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EVALUATION OF COMPRESSION AND COMPACTION CHARACTERISTICS OF PARACETAMOL TABLET USING FORMULATED CO-PROCESSED BINDER EXCPIENTS FROM PLANTAIN STARCH AND TRAGACANTH GUM

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Keywords:

Plantain starch, Tragacanth gum, Co-processing, Novel excipients, Tablet

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ABSTRACT: Purpose: The research developed a co-processed excipient from primary excipients. The novel excipients obtained from mixture of plantain starch and tragacanth gum were added to paracetamol granulation. This was with a view to enhance production of tablet with higher mechanical integrity without compromising its disintegration in gut or aqueous medium. **Method:** Unripe but mature plantain fruits were peeled to extract starch, after soaking. The starch was milled, sieved, oven-dried and re-sieved. Starch powder obtained was co-processed with tragacanth gum BP by two methods: (1) Co-grinding technique was achieved by geometric mixing of the starch and the gum in ratios, 1:3, 1:1 and 3:1. (2) Co-fusion was carried out by suspending tragacanth gum powder in a distilled water placed on water bath at temperature 50 °C. It was stirred until a mucilage was formed. Plantain starch was incorporated, when hot, in the above specified mixture ratios. Each co-processed excipient was weighed and added in concentrations, 3, 4 and 5% w/w, to the paracetamol granules as binders. The physical, compaction and mechanical properties of the granules were evaluated, using established procedures. The results were analyzed by a 2-way analysis of variance (ANOVA) with a p-value < 0.05 considered significant. **Results:** The results showed improved flow, compaction properties and better mechanical strength on the paracetamol granules, when 3% w/w co-fused (1:3) excipient was incorporated as a binder. It further revealed that binder excipient produced significant effects on the novel excipient functionalities, p< 0.05 considered significant. **Conclusion:** The study concluded that co-processing native plantain starch with tragacanth gum in ratio1:3, at 3% w/w concentration, when added to paracetamol granules resulted into a novel binder excipient with better pharmaceutical properties than all the excipients used.

INTRODUCTION: Drug substances are rarely administered alone; they are rather given as part of formulation in combination with other non-pharmaceutical substances, called excipients. In this case, the drug and the excipients must be compatible with one another to produce a drug product that is stable, efficacious, attractive, safe and easy to administer.

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The excipients in the tablet formulation are added in order to achieve intended functions such as, either to increase the bulk of the product, added as diluents, improve manufacturability, flowability, compressibility, act as binders that maintain tablet mechanical integrity or contribute to enhance disintegration and dispersion for gut dissolution [1].

Tablets are solid forms of mechanically strong drugs of different sizes and shapes, bond together under pressure in order to be delivered as a unit [2]. Since tablets can be made directly from powders and granules, the conditions, however, is that material used must have good compressibility and compactability to form a compact [3]. There are various types of tablets, ranging from swallow able, effervescent, chewable, sublingual to coated tablets. The advantages of tablets range from being cost-effective to manufacture compared to other drug delivery systems such as transdermal patches, injections, aerosols, *etc*. Other benefits of tablets are: (i) they are convenient to administer for/by patients. (ii) High prescription dosing. (iii) patient compliance.

Pharmaceutical powders comprise particle size distribution of between 50-1500 um (using sieve analysis) with varying from irregular, coarse, spherical to rhombical. Powders are characterized by segregation and agglomeration problems. While the particle size of powder has correlation with its flowability the shapes have an effect, not only on flowability, but also on consolidation, compression and compaction of the particles [4]. Pharmaceutical powders possess both inherent properties (particle size, shape and density) and derived properties such as Carr's compressibility index (CI), Hausner's ratio (HR), anlge of repose (AOR), *etc*. While the HR evaluated the ratio of powder tapped density to it's bulk density, CI measures the tendency of a powder to consolidate and this is related inversely to powder's flow. AOR is used to measure powder flow and it is the maximum angle between the plane of powder and horizontal surface. Tensile strength (TS), friability, crushing strength-friability/Disintegration (CSFR/DT) index evaluate the mechanical Integrity of the compact. It is well known that the nature of powders used and processing conditions are crucial for blend properties which invariably influence mechanical characteristics of the tablet formed.

Literature Review:

Compaction of Pharmaceutical Powders: The term, compaction is defined as the concurrent process of compression and consolidation of a two phase system, as a result of applied pressure. Compaction equations correlate the state of compaction parameters such as porosity, volume or density to the applied pressure [5]. The process of tablet formation is divided into three stages namely, die filling, compaction and tablet ejection. Powder materials are classified into two types based on their characteristic behaviour, viz: (i) brittle materials (ii) ductile materials. For example, standard pharmaceutical excipients such as microcrystalline cellulose (MCC) and certain pharmaceutically active ingredients (API) e.g. paracetamol, metformin, ibuprofen and mefenamic acid are materials difficult to compress in tableting. APIs and pharmaceutical excipients are often classified as brittle or ductile. This is based on their yield pressure and are determined by the Heckel analysis [7].

