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Formulation and Evaluation of Ibuprofen Tablets Prepared with Different Starches as Binders and Disintegrants for Enhanced Oral Drug Delivery

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ABSTRACT

Background: Chemical modification of starch by acetylation can improves its physicochemical properties such as solubility, swelling ability, and gelatinization, which are desirable for drug delivery.

Objectives: The objective of this research was to formulate ibuprofen tablets using different starches, namely, native or wild cassava tubers starch (Ampelocissus africana), acetylated wild cassava tuber starch, and maize starch, and to evaluate them along with a marketed ibuprofen tablets for pharmaceutical quality attributes for tablets.

Methods: Three batches of ibuprofen 200 mg tablets were prepared by wet granulation method using the starches as binders and disintegrants, with total of 100 tablets per batch. The tablets were produced using tableting machine and then subjected to routine pharmaceutical quality evaluations. A marketed ibuprofen 200 mg tablets, in which maize starch was used, were employed for comparison.

Results: All the formulated samples passed the uniformity of weight test, thickness and diameter tests, and disintegration test. However, the marketed ibuprofen tablets failed hardness, friability, and dissolution tests with average hardness test value of 6.441 kgf, percentage friability value of 1.33, and dissolution of more than 45 minutes. Similarly, maize starch ibuprofen tablets failed both the hardness and dissolution tests. For the Ultraviolet–visible drug assay, native and maize starches ibuprofen tablets, and marketed product failed the test.

Conclusion: We found that the acetylated native cassava tuber starch demonstrated improved drug release and better pharmaceutical quality parameters than other evaluated starches and marketed ibuprofen tablets.

Keywords: Ampelocissus africana; ibuprofen; acetylated starch; native starch

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INTRODUCTION

Generally, there are two categories of starch in the pharmaceutical industries: natural starch (native starch) and modified starch. The native starch has some limitations such as insolubility in cold water, low swelling capacity, low stability, and low paste resistance (1). Furthermore, many native starches including Ampelocissus africana (A. africana) cassava tuber starch were limited in their uses because they are unstable in terms of changes in temperature, pH and shear forces (2). However, these limitations can be overcome by modifications of the starch. Modification of starch is rearrangement of molecular structure, oxidation or substitutions of functional groups on the starch molecule. Modified cassava starch has the potential as a binder of tablets in direct compression method (3).

Poor quality drug preparations such as those that contain low amount of active pharmaceutical ingredient (API) will have low efficacy that may result in therapeutic failure and development of resistance (4). If the dosage form contained an excessive amount of API, this could result in adverse clinical effects such as toxicity in patients (5–8).

Polymeric materials play different roles such as binders, disintegrants, matrix formers, drug release modifiers, film coating formers, thickeners or viscosity enhancers, stabilizers, suspending agents, gelling agents, and bioadhesives, and they also possess some reactive functional groups in their molecular structure which include: hydroxyl group, amino acid group and carboxylic acid group that can be used for their chemical modifications to enhance their features (9–11). The modification can augment the positive effects of the natural polymers for effective drug delivery application (11,12).

Starch, a natural polymer, possess definite chemical structure and composition. It occurs widely as an important polysaccharide food reserve in seeds, swollen stems, tubers and roots (13). Starch is the second most abundant compound synthesized by plant cells after cellulose and exceeds cellulose in significant in terms of food value (13). Starch is a polysaccharide of glucose, and it is stored in the plants as granules composed of amylose and amylopectin (14). The biochemical chain responsible for starch synthesis involves glucose molecules produced in plant cells by photosynthesis (15).

