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Effect of Extracted Microcrystalline Cellulose from Dracaenea arborea Stem on Aceclophenac Tablet Formulation

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Authors' contributions

This work was carried out in collaboration between both authors. Author JIO the corresponding author designed the study, performed statistical analysis, wrote the protocols, the draft of the manuscript and managed the analyses of the study while the co author IEU managed the literature searches. Both the authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Micro crystalline cellulose (MCC) is a major derivative from the bio composite of natural materials such as *D. arborea* plant stem. It could be useful as a secondary binder and disintegrant in tablet formulation especially following direct compression technique anticipating it to provide high level of disintegration at low use level and utilizing dual mechanisms of wicking and swelling. Tablets of aceclofenac a BCS class II and non steroidal anti inflammatory drug (NSAID) which potently inhibits the cyclo oxygenase enzyme (COX-2) involved in prostaglandin synthesis was formulated by direct compression using MCC from *D. arborea* stem. Qualitative assessment of the plant extract was carried out and the presence of cellulose confirmed by the appearance of violet – blue coloration while the physicochemical and physicotechnical properties were comparatively evaluated with reference to avicel and corn starch. Three batches of aceclofenac tablets involving Batch A (*D. arborea* MCC), Batch B (Corn starch) and Batch C (Corn starch and *D. arborea* MCC in a 1:1 ratio), were implcated in the formulation. Physicochemical study of the MCC reveals a pH of 7.8, mean swelling index 1.14±0.05 ml and hydration capacity of 3.60±0.15 g while the pH of

corn starch is 3.90 with swelling and hydration capacity at 5.09 ± 0.03 ml and 8.26 ± 0.01 g respectively. Quality control evaluation of resulting tablet was investigated and the wetting time of batch A tablets was 1.50, batch B 2.30 and batch C 1.80 with percentage moisture content (%) of 60.5, 56.56 and 57.8 and disintegration time (minutes) of 0.22 ± 0.07 , 0.35 ± 0.051 and 1.60 ± 0.286 respectively. The drug release profile of batch A, reveals an initial burst release within 10 minutes followed by gradual release while batch C had consistent drug release which was maintained although faster than that of batch A after 10 minutes but batch B had the least drug release rate.

Keywords: D. arborea; extracted MCC; corn starch; Aceclofenac; tablets.

1. INTRODUCTION

Tablets as a dosage form, Tablets are solid dosage forms that comprise of medicaments 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 effects. In addition to the active ingredients, tablets contain a number of inert materials known as excipients that are either mixed with medicaments or added to and these includes binders. granules disintegrants, glidants and lubricants [1].

Microcrystalline cellulose: This is a purified and partially depolymerized alpha (α) cellulose derived from the pulp or stem of fibrous plants as *D.arborea* plant. MCC occurs as a white, odorless, tasteless and crystalline powder composed of porous particles [2]. It could be derived from any material that is high in cellulose ranging from pure cellulose commercial grade cellulose to ligno cellulose and it is widely used in the pharmaceutical industries as an excipient [3]. The MCC could mostly, be derived from special grade of purified alpha wood cellulose by severe acid or alkaline hydrolysis to remove the amorphous cellulose portions yielding particles consisting of bundle – like microcrystals [4].

The relevance of MCC, as an excellent pharmaceutical excipient is related to the ease of its compressibility when used in solid dosage formulation, usefulness as a filler and/ or binder in wet or dry granulation and direct compression of tablets. The direct compression is a simple and most advanced tablet manufacturing technique that offers product stability and improved process reliability with optimization of tablet disintegration [5].

The application of MCC in direct compression is linked to its excellent binding properties when used as a dry binder and it has disintegrant and lubricant properties. The MCC, do combine two useful properties of tablet requirements and aids in the production of very hard tablet which can disintegrate rapidly in water due to swelling of the MCC particles and the disruption of the bonding forces that hold the drug particles together [6].

Micro crystalline cellulose is a major derivative from the bio composites of natural materials formed by matrix (resin) as a result of natural fiber reinforcement and this has formed its extensive applications in pharmaceutical, textile, paper, manufacturing, buildings and civil engineering fields [7].

