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EVALUATION OF THE BINDING AND DISINTEGRANT ACTIVITIES OF STARCHES FROM UNRIPE BANANA FRUITS AND TUBERS OF IRISH POTATO ON DICLOFENAC SODIUM TABLET.

BY

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ABSTRACT

This study aims to assess the binding and disintegrant properties of starch(es) obtained from the fruits of unripe banana (*Musa acuminata*) and that obtained from the tuber of Irish potato (*Solanum tuberosum*) on diclofenac sodium tablets formulation. The banana fruits and irish potato tubers were processed and treated to prevent oxidation, filtered, dried, pulverised and packaged for analysis while granules for tablet formulation was obtained by wet granulation technique. In the process, four batches including, W1 (banana and Irish potato starch, ratio: 2:1), W2 (banana and Irish potato starch ratio:1:2), W3 (banana starch only) and W4 (Irish potato starch only) were prepared. Physico-technical properties of the granules were assessed then granules, compressed into tablets using single punch tableting machine and the resulting tablets, evaluated adopting various characterization techniques. The results obtained depicts the banana and Irish potato starches as having a pH of 7.8 and 8.0 respectively. Further comparative studies showed that irish potato and banana starch(es), had swelling capacity of 51.9 and 12.65 respectively, but both had hydration /water absorption capacity of 2.145. There was significant difference ($p<0.05$) in the proximate analysis results of the starches. Physico technical analysis of the formed granules showed the flow rate of 10.03, 10.45g/s, Hausner's ratio 1.10, 1.17 and Carr's index 8.70,14.60 respectively for the irish potato and banana starch(es). Tablets compressed from some batches did not meet the hardness specifications as they fell below 4kgF especially, W2=3.9 and W4 = 3.5 kgF), The percentage losses after the friability test for all the formed batches, were less than 1.0. The tablets determined for the active drug content gave values within the range of 95-101% while the profile for percentage of drug release showed that batch W4 (81.64%) had the highest release rate followed by W3(43.55%), W1(41.30) and lastly W2(24.91%) within 60 minutes.

Key words: Starch, *Musa acuminata* , *Solanum tuberosum*, disintegrant, binder, diclofenac sodium tablets.

INTRODUCTION

Starch is a polysaccharide composed exclusively of d-glucose. It is one of the most abundant organic compounds, serves as an energy reserve and can be isolated from leaves, stems, tubers, seeds, and roots of higher plants. Chemically, starch is a carbohydrate polymer consisting of anhydro glucose units linked by α-d-(1, 4) glucosidic bonds. It consists of two inherently incompatible molecules: amylose (15–30%), a linear polymer, and amylopectin (85–70%), a branched chain polymer and it can be used in a variety of industries including food, textiles, cosmetics, plastics, adhesives, paper, and pharmaceuticals (employed as a binder, diluent, and disintegrants) [1]

Disintegrants bring about tablet matrix break-up in an aqueous medium and are commonly classified further as superdisintegrants.

Normal disintegrants include starch and cellulose-based excipients such as corn starch, partially pregelatinized starch, microcrystalline cellulose, and low-substituted hydroxypropyl cellulose. In general, disintegrants are hydrophilic but insoluble in water or gastrointestinal juices.

Different theories, proposed for mechanisms of disintegrant action. include swelling, wicking (capillary action), strain recovery, interruption of particle-particle bonds, and heat of interaction and a synergistic combination of mechanisms.

Interruption of particle-particle bonds can be considered as one of the most important contributors to matrix break-up. Three different bonding mechanisms suggested to be of involvement in tablets formulation include: solid bridges, mechanical interlocking, and intermolecular forces active over various distances.

Among these three bonding types, intermolecular forces are considered to be the prevailing bonding type in compact formation [2]

A pharmaceutical binder is an excipient that holds the ingredients of a formulation such as tablets together. It acts as an adhesive in the formulation where they ensure the formulation with the required mechanical strength

BANANA

Description

Banana, *Musa acuminata* Colla. belongs to section Musa (formerly Eumusa) of the genus Musa and family Musaceae. [3]

Musa acuminata is an evergreen perennial although it is called a tree but it is a large herb with a succulent trunk. The trunk (known as the pseudostem) is made of tightly packed layers of leaf sheaths emerging from completely or partially buried corms.