Researchers have investigated the effect of starch modification. For example, Sweedman et al. (2013) stated that native starches were usually modified to improve their properties such as solubility, texture, swelling ability and ability to withstand high temperatures. Modification of starch can be done by physical, chemical, and enzymatic methods (17). Physical methods involve the use of heat and moisture, while chemical modifications introduce functional groups in to the starch molecule using derivatization reactions (e.g., acetylation, etherification, esterification, crosslinking) or involve breakdown reactions (e.g., hydrolysis and oxidation) (17). Some chemical modification techniques such as acetylation and cross linking reactions have been developed to produce modified starches with unique characteristics and uses (16). These methods changes starch polymer, rendering it highly flexible, and changing its physicochemical properties and structural arrangement to increase its value for food and pharmaceutical uses (16). This study aimed to formulate different batches of ibuprofen 200 mg tablets by using different starches as excipients (binder and disintegrant) that include wild cassava tuber starch, acetylated wild cassava tuber starch, and maize starch, and to evaluate the developed tablets for pharmaceutical quality attributes in comparison with a marketed ibuprofen 200 mg tablets produced with a maize starch as binder and disintegrant. The study also determined which of these starches produces the best ibuprofen 200 mg tablets and whether chemical modification of starch by acetylation could enhance binding and disitegration potentials in production of tablets.

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MATERIAL AND METHODS

Materials

Ibuprofen powder was purchased from FDC Limited (Mumbai, India). Talc, magnesium stearate, lactose, maize starch, and gelatin was purchased from Zayo-Sigma Chemicals Ltd., Jos, Nigeria. Native starch from wild cassava tubers and acetylated wild cassava tuber starch were produced in our laboratories at Usmanu Danfodiyo University Sokoto, Nigeria. Sodium dihydrogen tetraoxophosphate (98%), sodium tetraoxophosphate (99%), sodium hydroxide (96%), and hydrochloric acid (37%) were purchased from BDH Chemicals (British Drug Houses), United Kingdom. Distilled water was produced in-house by QuickFit water still (QWS4), UK.

Methods

Production of native, maize and modified ibuprofen 200 mg tablets.

Three batches of ibuprofen tablets were prepared by employing wet granulation method with one hundred tablets per batch, using ingredients in Table 1.

The ibuprofen powder was size reduced to fine powder and then mixed with lactose in a geometric dilution. The mixed powders were passed through a sieved number 30. Granulating mucilage (binding agent) was prepared by dissolving gelatin in 20 mL of distilled water with the aid of heating in a water bath and then mixed with starch dispersion in 20 mL of distilled water. The mixture was heated in a water bath until uniform mucilage was obtained. The mucilage (20 mL) was carefully added to the powder to form a wet mass. More mucilage was incorporated until a satisfactory damp coherent mass was obtained.

The obtained damp mass was forced to pass through coarse screen (600 μm mesh size). The collected granules were dried at 40oC for 8 hours. The dried granules were sieve (second sieving) using mesh size 400 μm. Disintegrating agent (second portion of starch), talc as glidant and magnesium stearate as lubricant were incorporated into the granules. Tablets were produced by compression using a single station tableting machine. The granules for each batch were compressed into tablets with predetermined loads on a single station rotary tablet press with 10.5 mm die and flat-faced punch assembly. A set of tablets were produced from each pressure. After ejection, the tablets were stored in airtight containers.

Evaluation of the Tablets

Weight variation test

Twenty tablets from each batch and marketed product were randomly selected and weighed individually using an electronic weighing balance. The mean weight and standard deviation were calculated for each sample.

Hardness test

Ten tablets from each batch and marketed product were randomly selected and placed between the spindle of the tablet hardness tester (ERWEKA Asia Pacific Ltd., Hong Kong). The pressure was applied by turning the kneeled knot to hold the tablets in position and then gradually increased the pressure until the tablets breaks. The applied pressure in kgf (kilogram crushing force) was then recorded.