1.1 Assaying of Cellulose Containing Materials

Given a cellulose – containing material, the carbohydrate portion that does not dissolve in a 17.5% solution of sodium hydroxide at 20 °C is α – cellulose consisting of true MCC while acidification of the extract precipitates β – cellulose and the portion that dissolves in base but does not precipitate with acid is Υ – cellulose [8].

1.2 Chemistry of MCC

The MCC has a chemical formulae of $(C_6H_{10}O_5)_{n,}$ it is insoluble in water, ethanol, ether and dilute mineral acids but slightly soluble in sodium hydroxide. It has a pH range of 5.0 - 7.5 and its loss of weight should be at the range of 8%. Pharmaceutical grade MCC, has good dissolution potential and compressibility and is a special form of cellulose consisting of fibrils by which individual crystals is held together by hydrogen bonding [9].

MCC is associated with an extremely low coefficient of friction that is both static and dynamic so that it has no lubricant requirement for itself however when more than 20% of a drug and other excipient is added lubrication becomes necessary [10].

Microcrystalline cellulose is used as a secondary binder and disintegrant in wet granulation, dry granulation and direct compression tablet formulation. It speeds up tablet disintegration, provides the highest level of disintegration forces at low use level and utilizes dual disintegration mechanisms of wicking and swelling for more rapid release of the active ingredients hence despite the tablet hardness, it does not hinder the release of the active material from the powder matrix [11].

1.3 Aceclofenac Tablet Formulation

Aceclofenac is a non- steroidal anti-inflammatory drug (NSAID) with higher anti-inflammatory activity comparable to conventional NSAIDS [12]. The aceclofenac potently inhibits the cyclo oxvgenase enzyme (Cox-2) involved in prostaglandin synthesis. It is orally administered for the relief of pains and inflammation in osteoarthritis, rheumatoid arthritis, and spondylosis ankylosing [13]. Aceclofenac belongs to the BCS class II, possesses poor aqueous solubility. and displays high permeability to penetrate into synovial joints of patients with osteoarthritis and related conditions [14].

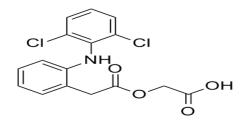


Fig. 1. Molecular structure of Aceclofenac

IUPAC =2-(-2-(2-(2,6-dichloroanilino) phenyl) oxy acetic Acid.

Molecular Formula = $C_{16}H_{13}CL_2NO_4$ melting point =149 - 153 °C

Aceclofenac is highly water insoluble and appears as a 100mg film coated tablet that is white to off white in color. It inhibits both isoforms of Cox enzymes involved in inflammation cascade (Cox-1 involved in prostacyclin production responsible for the protective functions of gastric mucosa whereas Cox-2 is an inducible enzyme involved in the production of mediators to inflammatory stimuli). Aceclofenac displays more selectivity towards Cox-2 and hence promotes gastric tolerance compared to other NSAIDS and it is found to inhibit the production of inflammatory cytokines, interleukins, and tumor necrosis factors [15].

The aceclofenac tablet is rapidly and completely absorbed from the gastro intestinal tract (GIT) and circulates mainly as unchanged drug following oral administration. It is highly protein bound (> 99%) volume of distribution approx. 25L and main route of elimination is via the urine with 70 - 80% of drug clearance. Common side effects include gastro intestinal disorders, enuresis, headache, dizziness, and drowsiness.

The objective(es) of this study is 1: to determine the suitability of the extracted MCC from *D. arborea* plant stem as an excipient in the pharmaceutical product formulations vis-à-vis the industries and comparable to standards (corn starch). 11: to formulate and investigate the properties of the extracted MCC as a binder and disintegrant on aceclofenac tablets by direct compression.