The inflorescence grows horizontally or obliquely from the trunk while the individual flowers are white to yellowish-white in colour and are negatively geotropic. Both male and female flowers are present in a single inflorescence. Female flowers are located near the base (and develop into fruit), and the male flowers located at the topmost top-shaped bud in between leathery bracts [4].

The fruit (a "berry") turns from deep-green to yellow or red, or, in some forms, green-and white-striped, and may range from 6.4-30 cm in length and 1.9-5 cm in width, and from oblong, cylindrical and blunt to pronouncedly 3-angled, somewhat curved and hornlike. The flesh, ivory-white to yellow or salmon-yellow, may be firm, astringent, even gummy with latex, when unripe but turns tender, soft (mellow) when ripe [5]

Fig 1: Banana bunch

Constituents/ Local Uses of Banana Fruit

Raw bananas (excluding the peel) contain 75% water, 23% carbohydrates, 1% protein, and negligible fat. A 100-gram serving as reference, supplies 89 Calories, 31% of vitamin B6, and moderate amounts of vitamin C, manganese and dietary fibre [6]

Bananas serve as a staple starchy food for many tropical populations and depending on the ripeness, the flesh can have a taste from starchy to sweet, and texture from firm to mushy.

Irish Potato

The potato is a tuber of the plant, *Solanum tuberosum* L. (Solanaceae). Potato plants are herbaceous perennials that grow about 60 cm (24 in) high, depending on variety, while the leaves dies after flowering, fruiting and tuber formation. They bear white, pink, red, blue, or purple flowers with yellow stamens. Tubers are formed in response to decreasing day length, although this tendency has been minimized in commercial varieties [7]

Scientific Classification

Irish Potato belong to the Kingdom: Plantae, Superdivision :Embryophyta, division: tracheophyta, subdivision: spermatophytina, species: tuberosum [8]

Constituents and Local Uses of Potato Tuber: A typical raw potato is 79% water, 17% carbohydrates (88% is starch), 2% protein, and contains negligible amount of fat.
The tubers are a staple starchy food and can be used to brew alcoholic drinks and serve as thickener and binder for soup and sauces [9].

Fig 2: Irish potato

DICLOFENAC SODIUM

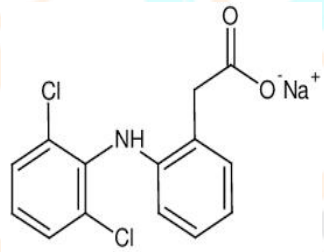

Fig.3: Chemical Structure
Molecular formula: $C_{14}H_{10}Cl_2NNaO_2$

Description
Diclofenac sodium is a non-steroidal anti-inflammatory drug (NSAID). the first nonsteroidal anti-inflammatory agent (NSAID) to be approved that is a phenylacetic acid derivative
It occurs as a white or slightly yellowish and hygroscopic, crystalline powder, sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96%), and slightly soluble in acetone. Diclofenac sodium has a melting point of about 280^{o}C [10]

Mechanism of Action
Diclofenac sodium has both analgesic and antipyretic activities. It acts by inhibition of cyclooxygenase (COX)-1 and COX-2, thereby inhibiting prostaglandin synthesis which plays a role in development of pain, fever and inflammation [11].

Pharmacokinetics
Diclofenac is efficiently absorbed from the gastrointestinal tract; peak plasma concentrations occur 1.5 to 2.0 hours after ingestion in fasting subjects and it has an elimination half-life of 1.5 hours in plasma [12]

Dosage Forms and drug interaction

Diclofenac sodium is formulated as tablets (prolonged-release and gastro-resistant tablets), prolonged-release capsules and topical gel [10]

Significant drug interactions have been demonstrated for aspirin (acetylsalicylic acid), lithium, digoxin, methotrexate, cyclosporin, cholestyramine and colestipol [11]

Precautions

Diclofenac sodium should be administered after meal so as to prevent damage to the stomach lining. It is contra-indicated in patients with gastric ulcers.