Friability test

Ten tablets were randomly selected from each batch and marketed product, and then dedusted using standard sieve. The tablets were weighed using analytical balance. Then the tablets were placed in an automated tablet friability tester (HMKTablet 1601, Dandong Hmktest Instrument Co., Ltd., China), and then subjected to spinning at 25 revolutions per minute for 4 min to roll and fall within the rotating chamber of the apparatus. After spinning, the tablets were dedusted and weighed again. The percentage friability was calculated using Equation 1.

$$\% \text{ Friability} = (\text{initial weight} - \text{final weight}) / (\text{initial weight}) \times 100 \quad \text{-----Equation 1.}$$

Disintegration test

A sample of six tablets were randomly selected from each batch and marketed product. The test was performed using a disintegration test apparatus (VSI-20, VSI Electronics Pvt. Ltd., India) equipped with columns that can accommodate six vessels and basket meshes where the tablets are placed, one tablet per vessel. The baskets were immersed in 900 mL of 0.1 M HCl. The machine was operated at 37°C and moved up and down with the help of a motor that controls a handler where the baskets are attached. The time when no granules of any tablets remained on the mesh was taken as the disintegration time using a stopwatch.

Standard calibration curve by ultraviolent visible assay

A standard stock solution of ibuprofen was prepared by dissolving 20 mg of pure ibuprofen powder with sufficient 0.1M sodium hydroxide solution to get a 100 mL solution. Various standard concentrations ranging from 2 μg/mL to 200 μg/mL were obtained from further dilution of the stock solution with 0.1M NaOH solution. The standard solutions were analyzed spectrophotometrically at 264 nm using a double-beam spectrophotometer, model ATE 4331 (ATICO, India). The mean absorbance of triplicate determinations was plotted against their corresponding concentrations to obtained a calibration curve.

Sample preparation

Ten tablets were randomly selected from each batch and marketed product, weighed, and then crushed into powders. A powder equivalent to 20 mg of ibuprofen was weighed into a volumetric flask and dissolved in 0.1 M NaOH to give a 100 mL solution. The solution was filtered using Whattman filter paper. The resulting solution was scanned at 264 nm. The average absorbance for the triplicate measurement of each batch and marketed product were extrapolated on the calibration curve derived from the pure ibuprofen powder to get the equivalent concentration, and then the percentage content was calculated.

Dissolution test

Dissolution test was performed using a basket type 4-compartment dissolution test apparatus (BJ-4 Disintegration Tester, China). Phosphate buffer (pH 6.8) solution, 700 mL, was used as the dissolution medium at 37 °C. The spinning speed was set at 100 rpm. A tablet from each sample was placed in each compartment, and the machine was operated. At 5, 10, 20, 30, 60, 90, 120, and 180 minutes, 5 mL of the dissolution medium was withdrawn and replaced with a fresh 5 mL of dissolution medium to maintain the sink condition. Each withdrawn sample was filtered with a syringe filter (0.45 μm), and the filtrate was diluted and its absorbance at 264 nm was measured using a UV spectrophotometer. The concentration of ibuprofen from acetylated, native, maize, and marketed ibuprofen 200 mg tablets and their cumulative percentage of drug release were calculated.

Results and Discussion

Production of Tablets

One hundred ibuprofen 200 mg tablets were formulated each from native, acetylated, and maize starches. The tablets produced for each batch were found to have a good physical appearance. They appeared off-white and are oblong in shape (Figure 1). The weight of the tablets for all batches were in the range of 290 mg to 270 mg. The tablets were stored in air-tight containers and cool place (25°C) before further analysis.

Uniformity of weight

The uniformity of weight test is a test that is used to ensure consistent dosing among the tablets in a batch and prevent cases of over or under-dosing. For tablets to pass the weight uniformity test, not more than two of the individual weight of the tablets should deviate from the average weight by ± 7.5% for tablet weighing 130 to 324 mg (18). The result obtained in Table 2 showed that all the tablets passed the test with percentage deviation less than ± 7.5%, which indicated that the tablets contained proper ingredients. In another study, varieties of cassava (*Manihot esculenta* Crantz.) starches where used to developed paracetamol tablets and their disintegrating properties were evaluated in comparison with maize starch (19). The tablets also passed the British Pharmacopoeia uniformity of weight test (<2 tablets ± 5% mean weight, none ± 10% mean weight, $n = 20$) (19).

