*International Journal of Pharmaceutical Science Invention*
*ISSN (Online): 2319-6718, ISSN (Print): 2319- 670X*
*www.ijpsi.org Volume 10 Issue 1 ǁ January 2021 ǁ PP. 34-41*

# Assessment of Mangif*era Indica* and Corn Derived Starches on Ibuprofen Tablet Formulation

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***Abstract***
*Starch is a carbohydrate consisting of large numbers of glucose monomers and its physicochemical properties differs from source to source. One of the recently discovered sources of starch is the seeds of Mnagifera indica. The starch component can be used as pharmaceutical excipient especially in tablet formulation as a binder and disintegrant with its activities being comparable to that obtained from Zea mays (corn). Ibuprofen tablet was formulated using the extracted Mangifera indica starch and cornstarch as binder and disintegrant. Three batches were formulated and designated as J1 (Mangifera indica starch used alone), J2 (cornstarch used alone) and J3 (Mangifera indica and cornstarch used in the ratio 1:1). There was high content of starch and carbohydrate in both sources (corn and Mangifera indica). The pH of the Mangifera indica starch was 4.25 and that of cornstarch 3.90. Physicotechnical properties of the ibuprofen granules formulated from the various batches were, studied and the compressibility index of batch J1 was 13.21± 0.05, J2- 7.55±0.17 and J3- 8.77±0.25. All the tablet batches disintegrated within the stipulated time of less than 15 minutes for uncoated tablets with batch J1 being faster followed by batch J3 then batch J2. The drug dissolution rate also followed the same pattern as the disintegration while the hardness, friability and uniformity of weight content of the formed tablets were within British pharmacopoeia specification of 5.05 to 5.45 kgf, 0.14 to 0 24 % and 7.5% uniformity of weight.*

***Key words:*** *Mangifera indica starch, cornstarch, ibuprofen, Tablet*

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Date of Submission: 21-02-2021 Date of acceptance: 04-03-2021

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## I. INTRODUCTION

Starch is a carbohydrate consisting of large number of glucose monomer units linked by glycosidic bonds. It is a food reserve substance in plant and is widely used in pharmaceutical industries for variety of reasons such as tablet and capsule diluent, disintegrant, glidant and binders [1].

The physicochemical properties of starch differs from source to source of the raw materials. The major sources include maize (corn), wheat, rice, yam and potato. Starch have also been extracted from sources such as millet, oat sorghum peas etc. Recently starches from seeds of fruits usually discarded after eating the pulp example mango, cocoa etc; were characterized and suggested to possess appreciable physicochemical properties suitable for application as pharmaceutical excipients [2].

One of the recently discovered sources for starch production is the seeds of *Magnifera indica* a species of flowering plant belonging to the family Anacadiaceae. It is a large fruit tree whose pulp is usually, consumed or processed in industries,while large amount of the seeds, are discarded as a solid waste.

The mango seed kernel on a dry condition is estimated to contain some vital components as starch, reducing sugars, protein, pectin, fat, tannin and moisture [3].The starch constituent can be extracted from *Mangifera indica* seed kernel following the method as described in the previous work by Ordu *et al* 2018

Corn (Zea mays) is an annual grass surviving only in one season and belongs to the family Poaceae. It is a staple food crop grown all over the world. The major chemical constituents of the corn kernel, is starch and this constitutes up to about 73% of the kernel weight [4]. Other carbohydrate contents include simple sugar, sucrose, glucose and fructose although the composition of the corn is genetically controlled [4].

**Tablets**

Tablet formulation consists of active pharmaceutical ingredients (API) compressed together with a mixture of other ingredients known as additives or excipients and the quality of the tablets is controlled by these additives [5].

The excipients play vital role in the design of the tablets dosage form by determining it functionality and performance, hence are regarded as pharmaceutically in active and physiologically inert but when

incorporated into the dosage form remain physically and chemically stable throughout the shelf life of the dosage form [6].

The excipients (disintegrants, binders , glidants, lubricants etc.), most not introduce micro biological contamination, be commercially available and can be manufactured or processed according to the required pharmaceutical standards and their method of incorporation with the API in solid dosage formulation involves any of such process (es) as direct compression, dry granulation and wet granulation.

