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Development and Evaluation of the Binding Properties of *Raphia hookeri* (Fam. Palmaceae) Gum in Pharmaceutical Tablet Formulations

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Authors' contributions

This work was carried out in collaboration between both authors. Author SOM designed the study, wrote the protocol and wrote the first draft of the manuscript. Author SM managed the literature searches, analyses of the study performed the spectroscopy analysis and the experimental process. Author SOM identified the species of plant. Both authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aims: This study was aimed to evaluate the potential of using *Raphia hookeri* gum as a binder in tablet formulations.
Study Design: Extract of *Raphia hookeri* gum was investigated as a binding agent in paracetamol tablet formulation in comparison with gelatin BP as standard binder.
Place and Duration of Study: Department of Pharmaceutics and Pharmaceutical Technology, Faculty of Pharmacy, University of Uyo, Uyo, Nigeria.
Methodology: Different concentrations of 1, 2, 3, 4 and 5% $^{w}/_{w}$ of *Raphia hookeri* gum and gelatin BP were used to formulate different batches of paracetamol tablets. The mechanical properties were assessed using crushing strength and friability tests while the drug release properties were assessed using disintegration time and dissolution time.
Results: The flow indices showed that granules formulated with *Raphia hookeri* gum did not

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possess good flow property whereas granules formulated with gelatin BP had a better flow property at all concentrations especially 5% $^{w}/_{w}$. The Carr's Index and Hausner's ratio fell within the acceptable limit of flow property. Tablets formulated with *Raphia hookeri* gum had better mechanical properties compared to those of gelatin BP. The crushing strength, disintegration and dissolution times increased with increased binder concentration while their friability decreased. *Raphia hookeri* gum produced tablets with stronger mechanical properties and longer disintegration and dissolution times than those containing gelatin BP.

Conclusion: This concludes/indicates that *Raphia hookeri* gum could be useful as a binding agent when high mechanical strength and slower release rates are desired as in controlled release formulations.

Keywords: Raphia hookeri gum; binding agent; paracetamol; mechanical properties; release properties; gelatin.

1. INTRODUCTION

Gums are pathological products formed upon injury of the plant or owing to unfavorable conditions such as drought, break down of cell walls (extracellular formation; gummosis) [1]. Gums could be natural, synthetic or semi-synthetic. There have been a lot of investigations into the use of gums gotten locally in various industries like paper, textiles, ink, cosmetics, petroleum and petrochemical and in the pharmaceutical industries, etc. In the pharmaceutical industries, gums are used for the following; binders, stabilizers, thickeners, disintegrants, suspending agents, emulsifiers, matrix formers and coating materials in micro encapsulation [2]. In recent times, cheap, available and eco-friendly binders have been studied by researches in Nigeria and their properties evaluated to see if they can replace expensive imported synthetic and semi synthetic binders.

Gum exudate from *Raphia hookeri* has been characterized by Nnabuk et al. [3] and Majekodunmi and Udemudo [4]. They concluded that *Raphia hookeri* gum could be used as a pharmaceutical excipient in the binding properties and in control release tablet formulations.

According to Majekodunmi and Udemudo [4], the *Raphia hookeri* gum has the following characteristics: carbohydrate (80.27±0.01), protein (1.63%), nitrogen (90.28%), low lipid, low vitamins, alkaloids (0.37±0.02), flavonoids (0.42±0.01), saponin(92.41± 0.01), phytic acid (6.22±0.02), soluble oxalate (8.71±0.02), total oxalate (18.1±0.01), ascorbic acid (6.40±0.01), niacin (3.70±0.01), thiamine (0.11±0.01), riboflavin(0.64±0.02), lipid(0.00), phenol (0.01±0.01). It also contains flavonoids and alkaloids suggest medicinal properties, and the biological role of alkaloids includes protection against allergies, inflammation, free radicals, microbes, virus and tumours.

Binders are agents used to impact cohesiveness to tablets which ensure that tablets remain intact during compression, to ensure free flow to the hopper and after compression as well as during use [5]. With the increase demand of gums in the research it is necessary to seek source of new gums [6].

