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Developing a solid oral dosage form with antioxidant properties from plantain peel

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ABSTRACT

Background: Plantain is used extensively for food in Nigeria due to its numerous nutritional values, which has resulted in the outer peel becoming a significant source of waste, contributing to environmental pollution. This study aimed at converting plantain peel into an oral anti-oxidant solid dosage form.

Methods: First, we subjected the aqueous plantain peel extract (APPE) and the ethanolic plantain peel extract (EPPE) to phytochemical screening to test for the presence of bioactive compounds of interest. After which, we evaluated the DPPH scavenging radical activity to determine the minimum inhibitory concentration of the extracts. Ethanolic extract came out stronger, hence it was considered for further studies. Using three different binders, plantain peel extract (PPE) was dispersed in a binary mixture of microcrystalline cellulose and aerosil as carrier and coating agent respectively.

Results: Fourier Transform Infra-Red (FTIR) returned no major interaction between the excipients used and the PPE. Flow properties exhibited by all batches were found to be near excellent concerning indices such as angle of repose, bulk and tapped densities, car's index, and Hausner values. Low yield pressure value was recorded for batch containing tragacanth gum as binder based on Heckel investigation, while the absolute walker coefficient value for the formulations was in the order PVP>tragacanth>gelatin. As compressional pressure increases, values for tensile strength increase and percentage friability decreases for batches containing tragacanth as binder, while a dominating linear segment was as well noticeable for the plot of specific crushing strength against compressional pressure. Tablet weight uniformity, diameter thickness, and disintegration test across all batches met compendial specifications. While no clear pattern was observed for the plot of the disintegration efficiency ratio, the batch containing PVP did show the least value.

In conclusion, tragacanth as a gum demonstrated superior binding ability in developing an oral tablet from the ethanolic extract of plantain peel.

1. Introduction

Plantain (*Musa paradisiaca*) is a perennial monocotyledon belonging to the kingdom Plantae, Division Magnoliophyta, Class Liliopsida, Order Zingiberales, family Musaceae, genus Musa and species paradisiaca[1]. It can grow to a height of up to 15 m and 0.6 m in width, having an aerial pseudo stem and submerged rhizome with a large pulpy and starch fruit. It is a preferred staple food in Nigeria with several nutritional values due to its abundant Phyto-nutrients. The outer peel which is the main by-product of plantain fruit could contribute to solid waste load and environmental pollution due to its high nitrogen and phosphorous content, and also its large water content that could make it susceptible to microorganism modification[2]. To convert plantain peel into useful products, they have been subjected to various investigations:

Nutritionally, the peels are rich in macro and micro-nutrients[2]. Pharmacologically, it has been proven to possess antimicrobial, anticancer, antioxidant, and wound-healing properties[1]. Physiologically, they counteract damage from free radicals known to destroy cellular lipids, proteins, and DNA via aerobic metabolism[3]. Phytochemically, plantain peels have been reported to contain bioactive compounds such as flavonoids, alkaloids, phenols, saponins, and

tannins[4].

Synthetically, extracts from plantain peels could serve as a capping and reducing agent for the creation of various metallic nanoparticles with numerous applications[5]. Toxicologically, the ripe plantain peel has been proven to be non-toxic and could positively impact hematopoiesis[5]. Traditionally, it is believed to reduce wrinkles by brightening the skin, decreasing puffiness of the eyes, hydrating the skin, fading acne scars, treating symptoms of psoriasis, and removing warts[1].

Despite the nutritional, pharmacological, and physiological benefits of plantain peels, there is lack of standardized oral dosage forms that harness the bioactive compounds present in the peels. While previous studies have explored the potential uses of plantain peels, there is limited research on developing scalable methods for formulating peel extracts into oral dosage forms, such as tablets. This study aims to address this gap by developing rational approach to quantify tablet manufacturing parameters and providing a valid tablet formula for plantain peel extract using simple mathematical models.

Materials and Methods

Materials

Avicel PH 102 (BDH chemicals, India), polyvinyl pyrrolidone (Sigma Aldrich, Germany), tragacanth (Loba Chemie, India), aerosil (BDH Chemicals, India), talc (Allied Chemicals, England), magnesium stearate (Merck, Germany), ethanol, methanol, hydrochloric acid, sulfuric acid (CDH, India), Dragendorf, ferric chloride, chloroform, benzene, phenol, ammonia solution, 2,2-diphenyl-1-picrylhydrazyl (DPPH), and ascorbic acid (Spectrochem, India).

Plantain peel extraction

Ripe plantain peels were picked as trash at the Idu industrial area of Abuja, Nigeria; thoroughly rinsed with potable water to remove debris and dirt. They were dried in an oven (Biobase, BOV-D35; China) set at 40 ºC for 3 days, pulverized with the aid of a blender, and sieved. 50 g of each of the sieved portions was soaked in 500 ml of absolute ethanol and distilled water respectively for 72 h. The resultant mixture was filtered and the filtrate was concentrated in a thermostatic water bath (Biobase; SY, China) set at 100 ºC. The extracts were stored in a desiccator until further analysis.

