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Research Article

Investigation of Avocado Pear (*Persea americana*) Seed Starch as Binder and Disintegrant in the Formulation of Paracetamol Tablet

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Abstract

Background: Avocado pear seeds are usually discarded as agricultural waste, the need arises therefore, to investigate their potentials as pharmaceutical excipients. Objective: The objective of this research was to extract, characterize, formulate and do in-vitro evaluation of the formulated paracetamol tablets. *Methods*: Ripe avocado (*Persea americana*) fruits were harvested in the month of April from a farm at Okada town. The seeds were authenticated by a taxonomist at the Department of Plant Biology, University of Benin, with Harbarium number UB/PB/24 0201. The seeds were prepared, dried and milled to fine powder and extracted using a standard procedure by Silva *et al*., 2013. The powder was subjected to phytochemical analysis and characterized for its micromeritic properties, and high-resolution analyses using differential scanning calorimetry, fourier transform infrared spectroscopy, scanning electron microscopy and x-ray diffractometry. Batches of paracetamol granules were prepared with avocado starch powder as disintegrant (2.5 - 15%w/w) and starch mucilage as binder (5.0 – 15 %w/v) using the wet granulation method. Granule flow properties were investigated before compression into tablets. Tablets were evaluated for physicochemical properties and drug-excipient interaction was investigated using DSC and FTIR. *Results*: Phytochemistry shows presence of saponins, flavonoids, tannins, alkaloids and glycosides. The starch was light-brown, odorless, tasteless and smooth in texture. Slightly soluble in water at room temperature, melting point range 102 - 114 ℃, moisture content 22.7 ± 2.40%; hydration capacity 2.76 ± 1.20 (g/g), swelling and moisture sorption capacities of 46.43 ± 1.50% and 115.34 ± 1.55%, respectively. Thermogram exhibited a single sharp peak of the extracted starch, FTIR shows no interactions, SEM and XRD results confirmed semi-crystalline powder with fluffy discrete particles. Granules exhibited fair to good flow properties; the tablets were uniform in weight, mean hardness values ≥ 58.84 N, friability 0.14 -1.56 %, disintegration times 0.50 – 11.12 mins and variable drug release 72.78 - 90.67% in 1.0 h. sss*Conclusion*: Tablets formulated with the extracted starch as disintegrant gave superior tablet properties, hence a viable local substitute that can be employed at higher concentrations as super-disintegrant and good mucilage binder at higher %w/v concentrations for oral solid dosage formulations.

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Keywords

Avocado Starch, Paracetamol, Tablet, Disintegrant, Binder

1. Introduction

Excipients are essential ingredients of a dosage form which are added to increase volume, aid flow, enable compactness and make a drug convenient to administer and are typically present in higher proportion than active pharmaceutical ingredients in most formulations [1]. They can also be used to modify the release of drug, thereby, influencing the absorption and subsequent bioavailability of the incorporated drug. Natural polysaccharides are widely used in the pharmaceutical and food industries as excipients and additives due to their low toxicity, biodegradability, availability and low cost Polysaccharides show range of versatile properties that offer high stability, safety, lesser toxicity, and a wide range of solubility features. Application of starch in pharmaceutical industry include being use as a binder, disintegrant, bulking agents and film-forming agents [2]. Starches used as pharmaceutical excipient are mainly as binder and disintegrant in the formulation of tablets and other solid dosage forms [3]. Avocado pear fruit (*Persea Americana*) is a medium sized (40-80 feet) evergreen tree in laurel family (Lauraceae). The shape of the fruit may be round, ovate or pear-shaped and the skin is different in color and appearance in all varieties [4]. Avocado pear is identified by various local names in Nigeria such as ube oyibo (Igbo), piha oyinbo (Yoruba) and avocado (Hausa) [5]. The demand for quality natural binders and effective disintegrants for oral solid dosage forms is higher than ever before, especially among formulation development scientists. The use of avocado pear seed starch as binder and disintegrant in the formulation of paracetamol tablet presents a potential alternative to commonly used pharmaceutical excipients. Avocado pear fruit has been studied for its antioxidative, anti-inflammatory and anti-diabetic activities [6]. However, the effectiveness, quality and stability of the avocado pear seed starch as binder and disntegrant in tablet formulation have not been extensively studied. In view of the foregoing, there is need to investigate its potential as a viable option in pharmaceutical tablet production.