Granulation: This is the process of particle enlargement involving wet and dry granulation through agglomeration technique which helps to transform the shape, size, surface, and density of powders to improve their physicochemical properties and handling. It is one of the most significant unit operations in the production of pharmaceutical dosage forms, mostly tablets and capsules. The process helps to transform fine powders into free-flowing, dust-free granules that are easy to compress.

Generally, granulation commences after initial dry mixing of the necessary powder ingredients along with the active pharmaceutical ingredient (API), so that a uniform distribution of each ingredient throughout the powder mixture is achieved. Although granules used in the pharmaceutical industry have particle size in the range of 0.2-4.0 mm, they are primarily produced as an intermediary with a size range of 0.2-0.5 mm to be either packed as a dosage form or be mixed with other excipients before tablet compaction or capsule filling. [13]

TABLETS

These are solid single-dose forms which comprise of medicament(s), usually with excipients compressed or molded into circular shapes with flat or convex faces, or other suitable shapes. They are formulated to release the active ingredients in a way that will achieve the desired effect, and their quality is controlled by a number of standard tests which may include uniformity of weight and content, hardness, friability, disintegration and dissolution [14]

Evaluation of Powders

Organoleptic properties

These are observable properties of a powder involving color, smell, taste, odour, feel and touch and these can be determined using the sense organs.

pH

pH is a measure of the hydrogen ion concentration in solution and is also referred to as the degree of acidity or alkalinity.

Swelling Capacity

The swelling capacity of a polymer is determined by the amount of liquid material that can be absorbed by it. This test can be done considering two methods such as: beaker and tea bag method although the method of Iwuagwu *et al.* (2004) [15] can be adopted.

The swelling capacity (S) can be calculated as:

$S = [(V_v - V_x)/ V_x] \times 100$ …….. (1)

Where; V_v = volume of sediment, V_x = volume of tapped dry powder

Hydration Capacity

The hydration capacity refers to the total amount of water held by a starch gel under a defined condition. Water hydration capacity is determined as the maximum amount of water that 1 g of material will imbibe and retain under low-speed centrifugation [16]

Hydration capacity = W_S/W_D …….. (2)
Where;
W_S = weight of the sediment formed, W_D = weight of the dry powder

Bulk Density

Bulk density defines the mass of bulk solid that occupies a unit volume of a bed, including the volume of all inter-particle voids

Bulk density= mass/volume …… (3)

Tapped Density

Tapped density of a powder is the ratio of the mass of the powder to the volume occupied by the powder after it has been mechanically tapped for a defined period of time. The tapped density of a powder represents its random dense packing

Tapped= mass/tapped volume ……. (4)

Angle of Repose

When granular solids are piled on a flat surface, the sides of the pile are at a definite reproducible angle with the horizontal levelled surface. This angle is called the 'angle of repose' of the material. The angle of repose is important for the design, processing, storage, and conveying systems of particulate materials. Materials with low angle of repose are highly flowable and can be transported using gravitational force or a little energy [17]

Angle of repose (θ), = $\tan^{-1}$ (2h/d) …….. (5)

Where; h= height of heap, d= diameter of the base of the heap

Aim of the Research

The aim of this study is to isolate starch(es), from unripe banana seeds and irish potato tubers and determine their efficacy, as an excipient (binder and disintegrant), in the formulation of Diclofenac sodium tablets.