**Ibuprofen**

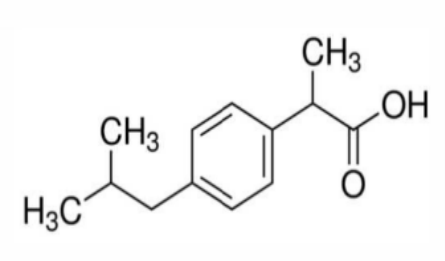


**Figure 1: Structure of Ibuprofen**

*Molecular formula:* $C_{13}H_{18}O_2$

This is a non-steroidalanti-inflammatory drug (NSAID)occurring as white powder or crystals with characteristic odor. It is soluble in aqueous solutions of alkali hydroxide and carbonate but slightly soluble in water with a melting point of $76^{O}C$ [7].

The most common side effects include gastric discomfort, nausea and vomiting although less than aspirin and indomethacin. Ibuprofen has prominent analgesic and anti- pyretic effects due to the inhibitory actions on cyclooxygenase (Cox-1 and Cox-2) involved in prostaglandin synthesis, which plays vital role in the production of pain, fever, and inflammation [8].

Ibuprofen is usually administered and well absorbed orally and is available as tablets, capsules, chewable tablets and oral suspensions occurring in strength of 200mg or 400mg tablets. The dose of ibuprofen in adult is 1.2g daily and in children 20mg/kg body weight less than 30 mg as overdose may lead to toxicity [9].

The ibuprofen should be taken after meals because of the possible damage of stomach or abdominal lining and it decreases the effect of aspirin by blocking the active site of platelet cyclooxygenase hence should be administered 8hrs before aspirin or 2-4hrs after aspirin [10].

The aim of the study is to determine the effect of extracted starch from German mango seed kernel a specie of *Mangifera indica*plant as a binder and disintegrant on ibuprofen tablet formulation and compare the effect with corn starch used alone and in combination (1:1) ratio with the extracted starch.

**Materials**

0.01N Sodium Hydroxide, 0.1N Hydrochloric acid, Magnesium stearate, talc, alpha Naphthol (10% alcoholic solution), Concentrated sulphuric acid, Light liquid Paraffin, Propylene glycol, Chloroform,ethanol, n-hexane, gelatin, , hot air oven (New life, DHG – 9023a, England), analytical weighing balance (Adventurer TM AR 2130, England), Centrifuge, Melting point apparatus, pH meter (Jenway 3510, England), viscometer (Brook field), desiccator, thermometer, 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), tableting machine (Erweka Single Punch). Ibuprofen powder (BDH, England), extracted *Mangifera indica* starch Pharm. Technology Lab. University of Port Harcourt), cornstarch

**Phytochemical Examination of Mango Starch**

Phytochemical screenings were carried on the extracted *Mangifera indica* starch to confirm its nature and composition. The following confirmatory tests such as Iodine and Molisch's tests were carried out to test for presence of starch and carbohydrate.

**Evaluation of Physicochemical Properties of *Mangifera indica* and Corn Starch**

**Determination of pH**

The pH of 1%w/v starch suspensions of both mango and corn starch(es) were determined in triplicates using a digital pH meter and results recorded.

**Determination of Viscosity**

The viscosity of 1% starch suspensions of both mango and corn starch were measured using a Brookfield viscometer at $37^{O}C$

**Determination of Water Absorption Index (Hydration Capacity)**

A 1.0g weight of mango and corn starch samples were suspended in 10ml distilled water at 30% RH in centrifuge tubes, stirred for 30 minutes, and then centrifuged at 3000 rpm for 10 minutes. The supernatant was decanted, and the weight of the gel formed recorded [11].

The water Absorption Index (Hydration capacity) was calculated as gel weight per gram of dry sample as:

$$WaterAbsorptionIndex\ (\%) = \frac{Boundwater\ \ (g)}{Weig\,htOFSample}\ x\frac{100}{1}$$

**Determination of Swelling Index**

A 0.2g weight of mango and corn starch samples were added to 10ml of water and 10ml of light liquid paraffin in different test tubes and mixed thoroughly. The dispersions were allowed to stand for 24 hours. The volumes of the sediment in the tubes were recorded [12].