Brittle Materials: These materials undergo extensive fragmentation which generally result in tablets of relatively high porosity. This is due to formation of large number of bonding points that prevent further volume reduction.

Ductile Materials: The materials will often result in tablets of low porosity, upon compression. This is due to higher degree of plastic deformation that enables the particles to move very close to one another.

Compression and Compressibility: Compressibility of pharmaceutical powders is referred to powder's ability to change its volume, when subjected to pressure and it has been used as an indirect method to measure the ability of the powder mass to result into solid compacts. Powders are the most used materials in the pharmaceutical industry and are difficult to be characterized. This is due to their own heterogeneity. Powders with certain characteristics are deemed to have good compressibility. In other words, such powders are suitable to be made into tablets through compression process. The moisture content and powder size distribution affect the powder's bulk density which are important in mechanical characterization of powder. Also, a close packing (tapped density) affects powder compression [8].

Consolidation Index and Rate of Consolidation: Consolidation of powders may reflect the inter-particle movement which results in measurable flow of powders. A change in density due to applied pressure has also been used as an index for

the consolidation behavior of powder. Intercept C is the consolidation index and slope K of the graph is the consolidation rate. An increase in consolidation index (C) is synonymous to increase in packing of the powder bed. Consolidation ensures a more effective packing order.

Compactability: Compactability sums up the powder's ability to form solid compacts from initial small particles' powder mass and it can be assessed by measuring the tensile strength of formed compact. During the manufacture of tablets, measures are taken to assure that they possess a required mechanical strength to avoid breaking when handling, while ensuring its disintegration after administration. Hence tensile strength is an essential parameter for consideration [2]. Tensile strength is a property of the compressed compact which measures the ability of a tablet to withstand forces that tend to pull it apart or to fracture it. Unlike the tablet's crushing strength which is determined by measuring force required to break the tablet into half, when applied diametrically. Tensile strength is a consistent basic property that measures tablet strength when the size / dimensions of the tablet change.

Tabletability: Tabletability describes both compaction process and mechanical properties of the tablet formed by providing information on the effectiveness of applied pressure in increasing tensile strength. This thus relates the compaction pressure to tablet strength. Tabletability is particularly useful because it clearly describes the effect of over-compression that results into tablets with lower tensile strength at higher pressures which invariably results into tablet defects such as lamination and capping [10]. Similarly, it has been shown that tensile strength of tablets made from a single compound depends on their porosity, irrespective of tablet dimension. In the same vein, there is a linear correlation between the tensile strength of tablet of binary mixture system with the percentage of its mixture. Tablet's tensile strength increases with compression pressure and decreases when the active pharmaceutical ingredients (API) is increased [2].

Granulation: Granulation is particle engineering steps that create excipient/API mix, improve flowability, compressibility and content uniformity. Without granulation there is possibility for segregation of dissimilar material during unit operations. Generally materials intended for compaction into tablet must possess two characteristics: (i) fluidity or rheology and (ii) compressibility. The ideal physical form for the flowability is spheres [11]. Spheres offer minimum contact surfaces between themselves and with the walls of the machine parts. But unfortunately, most materials do not easily form spheres. However shapes that approach spheres improve flowability. Granulation is the pharmaceutical process that attempts to improve the flow of powder materials by forming sphere-like or regularly shaped aggregates called granules [13].

Dry Granulation: This is a method employed to produce granules void of a liquid medium to enhance bonding between primary particles. Dry granulation is essentially important for drugs that are moisture-or heat-sensitive or for drugs that cannot undergo the drying process of wet granulation. The major disadvantage of the technique is, it can lead to the production of a large amount of fines of un-compacted materials.

Wet Granulation: This is a versatile method of granulation which is mostly applied to very fine and fluffy powders that are difficult to compress e.g. paracetamol powder. The process involves the massing of a blend of dry powders with a granulating fluid which results into production of finer, more free-flowing granules with improved flow, compressibility and content uniformity. The active pharmaceutical substances cum excipients are mixed as to achieve a homogenous mixing. This is followed by wet massing of the powder mix using the granulating fluid that contains binder which is usually in aqueous form. It can be added as slurry, solution or as suspension. The addition of granulating fluid results in the formation of bonds between particles. The resulting mass is wet-screened through a suitable sieve. The screened mass is then oven-dried. About 70% of the pharmaceutical industrial granulations are done by wet granulation. Easier handling, reduction of dust and fines, improved flowability, increased bulk densities, better uniformity of content cum reduced powder segregation during processing are among the numerous advantages the technique affords.