Thickness and diameter

The results for the thickness and diameter tests are presented in Table 3 which showed thickness variation in one tablet and three tablets for the native starch ibuprofen tablets and marketed ibuprofen tablets, respectively. However, the observed variations are minor and within the B.P. allowable limit of ± 5% (20). Similarly, Adjei et al. (2017) found that all the tablets produced with both cassava and maize starces exhibited good physical properties with satisfactory thickness and diameter (19). We found that the diameter of each tablet for all the batches and marketed ibuprofen tablets passed the requirement for diameter test since there was no significant variation in the diameter of each tablet.

Hardness test

The hardness test indicates whether an appropriate pressure was used during the tablet compression and if an adjustment on the tablet machine is required. If the tablet is too soft, it can be damaged easily during handling, packing, or shipping. On the other hand, too-hard tablets cannot disintegrate quickly, and the bioavailability of the API from the tablet can be significantly affected (21). A 4 kgf crushing force is considered the minimum force for a good tablet. From the result obtained in Table 4, the ibuprofen tablets prepared with native and acetylated starches passed the hardness test, as their crushing force were within the range of British Pharmacopeia (BP) specification of 4-6 kgf (20), which makes them have optimal ability to withstand fracture. However, the ibuprofen tablets prepared with maize starch and marketed ibuprofen tablets failed the test with hardness values of 6.070 ± 1.143 kgf and 6.441 ± 0.815 kgf, respectively. Therefore, only tablets prepared with the native and acetylated starches were found to have ability to withstand handling, packaging and shipping, as well as, be able to disintegrate well when administered. In contrast, other authors found that all the tablet formulations produced with cassava and maize starches complied with the BP specifications (19). This is probably because the starches were used as disintegrant only, which has minimal correlation with the crushing strength of tablets.

Friability test

Friability test was done to evaluate the ability of the tablet to withstand abrasion during packaging, handling, and shipping. According to BP, the percentage of friability should not be more than 1% (20). The obtained result in Table 4 showed that, not all the batches passed the friability test, with the values ranging from 0.37% to 1.33%. The ibuprofen made with maize, acetylated and native starches passed the test with percentage friability of 0.37%, 0.70%, and 0.70%, respectively. While the marketed ibuprofen tablets failed the test with a percentage friability of 1.33%. This showed that not all the marketed ibuprofen available in Sokoto metropolis can withstand abrasion in packaging, handling, and shipping. In contrast, the findings revealed by others authors showed that, with the exception of tablets that contained 10% w/w of cassava starch, all the tablets produced with cassava and maize starches passed the friability test (tablet loss ≤ 1%) (19). They further revealed that an increase in cassava starch disintegrant concentration did not produced any specific effect on tablet friability and there were no significant differences between the friability of tablets which contained cassava starch and those containing maize starch (19). This differences in findings can be attributed to the fact that Adjei et al. (2017) used the starches as disintegrants only and used polyvinylpyrrolidone (PVP) as binder, but in our own case both the starches were employed as binders and disintegrants.