Raphia hookeri gum is obtained from *Raphia hookeri* G. Mann and H. Wendl (Family Palmaceae). The raphia palms (Raphia) are a genus of about 20 species of palms native to tropical regions of Africa and especially Madagascar with one species (*R. taedigera*) also occurring in central and South America.

Many researchers have worked on several gums in the past: *Aegle marmelos* gum [7] was found to be useful for the preparation of uncoated tablet dosage form; Okro gum (from *Abelmoschus esculentus*) was found suitable as binder in the formulation of thiamine hydrochloride [8]; in sustained release [9]; Olibanum gum in binding properties [10], in sustained release [11], non toxic, as emollient and stiffening agent [12]; Beilschmiedia seed gum as a binder [12,13].

Even though literature scavenging revealed limited physicochemical properties of *Raphia hookeri* gum, to the best of our knowledge no attempt has been made to study the effects of the gum as binder in a tablet formulation. Therefore, the objective of this study was to investigate gum extracted from *Raphia hookeri* G. Mann and H. Wendl has a binding agent in a paracetamol tablet formulation.

2. MATERIALS AND METHODS

2.1 Materials

The materials used were paracetamol (BDH Chemicals Ltd. Poole, England), gelatin (BDH chemicals ltd Poole England), starch (BDH chemicals ltd Poole England), talc (BDH chemicals ltd Poole England) and gum extract of *Raphia hookeri* obtained from Itu Road suburb, Uyo, Nigeria. The gum obtained was as a result of the cut stem. The identification of voucher specimens was confirmed by Mr. Etafia, a botanical taxonomist of the Department of Pharmacognosy and Natural Medicine, Faculty of Pharmacy, University of Uyo, Uyo, Nigeria. The description of the collection and extraction has been done elsewhere [4].

2.2 Methods

2.2.1 Preparation of paracetamol granules

Granules containing 80% of paracetamol, lactose 9% and corn starch (11%) were prepared with different concentrations of 1, 2, 3, 4 and 5% $^{w}/_{w}$ of *Raphia hookeri* gum and gelatin BP as standard gum. Wet granulation method was used in preparing the granules. Appropriate quantities of paracetamol (80%), lactose (9%), corn starch (11%) were mixed using pestle and mortar and were moistened with the appropriate amount of binder solution (formed by forming a dispersion of the gum in hot water) to form a damp coherent mass. More water was added when necessary to obtain the required result. The resulting masses were screened through a 2 mm mesh size and then dried for 4 h at 60℃ in an oven. The coarse granules were then screened through a 1.00 mm mesh size.

2.2.2 Evaluation of granules properties

2.2.2.1 Bulk and tap densities

15 g of each granule batch was determined, using a weighing balance. For each batch, the weighed granules were placed in a 50 ml clean measuring cylinder and the volume occupied by the sample without tapping (bulk volume) was determined. Then after about 50 taps on the desk such that there was no variation in the volume, the tapped volume was then noted. The bulk and tapped densities were calculated as the ratio of weight to bulk and tapped volumes.

2.2.2.2 Hausner ratio

This was calculated as the ratio of the bulk volume to the tapped volume of each batch of granules.

2.2.2.3 Carr's index

This was determined using the equation below:

$$Carr's\ index = \frac{bulk\ volume - tapped\ volume}{bulk\ volume} \times 100\%$$

2.2.2.4 Angle of repose

This was done by clamping a clean dry funnel in a retort stand such that its tip is about 5 cm above a graph sheet placed on a flat horizontal surface. The tip of the funnel was blocked and the granules carefully poured into the funnel. The tip of the funnel was opened and the mean height and radius of the base of the granule heap were noted. The angle of repose was calculated using the formula

$$\text{Angle of repose } (\alpha) = \tan^{-1}\frac{height}{0.5base}\ or\ \tan^{-1}\frac{height}{radius\ of\ the\ base}$$

2.2.3 Preparation of tablets

The granules were compressed into tablets at a punching pressure of 30 kgN using the Erweka G.N.B.H tableting machine. Batches of 35 tablets were produced from the granules according to the table. The tablets produced were stored over silica for 24 h before evaluation.

