FORMULATION OF PARACETAMOL TABLETS USING MODIFIED STARCH OBTAINED FROM DIOSCOREA ALATA (DIOSCOREACEAE) AS A BINDER

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CERTIFICATION

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DEDICATION

This Project work is dedicated to God Almighty who gave me the grace and strength I needed throughout the course of this pursuit and to everyone who have contributed to the success of this project.

ACKNOWLEDGEMENT

I want to express my profound gratitude and ascribe all glory and honour to God almighty for keeping me alive and sustaining me till the end of the program

I Acknowledge with a deep sense of appreciation my project supervisor Prof. Florence E Eichie for her professional guidance, impactful contribution and support throughout this research.

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ABSTRACT

Background: Pharmaceutical manufacturing often relies on imported and synthetic binders, which can be costly and have variable availability. This study was aimed at evaluating starch from a locally sourced tuber, water yam (Dioscorea alata), as a cost-effective alternative. The study specifically compared the performance of native (unmodified) starch to pregelatinized water yam starch and corn starch.

Methods: Starch was extracted from fresh *Dioscorea alata* tubers. A portion of this starch was then pregelatinized by forming a starch slurry of 50g of the extracted starch in 100ml of water and then heating it at 80ºc until a gel was formed. The gel was dried at 55ºF, converted back to powdered form and subjected to physicochemical characterization. Three distinct batches of 500 mg paracetamol tablets were formulated using 0.5g/mL of corn starch, (2) native water yam starch, and (3) pregelatinized water yam starch as the binders. All tablet batches were evaluated for standard quality control parameters, including friability, disintegration time, and in-vitro dissolution.

Results: All formulations using water yam starch (both native and pregelatinized) produced tablets with excellent mechanical strength, as indicated by friability values well below the 1.0% pharmacopeial limit. The disintegration test, however, revealed critical differences. The corn starch tablets failed, with a disintegration time of over 2 hours. The native water yam starch tablets also failed, at 43 minutes. In striking contrast, the tablets made with pregelatinized water yam starch passed with an excellent disintegration time of 60 seconds. The dissolution results directly reflected this: the corn starch and native starch batches failed to release the drug, while the pregelatinized batch met the standard.

Conclusion: This study confirms that pregelatinization is an essential modification to unlock the potential of water yam starch. While native water yam starch acts as too strong a binder, pregelatinization transforms it into a highly effective, multifunctional excipient that provides both good binding and rapid disintegration. Pregelatinized Dioscorea alata starch is, therefore, a viable, locally sourced, and superior alternative to conventional binders like corn starch for immediate-release tablet formulations.

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CHAPTER ONE

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1.0 Introduction

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Tablets remain the most common and preferred method for drug delivery, but their formulation depends on critical excipients, especially binders, to ensure mechanical strength. Many binders used in the pharmaceutical industry are synthetic and imported, which leads to high production costs and supply chain instabilities. This directly impacts the final cost and availability of essential medicines**.**

To address this, this research is focused on finding cost-effective, readily available, and locally sourced alternatives. Natural starches from indigenous crops are a highly promising option. Water yam (*Dioscorea alata*) is a widely cultivated tuber that is rich in starch. This study, therefore, aims to extract, modify, and evaluate the binding properties of water yam starch, comparing it to conventional binders to determine its suitability for use in the formulation of paracetamol tablets.

Tablet dosage form

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1.1.1 Definition of tablet

A tablet is a solid dosage form of medication. it is formally defined as a compressed solid dosage form that contains a medicament (the active drug) with or without other inactive ingredients known as excipients. They are the most common and popular dosage form, valued for their accuracy, convenience and stability (Lachman, Lieberman and Kanig, 1990)

1.1.2 Classification of Tablets

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Tablets can be classified into three classes (SRMIST, n.d.).

A. Tablets ingested Orally

1. Compressed tablets
2. Delayed release tablets
3. Sugar coated tablets
4. Film coated tablets
5. Chewable tablets

B. Tablets used in oral cavity

1. Buccal tablets e.g vitamin C tablets
2. Sublingual tablets
3. Troches or lozenges
4. Dental cones

C. Tablets administered by other routes other than mouth:

1. Implantation tablets
2. Vaginal tablets

D. Tablets used to prepare

1. Effervescent tablets
2. Dispensing tablets
3. Hypodermic tablets
4. Tablet trituration

1.1.3 Advantages of Tablets

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1. Low cost
2. Lighter and compact
3. Easiest and cheapest to package
4. Sustained release product is possible by enteric coating
5. Objectionable odor and bitter taste can be masked
6. Suitable for large scale production
7. Greatest chemical and microbial stability over all oral dosage form (Lachman, Lieberman and Kanig, 1990)

1.1.4 Disadvantages of Tablets

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1. Difficult to swallow in cases of children and unconscious patients
2. Some drugs resist compression into dense compacts
3. Drugs with poor wetting, slow dissolution properties may not provide adequate bioavailability as tablets (Lieberman, Rieger and Banker 1990)

1.1.5 Tablet manufacturing process

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The production of most pharmaceutical tablets relies on one of three principal techniques: wet granulation, dry granulation, or direct compression. The selection of the most appropriate technique hinges on the specific characteristics of the active pharmaceutical ingredient (API) and the other ingredients (excipients), including their ability to flow, their compressibility, and their potential sensitivity to moisture or high temperatures

1. Wet Granulation

This technique is the most conventional and commonly employed method for creating compressed tablets. As its name suggests, this process utilizes a liquid (known as a granulation fluid, which is frequently water or an organic solvent) to agglomerate fine powder particles into larger granules that flow more easily.

Common Procedure:

a. Weighing and Mixing: The API and excipients (such as diluents and disintegrants) are measured and combined.
b. Wet Mass Formation: A liquid binding solution is introduced to the powder mixture to create a damp, cohesive mass.
c. Granulation/Sieving: The damp mass is passed through a screen of a predetermined mesh size to form wet granules.
d. Drying: The newly formed wet granules are then dried, commonly in a fluid-bed dryer or an oven, to eliminate the granulating liquid.
e. Dry Sieving (Sizing): The granules, now dry, are passed through another sieve to break apart any large clumps and ensure a consistent granule size.
f. Lubrication: A lubricant (e.g., magnesium stearate) and a glidant are blended with the dry granules.
g. Compression: This final granular mix is pressed into tablets.

Benefits:

1. Enhances the flow characteristics and compressibility of the powder blend.
2. Minimizes the separation of different components within the mixture.