Phytochemical screening of extract of ripe plantain peel

The method begins with the test for bioactive compounds in dried plantain peels extracted from two different solvents: aqueous (APPE) and ethanolic (EPPE). Phytochemical screening is a crucial step in this process as various bioactive compounds such as flavonoids, alkaloids, tannins, and phenolics are often associated with antioxidant properties and potential health benefits. We tested for the presence of alkaloids by observing precipitate when a portion of the extract in a test tube was shaken with 1 % HCl, and Dragendorff's reagent was added dropwise to the filtrate[6]. Saponin was present if a persistent frothing was observed when a portion of the extract was shaken with distilled water in a test tube[6]. Tannin was positive if a blue-green color was observed when ferric chloride was added to the extract in the presence of distilled water[6]. A reddish-brown coloration when the extract is dissolved in the chloroform and concentrated sulfuric acid added in a dropwise fashion confirmed the presence of steroid[6]. Cardiac glycoside was tested by dissolving the extract in glacial acetic acid containing a drop of ferric chloride followed by the addition of sulfuric acid to show a brown ring at the interface[6]. Flavonoid was tested when a small amount of magnesium powder and a few drops of HCl were added to the extract, and checked for red coloration[6]. The presence of anthraquinone was detected when 10 % ammonia solution and benzene were added to the extract to determine a reddish coloration[6]. A green precipitate when ferric chloride solution was added to the extract signified the presence of phenol[6].

Inhibitory concentration of DPPH radical scavenging property

Following phytochemical screening, the extracts undergo a DPPH (2,2-diphenyl-1-picrylhydrazyl) scavenging assay. This assay is widely used to evaluate the antioxidant activity of various substances by measuring their ability to donate electrons to neutralize free radicals. Various concentrations of each extract separately were transferred into 50 µg/ml of 2,2-diphenyl-1-picrylhydrazyl (DPPH) solution in a 1:1 ratio to obtain a calibration curve. After about 30 min incubation time, absorbance was read at 515 nm with the aid of a Cary 60 UV/VIS Spectrophotometer (Agilent Technologies) using methanol as blank; DPPH solution as control; and vitamin C as standard. The antioxidant property of each extract and their IC_{50} were evaluated by extrapolating the percentage of antioxidant activity using DPPH absorbance and its calibration curve[4].

Pre-compressional studies

PPE-Excipient compatibility study

To assess potential interactions between the plantain peel extract and the excipients used in the formulation, Fourier-transform infrared spectrophotometer (FTIR) was employed. Samples (PPE powder alone, and all compacts for direct compression) were analyzed using Magna-IR, 560 spectrometers; Perkin Elmer, USA[7].

Flow properties and densities determination

The angle of repose, flow rate, bulk density, tapped density,

and true density were evaluated using established methods from the literature[7,8]

Tablet compression

In a subsequent experiment, PPE was properly dispersed into a binary mixture of Avicel PH 102, which serves as a carrier agent that provides bulk and structure to the formulation; and Aerosil which acts as a coating agent that enhance flow properties and stability. After which 5 % binder was added; followed by 1 % magnesium stearate and 0.5 % talc as lubricant and glidant respectively (Table 1). The choice of these excipients is critical for ensuring that the final product maintains its efficacy and stability. The mixture was blended for about 2 min and then compressed with a single-station Manesty tableting machine (Shanghai, China). Tablets were then stored in a desiccator for about 24 hours to give room for elastic recovery. Binders were either PVP (synthetic), tragacanth (natural), or gelatin (animal source)[7].

Table 1. tablet formula

	PPE	Avicel	Aerosil	Binder	Stearate	Talc	Total (mg)
PPE/GEL	200	200	50	22.5	4.5	2.5	479.5
PPE/PVP	200	200	50	22.5	4.5	2.5	479.5
PPE/TRAG	200	200	50	22.5	4.5	2.5	479.5

Post-compressional studies

Weight Variation, friability, disintegration, and disintegration efficiency ratio were determined using an official compendial methods[9]. The weights, thickness and radius, and crushing strength of the tablets were accurately determined using an analytical balance (Metler Toledo, ME54E; USA), micrometer screw gauge (Ruddog, RP-0649, Australia), and hardness tester (Erweka, TBH 125, Germany); after which the following parameters were evaluated[9]:

Determination of relative density of tablets

$$D = w/\pi r^2 hpt$$

where: w = weight of the tablet (mg) r = radius of the tablet (m) h = thickness of tablet (m) ρt =true density of the material[8]

Tablet apparent density determination

$$pA = w/\pi r^2 h$$

where: w = weight of the tablet (mg) r = radius of the tablet (m) h = thickness of tablet (m)[8]

Tablet porosity evaluation

$$E = 1 - D$$

Where D= tablet relative density[10]

Tablet-specific crushing strength

$$SCS = CS/dh$$

Where CS=crushing strength, d=tablet diameter, and h=tablet thickness[10].