Excipients: There have been increased and advanced research activities in the field of excpients devolopment. And this has been directed towards the discovery and manufacturing of highly functional directly compressible excipients. Excpients are any other components other than the active pharmaceutical ingredients (APIs) that are added to, either increase the bulk of the product, function as lubricant, improve tablet's compressibility or to maintain tablet's mechanical strength.

Co-processing of Excipients: Co-processed excpients in tablet formulation have been shown to display superior improved performances over the conventional excipients. This is achieved by a science of particle engineering in which two or more excpients are combined into a single multifunctional excpient known as novel excipient. It provides a functional synergy of the interacting excpientscum masking the undesirable properties of the individual components [15, 16]. The main objective of co-processing is to design a product with added value by a balance of its functionality as it is generally done with a combination of materials that exhibit plastic deformation and brittle fragmentation characteristics. Co-processing must, neither bring chemical changes not toxic effects in excpients.

The main objectives of this research was to:

1. Develope a co-processed excpient from primary excipients- plantain starch and tragacanth gum BP;
2. Formulate paracetamol tablets using the co-processed excpient;
3. To evaluate the physical and compaction characteristics;
4. And to determine the mechanical properties of the paracetamol tablets.

The study showed that the method of co-processing influenced the properties of the resulting novel excipient.

MATERIALS AND METHODS

Materials: Paracetamol powder B.P (Manufactured by Tianjin Bofa, Pharmaceutical Junliang Cheng Industrial Zone Dongi District, Tiabjin China. Batch no: Y 153382); Unripe but mature plantain fruit (purchased in Ile-Ife, authenticated at the Faculty of Pharmacy Herbarium with FPI 2424); tragacanth gum B.P; Acetone (GFS Chemicals Inc Columbus OH 43223, specific gravity: 0.790 kg/L; Corn starch B.P. (BDH Chemicals Ltd., Poole, UK); Lactose B.P. (A B Knight and Co., London, UK).Friability Tester (Erweka-Apparatebau-G.m.b.H, Heusenstamin Kr Offenbach, made in Western Germany); Hobart planetary mixer (Hobart Canada Inc, Don Mills, Ontario. Model: N-50; Manesty tablet disintegration test unit (TD 75T176, Manesty Machines Ltd., Liverpool, made in England); Rotary tablet machine press (Emil Korsch, maschinefabrik Berlin 9347-72, pharmapress 100); Drying oven (Gallenkamp drying oven, Rex- C 900, made in England). The research was carried out in the department of Pharmaceutics, Faculty of Pharmacy OAU, Ile-Ife, Osun State, Nigeria.

Extraction of Plantain Starch: The unripe but, mature plantain fruit (*Musa paradisiaca* Linn. Family: Musaceae) was purchased from Ile-Ife market, Osun State, Nigeria. This was authenticated at the Faculty of Pharmacy herbarium with FPI number, 2424. The starch was extracted from the plantain fruits using established procedures [17]. The unripe but mature plantain fruits were peeled, sliced into pieces and were soaked in a distilled water for about sixty hours for softening. The softened plantain fruits were milled to a pulp, and distilled water was added to dilute the slurry which was then sieved using a cloth sieve. The procedure was repeated to fully extract the starch. Iodine test was carried out on the filtrate to confirm the presence of starch. The extracted starch was dried at 80 °C in hot air oven (Gallenkamp, drying oven, Rex-C 900, made in England). The dried mass was powdered using porcelain pestle/mortar and stored in an amber coloured screw capped bottle before use.

Co-processing of Plantain Starch with Tragacanth Gum B.P (Co-grinding Method): 25, 50 and 75 g of the plantain starch powder were weighed. Similarly 25, 50 and 75 g of powder tragacanth BP, (TRG) were weighed. The mixing of both powders was done geometrically in ratios, using a porcelain mortar and pestle to achieve a uniform co-processed mixture of PLS-TRG (1:3), (1:1) and (3:1).

The mixture was then sieved with 250 µm mesh and stored in an airtight container and labelled appropriately. 100 g each of the native binders (PLS and TRG) were also stored in an airtight capped bottles for future use. Fourier Transform Infrared Spectroscopy (FTIR) analysis was carried out on the stored powder mixture to ascertain any in-situ reactions.

Co-processing of Plantain Starch with Tragacanth B.P (Co-fusion Method): 25, 50 and 75g of tragacanth (TRG) were weighed and dispersed into a preheated distilled water in separate platinum dishes and were thoroughly stirred for 10 minutes at temperature, 50 °C, until a mucilage was formed. To the prepared pastes of TRG, when still hot, (in order to enhance proper binding between PLS and TRG), 25, 50 and 75 g of the plantain starch (PLS) were added in the ratios PLS-TRG, 1:3, 1:1 and 3:1. The novel co-processed excipient was oven-dried at 40 °C for eight (8) hours. The dried samples were milled and sieved (250 µm). These were kept in airtight bottles, labelled appropriately for future use. The samples were also subjected to FTIR analysis.

