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Evaluation of Co-Processed Excipients for Fast Disintegration of Aspirin Tablets Prepared by Direct Compression

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

Abstract

Background: Co-processed excipients are popular for direct tablet compression and give added economic value to product formulation. Specific benefits of co-processed excipients include improved flow, compressibility, disintegrating effect, and masking undesirable properties of individual excipients.

Objective: The aim of this study is to co-process physically modified (pregelatinized) *Musa sapientum* starch with lactose by fusion and evaluate the effect of the co-processed excipients on the disintegration properties of Aspirin tablet.

M**ethods:** Co-processed excipients were prepared from pregelatinized *Musa sapientium* starch and lactose by fusion in ratios of 1:1, 1:2 and 2:1 (BL1, BL2, and BL3 respectively) and evaluated for particle size, pH, moisture content, flow and swelling properties. Aspirin tablets were formulated using the excipients at ratio 5% $^{W}/_{W}$ by direct compression. (FM1, FM2, FM3 respectively). Sodium starch glycolate (FSG) tablet was also prepared as the standard and the formulations were assessed for hardness, friability and disintegration time. Data were analyzed using ANOVA.

Results: The co-processed excipients possessed excellent flow having a Carr's index between 18.39-20.78 and Hausner's ratio ≤ 1.25.BL1 had the highest swelling profile while BL3 had the lowest. Formulation FM1 and FM2 had the highest tensile strength of (0.16 N/cm2). Disintegration time of FM3 (4.28 min) was comparable to that of FSG (4.15 min).

Conclusion: Co-processing pregelatinized *Musa sapientium* starch and lactose by fusion influenced tablet disintegration and has potential to be used in manufacture of fast dissolving tablet formulations.

Keywords: Co-processing; *Musa sapientium* starch; Lactose; Disintegration

INTRODUCTION

Solid dosage forms by estimation constitute about 90% of all dosage forms used in the systemic administration of therapeutic agents (Jivraj *et al*., 2000). Tablets as a dosage form have widespread uses as a result of their convenience, stability, ease of manufacture and also the diversity of tablet types. Tableting components known as excipients contribute significantly to the successful formulation of robust tablets by modulating their processability, stability, and bioavailability (Mshelia *et al*., 2015).

Starches as an excipient are used in the pharmaceutical industry for a wide variety of reasons, such as a diluent, disintegrants, a glidant, or as a binder. Excipients play a major role in the activity of an active ingredient as regards its delivery, safety and the overall cost of a product. (Kundusubrata *et al*., 2013).

Disintegrants enable tablets and capsules to break down into smaller fragments so that the drug can be released for absorption. Modified starch, also called starch derivatives, is prepared by physically, enzymatically, or chemically treating native starch to change its properties. There has been increasing preference for direct compression (DC) as the method of choice in the formulation of tablets due to obvious advantages including shorter processing time involving fewer unit operations and suitable for heat or moisture sensitive active pharmaceutical ingredients (API) (Odeku *et al*., 2003). Over the years, research in the area of excipient development has focused on the co-processing of existing excipients to generate a novel excipient with improved functionality. (Saha *et al*., 2009).

Direct compression tablets are tablets that are compressed directly from powder blends of the active ingredient and suitable excipients. No pre-treatment of the powder blends by wet or dry granulation procedures is necessary. Limitations of direct compression tablets are segregation, cost, low dilution potential, re-workability, lubricant sensitivity, variation in functionality. Co-processed excipients combine brittle and plastic materials, such as lactose and starch, to create a complementary influence on flow and compressibility. Jacob *et al.*, 2007. Starch and lactose combined would produce a product with better flow, compatibility, and disintegrating properties (Anwar *et al.*, 2011).

Banana are a healthy source of fiber, potassium, vitamin B_6, vitamin C, various antioxidants and phytonutrients. Banana starch has the potential to be a commodity starch because it grows in abundance with little or no artificial inputs and also because of its specific properties and its potential production from low-cost.