3. Improves the consistency of the active drug content in the final tablets, which is especially important for low-dose medications.
4. Compatible with standard, conventional excipients.

Drawbacks:

1. It is a process with many stages, which makes it both time-intensive and expensive.
2. The involvement of heat and moisture renders it unsuitable for drugs that are thermolabile (heat-sensitive) or prone to hydrolysis (degradation in water)
3. It necessitates a larger manufacturing footprint and more pieces of equipment

2. Dry Granulation

This technique is selected when the ingredients for the tablet are intolerant of moisture or heat, which rules out the wet granulation method. It achieves particle agglomeration by compacting the powder blend, but without using any liquid binder. This approach is frequently employed for APIs that naturally possess cohesive properties.

Common Procedure:

a. Weighing and Mixing: The API, diluent, and a portion of the lubricant are combined.
b. Compaction (Slugging or Roller Compaction):
c. Slugging: The powder mixture is compressed on a heavy-duty tablet press to form large, coarse tablets known as 'slugs'.

d. Roller Compaction: The powder is fed between two rollers rotating in opposite directions, which draw the powder in and compact it into a dense sheet or ribbon.
e. Milling/Sizing: The compacted slugs or ribbons are then broken down (milled) into smaller granules of the required size.
f. Lubrication: The rest of the lubricant and any other excipients (like disintegrants) are added to the granules and mixed.
g. Compression: The final mixture is pressed into tablets.

Benefits:

1. Perfect for drugs that are sensitive to moisture or heat.
2. Involves fewer stages and requires less energy than wet granulation.
3. Reduces costs by eliminating the need for liquid solvents and the drying step.

Drawbacks:

1. Needs specialized machinery (like a roller compactor) or a heavy-duty press for the slugging method.
2. Can generate a substantial amount of airborne dust, necessitating effective dust-containment systems.
3. The resulting granules may not be as robust as those from wet granulation, which could lead to tablets with inferior mechanical strength.

3. Direct Compression (DC)

Direct compression stands as the most straightforward and economical technique for making tablets. It consists of mixing the API with specific excipients (termed direct compression excipients or fillers-binders) and then pressing this blend directly into tablets.

This method is only viable for drugs that already possess good flowability and compressibility, or when formulated with excipients that can bestow these characteristics upon the blend.

Common Procedure:

a. Weighing and Mixing: The API, direct compression excipients (such as microcrystalline cellulose), disintegrants, and lubricants are all measured and combined thoroughly in a blender.
b. Compression: The prepared powder mixture is then fed straight into a tablet press, where it is compressed into the final tablets.

Benefits:

1. The most economical method because it has the fewest steps, requires less labor, and involves lower equipment expenses.
2. Completely avoids the use of moisture and heat, making it ideal for sensitive drug substances.
3. A simpler process means quicker production times and a reduced likelihood of mistakes or cross-contamination.

Drawbacks:

1. Its application is restricted to drugs that are inherently easy to compress and flow well.

2. There is a greater potential for issues with content uniformity (consistent dosing), particularly for low-dose drugs, as fine API particles might separate from the larger excipient particles during handling.
3. It is heavily dependent on the use of specialized, and often more costly, direct compression excipients (Nagashree, 2015)

1.2 Pharmaceutical Excipients

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1.2.1 Definition of Pharmaceutical Excipients

In pharmaceutical science, excipients are defined as any component in a drug formulation other than the active pharmaceutical ingredient (API). These are substances that are intentionally included in a dosage form following a thorough evaluation of their safety.

While they were historically dismissed as "inactive" or "inert," excipients are now recognized as essential, functional materials. They are considered critical to the final medication's overall efficacy, safety, and performance. These non-medicinal substances often represent the largest portion of a formulation. They are indispensable for converting a potent API into a dosage form that is effective, stable, and acceptable for the patient to use (Patel R *et al*, 2020)

1.2.2 Primary Functions and Classifications of Excipients

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Excipients are chosen to serve a wide range of functions, including overcoming manufacturing challenges, managing the drug's therapeutic performance, ensuring product stability, and improving patient acceptance. They are generally classified by their primary function in the formulation.

Binders (or Adhesives): These substances are added to provide the cohesion necessary to hold the powder particles together. Their main purpose is to "bind" the API and other components, ensuring the tablet has the mechanical strength to remain intact after compression . Common examples include povidone (PVP), starch, and cellulose derivatives like HPMC.

Diluents (or Fillers): Diluents are used to increase the total volume (bulk) of the formulation. This is essential when the dose of the API is very small, as it allows for the creation of tablet that is practical and easily handled in terms of size. Some fillers, like microcrystalline cellulose, can also provide secondary functions, such as binding. Lactose and dicalcium phosphate are also common.

Disintegrants: These excipients are included to help the tablet break apart (disintegrate) into smaller fragments when it encounters fluids in the gastrointestinal tract. This process is vital for increasing the drug's surface area, which promotes its rapid dissolution and subsequent absorption. Highly efficient "super-disintegrants" include croscarmellose sodium, sodium starch glycolate, and crospovidone.

Lubricants: Lubricants are crucial components for the manufacturing process, especially in high-speed production. Their main function is to reduce the friction between the tablet's surface and the metal wall of the die cavity. This prevents the tablet from sticking to the punches and dies of the press, ensuring smooth ejection and preventing damage. The most widely used lubricant is magnesium stearate.

Glidants: Also known as flow-promoters, glidants are used to improve the flow characteristics of the powder blend. They work by minimizing the friction between particles, which allows the powder to flow smoothly and uniformly from the storage hopper into the die. This consistent

flow is essential for maintaining a uniform tablet weight and ensuring dose accuracy. Common examples include colloidal silicon dioxide (Aerosil®) and talc; (Van der Merwe *et al,* 2020)

1.2.3 Importance of Choosing Appropriate Excipients

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The selection of appropriate excipients is one of the most critical decisions in the entire drug development process. Far from being "inactive," these substances are essential functional components that ultimately dictate the final product's manufacturability, stability, safety, and overall performance. (Pockle *et al,* 2023).