TABLE 1: FORMULAE AND CODES FOR CO-PROCESSED EXCIPIENTS [ADEYEMI O.E, 2024, OAU]

Batch Ratio	Constituents	Codes	Plantain starch (g)	Tragacanth gum (g)
-	Plantain Starch	PLS	100	100
1:3	PLS:TRG	PLSTRG	25	75
1:1	PLS:TRG	PLSTRG	50	50
3:1	PLS:TRG	PLSTRG	75	25

Preparation of Binder Mucilage: The binder mucilage was prepared by weighing amount indicated on the **Table 2.** The weighed quantity was dispersed in the required amount of distilled water contained in a 50 mL glass beaker and heated with continuous stirring until mucilage was formed. The mucilage was used while hot in order to facilitate the binding of the powder bed [18].

Preparation of Paracetamol Granules with Primary and Co-Processed Excipients: The wet granulation method of massing and screening was used. A 165 g batch of paracetamol formulation (paracetamol 90 % w/w), lactose, corn starch (3 % w/w) was prepared using the formula given in the **Table 1.** All the ingredients were dry mixed for 5 minutes in a Hobart planetary mixer (Hobart Canada Inc., Don Mills, ON, Canada). This was moistened with appropriate amounts of binding slurry to produce granules of different concentrations from native plantain starch, tragacanth and co-processed plantain-tragacanth mixture. Massing was first done by the effective mixing of the dry powder mixtures with the mucilage for 4 minutes. The wet masses were made to pass through No.14 mesh sieve (1200 µm) so as to granulate the wet masses. The granules were dried in a hot air oven for 2 h at 60 °C and re-sieved through a No.18 mesh (1000 µm). The sieved granules were stored in the screw capped bottle for future analysis.

TABLE 2: BASIC FORMULATION TABLE [ADEYEMI O. E. 2024, OAU]

Ingredients	I	II	III
Paracetamol	90%	90%	90%
Binder	3%	4%	5%
Lactose(Diluent)	4%	3%	2%
CornStarch	3%	3%	3%

Determination of Physical Properties of Granules:

Granular Density: This was determined by the solvent pycnometric method [20]. using acetone as the displacement fluid. The 50 mL pycnometer bottle was washed, rinsed and oven dried before use. The empty bottle, with cap, was weighed before pouring acetone and re-weighed. The pycnometer was emptied and 1.0 g of the granules was gently poured into it, filled with acetone, covered and weighed. Three determinations were made and the mean value was recorded. This was repeated for all the granules samples. The particle density (ρT) was calculated as shown in the equation:

$$Pt = WPS / (W2+W1)-W3 \quad \text{.....1} \ [18]$$

where Pt is the particle or granular density, W1 is weight of empty pycnometer, W2 is weight of pycnometer and acetone, W3 is the wt of pycnometer, granules and acetone W is weight of granules and Ps is the specific gravity of acetone

Bulk Density: The diameter of the cylinder was determined. 30 g of each of the granule samples was weighed and poured into the dried 100 mL measuring cylinder in a slanting position at angle 45°. The height of the powder in the cylinder was measured and recorded as the bulk height. The determination was done in triplicate and the mean value was used. This was repeated for all the granule samples.

$$Pd = m/Vb \quad \text{.....2} \ ^{18}$$

Where Pd is the bulk density, m is granules weight and Vb is the granules bulk volume.

Tapped Density: 30 g of granules was poured into the 100 mL cylinder with a known diameter. The cylinder with the content was subjected to tapping for 100 times. The volume of the granules was measured and recorded as the tapped volume. This was done in triplicate and the mean value was taken. The determination was repeated for all the binder samples.

$$Pt = m/Vt \quad \text{.....3} \ ^{18}$$

Where Pt is the tapped density (g/dm³), m is the granules' weight (g) and Vt is the tapped volume (cm³)

Relative Density: Relative density RD was obtained by calculating from the knowledge of the bulk and density and particle density of the granules.

$$RD = Pb/Pt \quad \text{.....4} \ ^{18}$$

Where RD is the relative density, Pb is the bulk density and Pt is the tapped density.

Porosity: Porosity, ε was obtained by calculation from the knowledge of the bulk density and true density. Refer to equation 2.5. There is also a correlation between the packing fraction (Pf) and porosity, ε

$$\varepsilon = 1 - Pf \quad \text{……5} \ ^{18}$$

Where Pf is packing fraction.

Angle of Repose: The angle of repose (Ɵ) of 30 g of formulation granules sample was poured into the clamped glass funnel and was allowed to fall freely onto a flat base, placed. The height "h" was taken as the height of the granules conical heap and the radius"r" of the base was measured. This was done in triplicate and the average height was calculated and recorded. The angle was then calculated as

$$AOR = \tan^{-1}(h/r) \quad \text{.....6} \ ^{19}$$

Hausner's Ratio (HR): This was determined as the ratio of the initial bulk volume to the tapped volume.

$$HR = Vb/Vt \quad \text{.....7} \ ^{21}$$

Where Vb is the granules' bulk volume (cm³) and Vt is the granules' tapped volume (cm³).