METHODOLOGY

Materials

Magnesium stearate (Spectrum Chemicals, USA), Lactose BP, Sodium starch glycolate (BDH Limited, Poole, England), Talc (Sigma Aldrich, USA). *Musa sapientium* fruits were obtained from local farmers in Ago-Iwoye, Ogun State, Nigeria and the starch was extracted at the Pharmaceutics laboratory of the Faculty of Pharmacy, Olabisi Onabanjo University, Ogun state, Nigeria.

Starch isolation

Starch was extracted from the unripe banana by a modified method as described by Ganiyat *et al.*, 2017. The fruits were peeled and the pulp was diced into 5-6cm cubes (5kg total weight). They were then macerated in a blender for 3 minutes. The slurry was filtered through a muslin cloth followed by a sieve of 150µm to remove impurities. The supernatant was discarded, and then the sediment (starch) was washed several times with distilled water to remove impurities from the starch. It was then bleached with 2L of 0.075% (*w*/*v*) sodium metabisulphite for 6 h. The starch oven dried at a temperature of 50ºC overnight. The dried starch was then packed in an air-tight polyethene bag prior to analyses.

Pregelatinization

The aqueous starch slurry was made with 500g of native powdered starch and 2L of distilled water in a beaker which was heated in a water bath at 90ºC with continuous stirring for 45 minutes until a thick paste was obtained. The resultant paste was dried in a hot air oven at 40ºC for 48 hours. The starch flakes obtained were powdered using a laboratory mill and passed through 500µm sieve mesh and stored in an air-tight bottle.

Co-processing of banana starch and Lactose

Pregelatinzed banana starch was suspended in water to obtain a starch dispersion of 40% w/w. A paste was formed by stirring the dispersion over a water bath at 50ºC for 6 minutes. Lactose was incorporated into the paste by stirring over the water bath until homogenous, the paste formed was then oven dried at 40ºC for 2 hrs in a tray (Olayemi *et al*., 2021). The dried mass was milled using pestle and mortar and the powder was packaged in a suitable container and kept in the desiccator until further use.

Table 1: Composition for the preparation of co-processed excipients

Code	Starch: Lactose	Starch(g)	Lactose (g)
BL1	1:1	25	25
BL2	1:2	33.3	16.7
BL3	2:1	16.7	33.3

Evaluation of co-processed excipients

Particle size and morphology

The morphology and surface characteristics of the starch sample were analyzed using scanning electron microscopy (XL 30 ESEM, Philips, Eindhoven, Netherlands) at an accelerating voltage of 30 KV while the particle sizes of the starch sample were determined using the optical microscopy method.

Swelling power

The co-processed excipient (1 %w/v) was dispersed in water inside a beaker and heated for about 30mins in a water bath thermostated at 37ºC while stirring intermittently. The dispersion was centrifuged (Heraeus Sepatech Labofuge Ae, GmbH, Germany) for 30 minutes at 1500 rpm. The supernatant was then decanted, and the weight of the wet mass was calculated. The following equation was used to calculate swelling power (SP);

$$SP\ (\%) = \frac{weight\ of\ wet\ mass}{weight\ of\ dry\ powder} \text{ X } 100 \text{ …………….. (1)}$$

The swelling power of the co-processed excipient at 40, 50, 60, 70, 80, and 90°C was also assessed using this method.

Moisture content

This was determined using an infrared heating unit-equipped moisture tester (Ohaus MB 45, USA). Five (5 g) of the co-processed excipient was placed in the analyzer for 15 minutes at 105°C drying temperature, and the analyzer automatically calculated the excipient's moisture content in percentage.

pH determination

The pH of the supernatant liquid was measured using a pH meter (3510 model, Jenway, England) after dispersing a 2%w/v slurry of the excipients

Fourier Transformed Infrared (FTIR) Spectroscopy

FTIR Spectra were obtained for native banana starch, pregelatinized banana starch, lactose and the co-processed excipients using the spectrophotometer Spectrum BX 273, Perkin-Elmer, USA (Emeje *et al*, 2007). Pellets of the sample were scanned separately using KBr as dispersing vehicle. The same was repeated for each of the co-processed excipients. Signal averages were obtained at a resolution of 4 cm^{-1} and a scanning range of 350–4400 cm^{-1}

Angle of repose

The orifice of the funnel to be used was plugged and 5g of the co-processed excipient was poured into the funnel (Olowosuli, *et al,* 2011). The orifice (please indicate the size of the funnel orifice) was opened and the height and diameter of the powder heap formed were determined and the angle of repose (A) was calculated equation (2);

$$A = \tan^{-1} \frac{\text{heightof heap}}{\text{radius of heap}} \text{….………………..……… (2)}$$

Bulk and tapped densities.