Essential functions of Excipients

1. Impact on Drug Efficacy and Bioavailability

An excipient choice can directly determine whether a drug is effective. Many modern drugs are poorly soluble in water, and the right excipients are needed to "modulate bioavailability and solubility," which helps the drug dissolve in the gut so it can be absorbed. Furthermore, API-excipient interactions are a major concern. An incompatible excipient could potentially bind to the drug, preventing its release and rendering the medication ineffective. (Rao *et al,* 2020)

2. Ensuring Drug Stability and Shelf-Life

Medication must remain safe and effective from the day it is manufactured until the patient uses it. Excipients are the primary guardians of the API's stability. They are selected to protect the active ingredients from degradation caused by environmental factors like light, moisture, or oxidation. For example, with moisture-sensitive drugs like aspirin, it is critical to choose excipients that can effectively manage moisture within the tablet to prevent the API from breaking down and losing its potency. (Chaudhari & Patil 2012)

3. Enabling Manufacturability

A theoretically perfect drug formulation is useless if it cannot be mass-produced. Raw APIs often have very poor physical properties, such as inadequate flow or an inability to stick together, which makes large-scale production impossible. The properties of the excipients directly influence the success and efficiency of manufacturing operations like blending, granulation, and compression. Ingredients like diluents, glidants, and binders are essential for ensuring that every single tablet produced contains the identical, correct dose and possesses the required mechanical strength. (Dave *et al,* 2015).

4. Ensuring Patient Safety and Compliance

Excipients have a direct effect on the patient's safety and overall experience. They are used to mask bitter tastes or improve a tablet's appearance, which enhances "patient acceptability" and makes it more probable that a patient will adhere to their prescribed treatment.

This selection is especially crucial for vulnerable populations, such as the elderly and children. These patients have different physiological needs (e.g., difficulty swallowing or immature metabolic systems), and an excipient that is perfectly safe for an adult could be harmful to them. Moreover, emerging evidence shows that some excipients, once considered completely inert, can cause adverse hypersensitivity reactions in certain individuals. These can range from mild skin reactions to severe allergic responses, making their careful selection a critical safety consideration. (Belayneh *et al,* 2020)

1.3 An Overview of Pharmaceutical Binders: Function and Classification

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A binder, which may also be referred to as a granulating agent or adhesive, is classified as a pharmaceutical excipient. Its inclusion in a tablet formula is to bestow cohesive properties upon the powdered components. The fundamental role of a binder is to serve as an adhesive, binding the active pharmaceutical ingredient (API) with other excipients. This ensures the final compressed tablet possesses sufficient mechanical integrity to avoid breaking. These agents are critical in granulation procedures for the creation of granules and are equally important in direct compression for fostering strong, cohesive compacts. (Amol & Saudager,2017)

1.3.1 Classification of Binders

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1. Natural Binders

These are excipients sourced directly from plant or animal materials. Their popularity stems from attributes like being biodegradable, biocompatible, readily obtainable, and typically more economical.

Starches: This category covers starches from various origins, such as potato, corn, or modified forms like pregelatinized starch. Their widespread application is due to their adequate binding capacity and their secondary function as disintegrating agents.

Gums: Binders like acacia (also known as Gum Arabic) are conventional agents derived from the secretions of plants. While they are efficacious binders, their properties can be inconsistent, varying with their natural source.

Gelatin: This is a protein of animal origin that offers robust binding capabilities. Its use has declined due to concerns about its animal source and its potential to cause cross-linking problems in formulations. (Manish *et al,* 2010)

2. Semi-Synthetic Binders

This group consists of natural polymers, mainly cellulose, that have undergone chemical alteration. These binders provide a compromise, combining a natural base with the benefits of more predictable and consistent performance.

Cellulose Ethers: A prominent class that features Hydroxypropyl Methylcellulose (HPMC) and Hydroxypropyl Cellulose (HPC). These are exceptionally adaptable and efficient binders, suitable for direct compression and multiple granulation. The specific grade used (which can differ in particle size or molecular weight) determines the binding strength and also affects how the tablet breaks apart.

Microcrystalline Cellulose (MCC): Though its primary classification is often a diluent or filler, MCC possesses substantial binding capabilities. This is attributed to its capacity for plastic deformation when compressed, making it a crucial ingredient for formulas made by direct compression. (Dinda & Mukharjee, 2019)

3. Synthetic Binders

These polymers are created through chemical manufacturing, allowing for exact control over their characteristics, such as viscosity and molecular weight. This precision results in dependable and uniform functionality.

Povidone (Polyvinylpyrrolidone, PVP): As one of the most frequently used synthetic binders, PVP is valued for its powerful adhesive qualities. It is commonly applied in a liquid solution during wet granulation. The binding strength can be modulated by selecting different molecular weight grades, such as K30 or K90.

Copovidone: This binder is a copolymer made from vinyl acetate and vinylpyrrolidone. It provides effective binding and is suitable for use in direct compression as well as wet granulation.

Polyethylene Glycols (PEGs): Although PEGs are generally employed for other purposes, those with a higher molecular weight are capable of functioning as binders, particularly in manufacturing methods involving melt granulation. (Dinda & Mukharjee,2019)

1.3.2 Essential Qualities of an Optimal Binder

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For a pharmaceutical binder to be considered ideal for tablet production, it must meet several critical standards. These qualities ensure it functions correctly while protecting the final product's overall integrity, safety, and effectiveness.

1. Biologically Safe and Inactive: The binder must be non-toxic and non-irritating. It should be biologically inert, meaning it produces no pharmacological effects or adverse reactions within the body at the intended concentrations.
2. Formulation Compatibility: It is essential that the binder is chemically non-reactive with the active pharmaceutical ingredient (API) and any other excipients. It must not participate in chemical reactions that could lead to the degradation of the drug or alter the formulation's characteristics.
3. High Efficiency at Low Doses: An effective binder imparts the necessary binding strength and tablet integrity while being used in small proportions (generally 2-10% w/w). This efficiency

helps reduce the final tablet's size and weight and minimizes any potential interference with the drug's release.