Tensile strength of tablet

$$TS = \frac{2CS}{\pi dh}$$

Where CS=crushing strength, d=tablet diameter, and h=tablet thickness[10]

The parameters obtained above were fitted into:

Heckel plot

$$ln[1/(1 - D)] = KP + A$$

Where D=tablet relative density, and P=compressional pressure[11]

Walker equation

$$V^1 = -WlopP + Vsp$$

Where V^1=tablet specific volume and P=compressional pressure[12]

Results

Physical Characteristics and Phytochemical Screening

The aqueous and ethanolic extracts of plantain peel were brownish with a characteristics herbal smell and has smooth textures. The yields of aqueous and ethanolic extracts were 13.4 % and 11.3 %, respectively. Phytochemical screening revealed the presence of tannins, cardiac glycosides, flavonoids, saponins, anthraquinones, steroids, and phenols in both extracts. Alkaloids were absent in both extracts

Antioxidant Activity

Both extracts exhibited concentration dependent DPPH scavenging activity. (fig. 1) The ethanolic extract showed higher scavenging activity, comparable to vitamin C. The IC50 value for ethanolic extract was lower than that of aqueous extract (table 2).

Pre-Compressional Studies

FTIR analysis (fig. 2) showed no major interactions between the extract and excipients. The powder blends exhibited excellent flow properties (table 3).

Compressional Studies

Heckel analysis revealed plastic deformation for all batches. Walker equation showed that PVP has the highest compressibility coefficient. Porosity decreased with increasing compressional pressure.

Tablet Evaluation.

Tablets met compendial specifications for weight uniformity, diameter, and thickness. Formulation with tragacanth as binder had the least friability. All tablets passed the disintegration time test.

Discussion

The study demonstrated the antioxidant potential of plantain peel extracts, particularly the ethanolic extract, which showed higher scavenging activity. The presence of phenols, flavonoids, and tannins in the extracts may contribute to their antioxidant properties[13]. Other studies have shown that phenol in any extract will delay or prevent auto-oxidation of fats and oils[14]. This therefore will justify PPE as a potential antioxidant to treat free radical-mediated diseases.

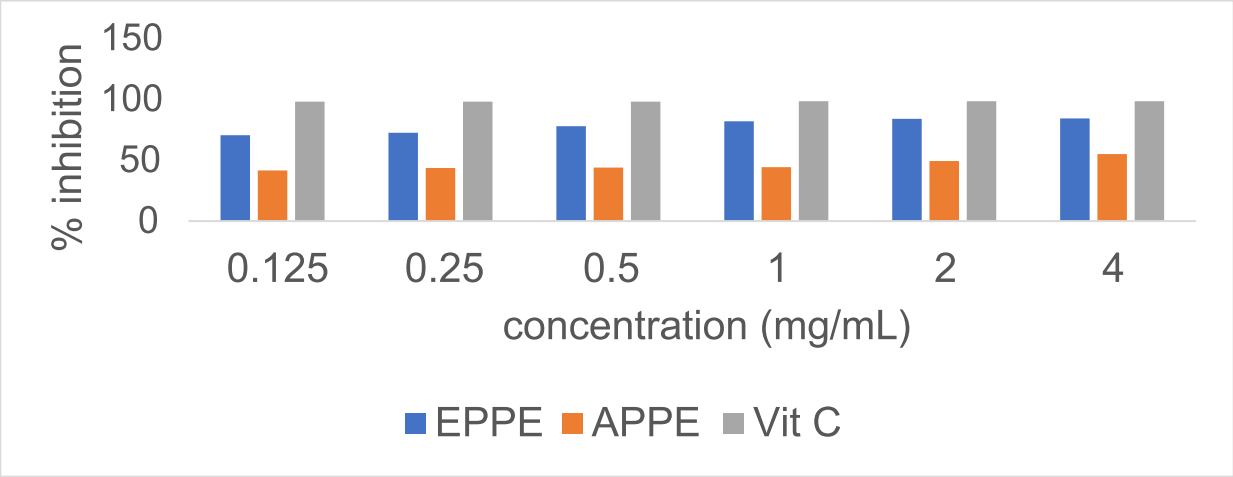

Fig 1. DPPH scavenging activities of aqueous (APPE) and ethanolic (EPPE) plantain peel extract.