Carr's Compressibility Index (CI): This was calculated from the difference between the tapped and bulk densities divided by the tapped density and the ratio is expressed as a percentage.

$$CI = 100 \times (Pt-Pb)/Pt \quad \text{.....8} \ ^{18}$$

Where Pt is the tapped density (g/cm³) and bulk density (g/cm³) respectively

Evaluation of Packing and Cohesive Properties of Paracetamol Granules:

Maximum Volume Reduction: The maximum volume reduction of granules bed was used to assess the particle re-arrangement behavior of the paracetamol formulation granules. 30 g of the sample was poured into a 100 mL measuring cylinder with a known internal diameter at angle 45°. The cylinder was tapped at 20, 40, 60, 80 and 100 and the heights were recorded. This was carried out in triplicate and the average calculated. The determination was carried out on all the formulation samples. A modification of Kawakita's equation for the densification of powders, by using the number of taps in place of applied pressure was used to interpret the result.

Angle of Internal Friction: Using the same recorded parameters above, the relationship between porosity and the number of taps, N used to induce consolidation of the granular bed was determined by plotting $\varepsilon^2 N/(I-\varepsilon)$ against N. The angle of internal friction is derived by determining

the angle made between the straight line and the abscissa when K-K_o is re-plotted against N from the equation

$$K = \varepsilon^2 N / (1- \varepsilon)$$

Where, K_o = intercept of the plot of K against N

N = the number of taps

ε = porosity

Consolidation Index and Rate of Consolidation: From the taps obtained above i.e. 20, 40, 60, 80 and 100 taps the corresponding granules height was measured and recorded. This was done in triplicate. The plot of log (ρtd – ρbd)/ρtd against log N was used to derive the equation,

$$Log(Pt-Pb) = K \log N+C.....9$$ [18]

Where, C is consolidation index; K is rate of consolidation

Flow Rate Determination for the Formulation Granules: 30 g of each of the granule samples was weighed and was poured into the machine funnel and subjected to machine agitation, until all the granules content was poured into the dish. The time taken for each flow was taken and recorded. This was done in triplicate for all the formulation granules samples. The formulae for flow rate is shown in equation:

$$FR = mass (g) / Time taken (sec).....10$$ [21]

Determination of Percentage Moisture Content of Paracetamol Granules: 2 g of each of the formulation granules was weighed. The initial weight of the sample was taken and recorded. The weighed granules were placed in the oven at 60 °C and dried to a constant weight. The weights were taken after oven drying and were recorded. Differential between the initial weight and the final weight was calculated and recorded.

Preparation of Paracetamol Tablet: The rotary tablet press punch was lubricated with a 2 % w/v magnesium stearate to prevent tablet sticking to punch surface. Tablets were prepared from compressed weighed 550 mg of formulated granules under predetermined compressional loads of 25, 30, 35, 40 and 45 kilo pounds (kp) (1 kp = 9.807 N) [22] of the rotary tablet press. The machine was manually operated to compress the granules. After the manual ejection from the press the compact formed was stored, with silica gels, inside a screw capped bottle to allow elastic recovery and to prevent falsely low yield values. The procedure was repeated for all other formulation granules. The tablet weight and thickness at each compressional force was taken and recorded accordingly.

Evaluation of Tablet Mechanical Properties:

Crushing and Tensile Strength: The crushing strength (N) was determined by placing the tablets between metal in metal plates of Erweka digital hardness tester and determining the load required to diametrically break the tablets into two halves. The results were taken only from the tablets that showed no sign of lamination and capping. Three different tablets from each compacted paracetamol formulation were weighed and their thickness measured, were subjected to hardness tester. The mean of the three determinations was taken and recorded. The tensile strength (N/m^2) TS was calculated from the formulae:

$$TS = 2F/\pi dh.....11$$ [18]

Where, F is the crushing strength (N), d is the tablet's diameter (cm) and h is the tablet's thickness (cm).

Friability Test: The Roche friability tester (ErwekaApparatebau, Germany) was set at rotating speed of 25 rev/min for a period of 4 minutes. Each of the tablet was weighed and average of the 10 tablets was calculated and recorded before subjecting them to friability test. The weighed tablets were put inside the friability tester and the machine was operated. Each of the tablets was weighed again after the test and the average was calculated and recorded. The differential between the initial average weight and the final average weight of the tablets was taken as the friability, (FR) The procedure was repeated for other tablets formulation. Friability is calculated by the formulae:

$$FR = w1-w2/w1 \times 100.....12$$ [19]

Where, w1 is the initial weight of the granules (g) before oven-drying and w2 is the granules' weight (g) after drying.