The bulk volume was recorded as the volume occupied by the co-processed excipient (5 g) in a measuring cylinder (100 mL). The measuring cylinder was tapped in the Stamp volumeter (STAV 2003JEF, Germany) and the volume after tapping was recorded as the tapped volume. Bulk and tapped densities were calculated using equation (3 and 4);

bulk and tapped densities;

$$\text{Bulk density (g/ml)} = \frac{weight\ of\ powder}{bulk\ volume} \text{ …………. (3)}$$

$$\text{Tapped density (g/ml)} = \frac{weight\ of\ powder}{tapped\ volume} \text{ ……… (4)}$$

Hausner ratio (HR) and Compressibility Index (CI).

These were calculated from data obtained from the

$$HR = \frac{tapped\ density}{bulk\ density} \text{ …………………….....…..…… (5)}$$

$$CI = \frac{tapped\ density - bulk\ density}{tapped\ density} \text{ X } 100 \text{ …. ….…… (6)}$$

Preparation of aspirin tablets using the co-processed excipients

Batches of 30 tablets each were prepared using the direct compression technique as in Table 2, using magnesium stearate and talc as lubricant and glidant respectively. A positive control batch was prepared using sodium starch glycolate (SSG), as super-disintegrant. Using a 10 mm punch and die set, 250mg of the powdered mixture was compressed into tablets using a single punch tableting machine (type and country of origin) operating at compression pressure of 10 Nm^{-2}. To allow for elastic recovery, the manufactured tablets were stored for 24 hours before evaluation.

Table 2: Formulations for preparing Aspirin tablets

Ingredients(mg)	Tablet(1:1)	Tablet(1:2)	Tablet(2:1)	Tablet(SSG)
Aspirin	75	75	75	75
Starch: Lactose(1:1)	12.5	-	-	-
Starch: Lactose(1:2)	-	12.5	-	-
Starch: Lactose(2:1)	-	-	12.5	-
SSG	-	-	-	12.5
Magnesium Stearate	12.5	12.5	12.5	12.5
Talc	qs	qs	qs	qs
Total	250	250	250	250

SSG-Sodium starch glycolate

Evaluation of aspirin tablets prepared with co-processed excipients

Uniformity of weight

The average weight of ten (10) randomly selected tablets were determined using an analytical balance (Mettler Toledo, ME303E/02, USA).

Tablet diameter and thickness

Using a micrometer screw gauge (Mitutoyo IDC-1012EB, Japan), the diameter and thickness of ten (10) randomly selected tablets were measured, and the average was calculated.

Friability test

Twenty tablets were weighed collectively (W1) and loaded into the friabilator (Erweka 66939 Friabilator, GmbH, Germany), which was set to rotate for four minutes at a speed of 25 rpm. The tablets were then dusted, re- weighed (W2), and the percentage of friability (F) was computed as follows:

$$F\ (\%) = \frac{W1-W2}{W1} \text{ X } 100 \text{ ---------- (8)}$$

Disintegration test

Disisntegration time was determined using 6 tabkets per batch in the disintegration tester (Erweka ZT4-4, Germany) containing distilled water at a temperature of 37±0.5ºC.

Tablet hardness

Using the hardness tester (Erweka 65770 hardness tester, GmbH, Germany), the hardness (kgF) of five (5) randomly chosen tablets was assessed, and the mean was computed.

Tensile strength

The formula below was used to calculate the tensile strength (TS) using the tablet's diameter (d), thickness (t), and hardness (F).

$$\text{TS } (N/cm^2)\ \frac{2F}{\pi dt} \text{ ..... (7)}$$

Data analysis

Statistical analysis was carried out using the analysis of variance (ANOVA) on the computer software GraphPad Prism(R) 4 (Graphpad Software Inc. San Diego, CA, USA) to compare the differences between the different formulations at 95 % confidence interval. Probability, p values, less than or equal to 0.05 were considered significant.