Materials / Equipments

Banana, Irish Potato (procured from a local market at choba, in Obio-Akpor L.G.A in Rivers state, Nigeria), Diclofenac Sodium Powder (china), Sodium Metabisulphite, 0.1N Sodium Hydroxide, Alpha Naphthol (10% Alcoholic Solution), Magnesium Stearate, Talc, Chloroform, Ethanol, N-Hexane, Acetone, Distilled Water, Hot Air Oven (New Life, DHG – 9023a, England), Analytical Weighing Balance (Adventurer TM AR 2130, England), Centrifuge, pH meter (Jenway 3510, England), Hardness tester (Erweka TBH 100, Germany), Friabilator (Erweka TAR 220, Germany), Disintegration Apparatus (Erweka ZT 122, Germany), Dissolution apparatus (Erweka TBH 600,Germany), UV Spectrophotometer (Jenway 6405 UV, England) and Tableting machine (Erweka Single Punch EP-1).

Method

Isolation of Starch

The unpeeled banana seeds and Irish potato tubers were thoroughly washed to remove adherent materials then peeled, rewashed and weighed. The washed materials were cut into small pieces dried and pulverized using a blender. The resultant pulp was soaked in sufficient quantity of water and added with 2ml of 0.1% sodium metabisulphite to prevent oxidation and discoloration of the final product then filtered through a muslin cloth. The filtrate was allowed to settle and 0.1N sodium hydroxide was added to remove ammonium or proteineous compounds. Excess sodium hydroxide was removed by washing severally with distilled water. The clear supernatant layer was decanted while the resultant moist starch was washed until a neutral pH was attained then dried in an oven at 40^{o}C for 48 hours. The dried mass was weighed, reduced to powder, packaged in a glass jar and stored for analysis.

Phytochemical Examination

Phytochemical screenings or tests include: Iodine Test for presence of starch and Molisch's test for carbohydrate.

Proximate Analysis of the starches

This involves various determinations such as:
Carbohydrate Determination by Cleg Anthrone Method

Lipid Determination following the Soxhlet Extraction Method

Protein determination by Kjeldahi Method applying the digestion, distillation and the Titration methods of analysis

Moisture determination effected by adoption of Air oven Method while Ash Determination was by Furnace Method

Acid Insoluble Ash Determination

Sample ash was determined by loss of ignition using muffle furnace at 630^{0}C. The weight of ash was calculated by subtracting the weight of empty crucible from the weight of crucible and ash.

The ash was dissolved in 10ml of concentrated Hydrochloric acid and diluted to 50ml with distilled water. The solution was filtered through Watman No. 541 filter paper which was previously dried in an air oven and weighed.

The Ash residue on the filter paper was re-dried on the air-oven and re-weighed. The weight of empty filter paper was subtracted from the weight of residue and filter paper, and this gave the weight of acid insoluble Ash [18].

Fibre Determination

Crude fibre was determined as the loss on ignition of dried residue remaining after digestion of sample with 1.25% Sulphuric acid and 1.25% sodium hydroxide solutions under specific conditions.

Evaluation of Physicochemical Properties of the Starches

pH

The pH values of 1% starch suspensions of both Banana and irish potato starch were determined using a pH meter.

Solubility

A 0.1g weight of Banana starch was weighed into 6 different test tubes. 10ml of various solvent (water, ethanol, n-hexane, chloroform, acetone and propylene glycol) were respectfully introduced into each of the six test tubes. The test tubes were shaken and observed for solubility. The procedure was repeated for irish potato starch

Flowrate of Mucilage

Mucilage was prepared by dispersing 2g of the banana starch in 15ml of distilled water. A 10ml of the dispersion was withdrawn using a 10ml pipette and allowed to flow out unaided. The time taken for the dispersion to exit the pipette was recorded. The procedure was repeated for irish potato starch.