Evaluation of Disintegration Properties:

***In-vitro* Disintegration Time:** The tablet's disintegration time was determined by the BP Manesty (Manesty Machines Limited, Liverpool, UK) disintegration test unit. Three tubes containing metal gauze at the bottom were suspended inside the glass tube (containing distilled water). 3 tablets, at each relative density, were taken from each formulation tablet, and placed on the wire mesh. The disintegration test unit was operated at temperature of 37±0.5 °C. The time taken for all the tablets to disintegrate and went through the wire mesh was recorded. This was repeated in quadriple and results were expressed as average of the determinations.

Determination of CSFR/DT Ratio: This was determined by dividing the value obtained from tablet's crushing strength (CS) by its friability (FR). The result obtained was then divided by the average time it took the tablet to disintegrate, i.e. disintegration time (DT).

RESULTS AND DISCUSSION: From **Fig. 1** the consolidated index (C) ranking order for the formulation at 4% w/w was: Co-fused, PLS-TRG (1:3) > Co-fused, PLS-TRG (3:1) > Co-grind, PLS-TRG (3:1) > TRG > Co-grind, PLS-TRG (1:1) > Co-fused, PLS-TRG (1:1) > PLS > Co-grind, PLS-TRG (1:3). This implies that Co-fused PLS-TRG (1:3) at a binder concentration of 4% w/w was able to aid the paracetamol granules bed to pack well.

It was generally observed that co-fused binders, at various combination ratios had highest consolidation indices at all concentrations of the binder used. This implies that co-fusion, as a method of co-processing of excipients, is better than co-grind and native excipients in facilitating proper packing of the granules.