RESULTS AND DISCUSSION

Particle size

The particle size of the native and modified starches and co-processed excipients are presented in Table 3. Particle size indicates how small or big the size of the particle. The size of a drug directly influences its absorption behavior, bioavailability, content uniformity, dissolution and flow-ability. Particle size also has significant effect on the densification of powders during die filling, particle rearrangement, fragmentation and elastic/plastic deformation

Adetunji *et al*., 2015. Pregelatinized starch had the highest particle size of 280 microns and starch:lactose(1:1) had the lowest particle size of 25 microns. The ranking of the mean particle size was in the order: PBS > BL3 (2: 1) > NBS > BL2 (1: 2) > BL1 (1: 1).

Moisture content

In product formulations, moisture content (MC), which refers to how much moisture is contained in a material, is crucial for a product's stability. Fast and accurate moisture measurement is crucial for control of starch molding production plants and for the safe storage and transportation of the final product.

pH

pH is a measure of hydrogen ion concentration, a measure of the acidity or alkalinity of a solution. Generally, the higher the pH value the higher the swelling power. Shieldneck and Smith (1971) reported similar findings. The pH scale usually ranges from 0 to 14. Aqueous solutions at 25°C with a pH less than 7 are acidic, while those with a pH greater than 7 are basic or alkaline. As shown in table 3, all samples show acidic behavior while NBS 7.1 shows a neutral behavior.

Crystallization, loss of powder flow, loss of mechanical properties of the product in addition to promoting microbial growth during storage are the result of the presence of moisture in any formulation Adane *et al*, 2006. It is therefore important to ensure that the amount of moisture in any formulation is within specified limits. All the products had inherent moisture content within the specifications of 15 % for starch-based excipients (B.P, 2002) as shown in Table 3. NBS has the highest value of moisture content, whereas BL2 has the lowest amount. This demonstrates that the flow property of BL2 is superior to NBS.

Flow properties

Parameters such as particle density, tapped density, bulk density, angle of repose, Hausner's ratio, Carr's compressibility index, were used in the assessment of flow properties of the powder samples and are also presented in Table 3. Most pharmaceutical powders have densities in the range of 0.1-0.7 g/mL (Hancock *et al*.,2003). The particle density of the excipients fell within the standard range of starches. The ranking of the particle density was PBS > NBS > BL1 >BL3 >BL2 while that of bulk density was BL2 > BL1 > BL3 > PBS > NBS. The Carr's index is a measure of flowability and compressibility of a powder while Hausner's ratio (ratio of tap to bulk density) provides an indication of the degree of densification. BL1 showed a better flow than the rest of the starch sample followed by BL2 based on their Hausner's ratio in table 3. The lower the Carr's index, the better the flowability but the higher it is the poorer the compressibility (Rakhi *et al*, 2008). Carr's index of 5-10, 12-16, 18-21, and 23-28 represent excellent, good, fair and poor flow properties respectively. Angle of repose as an indication of powder flow properties and usually follow standard range. When the angle of repose is more than 50° flow is poor, while below 30° indicates good flow and above 40° is suggestive of irregular flow. BL2, BL3 and BL1 indicates good flow while BL1 indicates irregular flow and NBS indicates poor flow. The result for WBC were generally the same though, it was high for BL3 and low for BL1.The ranking for Water Binding Capacity (WBC) is as follows BL3 > NBS > PBS > BL2 > BL1.