4. Robust Stability: The binder must remain stable in both its physical and chemical states during routine storage. It also needs to endure the conditions of the manufacturing process (like the heat from drying steps in wet granulation) without breaking down.
5. No Interference with Drug Absorption: A crucial requirement is that the binder must not negatively affect the drug's bioavailability. Although it provides cohesion, it must not prevent the tablet from disintegrating correctly or impede the dissolution and subsequent absorption of the API after administration.
6. Good Manufacturability: The binder should have properties that allow for easy handling and processing. It should blend homogeneously with other ingredients and, for wet granulation, be capable of forming a suitable granulating liquid.
7. Regulatory Compliance: The excipient must be approved by health authorities such as the FDA or EMA, confirming it meets all required quality and safety benchmarks.
8. Economic and Sourcing Practicality: Finally, the binder should be cost-effective and reliably available in a stable form from commercial suppliers. (Patel et al, 2007)

1.4 Starch as a pharmaceutical excipient.

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Starch is a key carbohydrate synthesized by plants, serving as their main molecule for storing energy. It is a fundamental part of the human diet and sees extensive use across multiple industries, including pharmaceuticals (Chaudhari & Patil,2012)

1.4.1 Composition of starch

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Starch is classified as a polysaccharide, indicating it is a large polymer constructed from repeating glucose monomer units. These units are joined by glycosidic bonds. Starch is fundamentally a mixture of two specific types of glucose polymers:

1. Amylose: This component typically accounts for 20-30% of the starch.

2. Amylopectin: This component makes up the larger portion, comprising 70-80% of the starch.

The specific proportion of amylose to amylopectin is not fixed; it fluctuates based on the plant source, such as potato, corn, wheat, or rice. (Beninca *et al*,2008)

1.4.2 Structure of starch

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Amylose

Amylose is characterized as a largely linear polymer. Its backbone is formed by glucose units connected mainly through α-(1→4) glycosidic linkages. Although it is predominantly linear, a small degree of branching can be introduced by α-(1→6) bonds. The geometry of the α-(1→4) linkages causes amylose chains to naturally form a helical shape, especially when in water or when forming complexes with iodine or lipids.

Amylopectin

In contrast to amylose, amylopectin is a significantly larger molecule with a highly branched structure. Its framework consists of short, linear chains of glucose units joined by α-(1→4) glycosidic bonds, much like amylose. However, these linear chains are intermittently linked to each other via α-(1Opening) glycosidic bonds, which create branch points. These branches occur roughly every 24 to 30 glucose residues, giving the molecule a complex, tree-like architecture. (Rodrigues & Emeje,2012)

Granular Structure

Inside the plant, starch is not free; it is stored as distinct, semi-crystalline particles known as starch granules. These granules are housed within specialized organelles—amyloplasts (in roots and tubers) or chloroplasts (in leaves). The size and shape of these granules are characteristic of their plant origin.

The amylose and amylopectin molecules within the granule are arranged in alternating semi-crystalline and amorphous layers (lamellae).

Crystalline Regions: These areas are primarily composed of the short outer branches of amylopectin molecules, which pack together in an ordered, double-helical fashion.

Amorphous Regions: These less-ordered zones contain the amylose molecules along with the branching points of the amylopectin.

This complex internal organization is responsible for the granule's typical properties, like its insolubility in cold water and its capacity to swell and gelatinize when heated in an aqueous environment. (Beninca *et al*,2008)

1.4.3 Primary Starch Sources

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Cereals:

Maize (Corn): Globally, maize is the biggest source of commercial starch, heavily used in both food processing and industrial manufacturing (Uhumwangho et al,2006)

Wheat: A primary source of starch, crucial for food items like pasta and bread, as well as for industrial applications (Uhumwangho *et al*,2006)

Rice: As a staple food for a vast part of the global population, rice starch is also utilized in cosmetics and food products (Uhumwangho *et al*,2006)

Tubers:

Potatoes: A major starch source, distinguished by its large granule size and unique functional characteristics, such as creating high-viscosity gels (Musa *et al;* 2011)

Sweet Potatoes: These are also grown specifically for their starch content. (Musa *et al;* 2011)

Roots:

Cassava (also called Manioc or Tapioca): A critical starch source, particularly in tropical climates, used widely in both industrial and food applications (Musa, Gambo & Bhatia,2011)

Yam: Multiple yam species are farmed for their starchy tubers, holding significant importance in Asia and Africa (Musa, Gambo & Bhatia,2011)

Legumes:

While peas, beans, and lentils do contain starch, they are not as frequently used for large-scale commercial starch production when compared to tubers and cereals (Hoover et al., 2010).

The specific characteristics of starch—such as its gelatinization temperature, granule size, viscosity, and the ratio of amylose to amylopectin—differ greatly based on the plant it comes from. This variation determines which starch is best suited for a particular use (Singh *et al.,* 2003).

1.4.4 Properties of starch relevant in tableting

Starch functions effectively as a binding agent because of specific physicochemical characteristics that influence its adhesive strength and performance during granulation and compression. These properties determine its suitability and efficiency in tablet formulation.

1. Granule Size and Shape (Morphology): Starch granules exhibit a wide range of sizes (approx. 1 to 100 μm) and shapes (such as oval, round, or polygonal). These features are characteristic of the plant source; for instance, potato starch has large, oval granules, while rice and maize starch granules are small and polygonal.

   Relevance: Granule morphology strongly influences powder flow characteristics and packing density. Powders with small or irregular granules typically flow poorly, which can result in non-uniform die filling and, consequently, variations in tablet weight. Larger, more spherical granules tend to have better flow. Compaction behavior is also affected by these morphological features.
2. Flowability and Density: Native (unmodified) starches are often cohesive and have small particle sizes, leading to poor flow properties. The packing behavior of the powder is assessed using bulk and tapped density measurements.

   Relevance: Consistent and rapid powder flow is critical for high-speed tablet manufacturing to ensure uniform filling of the tablet press dies. Poor flow leads to inconsistent tablet weights and potential issues with content uniformity. This is a primary reason why starch is often modified (e.g., pregelatinized) or granulated—to improve its flow prior to tableting.
3. Compressibility and Compactibility: These terms describe the ability of the starch powder to reduce in volume under pressure (compressibility) and to form a mechanically strong, stable tablet (compactibility). Native starch granules can exhibit significant elasticity.

   Relevance: Starch acts as both a filler and a binder. Its compaction properties are a key determinant of the final tablet's hardness and its resistance to breaking or crumbling (friability).

The inherent elasticity of native starch can sometimes cause tablet defects like capping (top of the tablet separating) or lamination (splitting into layers). Modified starches, or starch used as a paste in wet granulation, generally show better binding due to plastic deformation or the formation of solid bridges upon drying (Odeku and Picker-Freyer, 2007).

4. Swelling Power and Solubility: Starch granules absorb water and swell when exposed to it. The degree of swelling and the amount of soluble material that leaches out are dependent on the amylose/amylopectin structure and the temperature.

   Relevance: This property is the fundamental mechanism for starch's function as a disintegrant. When the tablet enters the gastrointestinal tract, the starch granules absorb body fluids, swell considerably, and generate internal pressure. This pressure builds up forces within the tablet structure to break apart, facilitating the release of the active drug.