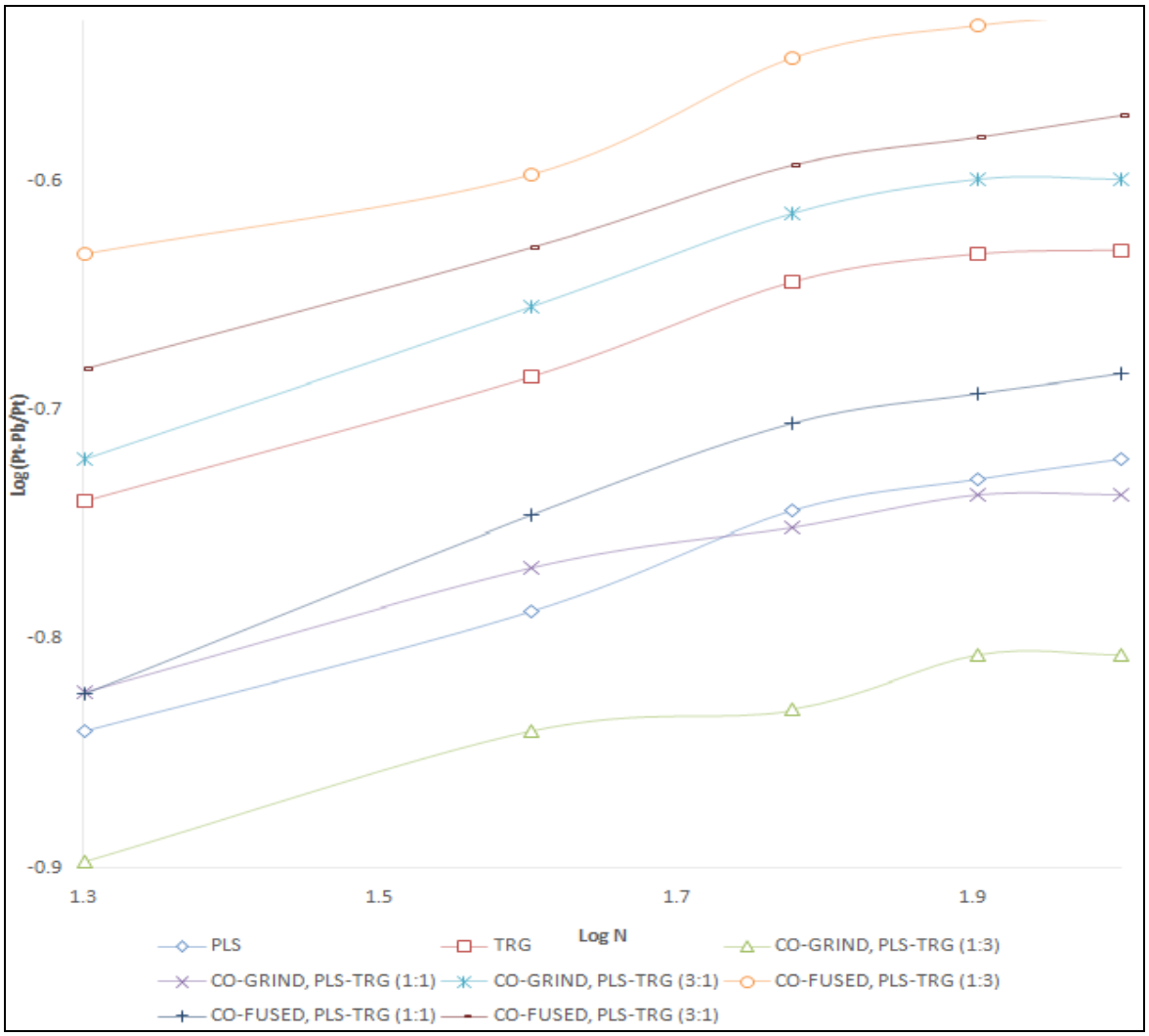

FIG. 1: PLOT OF DENSITY CHANGE, LOG (PT-PB)/PT AGAINST N OF PARACETAMOL GRANULES WITH 4% W/W NOVEL BINDER EXCPIENT

Descriptive Statistics:

TABLE 1: DEPENDENT VARIABLE: DENSITY MEASUREMENT

Excipients	Density type	Mean	Std. Deviation	N
Native binders	Bulk density	.54700	.053740	2
	Tapped density	.82600	.080610	2
	Particle density	1.21650	.053033	2
	Total	.86317	.304819	6
Co-processed	Bulk density	.58983	.081891	6
	Tapped density	.84150	.113638	6
	Particle density	1.23500	.034000	6
	Total	.88878	.284162	18
Total	Bulk density	.57913	.074805	8
	Tapped density	.83763	.101013	8
	Particle density	1.23038	.036067	8
	Total	.88237	.282861	24

Tests of Between-Subjects Effects:

TABLE 2: DEPENDENT VARIABLE: DENSITY MEASUREMENT

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1.724[a]	5	.345	53.473	.000
Intercept	13.812	1	13.812	2141.806	.000
Excipients	.003	1	.003	.458	.507
Density type	1.312	2	.656	101.749	.000
Excipients * density type	.001	2	.000	.052	.949
Error	.116	18	.006		
Total	20.526	24			

Descriptive Statistics:

TABLE 3: DEPENDENT VARIABLE: CSFR/DT

Concentration of binder	the three types	Mean	Std. Deviation	N
3%	Native binder	47.1750	33.54786	10
	Co-grind	69.9547	43.86166	15
	Co-fusion	149.3020	239.72539	15
	Total	94.0150	153.43017	40
4%	Native binder	112.0380	45.86319	10
	Co-grind	124.2060	83.01589	15
	Co-fusion	147.9100	170.93708	15
	Total	130.0530	116.90758	40
5%	Native binder	150.0890	140.60159	10
	Co-grind	128.0473	142.02360	15
	Co-fusion	119.4260	146.44860	15
	Total	130.3248	140.17714	40
Total	Native binder	103.1007	94.89266	30
	Co-grind	107.4027	99.71211	45
	Co-fusion	138.8793	186.01188	45
	Total	118.1309	137.57661	120

Descriptive Statistics:

TABLE 4: DEPENDENT VARIABLE: PY

Concentration of binder	the three types	Mean	Std. Deviation	N
Native binders	Native binder	227.54350	91.354661	2
	Co-grind	289.21067	88.532320	3
	Co-fusion	252.22500	39.082133	3
	Total	259.92425	67.532413	8
3%	Native binder	83.74000	7.127636	2
	Co-grind	103.28667	26.680304	3

	Co-fusion	185.63667	12.668782	3
	Total	129.28125	49.997774	8
4%	Native binder	112.72500	24.076986	2
	Co-grind	159.73333	61.918053	3
	Co-fusion	162.68000	28.713173	3
	Total	149.08625	43.809680	8
5%	Native binder	159.80000	31.282404	2
	Co-grind	149.77333	13.993643	3
	Co-fusion	160.79333	28.284187	3
	Total	156.41250	21.323978	8
Total	Native binder	145.95213	69.283455	8
	Co-grind	175.50100	86.510612	12
	Co-fusion	190.33375	45.820373	12
	Total	173.67606	69.221370	32

Tests of Between-Subjects Effects:

TABLE 4: DEPENDENT VARIABLE: PK (PLASTICITY)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	63.231[a]	14	4.517	196.564	.000
Intercept	7.765	1	7.765	337.922	.000
porosity	.011	1	.011	.477	.499
Rsquare	9.906	1	9.906	431.130	.000
Di	.014	1	.014	.595	.451
concentration	.370	3	.123	5.369	.009
type3	.254	2	.127	5.528	.014
concentration * type3	.936	6	.156	6.786	.001
Error	.391	17	.023		
Total	83.449	32			
Corrected Total	63.622	31			

a. R Squared = .994 (Adjusted R Squared = .989)

From the two-way ANOVA, on the appendix I, it was observed that native binders have higher mean values than their corresponding bulk and tapped densities. It was equally observed that paracetamol granules formulated with co-processed binder excpients statistically show higher mean value than the native binders. This then implies that co-processing of excpients has a significant effect on granules' bulk and tapped densities, taking the P value < 0.05, considered significant. It, then, means that co-fusion of PLS of lower particle density with TRG of higher particle density, in ratio 1:3 produced a novel excipient that enhanced paracetamol granules densification both at zero/low pressures.