Lot of research works abound in this search for other sources of starch to be used as binders and disintegrant [7-9]. Paracetamol is a widely used analgesic and antipyretic medication that is commonly administered in tablet form. In the formulation of paracetamol tablets, pharmaceutical excipients such as binders and disintegrants are used to ensure uniformity, stability and bioavailability of the drug products. However, some of these excipients have been associated with various side effects and safety concerns, which have prompted the search for alternative excipients that are safer, more effective and more readily available. This study aims to investigate the use of avocado pear seed starch as natural binder and disintegrant in the formulation of paracetamol tablet dosage form and compare its performance to commonly used standard excipients. This study is significant because it could potentially lead to the development of a new and natural excipient for use in pharmaceutical tablet manufacturing which could have important implication for the safety and efficacy of paracetamol tablets and other solid oral drug products.

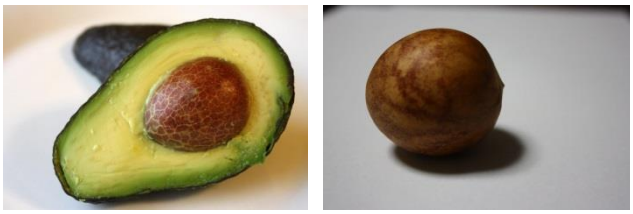

Figure 1. *(a). Image of clavate shaped avocado pear with seed (above), (b). Apex round shaped seed of avocado pear (below) [10].*

Avocado seed contains a variety of beneficial nutritional and bioactive compounds, including proteins, starch, lipids, crude fiber, vitamins, minerals and various phytochemicals [11].

2. Materials and Methods

2.1. Materials

Materials were procured from established local supplier, Sonitex Nig Limited, Benin City, Edo State, Nigeria. Paracetamol powder BP, Lactose anhydrous powder BP, Maize starch BP, Talc and Magnessium stearate (Qualikens Chemical Industries, New Delhi, India), Sodium chloride (Royal Salt Limited, Lagos). Chemicals used in this study were of analytical grades and were used as supplied by the vendors. Ripe avocado fruits were purchased from a market in Benin City, Edo State, Nigeria. The seeds were identified by a taxonomist (Dr Akinnibosun Henry Adewale) of the Department of Plant Biology and Biotechnology, University of Benin, Nigeria. Voucher specimen sample was deposited in the Herbarium unit of the Department with herbarium number (UBH-P408).

2.2. Methods

2.2.1. Preparation, Extraction and Purification of Avocado Pear Seed Starch

Starch extraction was performed based on the method by [12] and adopted by [13]. The avocado seeds, washed and cut into small pieces were infused with distilled water containing sodium metabisulfite (0.2% v/v) for 24 hours under refrigeration. Starch was extracted by crushing the raw material with 0.2% (v/v) sodium metabisulfite solution in an industrial mixer for 5 minutes. After homogenization, the mixture was sieved through 200 mesh (0.074 mm). Decantation was performed for 24 hours with resuspension in 0.2% sodium metabisulfite solution (v/v) and centrifuged at 1105 g for 12 minutes, supernatant was discarded and the decant was retained. The mucilage formed on the surface of the residue was removed. Starch residue obtained was washed thrice with distilled water, and dried in an oven at 40 ℃ for 12 hours. Resulting starch was milled to fine powder, weighed and percentage yield recorded and stored in a clean container under refrigeration.

2.2.2. Determination of Percentage Yield (%)

Percentage yield of avocado pear seed (APS) starch was calculated according to equation below [14].

$$Percentage\ yield\ \% = \frac{wt\ of\ extracted\ avocado\ pear\ seed\ starch}{wt\ of\ diced\ dried\ avocado\ pear\ seed} \times 100 \quad (1)$$

2.2.3. Organoleptic Properties of the Extracted Starch

Organoleptic properties refer to the characteristics of a substance that can be perceived through the senses such as taste, smell, texture, appearance and color [15]. Solubility and melting point of the extracted starch were also determined according to standard procedures [16].