The swelling index of the starch samples were calculated as:

$$S.I.(\%) = \frac{Volumeofsedimentinwater\ \ -volumeofsedimentinlig\ \ htliquid\ paraffin}{Volumeofsedimentinlig\ \ htliquidparaffin}\ x\frac{100}{1}$$

**Determination of Gelatinization Temperature**

The mango and corn starch samples were moistened with water and transferred into capillary tubes by means of intrusion. The temperature of gelling and the time from swelling to full gelatinization were recorded with a melting point apparatus and the results recorded [13].

**Determination of Solubility of Ibuprofen Powder**

The extent of dispersibility/Solubility of Ibuprofen powder was determined using such solvents as: n-hexane, hydrochloric acid, sodium hydroxide, acetone, chloroform and water then observation recorded.

**Preparation of Ibuprofen Granules**

The preparation of the ibuprofen granules was done following the wet granulation process of tablet formulation and adopting the formulae as in Table 1. The formulation was made in three batches such as: $J_1$ (Extracted mango starch as binder and disintegrant), $J_2$ (corn starch as binder and disintegrant) and $J_3$ (extracted mango and corn starch as binder and disintegrant,occurring in a 1:1 ratio).

**Table 1: Ibuprofen Granules formulation**

| INGREDIENTS COMPOSITION | WEIGHT PER TABLET (mg) | | | WEIGHT IN 150 TABLETS (g) | | |
|---|---|---|---|---|---|---|
| | Batch | | | Batch | | |
| | $J_1$ | $J_2$ | $J_3$ | $J_1$ | $J_2$ | $J_3$ |
| Ibuprofen | 200.0 | 200.0 | 200.0 | 30.0 | 30.0 | 30.0 |
| Mango Starch (binder) | 52.0 | - | 26.0 | 7.8 | - | 3.9 |
| Mango Starch (disintegrant) | 24.0 | - | 12.0 | 3.6 | - | 1.8 |
| Corn Starch (binder) | - | 52.0 | 26.0 | - | 7.8 | 3.9 |
| Corn Starch (disintegrant) | - | 24.0 | 12.0 | - | 3.6 | 1.8 |
| Gelatin | 2.0 | 2.0 | 2.0 | 0.3 | 0.3 | 0.3 |
| Talc | 1.0 | 1.0 | 1.0 | 0.15 | 0.15 | 0.15 |
| Magnesium Stearate | 4.0 | 4.0 | 4.0 | 0.6 | 0.6 | 0.6 |
| Total Weight | 283.0 | 283.0 | 283.0 | 42.45 | 42.45 | 42.45 |

**Physico-Technical Properties of Granules**

**Determination of Granules Densities**

**Bulk Density ($D_B$)**

A 2.0g weight of granules Batch $J_1$ was introduced through a funnel into a 100ml measuring cylinder, and the volume occupied by the granules was recorded. $D_B$ was given in g/ml. The procedure was repeated for granules'of batches $J_2$ and $J_3$.

**Tapped Density**

A 2.0g weight of granules Batch $J_1$ was introduced through a funnel, into a 100ml measuring cylinder, and then tapped 50 times on a padded tabletop, and the tapped volume recorded.

The procedure was also repeated for granules batches $J_2$ and $J_3$. $D_T$ was given in g/ml.

**Hausner's Ratio (H)**

This was calculated for the three batches of the granules as the ratio of the tapped density to the bulk densityas stated in the formulae below:

$$H = \frac{D_T}{D_B}$$

**Carr's Compressibility Index**

This was calculated for the three batches of the granules as the difference between the tapped and bulk densities, divided by the tapped density. It is expressed in percentage as:

$$\%\ Compressibility\ =\ \frac{D_T\ -\ D_B}{D_T}\ x\ \frac{100}{1}$$

**Addition of Exo-Excipients**

The exo-excipients (disintegrant, lubricant and glidant) were added to the granules based on the formula in Table 1. The granules were mixed properly before compression.