5. Gelatinization and Pasting Properties: When starch is heated in the presence of sufficient water, it undergoes gelatinization—an irreversible process characterized by the loss of crystalline order, granule swelling, and the leaching of amylose. With continued heating, the granules rupture and form a viscous paste. The specific temperature range for gelatinization and the viscosity profile are unique to the starch source.

Relevance: This behavior is essential for starch's role as a **binder** during wet granulation. A starch paste, created by heating a starch-water suspension, serves as the "glue" or adhesive solution used to agglomerate fine powder particles into larger granules. The viscosity of this paste is a critical factor that affects the granulation process and the final properties of the granules. (Rowe, *et al;* 2006)

1.4.5 Limitations of Native Starch

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1. Subpar Flow and Compaction: Native starch granules generally have poor flowability due to their cohesiveness, small particle size, and irregular shapes. Furthermore, they are often elastic and do not compress effectively, which results in tablets that lack sufficient mechanical strength (hardness). This poor compaction can also lead to tablet defects such as lamination or capping. Consequently, native starch is typically not a suitable choice for direct compression manufacturing.
2. Significant Moisture Attraction: Starch is inherently hygroscopic, meaning it has a strong tendency to attract and hold moisture from its surroundings. This characteristic can jeopardize the stability of drugs that are sensitive to moisture and may also cause the powder's flow and compression characteristics to change during storage.
3. Inconsistent Properties: Because starch is a natural product, its physicochemical attributes (e.g., moisture content, granule size, amylose-to-amylopectin ratio) can fluctuate based on its plant source, environmental conditions during growth, and the method of extraction. This lack of batch-to-batch consistency can result in unreliable manufacturing performance and variable final product quality.
4. Cold Water Insolubility: Native starch granules do not dissolve in cold water. While this insolubility is essential for its role as a disintegrant (as it allows the granules to swell), it

restricts its functionality as a binder. To be used as a binder, it must first be cooked with heat to form a gelatinized paste.(Rowe, sheskey & owen,2006)

To overcome these challenges, modified starches (such as pregelatinized starch) or granulation techniques are frequently employed to enhance the starch's properties, making it more suitable for dependable tablet production.

1.5 Pre-gelatinization of starch

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1.5.1 Definition of pre-gelatinization

Pre-gelatinization is a physical modification technique where natural starch is first cooked in an aqueous solution and subsequently dehydrated, often through industrial methods like spray or drum drying. The primary outcome of this procedure is the breakdown of the organized, semi-crystalline arrangement of the original starch granules. This yields a powdered substance that possesses the characteristics of cooked starch, most notably its capacity to quickly absorb moisture and expand in cold liquids (such as milk or water) without any thermal application. (Anastasiades *et al.,* 2002)

1.5.2 Methods of Starch Pre-gelatinization (Dry Heat, Hydrothermal, Chemical)

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Pre-gelatinization is a process that alters natural starch, allowing it to swell or become soluble in cold water by disrupting its granular makeup. While this is most often accomplished with hydrothermal methods, other physical and chemical treatments can also modify the starch's structure and characteristics.

Techniques for Modifying Starch to Achieve Pre-gelatinization includes

1. Hydrothermal Methods

These techniques employ a mix of moisture and heat to break down the starch granule's structure. They represent the most prevalent industrial pathways for manufacturing conventional pregelatinized starch.

Underlying Concept: Applying heat to starch in water's presence delivers the energy required to sever hydrogen bonds within the granule. This permits water absorption, swelling, a loss of crystalline structure, and the leaching of amylose. A swift drying process then preserves this altered, disrupted state

Specific Techniques:

Drum Drying: A starch slurry is spread as a thin layer on a heated, rotating drum. The intense heat simultaneously cooks the starch and vaporizes the water, leaving a dry, pregelatinized sheet that is subsequently milled into powder or flakes. (Nakron, *et al;* 2009)

Spray Drying: A starch slurry is atomized into a current of hot air. This process rapidly evaporates the water, cooking and drying the starch into fine particles at the same time.

Extrusion Cooking: Within an extruder barrel, starch is exposed to high temperatures, intense pressure, and significant shear forces with a controlled amount of moisture. This powerful thermomechanical action disrupts the granules and cooks the starch before it is expelled from the die and subsequently dried or milled.

Heat-Moisture Treatment (HMT) & Annealing (ANN): These are hydrothermal treatments that, while not typically causing complete gelatinization, do modify the granule's structure,

crystallinity, and swelling capabilities. HMT uses restricted moisture, whereas ANN uses surplus water below the gelatinization temperature (Xiao *et al*., 2023).

2. Dry Heat Treatment (DHT)

This is a physical modification that entails heating dry or low-moisture starch powder at high temperatures (frequently above 100°C) for a set duration.

Underlying Concept: Due to the absence of water, this method does not cause gelatinization. Instead, dry heat triggers structural reorganization within the starch granule. This can lead to some molecular degradation, alter the crystalline structure, and change how the starch swells and pastes. It can create partial disruption, which may slightly improve its ability to disperse in cold water.

Result: This treatment modifies properties such as solubility, swelling capacity, and susceptibility to enzymatic digestion. (Doublier, *et al;* 1994)

3. Chemical Modification

Chemical processes involve reacting starch with particular agents to attach new functional groups to its glucose units. Although this isn't "pre-gelatinization" in the traditional sense of cooking, certain chemical changes can dramatically boost starch's affinity for water, thereby promoting cold-water solubility or swelling.

Underlying Concept: The introduction of chemical groups interferes with the granule's internal hydrogen-bonding network. It can also enhance hydration by adding hydrophilic (water-loving) or charged groups.

The Impact of Pre-gelatinization on Starch's Physicochemical and Functional Properties

The process of pre-gelatinization fundamentally transforms the physical and functional characteristics of native starch, adapting it for high-performance roles in pharmaceutical manufacturing, especially for tablet production. . (Doublier,*et al;* 1994)

1.5.3 Effect of pre-gelatinization on the physicochemical properties of starch

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1. Swelling Index and Solubility:

Impact: Pre-gelatinization dramatically increases the starch's ability to swell and dissolve in cold water.

2. Flowability:

This property is significantly improved in comparison to native starch

3. Binding Strength and Compressibility:

Impact: The capacity for binding and the ability to be compressed into a tablet are markedly enhanced.