2.2.4. Qualitative Phytochemical Analysis of Avocado Seed Starch (APS)

Some qualitative phytochemical tests were performed on the APS starch in an attempt to characterize the starch. These include test for presence of saponins, alkaloids, anthraquinones, and flavonoids. These screenings were conducted according to standard analytical methods outlined by [17, 18] and were adopted to identify the presence of primary and secondary metabolites.

2.2.5. Formulation of Paracetamol Granules and Tablets

Paracetamol granules were prepared using avocado seed starch as disintegrant and as binder as shown in the formula of Table 1 and Table 2 employing wet granulation method.

Table 1. *Formula for the preparation of paracetamol granules using P. americana starch as disintegrant.*

Ingredients	Batches						
	I	J	K	L	M	N	O
Paracetamol (mg)	500	500	500	500	500	500	500
Avocado starch dry Powder (%w/v)	Qs (5%)	Qs (7.5%)	Qs (10%)	Qs (12.5%)	Qs (15%)	-	-
Maize starch BP mucilage (%w/v) (MSM)	-	-	-	-	-	Qs (5%)	Qs (10%)
Maize starch BP powder (5%w/w) (mg)	30	30	30	30	30	30	30
Microcrystalline cellulose (mg)	5	5	5	5	5	5	5
Lactose (mg)	62	62	62	62	62	62	62
Talc (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Magnesium stearate (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Compression weight (mg)	600	600	600	600	600	600	600

Table 2. Formula for the Preparation of Paracetamol Granules using P. americana Starch Mucilage (ASM) as Binder.

Roles	Ingredients	Batches						
		I	J	K	L	M	N	O
Drug	Paracetamol (mg)	500	500	500	500	500	500	500
Test binder	Avocado starch mucilage (ASM) (%w/v)	Qs (5%)	Qs (7.5%)	Qs (10%)	Qs (12.5%)	Qs (15%)	-	-
Standard binder	Maize starch BP mucilage (MSM) (%w/v)	-	-	-	-	-	Qs (5%)	Qs (10%)
Disintegrant	Dry maize starch BP powder (5%w/w) (mg)	30	30	30	30	30	30	30
Bulking agent	Lactose (mg)	67	67	67	67	67	67	67
Glidant	Talc (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Lubricant	Magnesium stearate (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Compression weight	600	600	600	600	600	600	600

Key: I: (5.0%ASM), J: (7.5%ASM), K: (10.0%ASM), L: (12.5%ASM), M: (15.0%ASM), N:(5.0%MSM), O:(10.0%MSM)

3. Results

Results of the physicochemical properties of extracted avocado seed starch (APS) powder are shown in the Tables below.

Table 3. Micromeritic properties of paracetamol granules formulated with different types and concentrations of APS.

Batch	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Carr's Index (%)	Hausner's Ratio	Angle of Repose ( )	Flow Rate g/sec
A	0.46 ±0.01	0.68 ±0.05	32.90 ±0.10	1.49 ±0.20	30.49 ±0.42	0.57 ±0.12
B	0.47 ±0.04	0.71 ±0.01	33.45 ±0.02	1.49 ±0.60	30.26 ±0.14	0.59 ±0.22
C	0.47 ±0.02	0.72 ±0.02	34.02 ±0.30	1.54 ±0.42	30.10 ±0.16	0.54 ±0.20
D	0.44 ±0.01	0.70 ±0.02	32.01 ±0.42	1.47 ±0.44	30.06 ±0.20	0.53 ±0.14
E	0.47 ±0.03	0.70 ±0.01	33.00 ±0.23	1.49 ±0.22	30.86 ±0.14	0.46 ±0.40
F	0.47 ±0.04	0.67 ±0.05	28.40 ±0.12	1.41 ±1.00	20.46 ±0.16	2.63 ±0.20
G	0.52 ±0.02	0.74 ±0.03	29.27 ±0.22	1.43 ±0.80	20.26 ±0.13	2.87 ±0.20
H	0.52 ±0.02	0.75 ±0.02	29.20 ±0.40	1.43 ±0.12	15.26 ±0.22	5.21 ±0.12
I	0.48 ±0.06	0.70 ±0.04	31.80 ±0.04	1.47 ±0.30	30.26 ±0.14	0.48 ±0.22
J	0.48 ±0.04	0.73 ±0.01	31.02 ±0.42	1.44 ±0.20	30.26 ±0.18	0.43 ±0.30
K	0.48 ±0.03	0.69 ±0.01	29.10 ±0.22	1.43 ±0.42	23.26 ±0.14	2.40 ±0.20
L	0.47 ±0.02	0.67 ±0.02	30.00 ±0.12	1.43 ±0.12	30.26 ±0.14	0.57 ±0.20
M	0.48 ±0.01	0.69 ±0.02	30.00 ±0.22	1.43 ±0.14	30.26 ±0.21	1.61 ±0.12
N	0.53 ±0.04	0.74 ±0.01	27.00 ±0.20	1.39 ±0.42	18.26 ±0.14	4.42 ±0.20
O	0.53 ±0.04	0.74 ±0.03	27.01 ±0.14	1.39 ±0.40	22.26 ±0.24	2.21 ±0.22