**Compression of Granules**

After the addition of the exo-excipients, the mixed granules were compressed into tablets using the single punch tableting machine at a pressure of 5kgF. The formed tablets were allowed to stay for 24 hours, before evaluation to allow for elastic recovery.

**Quality Control of Tablets**

**Weight Variation**

The weight of 20 randomly selected tablets were taken as a whole, and individually using an electronic balance. The mean weight was calculated and the variation in weight of the individual tablets from the mean was determined.

**Friability Test**

Ten (10) tablets were selected randomly from each of the batches and placed on a sieve, loose dust was removed with the aid of a soft brush. The de-dusted tablets were weighed into the drum of a friabilator, rotated at 25rpm for 4 minutes. The tablets were de-dusted again and re-weighted. The percentage friability was calculated as:

$$\%\ Friability\ =\ \frac{InitialWeight\ -\ Finalweight}{Initialweight}\ x\ \frac{100}{1}$$

**Crushing Strength Test**

The crushing strength of each of the ten tablets from the three (3) batches was determined using Erweka hardness tester. The mean crushing strength (diametric breakage) of each of the tablets was determined.

**Disintegration Test**

The disintegration rate of six tablets, selected at random from each of the three batches, was determined using a B. P. specified apparatus containing 0.01N sodium hydroxide at 37±0.5$^0$C. The mean disintegration time was determined there after.

**Preparation of standard calibration Curve**

A 50mg of pure Ibuprofen powder was placed in a 10ml volumetric flask, dissolved with 0.01N NaOH, and made up to the mark with the same solvent. Various dilutions of the stock solution were made to obtain 0.05, 0.10, 0.15, 0.20, 0.25 and 0.30mg/ml with NaOH, and the absorbance determined by UV spectrophotometer at 265nm wavelength. A standard calibration curve was obtained by plotting absorbance against concentration (mg).

**Dissolution Test**

The dissolution rates of the active drug from the tablets were determined using USP apparatus. 900ml of freshly prepared dissolution medium (0.01N NaOH) was transferred into the dissolution jars and maintained at 37±0.5$^0$C. The paddles were caused to rotate at 50rpm. Samples were withdrawn at 5, 10, 15 up to 40 minutes and analyzed spectrophotometrically for Ibuprofen at 265nm wavelength. Samples removed for analysis were replaced with equal fresh aliquots of the dissolution medium, and the percentage drug dissolved was calculated as:

Absorbance (y) = Slope (m) x Concentration (c)± intercept

Amount of drug released (mg/ml) =

$$\frac{\text{Concentration x dissolution hath volume x Dilution factor}}{1000}$$

Percentage drug released

$$\frac{Amountreleasedattime\ \ ,t}{Dose\ (mg)}\ x\ \frac{100}{1}$$

**Content of Active Ingredient**

Twenty tablets were selected at random from each of the three batches weighed and crushed to fine powder. The powdered drug (50mg) was weighed into a 50ml volumetric flask and dissolved with 0.01N NaOH, then made up to 50ml with the same solvent. The solution was filtered and 0.5ml of the filtrate was transferred and made up to10ml with 0.01N NaOH. The drug content was determined by measuring the absorbance of the filtrate at 265nm wavelength, using the UV spectrophotometer.

The percentage drug content = Calculated content x 100
Estimated content

Assay of Ibuprofen

The method modified and used was acid-base titration method. Twenty tablets were selected at random, from one batch of the formulation and weighed. A quantity of powder containing 0.5g ibuprofen was extracted with 20ml chloroform for 15 minutes and filtered through, a Whatman's filter paper. The residue was washed thrice with 10ml chloroform and the filtrate gently evaporated to dryness. The residue was then dissolved in 100ml of 96% ethanol and the solution titrated against 0.1N sodium hydroxide with two drops of phenolphthalein as indicator. The end point (pink color) was noted and the content of ibuprofen ($C_2$) calculated using the formula ($C_IV_I = C_2V_2$where $C_1$ and $C_2$ is initial and final concentration of ibuprofen and $V_1$ and $V_2$the initial and final volume of sodium hydroxide [14].