In essence, pre-gelatinization modifies starch from a material with poor flow and compressibility that requires cooking to function, into a highly functional excipient. It is valued for its cold-water hydration, excellent flow, and ability to act as a robust binder, making it a cornerstone of direct compression tablet manufacturing. (Zhu & corke,2011)

1.5.4 Pharmaceutical Applications of Pregelatinized Starch

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Pregelatinized starch is a multifunctional excipient widely employed in the pharmaceutical industry. Its utility stems from the superior flow, binding, and cold-water swelling properties it gains during its modification from native starch.

Key Applications

1. Dry Binder and Diluent in Direct Compression (DC): This is the primary and most valued application of pregelatinized starch. Unlike native starch, its enhanced flowability and excellent compressibility allow it to be mixed directly with active pharmaceutical ingredients (APIs) and compressed into tablets. This eliminates the need for a separate wet granulation step, making the manufacturing process simpler, faster, and more economical.

2. Binder in Wet Granulation: Pregelatinized starch is also used as a binder in traditional wet granulation. Its advantage here is its cold-water solubility, which means it can be added directly to the powder blend. This avoids the time-consuming and energy-intensive cooking step required to prepare a paste from native starch.

3. Disintegrant: Capitalizing on its rapid swelling in cold water, pregelatinized starch functions as an effective disintegrant. When included in a tablet or capsule, it quickly absorbs gastrointestinal fluids, swells, and exerts pressure that breaks the dosage form apart, facilitating the release and dissolution of the API.

4. Filler in Capsules: The superior flow properties of pregelatinized starch make it an ideal filler or diluent for hard gelatin capsule formulations. It ensures that the capsule-filling machinery can operate efficiently and that each capsule is filled with a uniform and consistent weight of the formulation.

5. Viscosity-Increasing Agent: In certain semi-solid or liquid formulations, it can be used as a thickening or stabilizing agent due to its ability to build viscosity in cold aqueous systems.(Zhu & corke,2011)

1.6 Water yam (*Dioscorea alata*)

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Water yam, scientifically known as *Dioscorea alata* and also commonly called winged yam, is a major staple food crop cultivated throughout the tropical and subtropical regions of the world. It is one of the most economically important species of yams.

Economic Significance: It is a vital tuber crop, particularly in West Africa, which accounts for most of the global yam production. Nigeria is the world's leading producer. It serves as a critical source of food and income for millions of people. (Lebot *et al;* 2023)

Nutritional Value: Water yams are recognized for its significant nutritional benefits. It often contains higher protein content and vitamin C compared to other common yam species. It is also noted for having a low glycemic index, making it a suitable food for diabetic patients. (Alamu, *et al;* 2019)

Health Benefits: The tuber contains various bioactive compounds, including antioxidants. Research highlights its potential health benefits, such as anti-inflammatory, anti-rheumatism, and anti-cancer properties. (A lamu *et al;* 2019)

Agronomic Advantages: D. alata is widely grown because it generally provides high yields, has good tuber storability (lasts long in storage), and often has a greater tolerance for non-staking cultivation methods. This reduces the high labor costs associated with staking, which is required for other species like white yam (D. rotundata).

Utilization: Water yam is versatile in the kitchen. It can be boiled, fried, roasted, or baked. It is also commonly processed into flour, which is used to make a traditional paste or dough (known

as "amala" in parts of Nigeria). Research is also exploring its potential as a source for biofuel (ethanol) production. (Lebot, *et al;* 2023)

Challenges: Despite its advantages, water yam is sometimes considered underutilized, often due to consumer preferences for the texture of white yam, especially for making "pounded yam." However, research is focused on identifying and promoting elite water yam genotypes that have food product qualities comparable to white yam. (Adinsi *et al.,* 2023

1.7 Aim of the study

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The aim of this study is to formulate paracetamol tablet using modified starch obtained from *Dioscorea alata (Dioscoreaceae*) as a binder. The specific objectives were to

1. extract starch from water yam (*Dioscorea alata)* tubers and modify it by hydrothermal pre-gelatinization.

2. Determine the physicochemical properties of the pregelatinized starch as binder

3. Formulate paracetamol tablet with the modified starch and characterize the formulated tablet

4. Evaluate the suitability of pre-gelatinized *Dioscorea alata* starch as potential tablet binder.

CHAPTER TWO

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2.1 Materials and methods

2.11 Materials

1. ***Dioscorea Alata Tubers***

Fresh tubers of *Dioscorea alata (*water yam) were purchased in a local market in Benin City and the species were identified by Department of Plant Biology, Faculty of Life Science, University of Benin, Benin City, Nigeria.

Family: Dioscoreaceae

Common Name(s): Water yam, Purple yam, Winged yam, Greater yam

Voucher Number: UBH-D604

Issued By: Prof. Akinnibosun Henry Adewale

Date Issued: 08/07/2025. Starch extraction was obtained from the tubers and was investigated as a binder in tablet formulation.

Paracetamol powder: paracetamol powder (BDH Chemicals, London) was used as a drug model as a poorly compressible pharmaceutical active ingredient in this study.

All other reagents employed in this study were all of analytical grade.

2.2 Methods

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2.2.1 Starch Extraction

Fresh and firm Dioscorea alata tubers (water yam) were selected, cleaned soil and debris using water and peeled using a kitchen knife ensuring both the brown outer skin and the underlying pinkish-purple cortex are removed. The white yam flesh was diced into small cubes and blended using an electric blender. The yam slurry was then poured through a muslin cloth, forcefully extracting all the liquid into a bowl leaving the fibrous residue behind in the cloth. The liquid, starch milk was left to sit overnight. after which were collected at the bottom of the bucket forming starch cake and a brownish, viscous liquid (the "supernatant"), which contains water-soluble impurities like proteins, sugars, and mucilage, was formed at the top. The supernatant layer was carefully decanted and disposed. Fresh distilled water was introduced to the starch cake and a spatula used to break up any clumps thoroughly re-suspending the starch in the water. The starch was allowed to settle once more for 4 hours and the water decanted from the top.

This washing and decanting cycle was repeated until the decanted water was almost completely clear. Following the last decantation, the damp starch cake crumbled into smaller pieces and transferred onto clean trays for drying in an oven at 50°C until starch became brittle and easy to break. The starch was milled until a fine consistent powder was formed. (Moorthy, 1991).