Table 2. IC_{50} antioxidant activity for aqueous (APPE) and ethanolic (EPPE) plantain peel extract

EXTRACT	Ic_{50} (mg/ml)
APPE	2.41
EPPE	- 7.60
Vit. C	- 428.60

The potential of antioxidants has prompted scientists to investigate natural compounds with antioxidant properties that are less toxic. DPPH often will test for antioxidant ability to donate hydrogen atoms to DPPH to form DPPH-H. The higher scavenging activity demonstrated by the ethanolic extract could probably be because the use of ethanol in the extraction mixture enhanced solvent polarity that aided the extraction of bioactive compounds such as phenol, flavonoids, and tannins present in the peel in larger amount, and as a result, the large number of hydroxyl groups present in the molecular structure was able to capture free more radicals[14]. The presence of antioxidants in some plantain peel species is believed to have helped protect against damage to the intestinal mucosa by modulating eicosanoid synthesis, and could also prevent cardiovascular diseases and cancer by exerting a strong antioxidant effect against lipid peroxidation[2]. The concentration when the extract has a free radical capturing capacity of 50 % was lower for EPPE, indicating a stronger antioxidant activity. Our data correlate with previous reports of ethanolic peel extract of some plantain species having better DPPH radical scavenging than those extracted with water or methanol, hence the choice of EPPE for further studies[4].

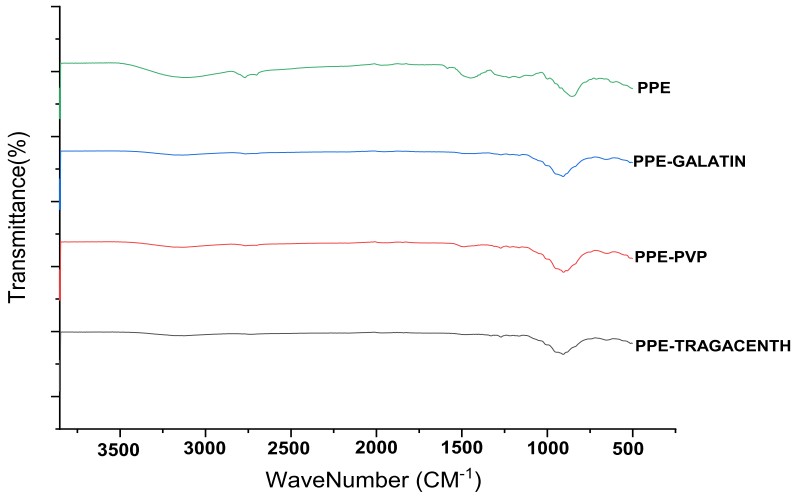

Fig 2. FTIR overlay of plantain peal extract and compacts for direct compression.

FTIR analysis is an analytical technique that provides information about molecular interactions based on vibrational transitions within molecules. In analyzing powders for pre-compressional studies, characteristics peak for all samples analyzed occurred at around 1000 cm^{-1} due to -CH stretching, while typical frequencies due to -OH stretching vibration band were found at 2920-3250 $cm^{-1,}$ and -C=O stretching found in the region of 1595-1995 $cm^{-1.}$ No major interactions between the excipients used and the API were noticeable since no peek specific in the extract was lost in the spectra of the tablet formulation and no new peaks were observed, suggesting that the integrity of bioactive compounds within PPE was preserved during formulation.

The ability of powders to flow freely in the process of tableting is a prerequisite for materials intended for direct compression since they exclude the granulation step that could have imparted the flowability of the powder blend. The near excellent flow properties exhibited by all batches was probably due to the sphericity of the particle shape and particle size of the materials that minimize modification of the blends to improve flow properties[15]. A good powder flow property will result in tablets that are uniform in weight and content.

Table 3. flow property for plantain peel extract powder containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

	AR (º)	BD (g/ml)	TD (g/ml)	HR	CI
PPE/GEL	33.03±0.44	0.29±0.01	0.30±0.00	1.14	11.06
PPE/PVP	31.27±0.27	0.28±0.01	0.29±0.01	1.12	11.44
PPE/TRAG	31.33±1.05	0.29±0.01	0.30±0.01	1.11	10.61

*AR=angle of repose, BD= bulk density, TD=tapped density, HR=Hausner ratio, CI=Car's Index

The formation of solid compacts is a function of the mechanical properties of the materials, and the mechanical properties of a powder usually are proportional to its response to the applied pressure at the time of compression. Subjecting a powder to mechanical stress could result in either an elastic, plastic, viscoelastic, or fragmentation deformation[10].