## II. RESULTS:

Table 2: **Preliminary confirmatory Tests**

| TEST | OBSERVATION | INFERENCE |
|---|---|---|
| **Iodine Test** | Intense blue-black coloration observed. | Starch present |
| **Molisch's Test** | A deep violet ring observed at the junction of the two layers. | Carbohydrate present. |

**Table 3: Physicochemical Properties of Mango and Corn starches**

| PARAMETER | MANGO STARCH | CORN STARCH |
|---|---|---|
| pH | 4.25 | 3.90 |
| Viscosity (cP) | 3.00 | 3.45 |
| Water Absorption Index (%) | 82.81 ± 0.02 | 82.87 ± 0.01 |
| Swelling Index (%) | 9.09 | 11.02 |
| Gelatinization Temp ($^O$) | 60 – 70 | 60 – 70 |

**Table 4: Physico-technical characterization of Ibuprofen Granules**

| Granules' Property | Granules' Batch | | |
|---|---|---|---|
| | $J_1$ | $J_2$ | $J_3$ |
| Bulk density (g/ml) | 0.46 ± 0.57 | 0.49 ± 1.53 | 0.52 ± 0.58 |
| Tapped density (g/ml) | 0.53 ± 0.58 | 0.53 ± 0.58 | 0.57 ± 1.15 |
| Hausner's quotient | 1.15 ± 0.01 | 1.08 ± 0.01 | 1.10 ± 0.03 |
| Compressibility Index (%) | 13.21 ± 0.15 | 7.55 ± 0.17 | 8.77 ± 0.25 |
| Angle of Repose ($^0$) | 28.8.1 ± 2.49 | 23.89 ± 2.09 | 25.17 ± 1.47 |

$J_1$ (mango starch only), $J_2$ (cornstarch only), $J_3$(mango and cornstarch of ratio1:1)

**Table 5: Evaluation of Tablet Properties**

| Batch Number | Hardness (KgF) | Weight uniformity (mg) | Friability (% w/v) | Disintegration time (minutes) |
|---|---|---|---|---|
| $J_1$ | 5.05 ± 0.29 | 237±0.12 | 0.24 | 10.45 |
| $J_2$ | 5.69 ± 0.19 | 238±1.24 | 0.14 | 14.22 |
| $J_3$ | 5.45 ± 0.22 | 245±2.13 | 0.22 | 13.27 |