2. MATERIALS

Extracted microcrystalline cellulose from *D.arborea* plant (Pharm Technology laboratory, University of Port Harcourt, Nigeria), Aceclofenac powder BP (Batch no: Al. ACF 007 11 14, Neutral code No: RA/DRUGS/RA1- 2399), Masanto hardness tester (Thermonink, China), friabilator (Erweka, Germany), Disintegration test apparatus (Chem science co. Nigeria), Spectrophotometer UV 2100 UnicoTm, Germany

3. METHODS

3.1 Qualitative Determination of Cellulose and Starch

A 10 ml solution of iodinated zinc chloride was added to 10mg of MCC cellulose powder on a watch glass. The color change was observed and recorded.

The presence of starch was tested by placing 0.1 g of corn starch on a crucible and a few drops of Lugol's iodine solution added to it. This was observed for confirmation of the presence of starch in the sample.

3.1.1 Organoleptic test

The color, taste, and texture of the alpha cellulose product (MCC) were observed physically and by touch.

3.1.2 Solubilty test

One gram (1.0 g) of the extracted MCC was placed in a test tube; distilled water was added and shaken vigorously. The behavior in water was noted after 10 minutes. All the tests were repeated on corn starch.

3.2 Microcrystalline Cellulose Powder Characterization

The physicochemical and physicotechnical properties of the microcrystalline cellulose isolated were comparatively evaluated with reference to pharmaceutical grade cellulose (avicel) and corn starch.

3.3 Bulk and Tapped Densities

A 2.0 g quantity (Wp) of MCC powder was gently poured through a short stemmed glass funnel into a 250 ml graduated cylinder. The volume occupied by the powder was taken as Vp. The powder was tapped on a padded table surface from a height of 7 mm until no further change in volume was observed. This volume (VpT) was taken as the tapped volume. The bulk and tapped density were computed using the formula:

$$Bd = \frac{Wp}{Vp}$$
$$Td = \frac{Wp}{VpT}$$

Where,

Bd is the bulk density. Td is the tapped density.

This same procedure was repeated in triplicates and for corn starch.

3.4 Carr's Compressibility Index and Hausners Ratio

The Carr's index (CI) and Hausner's ratio (HR) were computed from the bulk and tapped densities as:

$$HR = \frac{Td}{Bd}$$
$$CI = \frac{Td - BD}{Td} \times 100$$

3.5 Swelling Capacity

The swelling capacity of the MCC was determined as follows, the tapped volume occupied by 5.0 g of the alkali synthesized MCC

 (V_1) was noted. The powder was then dispersed in 85 ml of distilled water and the volume later made up to 100 ml with water. After 24 hours of standing, the volume of the sediment, V_2 was estimated and the swelling capacity was computed [16].

Where,

 V_2 = Volume of sediments.

 V_1 = Tapped volume of 5.0 g of MCC powder

The test was repeated for cornstarch powder.

3.6 Hydration Capacity

One gram (1.0 g) of the MCC powder (Y), was placed in a centrifuge tube and covered with 10ml of distilled water. The tube was shaken intermittently, for about 2 hrs and left to stand for 30 minutes before centrifuging at 3000 rpm for 10 minutes. The supernatant was decanted and the weight of the powder (X) after water uptake and centrifugation was determined [17]. Hydration capacity was calculated as:

$$\frac{X}{Y}$$

Where,

X=weight of microcrystalline cellulose before water update.

Y=weight of MCC after water uptake. This was also repeated for corn starch.

3.7 Moisture Sorption Capacity

The method of Ohwoavworhua and Adelakun (2005) was adopted. Two grams (2.0 g) of the MCC powder (W) was weighed and put in a tarred petri dish. The sample were then placed in a desiccator containing distilled water at room temperature and the weight gained (Wg) by the exposed sample at the end of a five-day period was recorded and the amount of water absorbed (Wa) was calculated from the weight differences:

$$Wa = Wg - W$$

3.8 Determination of Microcrystalline Cellulose True Density

The true density (Dt) of the cellulose powder was determined by the liquid displacement method using n-hexane as the immersion fluid and computed according to the following equations

$$\mathsf{Dt} = \frac{Wp}{((a+Wp)-b)} \times SG$$

Where,

Wp = the weight of powder. SG = the Specific gravity of solvent.

a = the weight of bottle + solvent, b = is weight of bottle + solvent + powder.