2.2.4 Evaluation of tablet properties

2.2.4.1 Crushing strength

10 tablets were randomly selected from each batch and their hardness determined using the Monsanto stokes hardness tester. Each tablet was placed between the spindle and anvil and pressure applied by turning the knob sufficiently to hold the tablet in position. The pointer on the scale was adjusted to zero reading and pressure gradually and steadily increased until the tablet breaks into two equal parts. The pointer reading from the scale was taken as the procedure was repeated for the 10 tablets from each batch. The mean and the standard deviations were then calculated.

2.2.4.2 Friability test

10 tablets from each batch of the formulated tablets were de-dusted, weighed and subjected

to vibration and shock in a Roche friabilator rotating at 25 rpm for 4 minutes. Thereafter, they were de-dusted, reweighed and the percentage loss in weight calculated using the equation.

$$\% \text{ friability} = \frac{loss\ in\ weight}{initial\ weight} \times 100$$

2.2.4.3 Disintegration test

The apparatus used in the test consisted of a plastic cylinder closed at its lower end by No 10 mesh steel wire gauze with each tug holding a tablet. The tug was suspended in distilled water at 37±0.5℃. The temperature was maintained thermostatically. The tube was raised and lowered at a constant rate through a standard distance. The up and down movement of the tug into and out of the distilled water (600 ml) put some pressure on the tablets. The time taken for the tablet to break down completely was noted.

2.2.4.4 Dissolution test

The Veego tablet dissolution apparatus was used. The tablet was placed in a wire mesh basket suspended in a dissolution medium of 900ml of 0.1 N HCl maintained at 37±1℃ in a water bath. The work mesh basket was rotated at a speed of 50 rpm and the experiment allowed to run for 1 h. 45 minutes for each tablet tested. 10 ml of the sample from each tablet were withdrawn after 5, 10, 15, 30, 45, 60, 75, 90, 105 minutes, and the dissolution medium replaced with 10 ml of the dissolution medium. The withdrawn samples were filtered and then analyzed for paracetamol content at 254 nm using a UV-Visible 2102 PC spectrophotometer. The concentration of the active ingredient released in a given time was then obtained from the standard Beer-Lambert's plot. A stock solution of 100 mg% of paracetamol was prepared by dissolving 100 mg of the drug in 100 ml of 0.1 N HCl. Various dilutions of the stock were made so as to obtain 0.02, 0.04, 0.06, 0.08, 0.10 mg% with 0.1 N HCl. A plot of absorbance (A) against concentration (mg%) of the drug was made from which the calibration curve constant K was determined from the slope of the graph.

2.3 Statistical Analysis

Statistical analysis was done to compare the effect of the different binders on the different groups using the software SPSS version 16.0 ANOVA with the Duncan post test. At 95% confidence interval, p values of < 0.05 were considered significant.

3. RESULTS

3.1 Physicochemical Properties of Granules

The results of the granules properties are shown in Table 1.

3.2 Mechanical and Release Properties

The values of crushing strength (CS), friability (F), Crushing strength - friability ratio (CSFR) and disintegration times (DT) of paracetamol tablets formulated with different concentrations of *Raphia hookeri* gum and gelatin are shown in Table 2.

The values of dissolution time tests are shown in Table 3.

The plots of percentage drug release from tablets containing different concentrations of *Raphia hookeri* versus time are shown in Fig. 1.