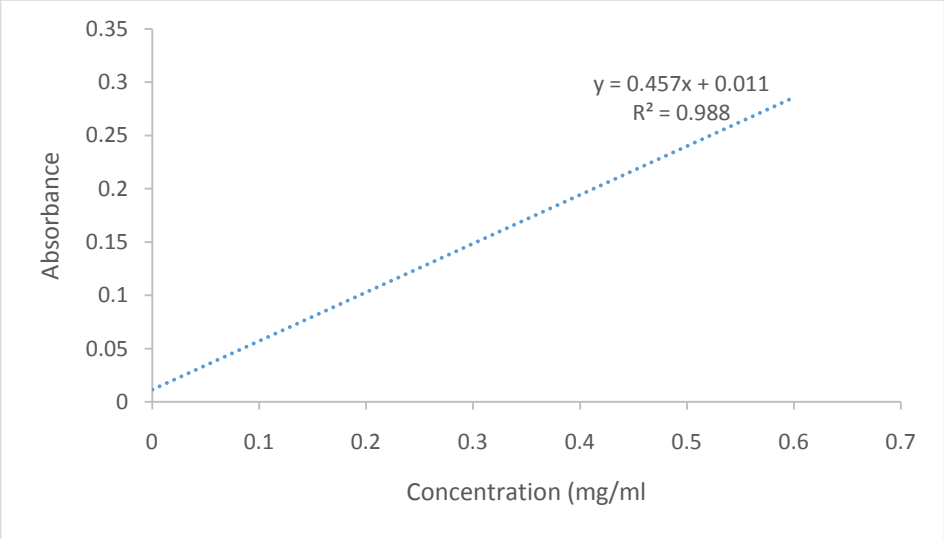


**Fig 2: PLOT OF ABSORBANCE AGAINST CONCENTRATION (mg/ml)**

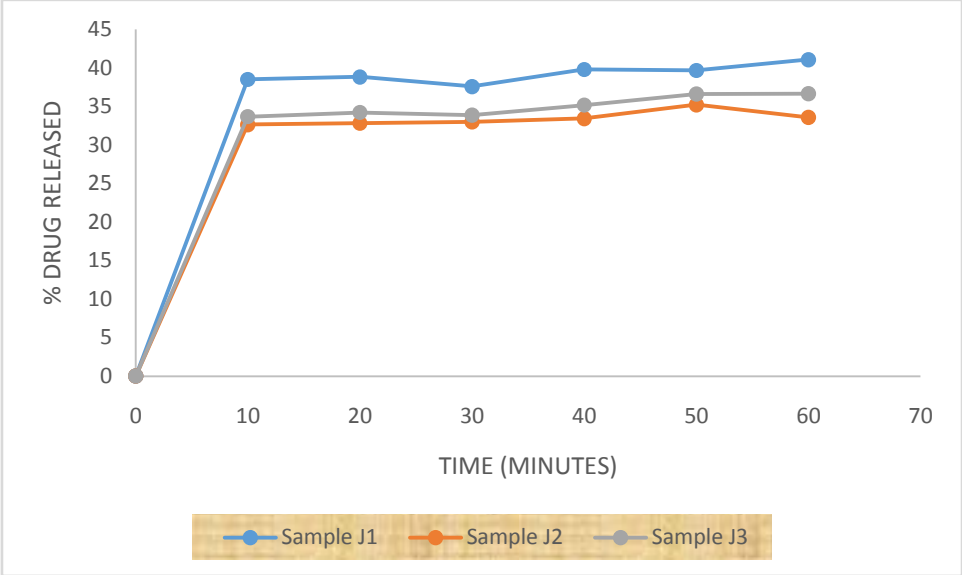


Fig 3: PLOT OF PERCENTAGE DRUG RELEASED AGAINST TIME (MINUTES)

**Table 6: Drug content for Ibuprofen Tablet formulation**

| Parameter | Batch Number | | |
|---|---|---|---|
| | $J_1$ | $J_2$ | $J_3$ |
| Absorbance (at 265nm) | 0.407 | 0.393 | 0.398 |
| Concentration (mg) | 0.876 | 0.846 | 0.845 |
| Expected content (mg) | 200 | 200 | 200 |
| Calculated content (mg) | 218.87 | 211.0 | 211.25 |
| Percentage drug content (% w/v) | 109 | 106 | 106 |
| | | | |

$J_1$(mango starch only) $J_2$(corn starch only) $J_3$ (mango and corn starches at ratio 1:1).

## III. DISCUSSION

Three batches of Ibuprofen granules were formulated using *Mangifera indica* starch only as a binder and disintegrant in batch ($J_1$), Corn starch only as a binder and disintegrant in batch ($J_2$) and combination of *Mangifera indica* and Corn starch in 1:1 ratio as a binder and disintegrant in batch ($J_3$).

From the evaluation of granules properties as shown in the table 4, there was an improvement in the flow behaviour of the granules formed when compared to that of ordinary mango and corn starch powders initially used reference to such characterization properties as compressibility index and Hausner's quotient [15]. The range of value from the batches as obtained for angle of repose (23.89 to 28.81) indicated excellent flow characteristics of granules made using the extracted German mango starch and Corn starch - already established andused as reference standard. The granules of both German mango starch and corn starch used alone and in combination had bulk density of 0.46g/ml - 0.52g/ml and tapped density of 0.53g/ml-0.57g/ml. Despite little increase in the bulk and tapped densities, all the granules formulated had Hausner's ratio of less than 1.25, and this falls within the official recommended values. This result gives an indication that the formed good granules possess good flow property. The compressibility index of the batches as obtained was in the range of 7.55%-13.21% and this is acceptable relative to the reference standard, hence indicates the possibility of a compact tablet formation if the starch (es) are incorporated as excipients in solid dosage formulation.