3.9 Porosity

The porosity (E) was calculated as:

$$\mathsf{E}=\frac{1-Bd}{Dt}\times 100$$

Where,

Bd = bulk density, Dt=true density of MCC cellulose

3.10 Angle of Repose and Bulkiness

Angle of repose was measured for both the MCC and corn starch. The method employed a funnel secured with its tip at a given height (h), 4 cm, above a plane paper placed on the horizontal flat surface. The powders were poured through the funnel until the apex of the conical powder pile touched the funnel. The diameters of the base of the powder heap was noted and the angle of repose (Θ) calculated using the formula:

 $\Theta = Tan^{-1} h/r$

r = radius of the base diameter, h = height of the funnel tip from horizontal surface.

Bulkiness: This was calculated as the reciprocal of the bulk density.

3.11 Tablet Formulation

Three batches of the formulation were made as given in the table.

Calculation:

The weight of each Tablet = Total amount of API + Exceptents Total number of Tablets Produced

% Composition of Aceclofenac = $\frac{Weight of API}{Tablet weight} \times 100$

3.12 Quality Control of Tablets

3.12.1 Weight variation

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

3.12.2 Fraibility test

Ten tablets were randomly selected and placed on a sieve, loose dust was removed with the aid of a soft brush. The dedusted tablets were weighed and placed on the drum of the fraibilator which rotated at 25 rpm for 4 minutes. The tablets were dedusted and reweighed. The percentage friability was determined using the formula:

% Friability =
$$\frac{Initial Weight - Final weight}{Initial Weight} \times 100$$

| Ingredient | Quantity per tablet | Quantity in total of 100 tablets | | |
|---------------------------|---------------------|----------------------------------|--|--|
| BATCH A | | | | |
| Aceclofenac (200mg) BP | 89% | 20.20g | | |
| Extracted MCC | 8.0% | 1.81g | | |
| Lubricant (mag. Stearate) | 2.0% | 0.45g | | |
| Talc | 1.0% | 0.23g | | |
| BATCH B | | | | |
| Aceclofenac (200mg) BP | 89% | 20.20g | | |
| Corn starch | 8.0% | 1.81g | | |
| Mag. Stearate | 2.0% | 0.45g | | |
| Talc | 1.0% | 0.23g | | |
| BATCH C | | | | |
| Aceclofenac (200mg) BP | 89% | 20.20g | | |
| Corn starch | 4.0% | 0.91g | | |
| Extracted MCC | 4.0% | 0.91g | | |
| Mag. Stearate | 2.0% | 0.45g | | |
| Talc | 1.0% | 0.23g | | |

Table 1. Formula for Tablet Formulation

3.12.3 Crushing strenght test

The crushing strength of each of the 10 tablets was determined for each batch using the Erweka TDH 100 hardness tester, and the mean crushing strength was noted.

3.12.4 Disintegration test

The disintegration rate of three tablets randomly selected from each batch was individually determined using the basket method in a B.P specified apparatus (Erweka) and in a medium of 0.1 N HCL at 37 ± 0.5°C. The mean disintegration time were calculated.

3.12.5 Preparation of 0.1 N HCL

An 8ml of concentrated HCL was carefully measured in a fume cupboard and thereafter transferred into a 1000 ml measuring cylinder containing 250 ml distilled water and then made up to volume [18].

3.12.6 Preparation of 0.2 N NAOH

A 2.0 gram of NaOH was weighed using a weighing balance and dissolved in a 1000 ml beaker containing 100 ml of distilled water. The solution was there after made up to 250 ml [18].

3.12.7 Preparation of 6.8 pH phosphate buffer

A 6.8 g crystal of Potassium dihydrogen phosphate was dissolved in 250 ml of distilled water in a 1000 ml volumetric flask and made up to volume. Thereafter, the prepared 0.2 N sodium hydroxide solution was used to adjust the pH to the required pH value of 6.8 using an electronic pH meter the buffer was carefully sealed using an aluminum foil and stored properly for further use [18].