Table 4. Physicochemical properties of formulated paracetamol tablets.

Batch	Weight (g)	Hardness (kg)	Friability (%)	Disintegration time (min)
A	0.604 ±0.05	6.70 ±0.05	0.70 ±0.10	1.15 ±1.20
B	0.610 ±0.04	8.70 ±0.10	0.48 ±0.02	1.66 ±0.60
C	0.626 ±0.02	8.25 ±0.15	0.14 ±0.30	0.91 ±0.42
D	0.599 ±0.02	7.30 ±0.02	0.70 ±0.42	0.63 ±0.44
E	0.608 ±0.05	7.25 ±0.12	0.71 ±0.23	0.51 ±0.22
F	0.599 ±0.01	6.05 ±0.50	1.47 ±0.12	0.51 ±0.10
G	0.606 ±0.03	7.40 ±0.25	0.76 ±0.22	> 15.00
H	0.606 ±0.01	6.50 ±0.20	1.04 ±0.40	4.67 ±0.12
I	0.609 ±0.02	8.00 ±0.04	1.50 ±0.04	0.25 ±0.30
J	0.609 ±0.04	8.00 ±0.13	1.56 ±0.02	0.50 ±0.20
K	0.608 ±0.05	8.35 ±0.25	1.12 ±0.10	0.51 ±0.40
L	0.609 ±0.02	8.55 ±0.11	1.10 ±0.11	0.58 ±0.10
M	0.610 ±0.02	8.70 ±0.50	0.92 ±0.05	0.78 ±0.30
N	0.606 ±0.02	7.30 ±0.12	0.96 ±0.04	> 15.00
O	0.608 ±0.01	8.10 ±0.20	0.76 ±0.10	11.12 ±0.30

All values were expressed as mean ±standard deviation

Table 5. Organoleptic, phytochemical and physicochemical and micrometritic properities of extracted avocado seed starch.

	Parameter	Remark
Oranoleptic	Appearance	Light brown
	Taste	Tasteless
	Odour	Odourless
	texture	Smooth
Phytochemical constituents	Starch	Positive
	Saponin	Positive
	Flavanoids	Positive
	Alkaloids	Positive
	Tannins	Positive
	glycosides	Positive
Physicochemical properties of avocado starch powder	Solubility (Ambient temp)	Not soluble
	Melting point (^{o}C)	102-114
	Moisture center (%)	22.7 ±2.46
	Hydration capacity	2.76 ±1.20
	Swelling capacity (%)	46.43 ±1.50
	Water sorption capacity (100% RH) %	115.34 ±1.55
		Average values

	Parameter	Remark
Micromeritics of extracted avocado seed starch	Bulk density (g/ml)	0.47 ±0.21
	Tappled density (g/ml)	0.71 ±0.12
	Carr's index (%)	33.80 ±1.26
	Hausner's ratio	1.51 ±0.10
	Angle of respose (^{o})	25.30 ±1.25
	Flow rate (g/sec)	0.133 ±0.09
	Particle/true density (g/ml)	0.029 ±0.06

3.1. Physicochemical Properties of Paracetamol Granules

Table 5 shows the phytochemical constituents present in the extracted avocado seed starch. According to previous research, the phytochemical constituents present in avocado pear seed are flavonoids, tannins, saponins, phenolics, antioxidant capacity, oxalates, phytates, and alkaloids [19]. A study of qualitative phytochemical screening on avocado (*P. americana*) seeds revealed the presence of saponin, cardiac glycosides, terpenoid, alkaloids and tannins [20]. Results obtained from sample extracted is in agreement with previous results of the researchers above.

