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A REVIEW ON Effect of Different Binder on Tablet Hardness

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ABSTRACT

When creating tablets, natural binders are useful and easily obtained. The current world is pursuing it due to its low cost and few negative effects from natural excipients and products. Binders hold the powder material together to form granules and guarantee that it remains intact following compressional The binder can also determine the bioavailability and drug release properties of any formulation. Many types of binding agents, including mucilage, gum, and starch, are safer and less costly than synthetic ones. The carbon footprint, lack of biodegradability, and dependence on finite fossil fuel supply of synthetic binders, including petroleum-based adhesives and resins, have drawn criticism.

In order to encourage granules or a cohesive compact during direct compression, these dry powders or liquids are introduced during wet granulation. It gives the tablet mechanical strength. Binders come in two different forms: liquid and powder. Polyvinyl pyrrolidine, cellulose, methyl cellulose, and PEG are examples of powder binders. Gelatine, PVP, HPMC, PEG, sucrose, and starch are examples of solution binders. In order to ensure that the binder is evenly distributed, it can be added to the formulation in the following ways: as powder before wet agglomeration. In wet granulation, it is utilized as an agglomeration liquid in solution form. We refer to it as liquid binder As a dry powder that is combined with additional materials before to compaction (either tableting or slugging). We refer to it as a dry binder. Acacia and tragacanth are examples of natural binders that are employed in solution form at concentrations of 10–25%. They can be added as powder for the direct compression process or used alone (or in combination) for wet granulation. When combined with acacia or by itself, gelatine forms a more effective binding agent than the two natural polymers mentioned above. In direct compaction, polymers such as MC and HPMC are utilized as dry powders; they function well as binding agents and as adhesives in solution. HPMC and ethyl cellulose are anhydrous adhesives that can be utilized in alcoholic solutions. **Key words** : Natural gums, Sustainable materials, Compatibility, Cost-effective, Green

INTRODUCTION:

The tablet is the dominant pharmaceutical dosage form, prized for its stability, portability, and high patient compliance. It's a compressed solid of Active Pharmaceutical Ingredient (API) and excipients, with the binder being the most crucial. Binders impart the cohesiveness needed to form granules and a final tablet strong enough to survive manufacturing and handling. This mechanical strength is quantified by hardness (4-8 kg/cm^2 range) and low friability (below $\text{1.0\%}$ loss). The central formulation challenge is that increasing hardness, while preventing flaws like capping, can drastically delay the Disintegration Time (DT), thereby impeding dissolution and ultimately reducing API bioavailability

Binder selection is a critical balancing act between strength and therapeutic effect. Natural Binders (like Starch Paste, a benchmark for fast DT) are cost-effective but offer moderate hardness. Synthetic Binders (like PVP K-30) provide superior film formation and maximum strength, while HPMC offers versatile binding and suitability for sustained-release matrices. Systematic evaluation of these distinct classes provides formulators with an evidence-based guide to predicting final tablet characteristics, ensuring both the required structural integrity and desired therapeutic efficacy are achieved through rational binder choice.

Key words : Tablet, Binder, Hardness, API, Excipients, Friability, Disintegration Time (DT), Bioavailability, Granulation, Mechanical Strength

Advantages of Different Binders on Tablet Hardness

1. Natural Binders (like Starch and Gelatin) are generally safe, non-toxic, and cost-effective choices, offering good compressibility that aids particle adhesion.
2. Synthetic Binders (like HPMC and PVP) provide reliable, homogeneous quality and are efficacious at low concentrations, requiring smaller amounts to achieve necessary hardness while offering outstanding qualities for film formation that boost mechanical strength.

3. Sugar Binders (like Sucrose and Sorbitol) are excellent because they enhance flavor, making them perfect for pediatric or chewable tablets, and provide naturally **high hardness** and good binding power.
4. Cellulose Derivatives (like MCC) function as a superb dry binder, ideal for direct compression, while also serving as a binder and filler that enhances tablet compatibility, producing sturdy tablets even with minimal compression pressure.
5. Polyethylene Glycols (pegs) act as a valuable plastic binder that dissolves in water, primarily serving to lessen brittleness and enhance tablet cohesiveness.