3.12.8 Preparation of standard calibration curve

The pure Aceclofenac powder (200mg) was placed in a 100 ml volumetric flask, dissolved with pH 6.8 potassium dihydrogen Phosphate buffer and made up to the mark with same solvent. A 1 in 10 ml dilutions were made with the solvent, and the absorbance determined by UV spectrophotometer at 245 nm. A standard calibration curve of absorbance against concentration (mg) was plotted.

3.12.9 Dissolution

The dissolution rates of the active drug from the tablets were determined using USP apparatus 11 (paddle). A 900 ml volume of freshly prepared dissolution medium (pH 6.8 Phosphate buffer) was transferred into the dissolution jars and maintained at 37 ± 0.5°C. The paddles were caused to rotate at 50 rpm. The tablet from each batch was then placed in the dissolution media and 10ml sample was withdrawn at 10, 20, 30, 40. 50. and 60 minutes. and Spectrophotometrically analyzed the for Aceclofenac concentration 245 at nm wavelength. Samples removed for analysis were replaced with 10 ml fresh aliquots of the dilution medium, and the percentage drug released was calculated as:

Absorbance = Slope × concentration ± intercept

Amount of Drug released (mg/ml) = Concentration × Dissolution bath Volume × Dilution Factor 1000

Percentage drug release =

Amount released at time(t) \times 100 [19] Dose (mg)

3.12.10 Wetting test

The wetting test as described by Ordu et al (2015) was conducted for 6 tablets of each formulation. Each tablet weighed prior to the test was placed in a petri dish containing a red dye solution, and the time of wetting the whole surface of the tablet was noted. The wetted tablet was weighed and the amount of water absorbed by the tablet was calculated. The result was thereafter recorded and expressed in % w/w relative to the initial tablet weight [20].

3.13 Assay of Aceclofenac

In this procedure, 20 tablets were accurately powdered. weighed and The powder equivalent to 100 mg of aceclofenac was transferred to 100 ml volumetric flask and 50 ml of methanol added. This mixture was mixed properly using a binatone mixer for 45 minutes and the volume made up to 100 ml with methanol. The mixture was filtered through Whatmann filter paper. Then 50 ml of the filtrate was transferred in a 50 ml volumetric flask and the volume was made up to the mark to give a resultant concentration of 100 µg/ml. Appropriate volumes of this solution were taken and absorbance of each solution was measured at 245 nm [21].

4. RESULTS

4.1 Preliminary Confirmatory Tests

The cellulose was confirmed by presence of a violet – blue coloration while starch was confirmed in the corn by presence of intense blue – black coloration.

5. DISCUSSION

The organoleptic properties of the MCC for D. arborea showed acceptable elegant properties in terms of color, taste and texture. This also applies to the corn starch powder used for the study.

Confirmatory tests carried out on the materials, shows the presence of cellulose and starch as constituents of *D. arborea* stem and corn hob respectively.

Results of the physicochemical characterization show that the bulk densities of the powders were within acceptable range where bulk density of powders depends primarily on the particle size, shape and the tendency of the particles to adhere to one another hence particles may pack in a way as to leave large void spaces between their surfaces. In this case the MCC powders are associated with larger void spaces than that of the corn starch.

Swelling is often an indication of tablets disintegration ability and this can be assessed by the swelling and hydration capacity. Following results obtained, the cornstarch has a higher ability to absorb and retain moisture than the extracted MCC although this could be of advantage if wet granulation method of tablet formulation was adopted. In this study direct compression was applied and there might be a possibility of instability as a result of influence of large amount of moisture especially in tablets formulated using the corn starch as a result of increased water retention ability.. Sequel to this effect, there could be an influence in the flow ability of the powder as a result of resistance caused by high level of moisture retained in the corn starch powder. This high moisture absorption and retention ability of the corn starch powder might also lead to increased binding effect increased hardness or brittleness of the tablet and delayed release of active components as a result of probable inter particulate bridge formation likely caused by presence of hydrogen bond. These activities might lead to a reduced therapeutic efficacy of the resultant product if not properly handled.