Table 1. Physicochemical properties of granules

Binder	BC ($\%^w/_w$)	FR (g/sec)	BD (g/mL)	TD (g/mL)	AR (θ)	HR	CI (%)
Rh (gum)	1	10.6±0.21	0.47±0.1	0.58±0.54	20.56±0.13	1.23±0.23	18.75±0.41
	2	9.93±0.12	0.45±0.24	0.58±0.21	18.97±0.01	1.26±0.21	21.20±0.12
	3	13.6±0.11	0.44±0.32	0.58±0.22	20.55±0.21	1.30±0.23	23.50±0.21
	4	18.5±0.3	0.42±0.21	0.57±0.31	19.39±0.13	1.33±0.14	25.00±0.41
	5	18.5±0.21	0.42±0.41	0.51±0.22	20.30±0.12	1.33±0.32	19.40±0.23
Gelatin	1	7.5±0.31	0.43±0.32	0.50±0.11	22.6±0.34	1.17±0.31	16.67±0.41
	2	9.38±0.23	0.43±0.22	0.52±0.24	25.2±0.13	1.21±0.1 4	17.14±0.32
	3	8.52±0.32	0.44±0.12	0.52±0.21	22.6±0.22	1.17±0.2 4	14.71±0.42
	4	8.67±0.23	0.44±0.11	0.52±0.42	23.8±0.21	1.17±0.2 2	14.71±0.11
	5	8.67±0.22	0.46±0.24	0.50±0.12	25.2±0.13	1.10±0.3 2	9.09±0.13

Rh gum (Raphia hookeri gum), BC (Binder Concentration), FR (Flow rate), BD (Bulk Density), TP (Tap Density), AR (Angle of Repose), HR (Hausner's Ratio), CI (Carr's Index)

Table 2. Values of crushing strength, friability, crushing strength-friability ratio and disintegration times of paracetamol tablets

Binder	Binder conc. (%)	CS (Kgf)	F (%)	CSFR	DT (min)
***Rh* gum**	1	5.34±0.43	0.80±0.11	6.68±0.15	14.43±0.31
	2	5.84±0.38	0.70±0.21	7.35±0.23	17.44±0.37
	3	6.00±0.14	0.60±0.32	10.17±0.11	18.01±0.99
	4	6.28±0.33	0.50±0.42	6.28±0.31	21.74±0.71
	5	6.72±0.12	0.39±0.14	17.23±0.42	28.6±0.79
Gelatin	1	4.6±0.53	0.80±0.23	5.75±0.33	5.22±0.14
	2	4.8±0.74	0.75±0.31	4.84±0.23	8.26±0.13
	3	5.9±0.33	0.60±0.25	10.00±0.12	11.87±0.38
	4	6.1±0.09	0.55±0.35	10.17±0.23	13.57±0.43
	5	6.6±0.21	0.50±0.24	11.19±0.51	16.12±1.79

Table 3. Dissolution profile of paracetamol tablets formulated with *Raphia hookeri* gum and gelatin

Binder	Binder Conc. (%)	Cummulative % drug release								
		Time (min)								
		5	**10**	**15**	**30**	**45**	**60**	**75**	**90**	**105**
***Rh*gum**	1	19	25	30	43	49	55	70	76	80
	2	12	16	19	25	40	52	70	73	78
	3	10	11	15	25	40	47	65	73	77
	4	9	11	15	23	32	41	60	72	76
	5	6	9	11	14	32	39	56	70	70
Gelatin	1	20	24	30	39	60	85	90	92	94
	2	15	20	22	33	58	72	83	85	88
	3	12	16	21	28	50	70	81	83	85
	4	10	15	18	25	43	65	72	81	84
	5	8	12	15	20	43	60	65	78	81