Table 4. Heckel and Walker parameters for plantain peel extract tablets containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder

	P_y	D_A	D_B	D_0	W '	Vsp
PPE/GEL	8.33	0.75	0.50	0.25	0.1565	0.0678
PPE/PVP	9.09	0.69	0.43	0.26	0.1604	0.0684
PPE/TRAG	3.03	0.68	0.42	0.26	0.1575	0.0705

Based on Heckel's investigation as presented in Figure 3 and Table 4, all batches showed no sign of initial curve nor initial fragmentation which indicates plastic type of deformation. Low yield pressure value recorded for batch containing tragacanth gum as binder could mean that the presence of slip planes in the micro structure of tragacanth enables it to undergo plastic deformation hence promoting rapid densification at low pressure to produce solid compacts during compression[10]. While the higher P_y value for batch containing PVP will induce a much slower onset and extent of plastic flow in PPE formulation. D_A values reveal that the relative density of plastic deformation for batches containing PVP and TRAG were similar but lower that than of GEL. Low D_A value is an indication of low area of contact between particles which depends on variables such as particle size and size distribution. Conversely, the high D_B value recorded for batches containing gelatin as binder correlates with its high degree of particle fragmentation which occurs simultaneously at the same time as the plastic and elastic deformation of the material. The deformation process of a particle is affected mainly by the molecular and crystal structure, therefore materials that are hard and brittle will tend to have more shear strength than tensile strength and as the particle size decreases, the densification mechanism proceeds to plastic deformation from fragmentation[16]. This seems to be the case here with the batch containing tragacanth, fragmenting at the initial stage of compression and exhibiting plastic deformation at the later stage. No significant variation among values for D_0 was noticed, although the slightly lower value for the GEL batch correlates with its low degree of initial packing, rearrangement, and densification during die filling.

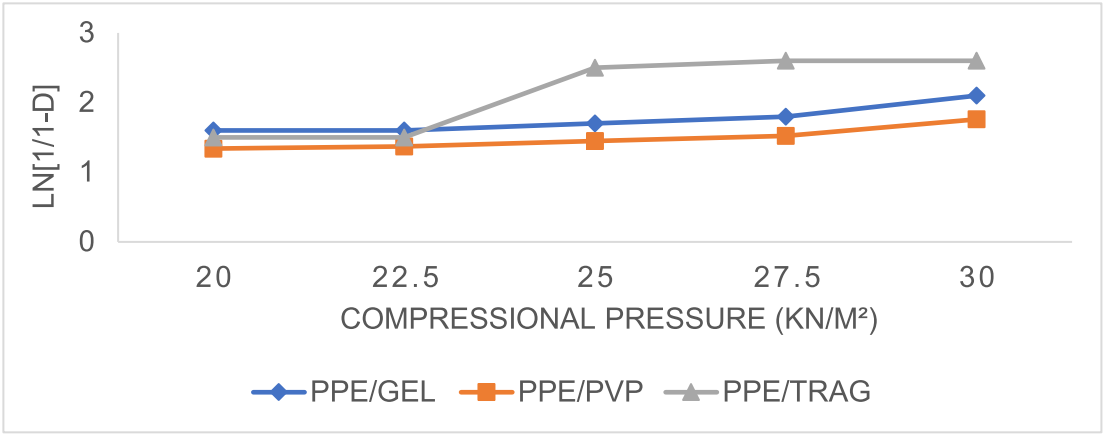

Fig 3. Heckel plot for formulation of plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

Similar to the Heckel analysis, the Walker equation provides an acceptable fit to the volume of reduction data aside from information for material plasticity (Fig. 4 and Table 4). The absolute walker coefficient value for the formulations was in the order PVP>tragacanth>gelatin. The higher the Walker value, the more readily the powder will reduce in volume. The lowest W^1 value recorded by gelatin shows that it will undergo plastic deformation slowly during compression compared to PVP. When pressure is applied to a powder bed in a confined space, particles will rearrange leading to the filling of the pore spaces, deformation, and reduction in volume hence increasing the packaging ability and density of the powder[17]. If a material presented with a tendency to deform under stress and consequently has a large compressibility coefficient, numerous new contact points may be created leading to the formation of newer strong bonds[18].