Hydration Capacity

A 1g of individual starch sample was placed in 15ml centrifuge tube and 10ml distilled water was added. The tube was closed properly and the content was shaken for 2 minutes and immediately centrifuged at 1000 rpm for 10 minutes. The supernatant layer was decanted and the weight of the wet starch was recorded. The hydration capacity was determined using the equation:

$$\text{Hydration capacity} = \frac{W_S}{W_D} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots (6)$$

Where; W_S = weight of the sediment formed, W_D = weight of the dry powder

Determination of Swelling Capacity

The tapped volume occupied by 1g of the starch(es), V_x was noted. The starch was dispersed in 5ml of distilled water and the volume, made up to 10ml with distilled water. After 48 hours of standing, the volume of the sediment, V_v was estimated and the swelling capacity was calculated:

$$S = \frac{(V_v - V_x)}{V_x} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots (7)$$

Where; V_v = volume of sediment, V_x = volume of tapped dry powder

Physicotechnical properties of the starches

Bulk density

A 10g weight of each starch sample was weighed and transferred into a clean, dry 50ml measuring cylinder and the volume occupied recorded. The bulk density was calculated as:

$$\text{Bulk density} = \frac{\text{mass}}{\text{volume}} \quad \ldots\ldots\ldots\ldots\ldots\ldots (8)$$

Tapped density

A 10g weight of the starch(es) was weighed and transferred into a clean, dry 50ml measuring cylinder. The measuring cylinder was tapped for 5minutes on a padded table top to a fixed height and the tapped volume was noted. Then the tapped density was calculated as;

$$\text{Tapped} = \frac{\text{mass}}{\text{tapped volume}} \quad \ldots\ldots\ldots\ldots\ldots\ldots (9)$$

Determination of solubility of diclofenac sodium powder

A 0.1g of diclofenac powder was weighed into four different test tube then 10ml of various solvents (water, ethanol, acetone and methanol) were respectfully introduced into each of the four test tubes. The test tubes were shaken and observed for powder dispersion/solubility.

Preparation of Diclofenac Granules

Weight of individual tablet = 115.8mg

INGREDIENTS	**W1 (%)**	**W2** (%)	**W3** (%)	**W4** (%)
Diclofenac sodium	86.36	86.36	86.36	86.36
Banana Starch	3.45	1.72	5.18	-
Irish potato Starch	1.72	3.45	-	5.18
Gelatin	1.72	1.72	1.72	1.72
Talc	1.81	1.81	1.81	1.81
Magnesium state	1.30	1.30	1.30	1.30
Methyl Paraben	0.17	0.17	0.17	0.17
Banana Starch	0.86	2.59	3.45	-
Irish potato Starch	2.59	0.86	-	3.45

Physico-technical Properties of Granules

Bulk and Tapped density: These was as previously carried out with powders

Flow rate

A 10g of granules of different batches were respectively poured into a blocked orifice of a plastic funnel clamped on a retort stand. The blocked orifice was later opened and the granules were allowed to flow out unaided. The time taken for the granule to exit the funnel was recorded.

Angle of repose

A plastic funnel was clamped on a retort stand at a fixed distance of 3cm from a flat surface. Sufficient quantity of each batch of starch granules was poured while orifice was closed with a fingertip. Upon removal of the blockade, the powder was allowed to flow through the funnel until the tip of the heap touched the orifice. The diameter of the heap was marked and measured and the angle of repose was calculated as:

$$\text{Angle of repose}(\Theta) = \tan^{-1}(2h/d) \quad \ldots\ldots\ldots\ldots\ldots\ldots (10)$$

Where; h= height of heap, d= diameter of the base of the heap

Hausner's ratio

This was calculated for all the batches as;

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}} \quad \ldots\ldots\ldots\ldots\ldots\ldots (11)$$

Carr's index

This was calculated for all the batches as;

$$\text{Carr's index} = \frac{\text{Tapped density-Bulk density}}{\text{Tapped density}} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots (12)$$

Compression of granules

The mixed granules were compressed into tablets using a single punch tableting machine at a pressure of 4kg.F while the formed tablets were allowed for elastic recovery for 24 hours before further evaluation

Quality control of tablets

Uniformity of Weight/ Weight Variation Test

Twenty tablets were randomly selected and weighed individually using an electronic balance.

The weights were recorded and the mean as well as the variation in weight were determined.