The tensile strength (TS) values of the paracetamol formulation with 3, 4 and 5%w/w concentrations of binders at specific applied pressure were determined. Generally the addition of binder in higher concentration is expected to increase the TS. The quantity of TRG>PLS was relevant in Co-fused binder (1:3) than in Co-grind (1:1) rank order. This is because native binder, TRG, when compressed led to the creation of more bonds that resulted into the formation of closer contact of the formulation granules. This results into a stronger compact, p value < 0.05, considered significant (appendix II).

Tablet weakness and vulnerability to attrition, abrasion and fracture due to stress is often assessed by friability. Co-processed binder is expected to produce less friable tablets. Similarly, it is expected that the friability should decrease with increase in binder concentration, which was observed at all the compression pressures [23]. The FR is statistically significant, p value < 0.05 (appendix II).

An increase in compression force leads to a decrease in tablet porosity and an increase in the mechanical strength due to closer contacts of granules [24]. The formation of stronger bonds causes reduction in water penetration which leads to an increase in disintegration time (DT). Disintegration time official requirement is DT < 15 minutes. From the descriptive analysis of the paracetamol tablets DT, their DT is considered significant p value <

0.05 (appendix II). The tensile strength (TS), along the compression pressures was observed for all the binders. The rank order of DT for tablet formulation with 3 %w/w concentration of binders follows: Co-fused<TRG< 0.05.

From the descriptive statistical analysis presented at the appendix II the results show that disintegration (DT), friability (FR) and tensile strength (TS) of the paracetamol tablets, formulated from the co-processed excipient, are statistically significant, $p < 0.05$. This makes the crushing strength-friability /disintegration time (CSFR/DT) index of the tablet produced to be better. The better value of CSFR/DT is needed to ensure best assessment of balance between the formulated tablet's strength and weakness on the compact's disintegration time [25].

The result also showed that the onset of plastic deformation of co-fused, PLS-TRG (1:3) excipient was the lowest compared with native and co-processed excipients. Likewise, the amount of plastic deformation occurring in the co-processed excipient was higher than the rest excipients, as depicted by its Pk value obtained (IV). It was also noted that the amount of the TRG in the co-processed excipient influenced the two parameters, Py and Pk obtained from Heckel and Kawakita analysis respectively. The Py and Pk are considered statistically significant (appendices III and IV).

Statistically, the co-fused excipient Py and Pk values showed the highest mean value (Py, 190.334 and Pk, 1.428), compared to native (Py, 145.952 and Pk, 0.331) and co-grinding (Py, 175.501 and Pk, 0.450) excipients, displayed at the appendices III and IV. This implies that the plasticity of the resulting novel excipient is dependent on co-processing of binders and the method of co-processing. From the descriptive statistics on appendix III, the Py mean values obtained showed that co-fusion technique is better than the co-grinding technique. It should be noted that the higher quantity of TRG in Co-fused, PLS-TRG (1:3) must have made its plasticity to be statistically significant. From the compressional studies on the paracetamol granules prepared with the 3% w/w concentration binder excpient, the Py (mean value,185.637) was higher than both at 4% and 5% w/w concentration with mean values of 162.680 and 160.793 respectively (appendix III). From appendix IV, the two-way ANOVA showed that fast onset of plastic deformation is dependent on the concentration of the binder used, ($P<0.05$). This can then be inferred that, though a minimum 3%w/w concentration of novel binder was needed to enhance faster onset of plastic deformation in paracetamol granules, such concentration may not be adequate to facilitate a total degree of plastic deformation.

CONCLUSION: The present research has shown that co-processing of a native plantain starch extracted from the unripe but mature plantain fruit with tragacanth gum resulted into a desired multi-functional novel excipient. The co-fusion method of co-processing with the selected mix ratio (1:3), at 3% w/w concentration influenced positively its functionalities as a novel excipient. The addition of the co-excipient as a binder into paracetamol tablet formulation led to improved physical, compressional, mechanical and disintegration of the tablet. Hence, co-fusion tecnique used to formulate the novel excipient improved the compactability, tabletability and a reasonable mechanical integrity for the paracetamol tablet under evaluation.

Contribution to Knowledge: The use of the co-processed excipient in paracetamol tablet formulation, as a binder resulted into tablets of desired mechanical strength without negative effects on the tablets ability to disintegrate. Through established procedures, the novel excipient was able to improve compressibility, compactability and tabletability of the formulated paracetamol tablet.

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