Table 3: Physicochemical and material properties of the excipients

Parameter	**NBS**	**PBS**	**BL1(1:1)**	**BL2(1:2)**	**BL3(2:1)**
Particle density (g/cm2)	0.42±0.02	0.61±0.01	0.57±0.03	0.33±0.03	0.35±0.03
Bulk density (g/cm2)	0.38±0.06	0.54±0.03	0.67±0.01	0.71±0.02	0.59±0.02
Tapped density (g/cm3)	0.54±0.01	0.77±0.01	0.91±0.02	0.87±0.01	0.83±0.01
Angle of repose (°)	53.20±0.03	24.22±0.03	33.22±0.01	20.13±0.04	23.58±0.03
Carr's Index	26.37±0.01	20.87±0.02	24.46±0.01	18.39±0.02	28.92±0.05
Hausner ratio	1.26±0.04	1.28±0.05	1.25±0.03	1.26±0.02	1.41±0.01
pH	7.10±0.03	6.20±0.02	4.60±0.02	4.8±0.03	5.4±0.03
Moisture content (%)	11.00±0.02	6.80±0.04	7.60±0.03	7.0±0.04	5.0±0.02
Particle size (microns)	62.5±0.03	280±0.02	25.0±0.03	120±0.01	62.5±0.03
Water Holding Capacity (%)	77.65±0.03	74.20±0.01	72.56±0.02	72 82±0.02	78.11±0.02

NBS - Native banana starch; PBS - Pre-gelatinized banana starch
BL1 - lactose by fusion in ratios of 1:1; BL2 - lactose by fusion in ratios of 1:2
BL3 - lactose by fusion in ratios of 2:1

Swelling capacity

The ability of granules to absorb water and enlarge in the presence of heat is measured by their swelling capacity (Olayemi *et al*., 2021). Even though to its applicability in industrial settings, this measure is also used to assess the behavior of materials over a wide temperature range. The swelling profile of similar exicipients is shown in Figure 1. Although no further increase was observed at 80°C, being that there was no further increase in granule size, an overall increase in swelling was observed with increase in temperature. The swelling peaked at 80°C, indicating that at these temperatures (37–80 °C), these excipients can be successfully used in formulations. High swelling indices imply that the materials would cause faster tablet disintegration. Swelling is another mechanism by which materials, particularly those containing starch, cause tablet disintegration. The results reveal that the co-processed excipient, BL3 is likely to cause tablets to dissolve more quickly than BL1 or BL2 can.

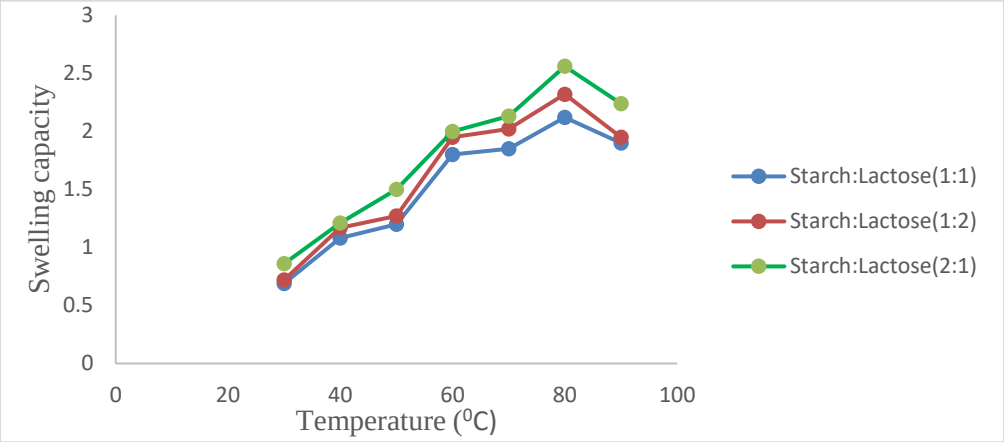


Figure 1: Swelling capacity of the co-processed excipients

Scanning Electron Microscopy

Scanning Electron Microscopy **(**SEM) analysis is routinely used to generate high-resolution 2D images of shapes/surface morphology of powder samples by focusing beam of high-energy electrons to generate a variety of signals at the surface of solid specimens. The SEM images of the starches and the co-processed excipients are shown in Figure 2. The co-processed excipients' larger agglomerates suggested the creation of a new polymer, (Okunlola, 2021). NBS had an extended structure in scanning electron micrographs, whereas PBS and lactose exhibited clumped irregular shapes, and CBS (co-processed banana starch) exhibited triangular agglomerates.