Friability test

Ten tablets were randomly selected from each batch and dusted gently with a soft brush. The tablets were weighed together and placed in a friabilator set to rotate at 25rpm for 4minutes. The tablets were obtained, dusted again and reweighed together. The percentage friablility was calculated as;

$$\frac{\%\ \text{friability loss} = \text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots (13)$$

Hardness/ crushing strength test

The hardness of ten tablets from each of the 4 batches was determined using Erweka hardness tester and the mean crushing strength also determined.

Disintegration Test

The disintegration rate of six tablet selected at random from each of the 4 batches was determined using a BP specified apparatus containing phosphate buffer (pH 6.8) at 37±5^{o}C. The mean disintegration rate was calculated.

Dissolution test

The dissolution rates of the active drug from the tablet were determined using USP apparatus. A 900ml of freshly prepared medium (phosphate buffer) was transferred into the dissolution jars and maintained at a temperature of 37±0.5^{o}C. The paddles were set to rotate at 100rpm. Samples were withdrawn at 5, 10, 15, 20, 30, 40, 50 and 60 minutes and analysed spectrophotometrically at 240nm wavelength. The samples removed for analysis were replaced with fresh aliquots of the medium and the percentage drug dissolved calculated as;

Concentration= slope x absorbance + intercept…….. (14)

Amount of drug released (mg/ml) = concentration x dissolution bath volume x dilution / 1000 ….. (15)

$$\text{Percentage drug dissolved} = \frac{\text{Amount dissolved at time, t}}{\text{Total amount dissolved}} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots (16)$$

Preparation of standard calibration

A 0.5mg weight of pure diclofenac sodium powder was placed in a 50ml volumetric flask, dissolved with phosphate buffer, and made up to the mark with the same solvent. Various dilutions of the stock solution were made to get 0.05, 0.10, 0.15, 0.20, 0.25 and 0.30mg/ml with the phosphate buffer, and the absorbance determined by UV spectrophotometer at 240nm wavelength. A standard calibration curve was plotted as absorbance against concentration.

Content of active ingredient

Ten tablets were selected at random from each of the four batches, weighed and crushed to fine powder. The powdered drug was transferred into a 50ml volumetric flask and dissolved with phosphate buffer, then made up to the 50ml mark with the same solvent. The solution was filtered and 0.5ml of the filtrate was transferred into a 10ml volumetric flask and made up to the mark with same solvent. The drug content was determined by measuring the absorbance of the filtrate at 240nm wavelength, using the UV spectrophotometer.

RESULT

Table 2: Preliminary Confirmation Test

TEST	OBSERVATION	INFERENCE
IODINE TEST		
Banana starch	Blue-black coloration	Starch present
Irish potato starch	Blue-black coloration	Starch present
MOLISCH TEST		
Banana starch	A deep violet ring observed at the junction of two layers	Carbohydrate present
Irish potato starch	A deep violet ring observed at the junction of two layers	Carbohydrate present

Table 3: Proximate Analysis

PARAMETER (%)	BANANA STARCH	IRISH POTATO STARCH
Yield	5.77	9.67
Moisture content	10.48 ± 0.04	10.52± 0.05
Crude protein	0.83 ± 0.02	8.26 ±0.014
Fat content	0.18 ± 0.01	0.23±0.01
Ash	1.20± 0.02	2.83± 0.014
Crude fibre	0.68±0.12	0.45 ±0.001
Carbohydrate by difference	86.63±0.03	77.71 ±0.10

Table 4: Physicochemical properties of Banana and Irish potato starch powders

Parameter	**Banana**	**Irish potato**
pH	7.8	8.0
Density (g/ml) (1% dispersion in water)	1.0009 ± 0.0002	1.0016 ± 0.0002
Swelling Capacity (%)	12.35 ± 3.25	51.9 ± 14.8
Swelling Index	0.895 ± 0.025	0.665 ± 0.065
Hydration Capacity	2.335 ± 0.035	2.145 ± 0.055