Granule properties such as angle of repose, flow rate, bulk density, tapped density, Hausner's ratio and Carr's compressibility index are shown in Table 3.

Granules with good flow properties typically have an angle of repose (25^o – 30^o), Hausner's ratio (< 1.25) and Carr's compressibility index (< 25%) respectively [21]. Carr's compressibility index and Hausner's ratio are measures of the relative importance in the inter-particulate interaction in the free flowing powders [18]. From the results in Table 3, it was observed that Hausner's ratio and Carr's index for binding property of the three batches (Maize starch mucilage MSM, and APS starch) of paracetamol granules exhibited good powder flow properties. Angle of repose is the angle at which a pile of granular or powdered material naturally comes to rest due to the balance between gravitational force between particles [22]. Bulk density is essential for understanding the flow properties of powders while tapped density on the other hand helps access how well particles pack together and their ability to settle during transportation and storage [21]. The average bulk density of maize starch mucilage (0.51 ±0.07), and APS starch (0.45 ±0.05) for binding property and bulk density of dry maize starch (0.44 ±0.03) and APS starch (0.48 ±0.01) for disintegrating property are shown in Table 3 respectively. These values agree with past findings which state that powder with good flow properties typically has bulk density within 0.20- 0.60 g/cm^3 although it vary based on specific characteristics of the powder and its intended application [23].

3.2. Evaluation of Physiochemical Properties of Paracetamol Tablet

Disintegration time is crucial in pharmaceuticals to determine how quickly a tablet breaks down into smaller particles [18]. According to B.P (2008), unless otherwise specified, oral and uncoated tablets should disintegrate within a time frame of 15 minutes. From the results shown in Table 4. all tablet batches disintegrated within the standard recommendations [24]. Hardness test aims to measure the ability of tablets to resist breakage during packaging, handling and transporting [21]. Previous research work states that for tablet's hardness test to be considered, the minimum crushing strength should be ≥ 4 kg/f. [25]. Table 4 shows hardness values of all tablet batches fell within acceptable BP range. Friability test assesses tablets' ability to maintain its structural integrity, able to withstand handling and transportation without excessive erosion or damage. Unlike the crushing strength, friability measures surface deformation. A tablet is considered to pass the friability test if the weight loss after the test is ≤ 1% [21]. Table 4 shows that all batches of MSM 10.0%, APS 7.5%, APS 10.0% used as binder, MSM 2.5% - 10.0%, APS 5.0%, 7.5%, 10.0% used as disintegrants passed the friability test with values ≤ 1%.