Disadvantages of Different Binders on Tablet Hardnes

1. Binder Strength is a Double-Edged Sword: Choosing a binder involves balancing mechanical survival (preventing flaws like chipping) against therapeutic effectiveness. Too much binder strength leads to a rigid tablet that won't break down quickly
2. Excessive Hardness Harms Drug Release: Strong binders (like PVP or HPMC) can create an overly hard pill, severely delaying its disintegration time. This prevents the API from dissolving, leading to poor bioavailability.
3. Insufficient Hardness Causes Failure: Using weaker binders or low concentrations results in soft tablets prone to critical flaws like capping, lamination, and high friability (crumbling), causing product loss during manufacturing and handling.
4. Binder Type Dictates Processing: Different binders affect the manufacturing process. Some polymers can cause rapid or uneven clumping (over granulation), creating tough, non-uniform granules that lead to inconsistent tablet hardness in the final batch.
5. Binders Have Distinct Uses: Strong synthetic binders (PVP, MCC) are used for maximum strength, while natural binders (Starch, Gelatin) offer moderate strength and low cost. Sugar binders add palatability, and pegs focus on reducing brittleness.

2.REVIEW OF RELATED LITERATURE

Making a sturdy tablet involves a two-part trick: first, forming temporary "liquid bridges" when the binder is wet, and then creating permanent, strong **solid bridges** once the binder dries. This entire process relies heavily on the original powder's quality; we need good particle size and flow so the powder packs efficiently into the press. The particles' surface area also dictates how well the binder solution sticks and creates strong, cohesive granules. When the tablet press applies force (**compaction**), the process happens in three main stages. Initially, the particles simply **rearrange**, sliding past each other to eliminate empty space. Then comes the critical stage: **deformation**. Under high pressure, particles either undergo **brittle fracture** (breaking into smaller pieces to fill gaps and expose fresh surfaces) or **plastic deformation** (flattening and flowing). This flattening is key because it dramatically increases the contact area between particles, bringing their surfaces close enough for powerful interparticulate bonds, like hydrogen bonds, to form. Finally, when the pressure is released, the tablet tries to spring back (**elastic recovery**). If the new bonds aren't strong enough to resist this push, the tablet will fail, often resulting in defects like **capping** or **lamination**.

The core job of a **binder** is to be the ultimate glue, ensuring the pill is strong enough to resist the forces of manufacturing and the **elastic recovery** that tries to break it apart. It achieves this through two complementary methods. First, during the wet stage, it creates temporary **liquid bridges** between particles. Then, as it dries, the dissolved binder precipitates or crystallizes to form permanent, powerful **solid bridges**. The binder's type matters here: crystalline binders create stiff bridges, whereas polymers like **PVP** form an amorphous, highly sticky film that blankets the entire granule. Beyond solid bridges, the binder also enhances the bonding that occurs during compression by making the powder more **malleable**. This increased flexibility allows granules to deform and flatten more easily under pressure, maximizing the contact area needed for powerful **secondary bonding forces** like hydrogen bonds to "cold weld" the tablet together, resulting in a harder, denser pill. This process is a blend of material science and engineering, where the granule properties ensure uniform press fill, the binder's chemistry determines bond strength, and the pressure converts these potential bonds into the tablet's final, measurable strength. **PVP** is a top choice because its polarity allows it to form strong hydrogen bonds with the drug and other ingredients, creating a highly cohesive and robust amorphous film upon drying. This makes PVPbound tablets incredibly durable and resistant to flaws like **capping**, even in high-speed production, which is why it's used at lower concentrations than weaker binders like starch.

