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Formulation Properties of Acetylsalicylic Acid Tablet Using Novel Starch from Cola nitida

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ABSTRACT: *The nut of Cola nitida Vent was extracted and examined for its starch constituent and physicochemical properties. The starch was isolated using 1%w/v sodium metabisulphite solution. The starch obtained had a fine texture, white, tasteless and odourless with a pH of 5.5 and moisture content of 9.67%. 75 mg acetylsalicylic acid tablet was formulated with novel starch using direct compression method. The formulated tablets conform to the pharmacopoeia standard for weight uniformity, disintegration time, friability and hardness. The values obtained from the test sample tablet were compared with the values obtained from 3 other brands of 75 mg acetylsalicylic acid tablet bought from the market. ANOVA with Duncan Hoc test was performed on graphpad instat software to determine the statistical comparison among the samples at $p < 0.05$. Values were represented as mean ± standard deviation. There was no significant ($P>0.05$) difference in the disintegration and hardness profiles of the test sample and most of the commercial brands of acetylsalicylic acid tablets.*

KEYWORDS: *kola starch, acetylsalicylic acid, physicochemical and formulation.*

I. INTRODUCTION

Starch is one of the most widely used bio-materials in the food, textile, cosmetics, plastics, adhesive, paper and pharmaceutical industries (Manek et al, 2012). The diverse industrial usage of starch is based on its availability at low cost, high calorie value, inherent excellent physiochemical properties and the ease of its modification to other derivatives (Omojola et al, 2010). As a result of competing demands for starch as food, pharmaceutical and industrial uses coupled with the need to attain self sufficiency in starch production; there is a need to find other high yield sources of starch other than cassava, maize and potato (Gebre-Mariam and Schmidt, 2006). Starch extracted from various locally available tubers and rhizomes have been studied by many researchers and have several applications in industries.

There is dearth of information on the isolation and characterization of starch from Cola nitida.
The objectives of this study was therefore to isolation and characterization starch from Cola nitida and use the novel starch in the formulation of acetylsalicylic tablet

II. MATERIALS AND METHODS

Materials: Cola nitida was purchased from Akpan Andem market in Uyo, Nigeria. Sodium metabisulphite (Sigma Aldrich, USA), Acetylsalicylic Acid, Stearic Acid, Talc (BDH chemicals ,England). Other chemicals and reagents were of laboratory grade.

Method of starch isolation

The kola starch was isolated using the method of Builders et al (2004) as modified by Omojola et al., (2010).

3kg of Cola nitida was washed in water, crushed and soaked for 1 hour in 2 L of 1% sodium metabisulphite solution at room temperature. Nuts were removed and wet milled into a homogenous fine paste using a domestic blender. The paste was dispersed in a 2L of 1% sodium metabisulphite and filtered through a muslin cloth. The suspension was allowed to settle and the supernatant decanted.

The sediment starch layer was re-suspended in sodium metabisulphite solution and the process repeated 4 times. At each stage of the washing, the suspension was allowed to stand for 90 min to allow proper sedimentation after which the supernatant was decanted. The mucilage on the starch was scraped continuously until a pure starch was obtained. The resulting starch was dried at 60° C in a hot air oven, pulverized, weighed and stored in cellophane wrap for analysis.

pH determination

2g of kola starch was shaken in water for 5minutes and the pH determined using pH meter.

Moisture content determination

3g of kola starch was weighed into a crucible and placed in an oven with a temperature of 105_oC and dried for 16-18hours to constant weight. (AACC, 2005).

FORMULATION OF ACETYLSALICYLIC ACID TABLET

75mg acetylsalicylic acid tablet was formulated by direct compression method.

Formula

	quantity per tablet	quantity per 100tablet
Acetylsalicylic acid	75mg	7.5g
Kola starch	30mg	3.0g
Stearic acid	4.5mg	0.45g
Talc	4.5mg	0.45g

Tests carried out on tablets

3 different brands of 75mg acetylsalicylic acid tablets and test sample were also evaluated.

Uniformity of weight

20 tablets were randomly selected from the different brands of acetylsalicylic acid tablet and each tablet was weighed individually on an analytical balance and the weight recorded. The mean tablet weight and standard deviation was calculated (BP, 2002).

Disintegration time test

Disintegration time test was performed using a double unit disintegration time apparatus . A 900ml beaker was filled with water in both sides of the disintegration time apparatus maintained at 37+_2°C. Six tablets were randomly selected from each brand of acetylsalicylic acid tablet for the test (BP, 2002).