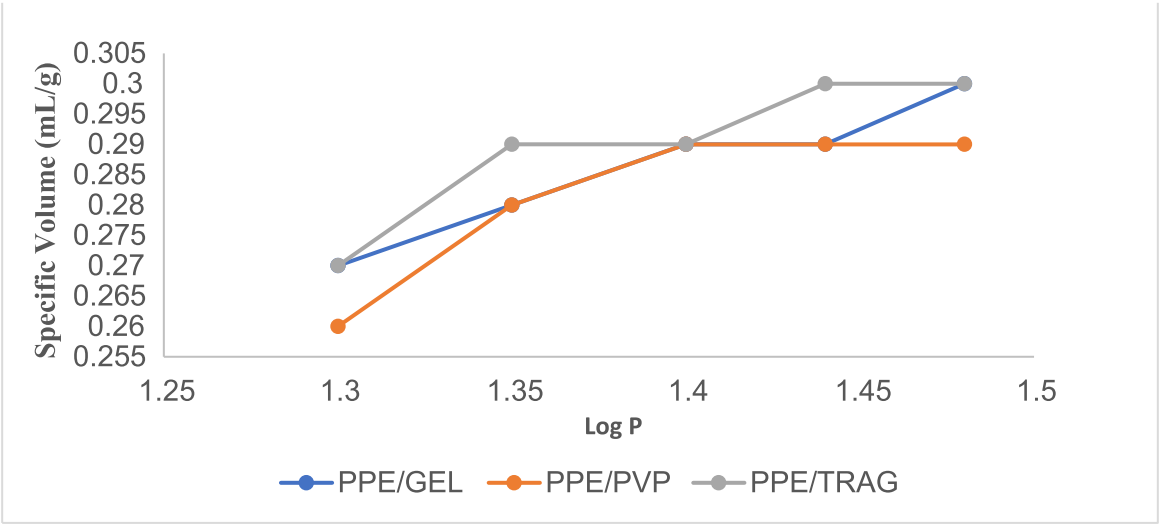

Fig 4. Walker plot for formulation of plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

The plot of porosity versus compressional pressure (fig. 5) was an inverse relationship which underscores previous studies. This relationship represents a true scenario of the compressional properties of a formulation. Ideally, when pressure is applied to a material, the voids within particles are removed to reduce the porosity of the powder[19]. Our study showed PPE/TRAG to have the highest porosity values thereby reaffirming the superiority of TRAG as a binder over GEL and PVP in this case.

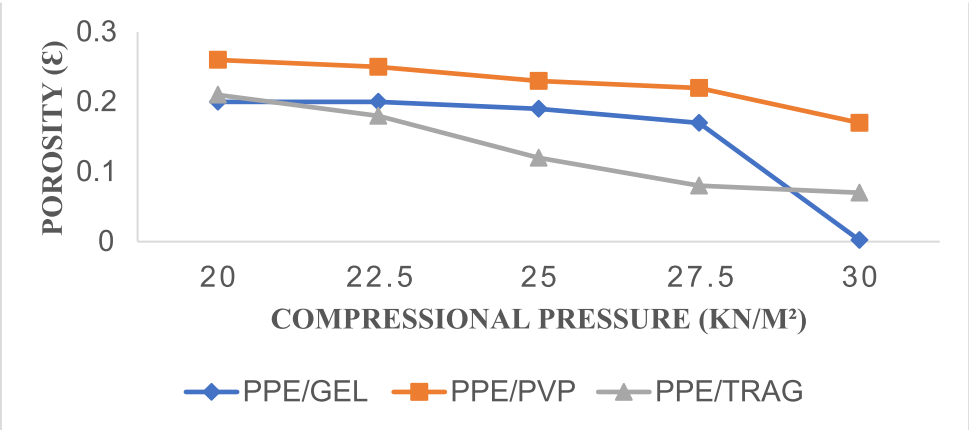

Fig 5. Porosity plot for formulation of plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

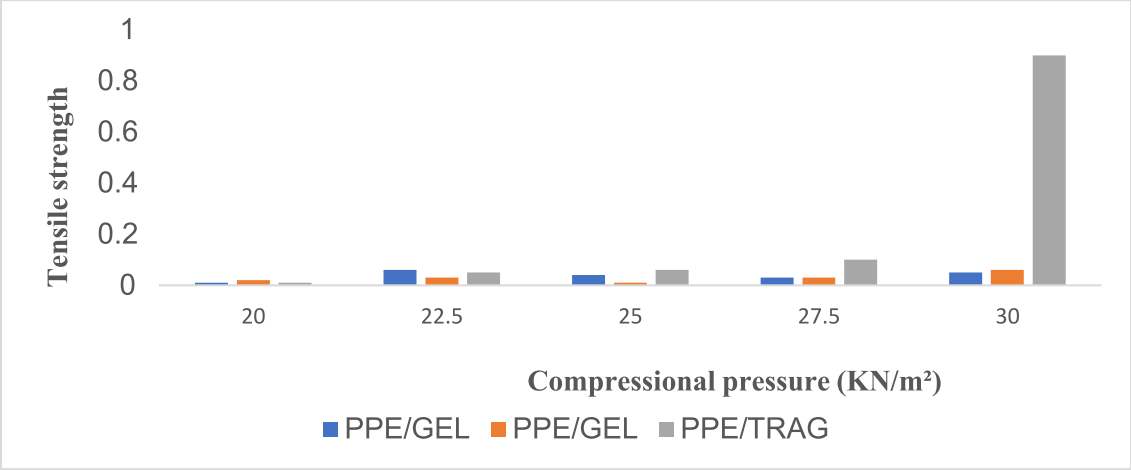

Fig 6. Plot of tensile strength versus compressional pressure for plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