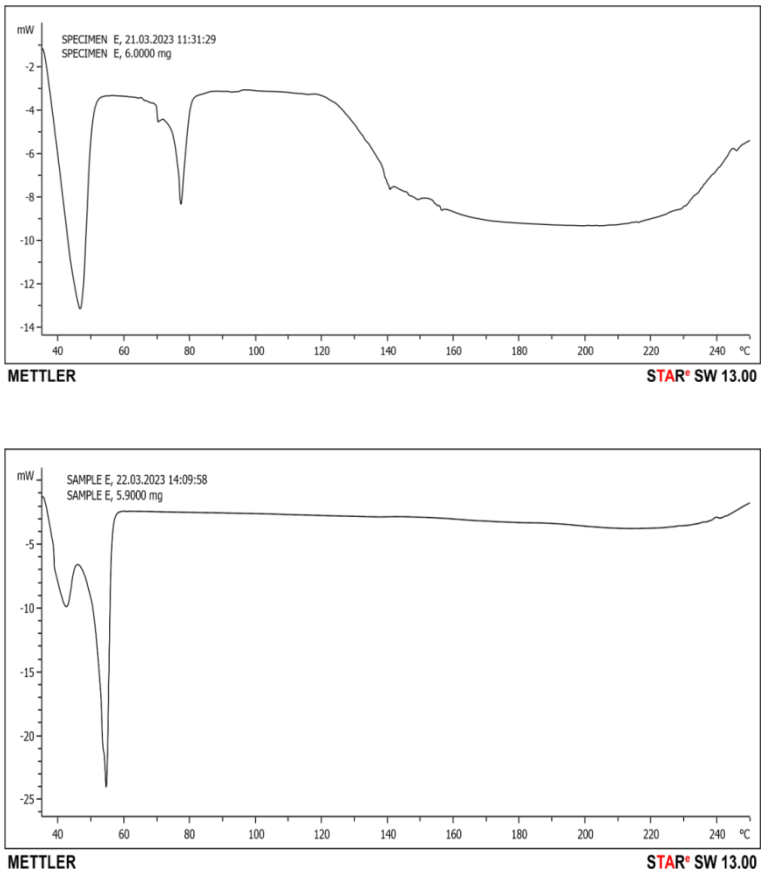

Figure 2. *(Above) DSC thermogram of pure avocado pear seed (APS) starch (Below). DSC thermogram of APS starch in paracetamol tablet formulation.*

Differential scanning calorimetry (DSC) measures the heat flow into or out of a sample as it is subjected to controlled temperature changes. DSC analysis provides insights into the thermal behavior including heat capacity, melting point and transitions between amorphous and crystalline states [26]. In Figure 3 (above), DSC thermograph shows a melting peak on the DSC curve, this peak corresponds to the transition of the crystalline regions of starch from solid to liquid as they reach their melting point but that there is no additional peak or distinct demographic event observed between the drug and the APS (*Persea americana*) starch. Furthermore, the APS starch demonstrates no interaction with other excipients utilized in the formulation (below).