Friability testing

10 tablets were randomly selected from all the brands of acetylsalicylic acid tablet available and weighed on an analytical balance. The weight was recorded and the tablets were placed in one of the drums of the Roche friabilator and rotated 100 times. After 100rotations the tablets were removed from the Roche friabilator and reweighed (BP, 2002). The weight was compared with the initial weight and the percentage friability loss was determined.

Hardness test

10 tablets were randomly selected from the different brands of acetylsalicylic acid tablet and individually placed between the platens of the hardness tester. The hardness tester was screwed until the tablets broke and the reading taken (BP, 2002). The hardness was measured in kilogram force(kgf). The pressure at which the tablet was crushed was recorded and the average hardness and standard deviations was calculated.

Results and Discussion

The physicochemical properties of kola starch are shown in table 1.

Table 1: Physicochemical Properties of Kola Starch.

PARAMETER	RESULT
Colour	White
Taste	Tasteless
Odour	Odourless
Texture	Fine
pH	5.5
Moisture content	9.67%

Table 2: Tablets properties

Brand	Weight uniformity g (mean ± SD)	Friability % loss (mean ± SD)	Hardness kgf (mean ± SD)	Distegration time (sec) mean ± SD
Test sample	0.11 ± 0.01	0.6 ± 0.11	4.06 ± 0.17	8.65 + 0.17
Vasoprin	0.15 ± 0.01	0.93 ± 0.07	4.0 ± 0.26	9.38 + 0.05
Emprin	0.12 ± 0.01	0.6 ± 0.01	4.3 ± 0.24	10.68+0.24
Microprin	0.28 ± 0.00	0.6 ± 0.06	8.0 ± 0.38	*

*Tablet did not disintegrate after 1 hour

III. DISCUSSION

Kola starch was successfully isolated from Cola nitida. The starch obtained was white, tasteless, and odourless, with a fine texture (Table 1). It has a pH of 5.5 which is the same the pH of corn starch and within the pH range of 3-9 for starches used in the pharmaceutical, cosmetic and food industries (Omojola et al, 2010).Kola starch has a moisture content of 9.67% which is within the official moisture content recommendation of starch (B.P, 2008). The maximal allowable moisture content for corn starch is 14% or less (Hayma, 2003).

Tablet properties

The percentage variations of the tablets (Table 2) as stated earlier conforms to the standard for weight uniformity which states that a tablet 80 mg or less should have a deviation of not more than 10% (Ofoefule et al, 2002).

Disintegration time test measures the time required for tablets to break into smaller particles. The British Pharmacopoeia (2008) stipulates a disintegration time of not more than 15min for uncoated tablets. Test sample tablet (8.65 ± 0.17), vasoprin (9.38 ± 0.05) and emprin (10.68 ± 0.24) disintegrated in less than 15min which is the limit for normal release tablets (Ofoefule et al, 2002). Microprin failed the test for disintegration since it took more than 1h to effect disintegration.

Statistical analysis showed that, test sample tablet (4.06 ± 0.17) had similar ($P>0.05$) hardness profile with vasoprin (4.00 ± 0.26 and emprin (4.30 ± 0.24). however, the disintegration profile of microprint was significantly ($P<0.05$) higher than the other batches..

Normal tablet hardness ranges from 4-6kgF (1kg = 1newton), (B.P, 2008).

From the study the sample tablet, vasoprin and emprin passed the hardness test for normal tablet while microprin exceeded the range for normal tablet hardness which maybe due to the type and concentration of binder used in its formulation.

The pharmacopoeal limit for friability is less than or equal to 1% (B.P, 2008). From the study, all the brands of tablet met the pharmacopoeia standard (Table 2).

IV. CONCLUSION

Some physicochemical properties of Cola nitida starch have been examined and these properties have shown to conform to the standard test for starches used for industrial purposes.

The study has shown that Cola nitida will be a good source of starch and a biomaterial for industrial use. Cola nitida starch will help reduce the burden on starch obtained from well known sources such as corn, cassava, poatao.

75 mg acetylsalicylic acid tablet formulated conformed to the official standards of disntegration time, weight uniformity, friability and hardness. The values were compared with other brands of 75 mg acetylsalicylic acid tablets and the result was positive indicating that the sample acetylsalicylic acid can be used for pharmaceutical dosage forms.

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