2.2.2 Starch testing/ identification

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1g of the powder was placed on a tile and a slurry made by adding few drops of distilled water. Two drops of the iodine solution was added to the paste and was observed for color change (Cochran,*et al;* 2008)

2.2.3 Starch Pre-gelatinization

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A Slurry was prepared by mixing 50 grams of starch in 100ml of distilled water contained in a glass beaker. The starch slurry was placed on a hot plate at 80°C and was continuously stirred until all starch granules were completely broken down and gelatinized. The starch gel was then transferred to an oven tray forming a thin layer and was placed in the oven at 55°C for drying. After the drying process is completed, remove the hard starch sheets was removed from the tray, fragmented into smaller sections. The dried starch was then milled until fine powder was formed. To ensure a consistent particle size, The powder was passed through a laboratory sieve.

2.2.4 Tableting procedure

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1. Tableting process using Un-pregelatinized extracted water yam starch and corn starch as binder (Wet Granulation)

The Active pharmaceutical ingredient, paracetamol powder, lactose (filler), Talc (glidants) and Magnesium stereate (lubricant) were mixed using mortar and pestle. A binder paste (starch paste) was formed and added to the mixed powder carefully mixing everything together forming wet granules. The wet granules were dried and milled. The dried milled granules were loaded into the hopper of a tablet press and compressed into tablets

2. Tableting process using Pregelatinized *Dioscorea alata* starch (Direct compression)

The active pharmaceutical ingredient (API) and the excipients were processed individually by milling to produce a uniform and desirable particle size for all components. After which they were all mixed together using a mortar and pestle. The powder mix was then fed into the hopper of a tablet press. The machine then directly compresses this blend to form the tablets.

Table 2.1 Formula for tableting using pregelatinized water yam starch as binder

Ingredient in mg	**Quantity (mg) of batches**		
	A	**B**	**C**
Paracetamol Powder	500	500	500
Lactose	65	65	65
Pregelatinized Yam Starch	25	0	0
Native Yam Starch	0	q.s	0
Corn Starch	0	0	q.s
Talc	5	5	5
Magnesium Stearate	5	5	5
Total	600	600	600

2.3 Characterization of Powder

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2.3.1 Determination of Bulked and Tapped densities.

10g of each of the different batches of the mixed powders were weighed into clean 50ml measuring cylinder and the volume Vb (Bulk volume) occupied by each of the sample without tapping was noted. The cylinders were tapped 100 times on a hard table top and tapped volume Vt were recorded. The bulk densities Db and tapped densities Dt were calculated as ratio of mass to volume

$Db = \frac{M}{Vb}$ ..... (2.1)

$Dt = \frac{M}{Vt}$ ..... (2.2)

2.3.2 Carr's compressibility index and Hausner' ratio

Carr's compressibility index and Hausner' ratio were calculated using the following equations

$HR = \frac{Dt}{Db}$ ..... (2.3)

$CI = (Dt - Db/Dt) \times 100$ ..... (2.4)

2.3.3 Angle of repose

A clean glass funnel was clamped on a retort stand such that the perpendicular height of the tip of the funnel was 8.5cm from the flat table surface with a clean sheet of paper. 10g of the mixed powder was poured into the funnel with the opening of the funnel blocked with a cotton wool. This was removed and a powder heap was formed. The height (H), Diameter and radius (R) was measured in cm. and the angle of repose was calculated using the formula below

$$Tan\ \theta = \frac{H}{R}$$

Where Θ = angle of repose

H= height of the powder

R= radius of the heap formed

2.3.4 Flow rate

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This was calculated by dividing the mass of the powder passed through the orifice by the time taken to flow through the orifice, (Akhgari, Sadeghi & Dabbagh, 2014).

2.4 Tablet characterization.

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2.4.1 Uniformity of weight

The average weight of tablets in each batch was determined by individually weighing 10 tablets from each batch, calculating the average weight and comparing the weight of each tablet with the average weight.

2.4.2 Friability Test

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The weight of 10 tablets in each batch was determined, and the tablets were subjected to cascading and free fall shocks in the drum of the friabilator. The tablets were re-weighed after dusting off adherent particles and the percentage friability calculated using the formula below

% friability = (intial weight of tablet- final weight of tablet)/ initial weight × 100%

2.4.3 Disintegration Time Test

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Six tablets from each batch were individually subjected to the BP disintegration test. The mean value and the standard deviation of the disintegration time were calculated per batch. The disintegrating medium was kept at 37± 5ºc

2.4.4 Dissolution Test

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The dissolution test was carried out using the paddle method. The tablets were placed in a beaker containing 900ml of the dissolution fluid (0.1N HCL maintained at 37 ± 1.5ºc)

Aliquots of 5ml, 10ml, 10ml, 10ml, 10ml, 10ml, 10ml, were withdrawn at selected time interval (5- 60 minutes) using pipette. The sample was then analyzed using a UV-Visible spectrophotometer(UNICO™ 2011, UK) at 243nm to obtain their absorbance value.

CHAPTER THREE

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3.0 Results and discussion

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3.1 Presence of Starch

A Purple color was observed upon addition of lugol's iodine to the extracted starch sample, thus confirming that the extracted product was starch.

Flow and Packing properties

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Table 3.1 Flow properties of powder mix

Charateristics	Batch A	Batch B	Batch C
Bulk density (g/cm^3)	0.33	0.43	0.5
Tapped density (g/cm^3)	0.5	0.63	0.71
Carr's index (%)	34	31.7	29.6
Hausner ratio	1.52	1.47	1.42
Flow rate(g/sec)	0.5	0.56	0.075

The pre-compression parameters of a powder are critical for predicting its flowability and compressibility and uniformity of weights of resulting tablets, which determines its suitability for tablet manufacturing, particularly in direct compression. The data for Batch A (Corn Starch),

Batch B (Native Yam Starch), and Batch C (Pregelatinized Starch) on their densities, Carr's Index, Hausner's ratio, and flow rate are presented in Table XX above..

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The standard classification for flow properties, as derived from the United States Pharmacopeia (USP) (1174), is used for this analysis

From the result above, corn starch (Batch A) showed a Carr's Index of 34% and a Hausner's ratio of 1.52.

Native Yam Starch (Batch B) showed a Carr's Index of 31.7% and a Hausner's ratio of 1.47.

According to the USP standards, both of these powders fall into the "Poor" to "Very Poor" flowability and compressibility range. This is expected, as native starch granules are small, light, and possess high inter-particulate friction, leading to poor powder flow. Their low bulk densities (0.33 and 0.43 g/cm³, respectively) further confirm this.

The direct flow rate measurements (0.5 g/s for Batch A and 0.56 g/s for Batch B) confirm this "poor" classification. Powders with flow rates this low are not suitable for direct compression, which requires excellent and consistent flow to ensure uniform die filling at high speeds.