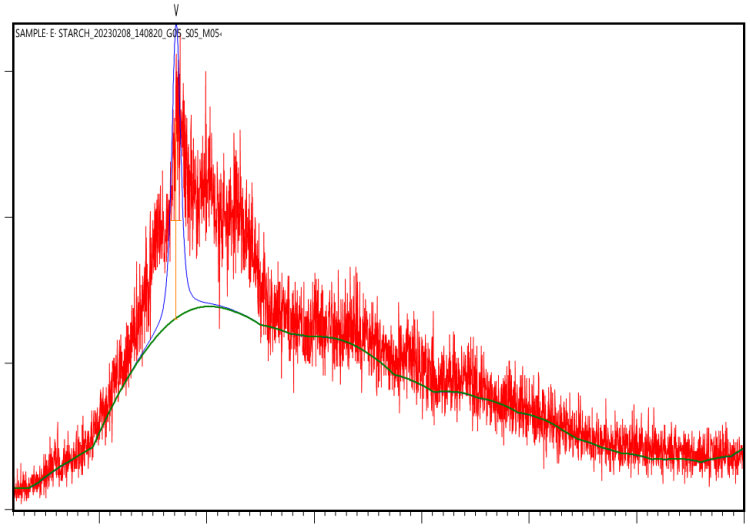

Figure 3. *X-ray diffractometry (XRD) patterns of pure APS starch.*

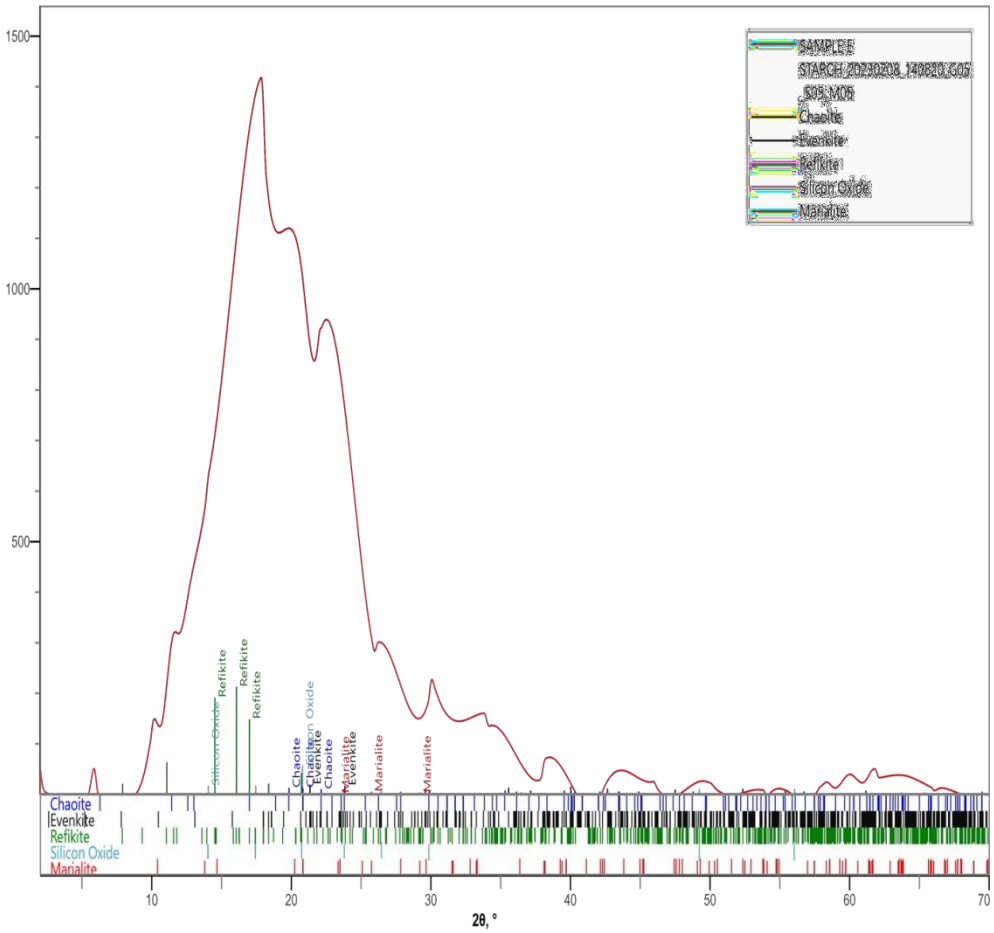

Figure 4. *X-ray diffractometry (XRD) patterns of paracetamol tablet formulated with APS starch.*

X-ray diffraction (XRD) is a technique used to study the crystallographic structure of materials including crystalline and semi-crystalline substances. The exact XRD pattern can vary based on factors like the source of starch, its degree of crystallinity and any treatments it undergone [27]. X-ray diffraction (XRD) results show distinct diffraction peaks that correspond to the periodic arrangement of crystalline regions within the APS starch. These peaks indicate the repeating pattern of the APS starch molecules in the crystalline sections. The amorphous regions are where the APS starch molecules lack a regular pattern which generally does not produce distinct diffraction. The XRD results confirmed APS starch to be semi-crystalline with 'puffy' appearance.

3.3. Results of Fourier Transform Infra-Red (FTIR) Spectra

Results of compatibility studies using FTIR test analysis (Table 5), show no interaction between the active drug (paracetamol), avocado pear seed starch (APS) and other excipients in the formulation as evident by no new peak(s) in the spectra.

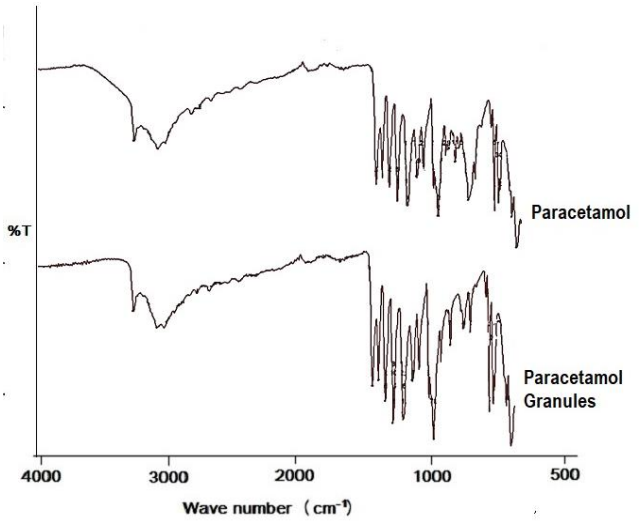

Figure 5. *Fourier transform infra-red (FTIR) Spectra of pure paracetamol powder and paracetamol granules.*