Crushing strength is a measure of the force required to break or crush a tablet and 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. The primary role of binders is to provide the cohesiveness essential for the bonding of solid particles under compaction to formulate tablet. Binders may improve the hardness of tablets by enhancing inter and intra granular forces. A range of 4-8kgF have been given as values obtainable for crushing strength of tablets, as excess amount of binder's and compression pressure may make the compressed tablets too hard such that it may not disintegrate within the desired time. Therefore, binder concentration must be controlled in order to produce tablets that are not too hard as to impair absorption or cause tablets to be excreted unchanged, as well as tablets that are soft which will not withstand handling stress.

From the result shown in Table 3, the Batch A, B, and C shows a reduced crushing strength just a little below the standard this may be due to the lower pressure applied during compression process and also the influence of the tableting machine.

| Parameter | | Cellulose | Corn starch |
|------------------------------|-----------|-----------------------------|---------------------------|
| BULK DENSITY(g/ml) | Mean ± SD | 0.33 ± 0.00 | 0.40 ± 0.03 |
| Tapped Density(g/ml) | Mean ± SD | 0.46 ± 0.01 | 0.48 ± 0.22 |
| Hausners Ratio | Mean ± SD | 1.38± 0.03 | 1.20 ± 0.02 |
| Carr's Compressibility Index | Mean ± SD | 27.73 % ± 0.02 | 20.03% ± 0.28 |
| Angle of repose (Θ) | Mean ±SD | $(28.20 \pm 0.03)^{\Theta}$ | (26.30±0.01) [⊖] |
| pH | | 7.8 | 3.90 |
| Swelling index | Mean±SD | 1.143 | 5.09 |
| Hydration capacity | Mean±SD | 3.60 | 8.26 |

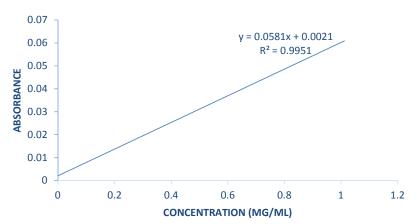
| Batch No | Concentration of binder/disintegrant | Hardness (kg/f) | Weight variation (%) | Friability (%w/w) | Disintegration time (minute) |
|-------------|---|--------------------|-------------------------|----------------------|------------------------------|
| А | 7%w/w MCC | 2.66±0.457 | 245.3±5.487 | 3.92±0.003 | 0.22±0.057 |
| В | 7%w/w corn starch | 2.47±0.481 | 243.7±7.180 | 5.57±0.0045 | 0.35± 0.051 |
| С | 3.5%w/w each of MCC and cornstarch | 3.20±0.361 | 243.8±8.140 | 4.06±0.002 | 1.60±0.286 |

Table 3. Result of the physico chemical properties of formulated aceclofenac tablets

KEY: A= MCC serving as only binder/disintegrant, B= Starch serving as only binder/disintegrant. C= MCC is combined with cornstarch ratio 1:1 as binder/disintegrant.

| Table 4. Wettin | g time and | percentage | moist | ure a | bsorbed |
|-----------------|------------|------------|-------|-------|---------|
|-----------------|------------|------------|-------|-------|---------|

| Samples | | | | |
|---------------------|------|-------|------|--|
| | Α | В | С | |
| Mean time (minutes) | 1.50 | 2.30 | 1.80 | |
| % Moisture absorbed | 60.5 | 56.56 | 57.8 | |



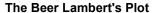


Fig. 2. Plot of absorbance against concentration (mg/ml)

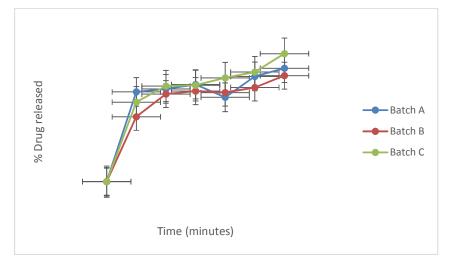


Fig. 3. Plot of percentage drug released against time (minutes)

Friability is another mechanical properties of tablets specified by the official compendia, and is expected not to exceed a value of 1.0%. It is a surface deformation of tablets, which could occur as a result of the morphology of the tablet, as the rougher the surface of the tablet, the more friable it would be. However it is worthy to note that the tablets batches failed the friability test as shown in Table 3 which were above the 1% limit. This could also be attributed to the compression pressure, air entrapment within the powder during mixing and compression respectively.

