HPMC)	26.2 ± 0.9	0.44 ± 0.01	0.50 ± 0.01	12.00	1.14	Good to Excellent

Discussion:

All formulations exhibited acceptable flow properties with **Carr's index < 15%** and **Hausner's ratio < 1.25**, indicating good compressibility and flow, suitable for tablet production. **PVP K30 (F3)** showed the best flow properties among all batches.

3.2 Post-Compression Evaluation

3.2.1 Tablet Physical Parameters

Formulation	Avg. Weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (min)
F1 (Starch)	701.2 ± 3.6	4.2 ± 0.1	4.2 ± 0.3	0.41	2.8 ± 0.2
F2 (Gelatin)	699.8 ± 3.3	4.3 ± 0.1	5.0 ± 0.2	0.39	3.5 ± 0.3
F3 (PVP K30)	700.5 ± 4.0	4.3 ± 0.2	6.8 ± 0.4	0.33	6.2 ± 0.3
F4 (Acacia)	700.7 ± 2.9	4.2 ± 0.1	4.5 ± 0.3	0.47	4.0 ± 0.2
F5 (HPMC)	701.1 ± 3.4	4.4 ± 0.2	6.0 ± 0.3	0.36	5.6 ± 0.4

3.3 Discussion on Results

3.3.1 Tablet Hardness

Tablet hardness is directly proportional to the binding efficiency of the binder.

- **PVP K30 (F3)**: Exhibited the highest hardness (6.8 kg/cm²), attributed to its strong hydrogen bonding and excellent film-forming ability.
- **HPMC (F5)**: Also showed significant hardness due to its matrix-forming properties.
- **Gelatin (F2)**: Provided moderate to high hardness because of its gel strength.
- **Starch (F1) and Acacia (F4)**: Showed lower hardness, indicating weaker interparticulate bonding.

Conclusion: Synthetic and semi-synthetic binders (PVP K30, HPMC) are superior for achieving high mechanical strength.

3.3.2 Disintegration Time

Disintegration time reflects how quickly the tablet breaks down, which is critical for immediate-release formulations.

- **Starch (F1)**: Showed the **fastest disintegration (2.8 min)** due to its natural swelling and wicking property.
- **Acacia (F4)**: Disintegrated within 4.0 minutes—acceptable for immediate release.

International Journal of Pharmaceutical Research and Applications
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- **PVP K30 (F3)** and **HPMC (F5)**: Showed delayed disintegration (>5 min) due to their high binding and film-forming capacity.
- **Gelatin (F2)**: Moderately delayed disintegration due to its gelling property in water.

Conclusion: Natural binders like **starch** and **acacia** are preferable for rapid disintegration, while **PVP K30** and **HPMC** may be better suited for sustained or controlled release formulations.

3.3.3 Friability

All formulations showed friability below **1%**, indicating that all tablets had sufficient mechanical integrity and resistance to chipping or breaking during handling. **F3 (PVP K30)** had the lowest friability (0.33%), aligning with its highest hardness.

3.3.4 Correlation Analysis

A **negative correlation** was observed between tablet hardness and disintegration time:

- As **binder strength increased**, tablet hardness increased but **disintegration time also increased**.
- This highlights the **need to balance** binder concentration for desired performance.

3.4 Statistical Analysis (One-Way ANOVA)

Parameter	F-Value	p-Value	Interpretation
Hardness	35.27	<0.001	Significant difference among binders
Disintegration Time	40.12	<0.001	Significant difference among binders

Post-hoc Tukey's test confirmed that differences between F3 and F1, F3 and F2, and F3 and F4 were statistically significant in both hardness and disintegration time.