Table 5: Physico-Technical characterization of Banana and Irish potato starch

POWDER PROPERTY	**BANANA STARCH**	**IRISH POTATO STARCH**
Flow rate (1%w/v dispersion of starch)	1.663± 0.005	2.253± 0.012
Bulk density (g/ml)	0.353± 0.009	0.503± 0.02
Tapped density (g/ml)	0.52± 0.014	0.63± 0.032

Table 6: Physico-Technical characterization of diclofenac sodium Granules

Granule Property	Granule Batches			
	W1	W2	W3	W4
Flow rate	10.15± 0.002	10.03± 0.002	10.45± 0.001	10.10± 0.001
Angle of Repose	34.13 ±0.01	33.70±0.02	34.10±0.02	33.64±0.01
Bulk Density (g/ml)	0.42±0.01	0.41±0.01	0.43±0.03	0.41±0.01

Tapped Density (g/ml)	0.46±0.01	0.48±0.02	0.49±0.01	0.47±0.01
Hausner's quotient	1.10±0.01	1.17±0.01	1.14±0.01	1.15±0.01
Carr's Index	8.70±0.02	14.6±0.01	12.24±0.02	12.77±0.02

Table 7: Evaluation of Tablet

Batch number	**W1**	**W2**	**W3**	**W4**
Hardness (KgF)	4.0± 0.32	3.9 ±0.37	4.0 ±0.32	3.5± 0.45
Weight Variation (g)	0.114± 0.001	0.113± 0.013	0.115± 0.043	0.114± 0.032
Percentage Deviation (%)	±0.001	±0.011	±0.037	±0.028
Friability (%w/v)	0.5	0.27	0.10	0.50
Disintegration (minutes)	> 15	>15	>15	>15
Content Of Active Ingredient (%)	98	99	98	99

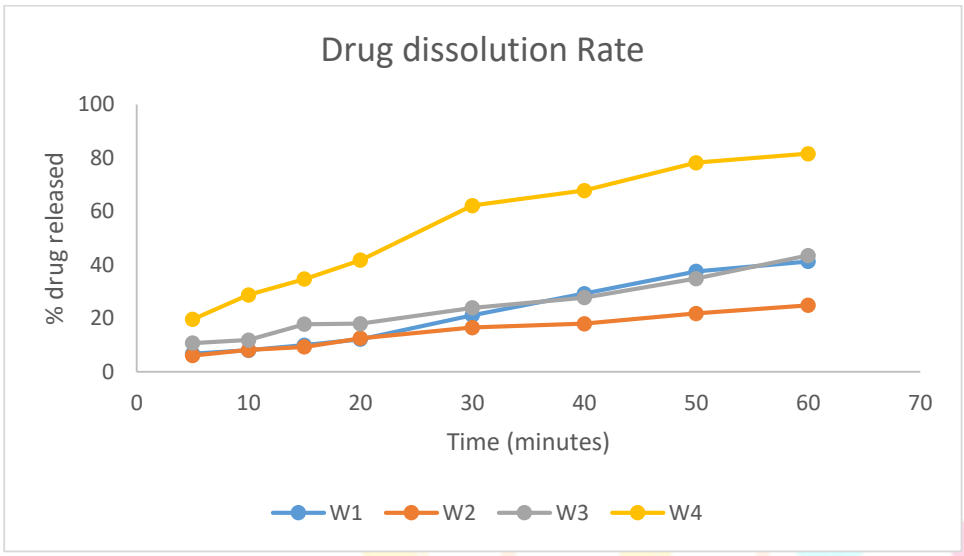

Fig 4: Percentage drug released against Time (minutes)

***Note:** W1: contains Banana and Irish potato starch (2:1), W2: contains Banana and Irish potato starch (1:2) W3: contain unripe Banana starch only, W4: contain Irish potato starch only

DISCUSSION

From the result obtained, the percentage yield of unripe banana and Irish potato starch was 5.77% and 9.67% respectively indicating their relative abundance. Based on phytochemical analysis of the extracted starches, treatment with Lugol's solution gave an intense blue-black coloration confirming the presence of starch while reaction with Molisch's reagent gave a purple ring indicating the presence of Carbohydrate in both starches.