Batch C showed a marked increase in both bulk density (0.5 g/cm³) and tapped density (0.71 g/cm³). This is a positive result, as pre-gelatinization ruptures the starch granules, creating denser, more compact particles. This is also reflected in its improved compressibility indices: the Carr's Index (29.6%) and Hausner's ratio (1.42) are the best of the three batches, placing them in the **"Poor"** category. This is a clear improvement from the "Very Poor" status of the native starches.

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Contradictory Flow Rate: The most significant finding is the extremely poor flow rate of 0.075 g/s. This value is drastically worse than that of the native starches and indicates that the powder is practically non-flowing.

This data presents a classic conflict between indirect and direct methods of flow measurement. The native starches (A and B) performed as expected, with all indicators pointing to "very poor" flow. The pregelatinized starch (C) showed successful densification and an improvement in its indirect flow indices (Carr's and Hausner's). However, the direct flow rate measurement for Batch C reveals the true nature of the powder. While the modification made the particles denser (improving the compressibility index), it also likely made them more **cohesive or "sticky"**. Pregelatinized starch is an excellent binder because it is adhesive. This cohesiveness severely impedes the powder's ability to flow, even more so than the native starches.

In summary, this discrepancy highlights why relying solely on Carr's Index and Hausner's Ratio can be misleading. While Batch C's compressibility appears improved, its abysmal flow rate (0.075 g/s) would make it unsuitable for direct compression tableting without the inclusion of a significant amount of a glidant, such as colloidal silicon dioxide.

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3.3 Physicochemical properties of tablet

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1. Friability Test and Hardness Test

Table 3.2: Friability and Hardness test for paracetamol tablets formulated with corn starch, Native water yam starch and pregelatinized water yam starch as binder

	Friability test	Hardness test
Batch 1 tablets	0.33%	6.66±0.27 KP
Batch 1 tablets	0.46%	6.28±0.99 KP
Batch 1 tablets	0.50%	6.10±0.16 KP

The friability test is a critical quality control measure for tablets. It accesses physical resistance to shock and abrasion during handling, packaging and shipping. It is typic ally expressed as a percentage loss in tablet weight after being subjected to a standardized tumbling process.

The united state pharmacopeia (USP) standard for acceptable tablet friability is generally less than 1.0% weight loss. All three results are significantly below the accepted regulatory limit of 1.0%.

The low percentage weight loss confirms that the tablet formulation and manufacturing process including binder effectiveness is robust enough to ensure the physical integrity of the tablets.

The minimal weight loss suggest that the product will withstand the rigors of post-compression processing such as coating, blistering and bulk transportation without compromising the dosage quality.

The tablet hardness test also called tablet breaking force is a critical quality control attribute as it measures the mechanical strength of the tablet. This test is crucial for ensuring tablets can withstand the mechanical stress encountered during manufacturing, packaging, shipping, and handling by patients.

The acceptable range for tablet hardness according to USP is 4 – 10 KP with many formulations targeting a narrower range such as 5 – 8 KP. All three individual results fall within the common target range. This shows that tablet hardness is sufficient to withstand then rigors of mechanical handling and subsequent processing steps. The hardness level is also not excessively high as this can affect the disintegration property of the tablet negatively. (increase disintegration time).

1. Disintegration time test

Table 3.3: Disintegration time test for paracetamol

Tablet no	Batch 1 Tablets	Batch 2 Tablets	Batch 3 Tablets
1	>2hours	2550.0±124.9	550
2	>2hours	47mins	50 secs
3	>2hours	40mins	60 secs
4	>2hours	42mins	60 secs
5	>2hours	45mins	80 secs
6	>2hours	40mins	60 secs
Average	>2hours	42.5±2.08mins	55.4±4.56 secs

According to the United state pharmacopeia (USP), Immediate release uncoated tablet should disintegrate within 30minutes. The batch 1 tablets which contain corn starch as binder fails the disintegration test as it has an average disintegration time greater than 2hours.

The batch 2 tablets which contains un-pregelatinized water yam starch as binder have an average disintegration time of 35 minutes which exceeds the standard time according to USP by 5minutes and is considered fair.

The batch 3 tablets which contain pre-gelatinized water yam starch has binder has a disintegration time of 1minute (60 seconds) and hence excellently passes the disintegration time test

CHAPTER FOUR

CONCLUSION AND RECOMMENDATION

4.1 Conclusion

This study was designed to evaluate starch extraction obtained from Dioscorea alata (water yam) as a locally sourced alternative to conventional binders. The results demonstrated a clear and significant finding: Water yam starch works as a binder and it's functionality is critically dependent on its modification.

The tablets formulated with the corn starch as control failed disintegration testing, with a time of over 2 hours. This highlights the poor performance of this conventional binder under the tested conditions.

The native (un-pregelatinized) water yam starch also failed to meet pharmacopeial standards, with a disintegration time of 43 minutes. While the low friability of this batch indicates that native starch does possess strong binding properties, it is unsuitable for immediate-release tablets because it "over-binds" the tablet, preventing it from breaking apart.

However, the pregelatinized water yam starch formulation was a complete success, showing an excellent disintegration time of just 60 seconds.

In conclusion, this work successfully demonstrates that while native water yam starch is an ineffective excipient, the simple modification of pre-gelatinization transforms it into a high-performance, multifunctional excipient. The pregelatinized starch not only acts as an effective binder (proven by good friability) but also functions as a powerful disintegrant, promoting rapid

tablet breakup. This makes pregelatinized Dioscorea alata starch a superior and highly promising, locally sourced, and cost-effective alternative to both corn starch and its native, unmodified form.

4.2 Recommendations

Based on the findings of this study, which successfully demonstrate the high efficacy of pregelatinized water yam starch as a pharmaceutical excipient, the following recommendations are made;

1. Formulation optimization ; Further investigation should be conducted to determine the optimal concentration of the pregelatinized water yam starch. This will help establish the ideal balance between mechanical strength (hardness) and rapid drug release (disintegration).
2. Stability studies; The optimized paracetamol formulation developed using this novel excipient must undergo accelerated stability testing in accordance with ICH guidelines. This is a critical step to establish a viable shelf-life for the product.
3. Dissemination and impact; These positive findings should be prepared for publication. Sharing this research will formally highlight pregelatinized Dioscorea alata starch as a viable, cost-effective, and locally-sourced alternative to more expensive, imported excipients, which could be of significant benefit to the region’s pharmaceutical industry.

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