Disintegration time test

A disintegration test is required to ensure that the tablets will be able to break into pieces when it come in contact with aqueous fluids (21). The disintegration test determined how long it takes for a solid oral dosage form to break apart completely. The higher the disintegration time, the lower the dissolution rate, and this lead to poor absorption. The disintegration time should fall within 15 minutes for uncoated tablets, and 30 minutes for film-coated tablets, according to BP specification (20). Failure of tablets to disintegrate within this time could be due to a high amount of binder, inadequate disintegrant, or high compression force. The result obtained in Table 4 indicated that, the disintegration time for all the evaluated ibuprofen tablets was less than 15 minutes. Therefore, the evaluated tablets from all batches and marketed product passed the disintegration time test. The fastest disintegrating ibuprofen tablets were the ones made with native and acetylated starches, with disintegration time of 1.933 ± 0.829 and 3.825 ± 1.741, respectively, while the slowest was the one from maize starch and marketed ibuprofen tablets which both have disintegration time of around 9 minutes (Table 4). In an agreement with these findings, Adjei et al. (2017) also found that all the tablets formulated with cassava and maize starches passed the official disintegration test for uncoated tablets with disintegration times of ≤15 min (19). Similar findings were reported by another team of researchers who evaluated the disintegrating effect of modified starches such as starch citrate and starch phosphate in tablet formulations in comparison with sodium starch glycolate (22). They found that all the tablet formulations were of good quality with regard to weight variation, hardness, friability, and drug content and disintegration time (22). It was also reported that chemical modification of starch, potato starch to starch phosphate, has led to an improvement of its pharmaceutical properties and served as efficient disintegrant (23).

Drug assay

The drug assay is an essential quality control test because all of the physical properties of a drug product were designed to facilitate drug release from the product. Therefore, regardless of how

effective the product is, in terms of physical properties, failure to meet the standard for API content should result in poor quality of that drug product (24). The assay of ibuprofen 200 mg tablets was carried out by ultra-violets visible spectroscopy and the results are presented in Table 5. According to the standard of British pharmacopeia, ibuprofen tablets should contain between 95 % to 105 % of the label amount of ibuprofen (20).

The result obtained in Table 5 revealed that only ibuprofen tablets produced with acetylated starch conformed with the B.P. Specifications for the percentage content of active ingredients in the range of 95% to 105%. The ibuprofen tablets made with the acetylated starch passed the test with a percentage drug content of 95.14%, while the tablets made with maize, native and marketed starches failed the test with percentage drug content of 111%, 78.96%, and 108%, respectively. The percentage of drug content for maize starch ibuprofen and marketed ibuprofen were beyond the upper limit, while native starch ibuprofen was below the lower limit of B.P. requirement. This result indicated that acetylated starch was more suitable for ibuprofen delivery as compared with the other starches and marketed product.

Dissolution test

Dissolution studies of oral solid dosage forms is a critical test for the bioavailability of API. British Pharmacopeia required that, for each conventional immediate-release tablet tested for dissolution, the API in the dissolution medium should not be less than 70% of the prescribed amount within 45 minutes (20). The results obtained from the analysis in Figure 2 indicated that only acetylated starch and native starch based ibuprofen tablets passed this BP specification for dissolution test. It was observed that these two batches released more than 70% of ibuprofen within 45 minutes. However, maize starch ibuprofen and marketed ibuprofen failed the test as they failed to release at least 70% of API within 45 minutes (Figure 2). Other authors also found that starch extracted from native cassava tubers have better dissolution properties than maize starch in tablet formulations (19). Modification of potato starch to starch phosphate has led to enhancement of qualities of tablets such as weight variation, hardness, friability, drug content and disintegration time (23).

Conclusion

One hundred ibuprofen 200 mg tablets each of starches from native cassava tubers (*Ampelocissus africana*), acetylated native cassava tubers, and maize were successfully produced and evaluated for pharmaceutical qualities, according to the official compendium. The starches were used as binders and disintegrants. The result of the tablets evaluations indicated that all the batches of the tablets and marketed product passed uniformity of weight, thickness and diameter, and disintegration tests. However, maize starch ibuprofen and marketed ibuprofen tablets failed the hardness, drug assay, and dissolution tests. The marketed product also failed the friability test. The ibuprofen tablets prepared with native cassava tubers starch was found to fail only drug assay test, while the ibuprofen tablets prepared with acetylated native cassava tubers has passed all the conducted quality control tests. Therefore, the findings of this research revealed that, chemical modification by acetylation of native cassava tubers (*Ampelocissus africana*) has led to the improvement of drug delivery potentials for native cassava tubers, hence the acetylated native cassava tubers can be used as an excipient for effective oral drug delivery application.