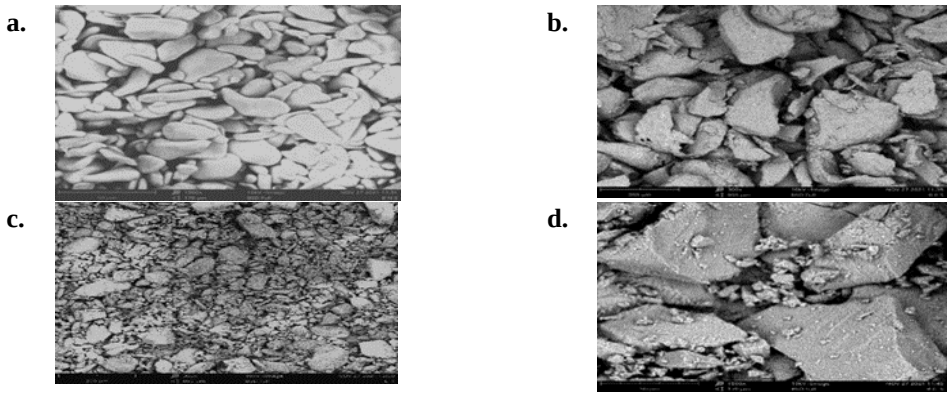


Figure 2: SEM images (x1500) of (a) native banana starch (b) pregelatinized banana starch, (c) lactose (d) co-processed banana excipient

Fourier Transmission Infrared Spectra (FT-IR)

The FTIR spectroscopy is used to determine functional groups and structure of a chemical substance by passing Infra-red (IR) radiation through the sample and measuring the fraction of the radiation that is absorbed at a particular energy.

The FTIR spectra for the starches and co-processed excipients are shown in Figure 3. The spectrum for the NBS stretches at 3268 cm^{-1} and 3525 cm^{-1} which depicts hydroxyl functional group at 2899 cm^{-1} and 2933 cm^{-1} depicts cycloalkane functional group, 670 cm^{-1} depicts C-S linkage, 760 cm^{-1} depicts C-H group and 1017cm^{-1} and 1073cm^{-1} depicts C-O-C group. For CBS stretches at 3257cm-1 depicts hydroxyl group, 1429 cm-1 depicts aromatic ring, 995cm-1 -1077 depicts C-O-C group and 764cm^{-1} C-H group.

For PBS stretches at 3257 cm^{-1} depicts hydroxyl group, 760cm^{-1} to 846 cm^{-1} depicts C-H group and 928cm^{-1} to 1148 cm^{-1} depicts C-O-C group.

For Lactose stretches at 3261 cm^{-1} to 3526 cm^{-1} depicts hydroxyl group, 1423 cm-1 depicts aromatic group, 1032 cm^{-1} to 1166 cm^{-1} depicts C-O-C group, 670 cm^{-1} depicts C-S group and 749 cm^{-1} depicts C-H group. The results of the tablet, mechanical and release properties of the formulated aspirin tablets containing the co-processed excipients and SSG are presented in Table 4

Uniformity of weight

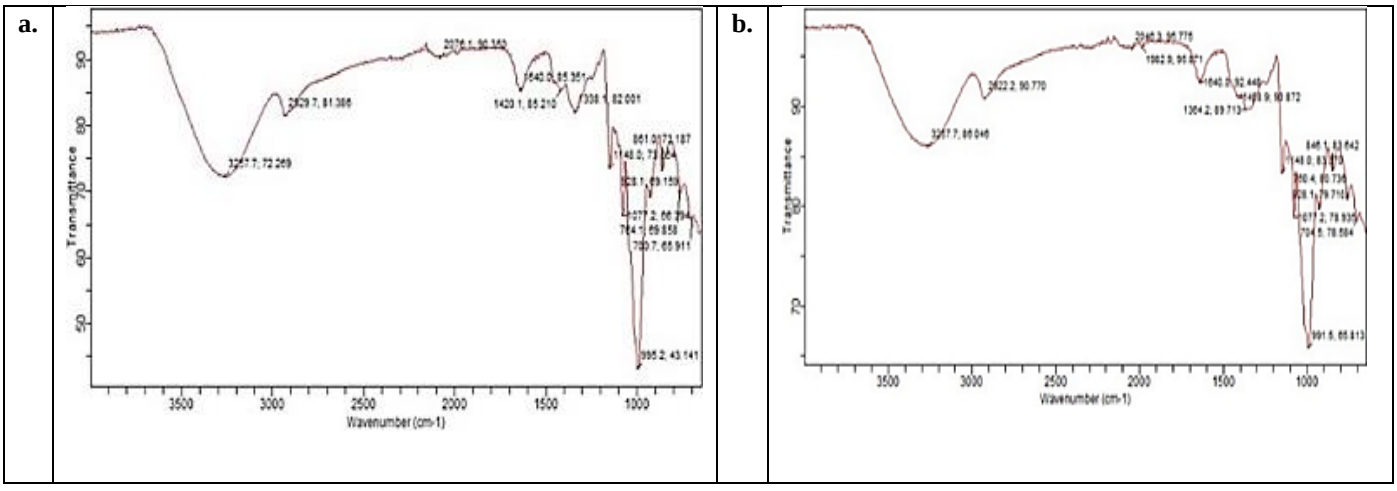
The average weight of all tablets was within the range of 235 and 246 mg, which is within the 5% range that is allowed for variance in tablets as per USP specifications (USP, 2016). Uniformity in weight of tablets has been attributed to the uniform flow of the formulation mix during the filling of the die leading to compression. This is crucial since poor flow will result in a large range in tablet weight, which could negatively affect the consistency of the tablets' contents and may lead to inconsistent bioavailability of the active ingredient (Apeji *et al*, 2017).