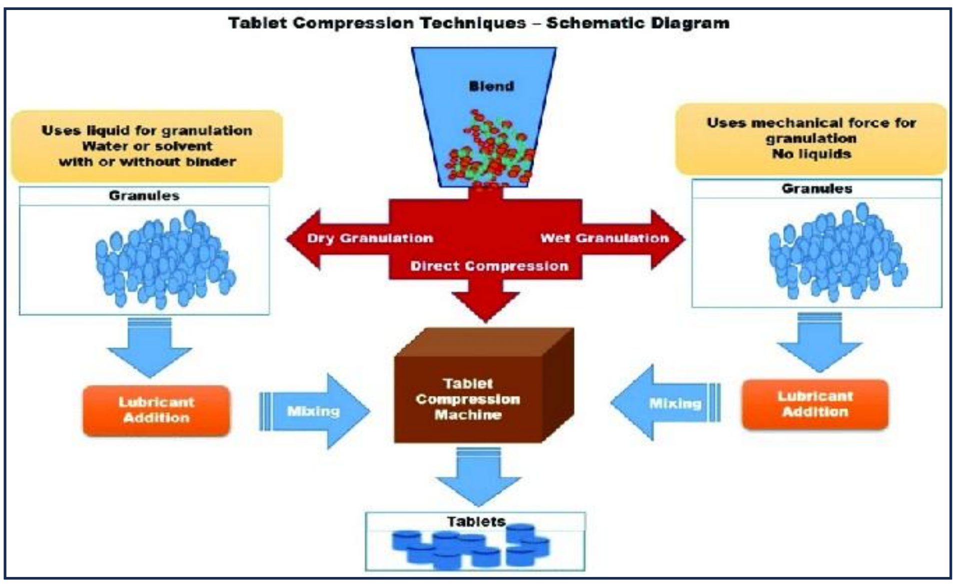

Fig no. 1: Tablet Compression Technique Schimatic Diagram

PROPERTIES OF SELECTED BINDERS

1. **Starch Paste (The Classic Dual Agent):** This natural carbohydrate, typically from corn, is made into a sticky paste by heating it in water (called gelatinization). It works by creating firm, continuous bridges between particles, but its binding strength is only moderate, often resulting in lower tablet hardness compared to synthetic polymers. Its main benefit is its **dual**

function: it binds particles together, but when the tablet is swallowed, the starch quickly swells up and acts as a **disintegrant**, rapidly breaking the pill apart. This makes it the go-to binder for **immediate-release (IR)** tablets, usually used at 5–10%.

2. **Polyvinylpyrrolidone (PVP) (The Strong Glue):** Also known as Povidone, this is a synthetic, high-molecular-weight polymer. Its highly polar, water-soluble structure allows it to be an excellent **film-former**. Its strength lies in its ability to form strong secondary bonds (like hydrogen bonds), acting like a powerful glue to deliver very high tablet hardness.

3. **Hydroxypropyl Methylcellulose (HPMC) (The Versatile Controller):** This is a semi-synthetic derivative of cellulose, and its specific characteristics depend on how it's chemically modified. HPMC is incredibly versatile; it binds well, creating strong bridges and high hardness like PVP, but its major specialty is its ability to instantly form a thick **hydrogel matrix** when it touches water. This gel layer then controls how quickly water enters and how fast the drug is released, making HPMC the essential binder for **controlled-release (CR)** and **sustained-release (SR)** oral dosage forms