Conflict of interest

There is no conflict of interest to declare.

Tables and Illustrations

Tables

Table 1: General tablet composition for all the prepared batches

S/no.	Ingredients	Weight for 1 tablet in (mg)	Weight for 100 tablets in (g)
1	Ibuprofen	200.00	20.00
2	Lactose	55.00	5.50
3	Starch	7.30	0.73
4	Gelatin	7.30	0.73
5	Distilled water	0.4 mL	40 mL
6	Starch	23.40	2.34
7	Talc	6.00	0.60
8	Magnesium stearate	0.60	0.06
Total		300.00	30.00

Table 2: Uniformity of weight of different sample of ibuprofen tablets for native, maize, acetylated, and marketed product.

Type of ibuprofen tablet	Total weight (g) of 20 tablets	Mean weight (g) ± S.D.	No. of tablets deviating by ± 7.5%	Inference
Maize starch	5.68	0.2840 ± 0.0099	1	Passed
Native starch	5.67	0.2835 ± 0.0142	0	Passed
Acetylated Starch	5.64	0.2820 ± 0.0280	2	Passed
Marketed tablets	7.48	0.3740 ± 0.0131	1	Passed

Table 3: Results for thickness and diameter test of ibuprofen tablets

Type of ibuprofen tablet	Mean thickness (mm) ± S.D.	Mean diameter (mm) ±S.D.
Maize starch	0.40 ± 0.000	1.20 ± 0.010
Native starch	0.40 ± 0.002	1.20 ± 0.008
Acetylated starch	0.40 ± 0.000	1.20 ± 0.006
Marketed product	0.49 ± 0.009	1.0 ± 0.0015

Table 4: Results of hardness, disintegration, and friability tests of ibuprofen 200 mg tablets

Type of ibuprofen tablet	Hardness (kgf) ± S.D.	Mean disintegration time (min.) ± S.D.	Friability (%)
Maize starch	6.070 ± 1.143	9.647 ± 1.190	0.37
Native starch	5.439 ± 1.157	1.933 ± 0.829	0.70
Acetylated starch	5.958 ± 0.362	3.825 ± 1.741	0.70
Marketed product	6.441 ± 0.815	9.320 ± 1.050	1.33

Table 5: Percentage drug contents of ibuprofen tablets

Type of ibuprofen tablet	Percentage drug contents ±S.D.
Acetylated starch	95.14 ± 0.06
Native starch	78.96 ± 1.20
Maize starch	111 ± 0.01
Marketed product	108 ± 0.00

Figures



Figure 1: Photograph of ibuprofen 200 mg tablets produced with acetylated starch.

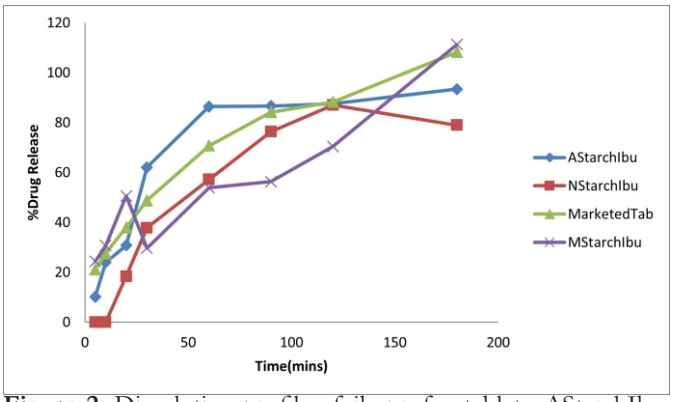


Figure 2: Dissolution profile of ibuprofen tablets. AStarchIbu, acetylated starch ibuprofen tablets; NStarchIbu, native starch ibuprofen tablets; MStarchIbu, maize starch ibuprofen tablets; MarketedTab, marketed ibuprofen tablets

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