Tablet thickness and diameter

When packing tablets, the thickness and diameter must be taken into account because different tablet sizes will have an impact on the amounts required for the final packaging vessel, Chaturvedi *et al*, 2017. Tablet diameter and thickness were respectively in the range of 2.75 mm to 3.95 mm and 10.01- 10.12mm.

Hardness of the tablet

One of the criteria used to describe a tablet's mechanical strength is its hardness, which illustrates how well the tablet can survive the operations required for its production, transit, storage, and use. According to reports, uncoated tablets need to be between 4 and 8 kgF hard, though the exact requirements can change based on the ingredients employed in the formulation Quodbach, *et al.*, 2014. Table 4 shows tablet hardness to be within this limit in the order FM1 (7.8 kgF)> FM2 (7.4 kgF) >FSG (6.5kgF)> FM3 (6.0kgF). Tablets prepared with the equal concentration of starch and Lactose (FM1) were found to be the strongest signifying that increasing the concentration of starch or lactose in the co-processed excipient (FSG, FM2 and FM3 respectively) contributed to decreasing tablet strength (Odeku *et al.*, 2007).



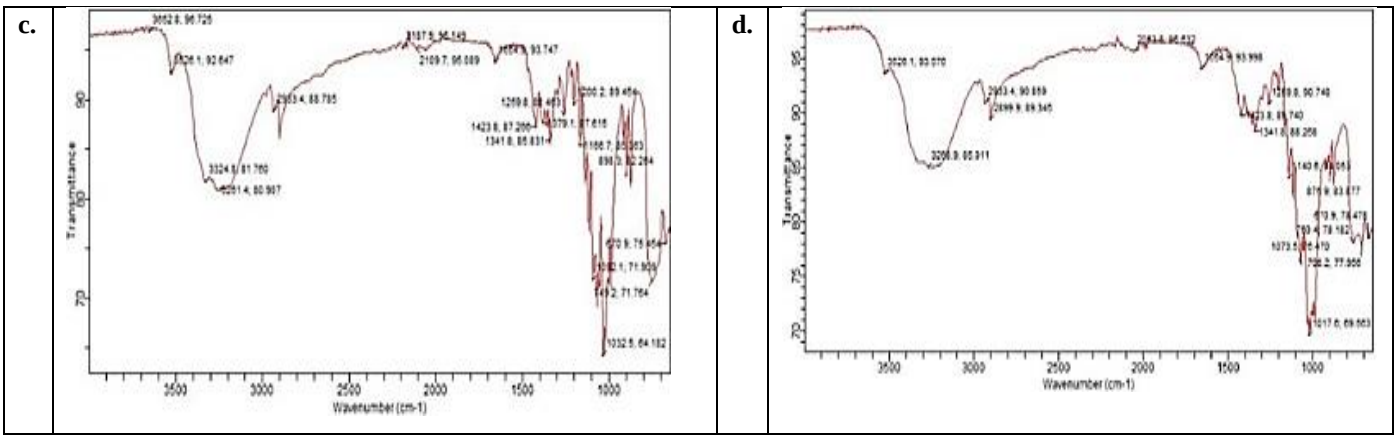


Figure 3: FTIR spectra of (a) native banana starch (b) pregelatinized banana starch, (c) lactose (d) co-processed banana excipient