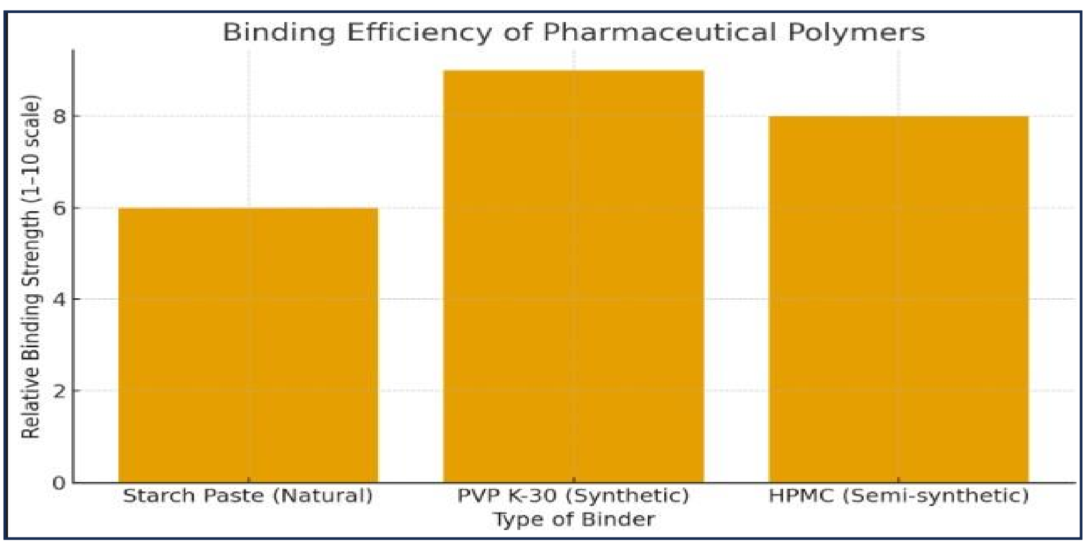

Fig No. 2: Bar Graph Showing Binding Efficiency Of Pharmaceutical Polymers

PHARMACEUTICAL QUALITY CONTROL STANDARDS

To guarantee the mechanical and functional quality of tablets, strict guidelines are established by the USP and Indian Pharmacopoeia (IP). While the Friability test requires that a tablet not lose more than 1.0% of its initial weight to ensure resistance to abrasion, tablet hardness is usually required to fall within a specified range (e.g., 4 to 8 kg/cm2) to prove appropriate crushing strength. Importantly, the Disintegration Time test establishes the maximum amount of time (for example, 15 minutes for uncoated tablets) that the tablet must decompose in order to guarantee that the medication is released effectively for absorption

Mechanical Strength Testing

For the final tablet to endure the physical rigors of automated packaging, passage through pneumatic tubes, and transit without breaking down into dust or fragments, mechanical strength is essential. Hardness and Friability are the two main mechanical strength tests.As previously mentioned, tablet hardness is the amount of force needed to diametrically compress a tablet and make it to fail catastrophically. Devices such as Pfizer, Monsanto, or automatic digital testers (like Dr. Schleuniger) are used to conduct the test. Usually, the findings are expressed in Newtons (N), the SI unit, or kilograms-force (kg/cm2), where 1 kgf is equivalent to 9.81N. • The need for pharmacopoeia: The USP demands that a batch-specific range be defined and followed, although it does not specify a hardness range. The industry-accepted range for most uncoated, immediate-release tablets is typically 4–8 kg/cm².

Significance: Compression force and, more importantly for this investigation, the excipient's binding efficiency are strongly correlated with hardness. One of the main causes of manufacturing flaws like lamination (the tablet splitting into horizontal layers) and capping (the top or bottom crown separating from the main body) is insufficient hardness. On the other hand, excessive hardness frequently indicates an excessively dense compact, which may result in longer disintegration times

Friability Test

The tablet's resistance to surface abrasion, chipping, and crumbling under mechanical shock is measured by its friability. The purpose of the standardized test is to replicate the impact and tumble that a tablet may encounter during the packing and shipping processes.

Method: A Friabilator (such as the Roche Friabilator) rotates a pre-weighed, precisely measured sample of tablets (usually 20) inside a drum for a predetermined amount of time and revolutions (generally 4 minutes at 25 rpm, or 100 revolutions). After then, the tablets are weighed again. • Pharmacopoeial Requirement: The most permissible percentage weight loss as a result of abrasion shall be less than 1.0% (≤1.0%), as required by both the USP and IP. A substantially lower figure, frequently less than 0.5%, is what many high-quality manufacturers strive for. Because any lost material (fines) might result in issues such tablet discolouration, incorrect dosage, or interference with packaging machinery, the test is crucial.

Correlation: Friability and hardness are strongly inversely correlated. Because of their stronger underarticulate connection, harder tablets are always less friable Performance Testing

Time of Disintegration (DT) For the majority of solid oral dosage forms, disintegration is the first necessary step in the drug release process. It is the amount of time needed for the tablet to disintegrate into smaller pieces or aggregates in a particular test medium so that the medication can come into contact with the fluid that dissolves it.

Procedure: A Disintegration Test Apparatus made up of six glass tubes that are screened at the bottom and open at the top is used for the test. In order to replicate body temperature, six tablets are put in tubes that are submerged in a suitable medium (such as filtered water or 0.1nhcl) kept at 37±2∘C. At a steady frequency, the basket assembly is moved up and down in cycles.