Quality control tests involve series of procedures intended to ensure that a formulated product (pharmaceutical tablets) adheres to defined sets of standards. These tests include uniformity of weight, crushing strength (hardness), friability, disintegration, dissolution and assay of drug content. The crushing strength is an important in-process test to assess whether the tablets produced are firm enough to withstand breakage, chipping or crumbling, and yet not so hard as to delay disintegration[16]. The primary role of binders is to provide the cohesiveness essential for the binding of solid particles under compaction to form a tablet. Binders may improve the hardness of tablets by enhancing intergranular and intragranular forces. A forcerange of 4kgf to 8kgf have been recommended as values accepted for crushing of tablets. From the results shown in table 5, all the tablets batches passed the test with a mean crushing strength range of 5.05kgf to 5.45kgf.

Friability test is an attrition resistance method that evaluates the characteristics of a formulated tablet upon subjection to various forces during handling between the productions up to product administration [17]. It is a mechanical property of tablet specified by official compendia and it is expected not to exceed a value of 1%.

From the result in table 5, all the tablet batches formulated passed the test with values ranging from 0.14% to 0.24%.

For uniformity of weight, weight variation obtained as shown in table 5 range from 2.08mg to 2.45mg and variation of 4 to 5%. This shows that all the tablet batches passed the uniformity of weight test, as they did not exceed the British Pharmacopoeias specification of 7.5% [18].

Disintegration test is a measure of the time taken for a tablet to be broken down into smaller particles in physiological medium. The acceptable requirement for disintegration time for uncoated tablet is 15minutes. From the result in table 5, the disintegration time of the tablet batches formulated range from 10.45minutes to 14.22minutes, which show that all the tablet batches passedthe test, though some values were close to the limit specified in the reference (official) book.

Dissolution studies provide an insight into the release or absorption of drugs component from a dosage form. Certain factors that affect drug dissolution include; the type and nature of binders, hardness of tablets, surface area and composition, distance of diffusion, solubility of active drug and the formulation process [17]. The standard dissolution process for uncoated Ibuprofen tablets stipulates that not less than 85% of the labelled drug content is dissolved within 60 minutes.

From the result shown in the figure 3, it was observed that the batch formulated with only Mango starch[batch J1] gave the fastest rate of the drug release while the batch formulated with only Corn starch (batch $J_2$) had the lowest dissolution rate. The tablet batch formulated with 1:1 ratio of combined mango and corn starch(es), showed intermediate dissolution rate between that of batch $J_1$ and $J_2$ tablets. This result therefore implies that tablet of batch $J_1$ has the least binding property, but could have better disintegrant property, while tablet of batch $J_2$ showed the appreciable binding ability but lower disintegrant ability. Tablets of batch $J_3$ (with combination of *Mangifera indica* and corn starch at 1:1 ratio) exhibited moderate binding and disintegrant activities. This result has shown that the combination of mango starch to Corn starch in equal ratio (1:1), enhanced the tablet disintegration and this disintegrant property contributed to the faster release of the drug content than when Corn starch was used alone though there was reduction in the corn starch binding effect.

In the drug content evaluation, the official standard in the monogragh recommends a range of 90% to 110% drug content [17]. From the study, it was observed that all the formulated Ibuprofen tablets were within the recommended limits as shown in table 6. This also depicts that no interaction occurred between the excipients and the active Pharmaceutical ingredient (API) used in the formulations.

CONCLUSION

Extracted starch from the seed kernel of German mango a specie of *Mangifera indica* is been verified to have good disintegrant property especially when used in oral solid dosage pharmaceutical formulations. This analogy is being supported by an outcome of short disintegration time and increased release rate as observed with ibuprofen tablet formulated using the starch The disintegration, deaggregation and eventual absorption could be more enhanced with mango starch formulated tablets than that formulated using corn starch which from the study seems to be more associated with greater binding than disintegrant property.

Following the outcome of this study, starch from the seeds of German mango locally known as opioro in Nigeria, should be properly sourced and harnessed to help,enrich the availability of local pharmaceutical excipients and divert attention away from the economydepreciating imported synthetic materials.

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Ordu J I, et. al. "Assessment of Mangifera Indica and Corn Derived Starches on Ibuprofen Tablet Formulation." *International Journal of Pharmaceutical Science Invention*, vol. 10(01), 2021, pp 34-41. Journal DOI- 10.35629/6718