Tensile strength

FM1 and FM2 was observed to have the highest tensile strength (0.16N/cm2 and 0.16N/cm2) while FSG had the least (0.11 N/cm2) indicating that with increase in co-processed excipient, there was decrease in tensile strength. Although reports have demonstrated that high concentrations of starch disintegrants could have the ability to weaken tablet strength. Odeku *et al.,* 2007

Friability

Friability is defined as the percentage of weight loss of powder from the surface of the tablets due to mechanical action. This test is performed to measure the weight loss during transportation. It is a supplementary test for Uncoated / Compressed Tablets other than physical measurement e.g. Hardness (Tablet Breaking Force). Friability measures the strength of the tablet via resistance to fracture and abrasion. All the tablets had values between 0.2and 0.4% which is < 1 % specified as an acceptable limit (Saleem *et al*., 2014).

Disintegration

Disintegration is the mechanical breakdown of a tablet into smaller particles as a result of the breakage of inter-particle interactions generated during tablet compression (Silva *et al.,* 2018). If disintegration does not occur, only active ingredients near the surface of the tablet dissolves and so are available for absorption activity (Silva *et al.,* 2018). All the tablets were observed to disintegrate between 4.15 and 7.37 min which is within the official specification for disintegration of immediate release uncoated tablets (B.P, 2002). Disintegration time of FM3 (4.28 min) was found to be similar to that of the reference formulation (FSG; 4.15 min) but significantly different at $p < 0.05$ from that of FM2 (6.32 min) and FM1 (7.37 min). Shorter disintegration time of FM3 could be attributed to the composition of the excipient used in its formulation (starch to Lactose; 2:1) in which the higher starch content enhanced more rapid water uptake and breakdown of the particles holding the tablet together. This illustrates how a higher starch concentration affects the quick breakdown of prepared excipients. Disintegrants are known to rapidly absorb water and expand, creating an internal force that is greater than the force keeping the particles together and causing the tablet to crumble. (Liberman *et al.,* 1989).

Table 4: Tablet properties of Aspirin tablets formulated using the prepared co-processed excipients

Superdisintegrant	Code	Weight (mg)	Thickness (mm)	Diameter (mm)	Hardness (Kg/F)	Tensile Strength (N/cm^2)	Friability (%)	Disintegration time (min)
Starch: Lactose1:1	FM1	246±0.01	3.12±0.02	10.05±0.04	9.8±0.02	0.16±0.02	0.4±0.01	7.37±0.03
Starch: Lactose1:2	FM2	241±0.03	2.75±0.01	10.07±0.01	7.4±0.02	0.16±0.03	0.2±0.01	6.32±0.04
Starch: Lactose2:1	FM3	234±0.00	3.00±0.01	10.12±0.03	6.0±0.03	0.12±0.04	0.3±0.02	4.28±0.05
SSG	FSG	240±0.01	3.95±0.04	10.01±0.02	6.5±0.01	0.11±0.01	0.2±0.01	4.15±0.01

CONCLUSION

From this study Aspirin tablets were successfully prepared by direct compression method using pregelatinized *Musa sapientum* starches co-processed with Lactose. Co-processed excipients prepared from

Musa sapientum starch and lactose by fusion were found to influence tablet mechanical strength and disintegration.

The incorporation of co-processed excipients with a higher starch content (BL3) in the aspirin tablet formulation (FM3) demonstrated faster wetting than the formulation using sodium starch glycolate (FSG), the reference disintegrant, while also having comparable disintegration times with the same reference formulation. This study demonstrates that, in place of imported and more expensive disintegrants, the co-processing of *Musa sapientum* starch and Lactose (2:1) by the fusion method can be used to create fast-dissolving tablet formulations.

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