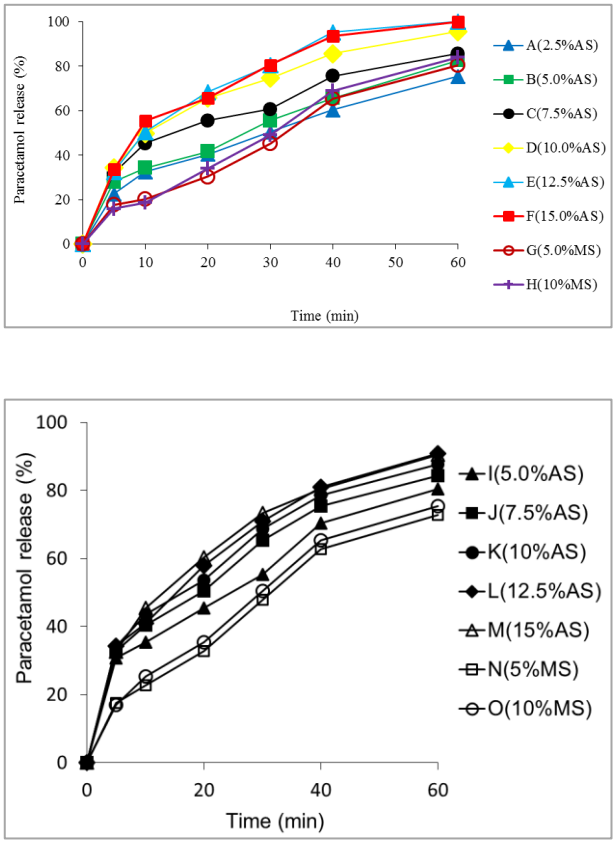

Figure 6. *Dissolution profiles of paracetamol tablets formulated with APS as binder (Above) and as disintegrant (Below).*

3.4. *In-vitro* Dissolution Profiles

The release profiles of the different batches of paracetamol tablets are shown in Figure 6 (above) and (below) respectively. Generally, there were close similarities between the release profiles of the tablets irrespective of the test starch used as binder or disintegrant. The tablets exhibited increased drug release with increase in the avocado starch either as disintegrant or as binder.

All the tablet formulations irrespective of composition achieved at least 70 % of the drug release in 1.0 h, However, not all the batches of the tablets passed the British Pharmacopoeia (BP, 2003) dissolution test for tablets which specifies that at least 70 % of the drug should be in solution after 30 min. The difference in drug release from these tablet formulations was observed to be significant at $p < 0.05$ when comparison is made between those batches with the starch as disintegrant or binder and the control batches with maize starch as dinsitegrant or binder. Again, it can be seen that even though tablets containing the test starch as binder disintegrated faster, the disintegration-dissolution theory is not followed here. This can be explained to be due to possible formation of a mucilaginous layer around the drug particles which contributed to retardation of drug release [28].

4. Conclusion

Tablets formulated with Avocado pear seed starch (APS) powder as disintegrant and as binder were uniform in weights, had hardness values ≥ 6.0 kg, but showed variable friabilities. Tablets formulated with the starch either as disintegrant or as binder exhibited super-disintegrant properties, showed variable drug release profiles with all the batches achieving 70% drug release within 1.0 h. Compatibility studies revealed no interactions between paracetamol and other excipients used in the formulation. The research results revealed the suitability of a novel super-disintegrant, avocado pear seed (APS) starch, in paracetamol tablet formulation.

Abbreviations

DSC	Differential Scanning Calorimetry
FTIR	Fourier Transform Infra-red
SEM	Scanning Electron Microscopy
XRD	X-ray Diffractometry

Conflicts of Interest

The authors declare no conflicts of interest.

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