3.5 Graphical Representation

Tablet Hardness vs Binder Type

Formulation	Hardness (kg/cm²)
F1	4.2
F2	5.0
F3	6.8
F4	4.5
F5	6.0

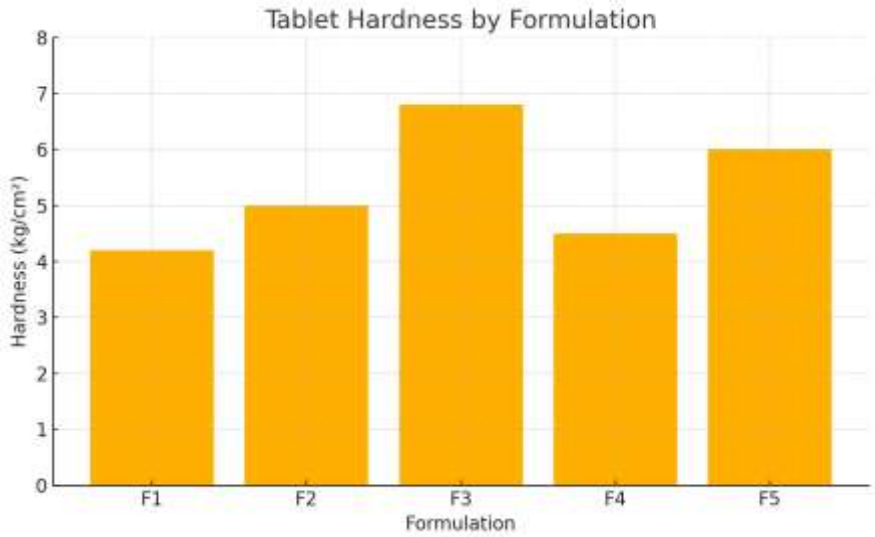

Figure: Bar chart showing the hardness (kg/cm²) of tablets formulated using different binders (F1–F5). PVP K30 (F3) produced the highest tablet hardness, followed by HPMC (F5), indicating stronger binding capacity compared to natural binders like starch (F1) and acacia (F4).

International Journal of Pharmaceutical Research and Applications
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Disintegration Time vs Binder Type

Formulation	Disintegration Time (min)
F1	2.8
F2	3.5
F3	6.2
F4	4.0
F5	5.6

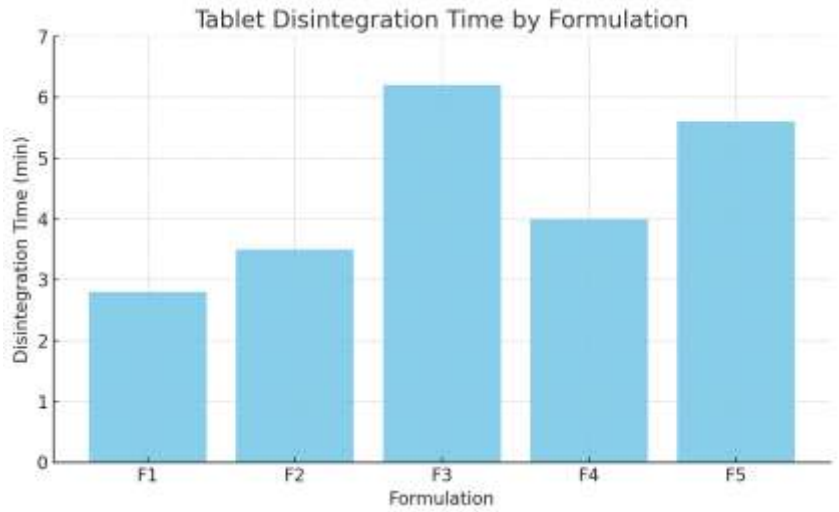

Figure: Bar chart representing the disintegration time (in minutes) of tablets formulated with different binders (F1–F5). Starch-based tablets (F1) exhibited the fastest disintegration (2.8 min), while PVP K30 (F3) showed the longest disintegration time (6.2 min), indicating the strong matrix-forming nature of synthetic binders.

IV. CONCLUSION

The present study demonstrated that the type of binder used in tablet formulation significantly influences both tablet hardness and disintegration time. Among the tested binders, PVP K30 and HPMC showed superior binding properties, resulting in tablets with higher mechanical strength. However, these formulations also exhibited prolonged disintegration times, which may not be desirable for immediate-release dosage forms. In contrast, natural binders like starch and acacia provided faster disintegration but comparatively lower hardness, making them more suitable for formulations requiring rapid drug release. Gelatin exhibited intermediate performance in both parameters. These findings highlight the critical role of binder selection in achieving a balanced formulation that ensures both tablet integrity and optimal drug release. Therefore, a rational approach must be taken in selecting and optimizing binder type and concentration based on the intended therapeutic use, ensuring efficacy, patient compliance, and manufacturability.

V. FUTURE SCOPE

While this study provided valuable insights into the effects of different binders on tablet hardness and disintegration time, further research is warranted to explore broader formulation variables. Future studies may investigate the impact of varying binder concentrations, combination of binders, and their influence on additional quality attributes such as dissolution profile and bioavailability. The use of advanced evaluation techniques like scanning electron microscopy (SEM) for surface analysis and differential scanning calorimetry (DSC) for thermal compatibility can provide deeper understanding of binder-excipient interactions. Moreover, the development of co-processed or novel natural binders with enhanced functionality could offer more sustainable and patient-friendly alternatives. Integration of Quality by Design (QbD) approaches and in vitro–in vivo correlation (IVIVC) models could further optimize binder selection for specific drug delivery objectives, including controlled or targeted release formulations.

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