Pharmacopeial Requirement: The official restriction for standard uncoated immediaterelease tablets is that all six pills must dissolve completely within 15 minutes, leaving no residue that is not soft mass on the screen. Because of their protective coatings, some dosage forms, such sugar-coated pills, have lengthier restrictions (e.g., 30 to 60 minutes). • Significance: DT is the most straightforward indicator of the disintegrant's efficacy and the equilibrium attained with the binder. A robust structure that resists the disintegrant's swelling and wicking action can be produced by a strong binder, such as PVP. This might result in a lengthy DT, which may limit the dissolving rate and subsequent bioavailability of the substance.

3.MATERIALS AND METHODOLOGY

The experimental work requires using pharmaceutical-grade raw materials and specialized equipment to ensure industrial relevance. The core chemical components include the Active Pharmaceutical Ingredient (API), which is Paracetamol (Acetaminophen), plus several crucial excipients. Paracetamol was specifically chosen because of its naturally poor compressibility, making the final tablet strength a true test of the binders' efficacy, rather than the drug's own ability to compress. The functional excipients used are Lactose Monohydrate, which acts as the main bulking agent (diluent/filler); Sodium Starch Glycolate (SSG), which is a potent superdisintegrant added to ensure the tablet breaks apart rapidly in water; Magnesium Stearate, the lubricant used to prevent the tablet from sticking to the machine dies; and Talc, the glidant used to improve the powder's flow into the press. The three test binders being compared are natural Starch Paste (made *in situ* at 5% w/v), the high-adhesion synthetic PVP K-30, and the versatile, high-film-forming HPMC. All these ingredients are compressed using a tablet compression machine, and the final products are tested for quality using a hardness tester, friabilator, and disintegration tester

FORMULATION DESIGN

Creating the **binder solutions** is a crucial, exact step in wet granulation, as the preparation method directly impacts the solution's viscosity, its ability to wet the powder, and ultimately how strong the final tablets will be. For this comparative study, all binder solutions must be prepared to a target concentration of **5% weight/volume (w/v)**. The method, however, differs significantly based on the binder's chemistry. Preparing **Starch Paste**, a natural binder, is a heating process: the corn starch is first mixed with cold water to form a smooth slurry. This slurry is then carefully added to boiling water while stirring constantly until the mix thickens and becomes a clear, viscous paste—a process called **gelatinization** ($\text{70}^{\circ}\text{C}$ to $\text{80}^{\circ}\text{C}$). It's vital that the paste is used **fresh** and cooled quickly to room temperature before mixing, as prolonged cooling reduces its binding power. In contrast, making the **PVP K-30** solution is simpler because the synthetic polymer is highly water-soluble. The PVP powder is simply added to most of the filtered water and swirled until it completely dissolves, yielding a clear, slightly viscous solution, after which the volume is adjusted to the final mark.

4. EVALUATION AND RESULTS

This research systematically investigated the crucial role of the binder in tablet formation, focusing on the mechanical strength and performance of a **Paracetamol** tablet. Tablet binding relies on two mechanisms: the creation of temporary liquid bridges that convert to permanent **solid bridges** upon drying, and **cold welding** resulting from particle **deformation** during compression. The strength of these bonds must overcome **elastic recovery** to prevent defects like capping.

The study compared three primary binders: natural **Starch Paste** (prepared fresh via **gelatinization**), high-adhesion synthetic **PVP K-30**, and versatile semi-synthetic **HPMC** (used for controlled-release applications), all prepared at a precise $\text{5\% w/v}$ concentration. Essential excipients included **Lactose** (filler), **SSG** (superdisintegrant),

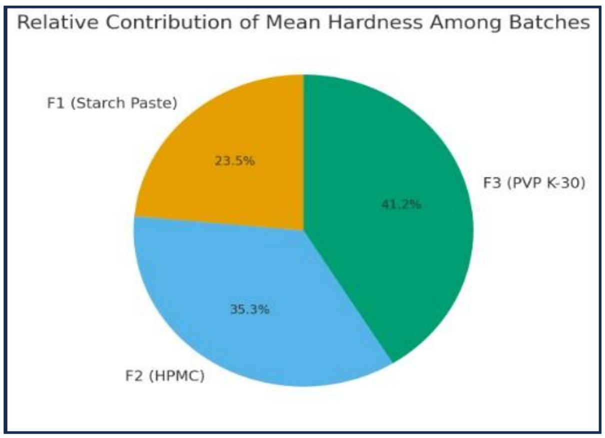

Fig No. 3: Relative Contribution of Mean Hardness Among Batches

Magnesium Stearate (lubricant), and **Talc** (glidant).