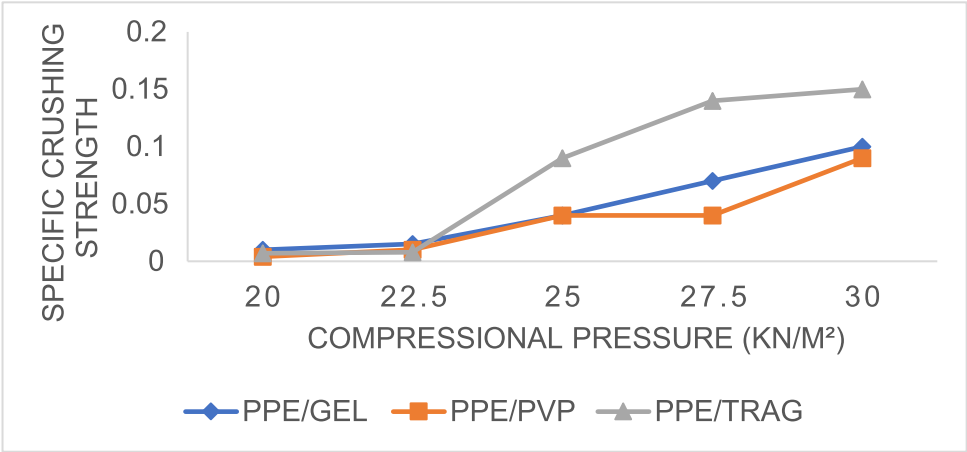

Fig 7. Specific crushing strength plot for formulation of plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

We measured the bond strength of the formulated PPE tablets mechanically by extrapolating the tensile strength values against the compressional pressure. As compressional pressure increases, values for tensile strength for batch containing tragacanth as binder increases (Figure 6) probably due to the interparticulate force of attraction and mechanical interlockings between the PPE and other excipients as they are brought together by the binder. Studies have proven that as the surface area of contact increases, the degree of bonding increases leading to a greater tensile strength value[20]. This also implies that the amount of plastic deformation during the compression process was greater in the PPE/TRAG batch which was also evidenced by its low P_y value.

For a plot of specific crushing strength against compressional pressure (Figure 7), no clear pattern was observed especially at higher pressures where tendencies to laminate are distressing hence making it difficult to define a minimum or critical compressional force for all batches, however, a dominating linear segment was noticeable for PPE/TRAG batch which correspond to the plot of tensile strength against pressure.

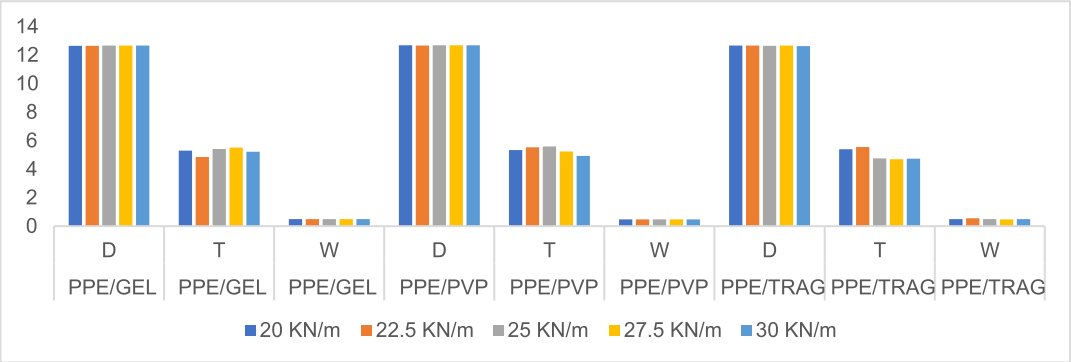

Fig 8. Weight variation (W), thickness (T) and diameter (D) values for plantain peel extract tablets containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

Tablet weight uniformity, diameter, and thickness across all batches met compendial specifications (Table 8). Not more than the weight of two tablets was seen to deviate from the mean weight of twenty tablets by more than 5 %, and no significant difference was noticed in the diameter and thickness values at each pressure across batches[21].

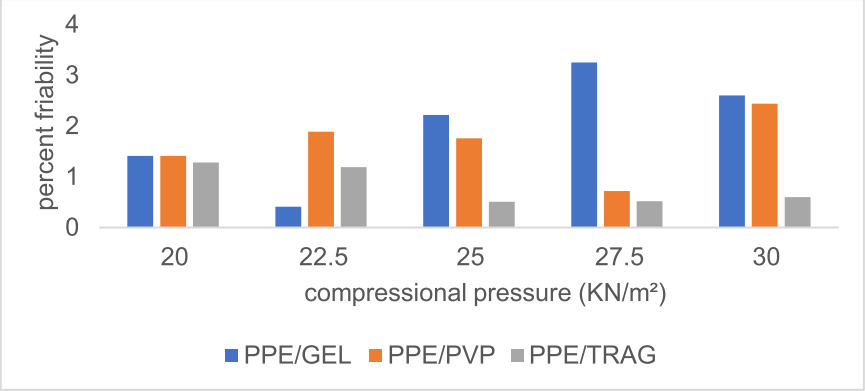

Fig 9. Plot of percentage friability against compressional pressure for plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