All the tablets passed the uniformity of weight test as they did not exceed the pharmacopoeia specification of 5%.

The disintegration test measures the time it takes a tablet to break into granules and smaller particles in physiological medium. It is an important step in the release of drugs from pharmaceutical dosage forms. The British pharmacopoeia requirements for disintegration of uncoated tablets is 15minutes. The result of the disintegration, compliments that of the crushing strength and friability, as the tablets exhibited a short mean disintegration time of less than 5minutes as it relates to directly compressed tablets and even occured in seconds (0.22sec, 0.35sec) except batch C which disintegrated at 1.60minutes.

This result indicates that the formulation excipients are outlined with characteristic pores influencing the tablet to disintegrate fast enough and release the active ingredient (aceclofenac). Based on the outcome therefore, the tabletting method and compression pattern adopted seems suitable for the formulation of a fast dissolving tablet due to its very rapid disintegration rate. The longer disintegration time in Batch C, could be attributed to a greater increase in the binding bridges and bonds and reduction in void spaces resulting from the combined effect of the extracted MCC and the corn starch powders and higher pressure input during compression of the power mass [1].

Dissolution study relatively gives an insight into the release of a drug from a dosage form. It is used as an indirect method of measuring drug availability, especially in assessment of formulation factors and manufacturing methods that may affect bioavailability. Result of the tablet release profile reveals that all the batches (A, B and C) had a good tablet release and dissolution profile. This was also supported by results obtained from the wetting tests conducted where all the batches formulated had complete tablet wetting within 1.5 – 2.30 minutes upon immersion to a red dye solution in a petri dish. However, the batch A containing MCC as the binder and disintegrant had the greatest release at 10minutes (56.02%), and 50minutes (51.15%), while the Batch C where MCC and cornstarch were combined in equal ratio had the greatest release at 50minutes (51.42%) while the non MCC containing batch B (cornstarch alone) had release profile peak at 60minutes (52.69%) respectively. This ability to enhance fast release of the active component from the tablet formulation therefore makes extracted microcrystalline cellulose from D. arborea stem very suitable as an excipient in the formulation of an aceclofenac fast dissolvable tablet.

The tablets properties analyzed showed good prospect following the use of aceclofenac as the API. The decreased hardness observed from the tablet formed by direct compression method recommends the suitability of the extracted MCC from D. arborea stem in comparison with corn starch when both are used alone as fast dissolving tablet excipients as it has assisted in lowering the disintegration and dissolution time of the aceclofenac tablet formulated. Based on the result therefore the extracted MCC seems to enhance quick onset of the drug action and high bioavailability of the API, if such is used as an excipient to enhance disintegration and binding of the tablet. From the study, the individual materials contributed to enhancing tablet binding and disintegration but the combination of the excipient (extracted MCC and corn starch) in a 1:1 ratio exerted the greatest effect. Therefore, combination of such excipients could be of great potential and economic benefit hence reliable substitute for standard binders and disintegrants especially in the formulation of fast dissolving tablets

6. CONCLUSION

Aceclofenac tablets from batch A- formulated with *D. arborea* MCC caused rapid disintegration than batch B made with corn starch alone. This could be due to presence of large void spaces which allowed for ease of water penetration rather than formation of bridges due to water retention effect of corn starch as in batch B, hence the extracted MCC, acted as a good tablet disintegrant while the corn starch seemed to exert more binding than disintegrant effect. Therefore the corn starch is more effective as a binder than disintegrant. Combination of the two excipients (extracted MCC and cornstarch) resulted in a synergestic binding and disintegrant action leading to rapid dissolution and release of the active drug moiety.

The extracted MCC from *D. arborea* stem therefore, seems useful more as a tablet disintegrant and combination of the MCC and cornstarch more adequate in enhancing drug release from pharmaceutical tablets. Effort should therefore, be geared towards large-scale production of MCC from the stem to cushion the economic effect of synthetic raw material such as avicel importation from foreign sources.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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