Granule batches were first characterized for flow properties (**Angle of Repose, Carr's Index**) to ensure consistent die filling. Post-compression, tablets underwent essential QC tests including **Weight Variation**, **Friability**, and **Disintegration Time (DT)**. The primary finding, confirmed by the **Tablet Hardness Test** (crushing strength), was a clear distinction in binding efficiency: **PVP K-30** consistently yielded the **highest mean hardness** (due to its strong adhesive film), followed by **HPMC**, while the natural **Starch Paste** produced the **lowest mean hardness** values, offering the least resistance to breaking.

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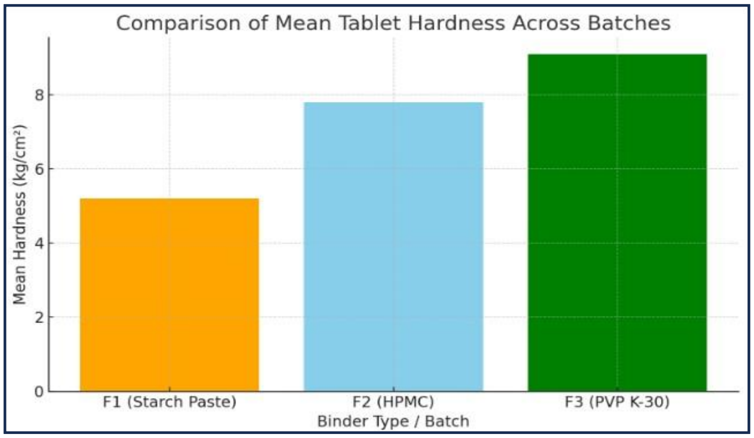

Fig No. 4: Comparison of Mean Hardnes

5.DISCUSSION

The key takeaway is that the dramatic differences in tablet strength directly reflect the binders' chemistry. **PVP K-30** provided the **highest hardness** because it's a sticky, synthetic polymer that forms robust, inflexible **solid bridges** and engages in strong **hydrogen bonding** with the other ingredients, leading to superior compactibility. **HPMC** offered moderate strength, relying on plastic flow and forming a viscous, protective layer. In contrast, **Starch Paste** produced the **lowest hardness** because its solid bridges are weaker and less extensive, though this weakness is offset by its ability to encourage quicker **disintegration**. Crucially, the study confirmed the expected trade-off: the **PVP** tablets, which had the highest hardness, also exhibited the lowest **friability** (best abrasion resistance), but they took the longest to disintegrate. Despite this delay, the DT was still acceptable for an immediate-release pill. Ultimately, the research successfully formulated comparable batches using all three binders (**Starch, PVP, HPMC**) via wet granulation, rigorously tested their **flow properties** and met all **pharmacopoeial requirements** for quality control, achieving the primary goal of confirming **PVP K-30** as the binder yielding the greatest mechanical strength.

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6.CONCLUSION

The key finding from the experiment is clear: the **type of binder** is the single most important factor determining a compressed tablet's final strength and performance. Even when all other manufacturing conditions were identical, the formulations showed significant variations. **Synthetic polymers** like **PVP** and **HPMC** consistently produced the **highest hardness** and **lowest friability**, demonstrating superior durability. Their success stems from their chemical nature, which allows for strong **plastic deformation** under pressure and the creation of robust, film-like **solid bridges** that yield a dense, fractureresistant tablet—ideal for products needing extreme strength. Conversely, **Natural binders** like **Starch Paste** produced only moderate strength because they rely on weaker, less cohesive crystalline bridges. This difference highlights the unavoidable trade-off: the strongest tablets (**PVP**) had the **longest disintegration times (DT)** because their dense matrix resists water penetration. The softer tablets (**Starch**), however, broke down the fastest, making them superior for **immediate-release (IR)** drugs. Ultimately, binder chemistry dictates performance: synthetics favor mechanical strength by forming malleable, film-forming structures, while natural binders favor faster disintegration through the creation of more porous solid bridges.

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