Formulation with tragacanth as a binder was the least friable (Figure 9), with compressions at pressure 25, 27.5, and 30 KN/m^2 meeting compendial specification of not less than 1 %. We can however attribute the ruggedness of this batch to the low degree of particle fragmentation which makes them not break easily and subsequently not yield to plastic deformation even at high pressure.

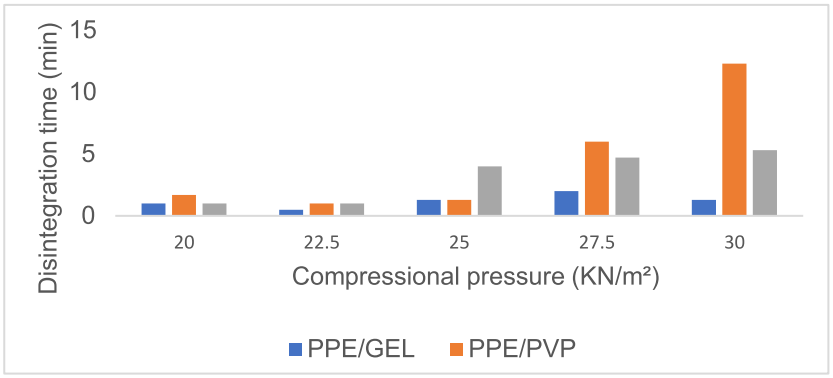

Fig 10. Plot of disintegration time against pressure for plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

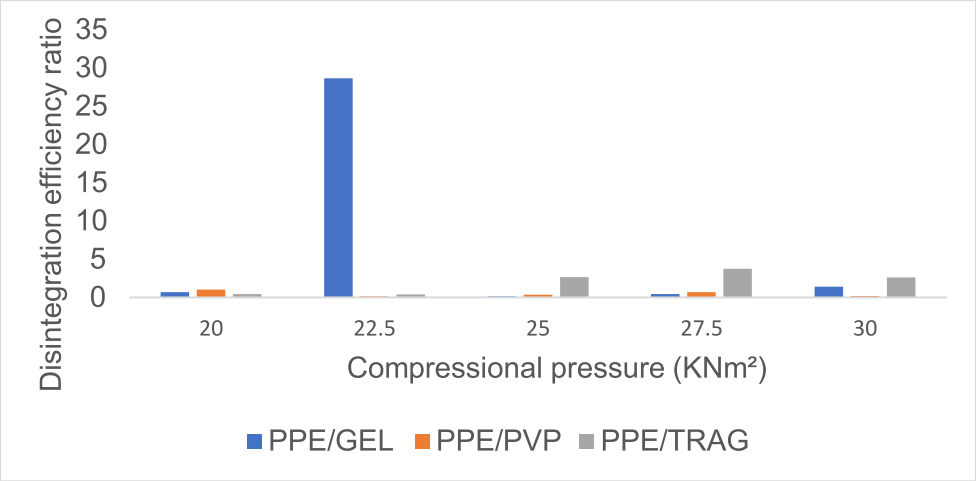

Fig 11. Plot of disintegration efficiency ratio against pressure for plantain peel extract containing gelatin (PPE/GEL), polyvinyl pyrrolidone (PPE/PVP), and tragacanth (PPE/TRAG) as binder.

All tablets irrespective of the binder passed the disintegration time test (Fig 10) for a conventional tablet (< 15 min). This implies that the breakdown of interparticle interactions generated during compaction was satisfactory[22, 23]. The disintegration efficiency ratio which measures the balance between the mechanical and disintegrant properties of tablets, did not show any clear pattern in our formulation (Figure 11), however, the batch containing PVP had the least value across formulation pressure.

Conclusion

In conclusion, this study demonstrated the potential of plantain peel extract as a source of bioactive compounds with antioxidant properties. The ethanolic extract of plantain peel (EPPE) showed stronger antioxidant activity compared to the aqueous extract, likely due to the enhanced extraction of phenolic compounds. The formulation of EPPE in to tablets using different binders (tragacanth, gelatin, and PVP) was successfully achieved, with the batch containing tagacanth exhibiting superior properties, including better flowability, compressibility, and tensile strength. The tablets met compendial specifications for weight uniformity, diameter, thickness, friability, and disintegration time. These findings suggest that EPPE could be developed into a viable oral dosage form with potential health benefits, warranting further investigation into its therapeutic applications.

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