The physicochemical and Physico-Technical properties of the extracted starches were determined and the result showed that the unripe banana and irish potato starches had hydration Capacity (water absorption index) of 2.335 and 2.145; swelling index of 12.35% and 51.9% respectively. The relatively low values of the water absorption index could be due to low porosity, less crystallinity and increased amorphous nature of the starches although more pronounced with the unripe banana starches which due to the fluffy nature had low water retention and swelling capacity but the irish potato starch had high water retention ability despite having lower absorption index. These activities could be envisaged by the molecular structure and morphology of the various starches as shown in figure 3 where the irish potato starch though less porous but appeared slightly crystalline and hence able to enhance fluid penetration and retention in the interstices of the particles thus resulting to better fluid retention, swelling and probable burst effect.

The pH of the extracted banana and irish potato starch were found to be 7.8 and 8.0 respectively and this depicts the starches as suitable for the human physiological system.

The Powder bulk density is the ratio of the mass of untapped powdered sample and its volume, including the contribution of inter-particle void spaces while the tapped density explains the density of the powder after packing which gives an insight on how well the powder will compact to form tablets [31]. From the study, the unripe banana and irish potato starch had a bulk density of 0.353g/ml and 0.503g/ml, Hausner's ratio, 1.47 and 1.25; Carr's index 31.98% and 20.06%; while flow rate and angle of repose were, 1.663g/s and 2.253g/s, 40.6^{o} and 40.2^{o} respectively and these infers the starch powders to exhibit fair flow.

The diclofenac sodium granules were formulated in four batches as: W1, W2

W3 and W4.

Evaluation of the formed granules, depicts an improvement of flowrate as the starch powders were not able to flow in their fine state. The angles of repose of the granules were in the range:33.64^{o}-34.10^{o}, the flow rates, 10.03-10.45g/s, bulk densities, 0.41g/ml-0.43g/ml and tapped densities, 0.46g/ml-0.49g/ml while the Hausner's ratio was within the range of 1.10-1.17; and the Carr's index, 8.70%-14.6% thus, the granules exhibited excellent flow than the powders.

Weight uniformity is an indication of the amount of active pharmaceutical ingredient (API) in a tablet but it is not a guarantee of the API uniformity in all the tablets. The variation of the weight of individual tablets is a valid indication of the corresponding variation in the drug content and from the results obtained, none of the tablets had a deviation of more than +10% implying that the tablets complied with weight uniformity test as specified in the reference standard.

The USP standard for hardness and crushing strength of tablet is between 4-7kgF, tablet batches of W1 and W3 passed the hardness test as they fell within standard specification but batches W2 and W4 fell below the specification. This could be related to the more porous and crystalline nature of the irish potato starch and its high water retention which could lead to high moisture content in the sample batch.

Friability test is used to evaluate tablet resistance to abrasion and reference specification depicts the value not to exceed 1% and in this study, the friability for all the tablets were less than 1% implying that all the batches complied with the specification.

The content of active ingredient test determines the concentration of the API in a tablet and according to the British pharmacopoeia, the concentration of API is accepted if it is within 90%-110%. From the result, all the batches have their concentration of API (Diclofenac Sodium) within this range and hence complied with the specification.

The USP specifies that uncoated tablets should disintegrate within 15minutes. From the results, all the tablets from all four batches were unable to

disintegrate within 15minutes. However, disintegration could be influenced by the hardness of the tablets, binder and lubricant used, as well as composition and compression pressure. Dissolution test measures the concentration of the drug product in a given medium at a specific time. From the result obtained, after 60 minutes of analysis, 100% of the drug content was not released. However, batch W4 had the highest drug release followed by W3, W1 then lastly W2.

CONCLUSION

Diclofenac tablets can be formulated using starch derived from unripe banana and irish potato as binder and disintegrant. Both starches obtained from these sources showed promising characteristics as suitable pharmaceutical excipients. However, further research needs to be carried out in order to fully harness their potentials.

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