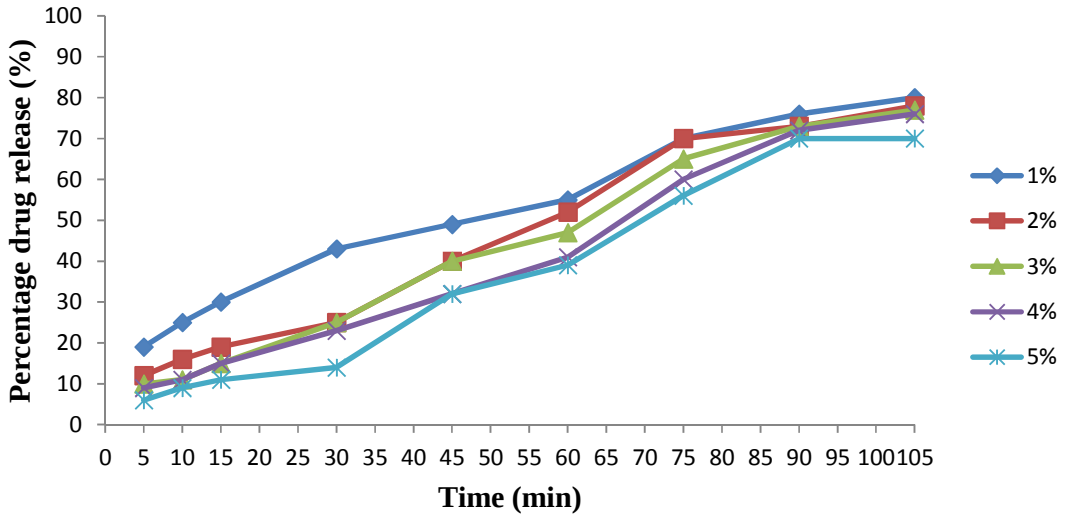

Fig. 1. Plots of percentage drug release vs. time for tablets formulated with *Raphia hookeri* gum as binder

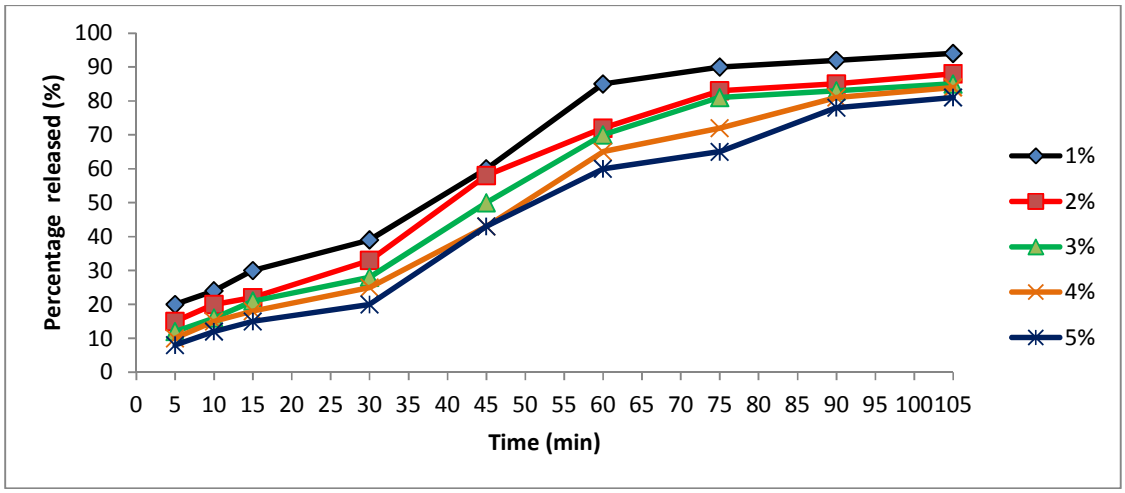

Fig. 2. Plots of percentage drug release vs. time for tablets formulated with gelatin as binder

The plots of percentage drug release for tablets containing different concentrations of gelatin gum versus time are shown in Fig. 2.

4. DISCUSSION

4.1 Properties of Granules

Several indices exist for the determination of the extent to which a given material possesses essential properties before the particulate material can be tableted. Lund [14] outlines these properties to include quick and uniform flow into the die, coherence when subjected to a compressive force and quick and easy ejection of the finished tablet from the press.

In this study, the computed indices to evaluate the granule flow properties were angle of repose, rate of flow, bulk and tapped densities from which the Carr's compressibility indices and Hausner ratio for each granule batch.

The flow rate for the granules prepared with different concentrations 1, 2, 3, 4, and 5% of *Raphia hookeri* gum were respectively 10.6, 9.93, 13.6, 18.5, 18.5 g/sec respectively whereas those of gelatin were 7.5, 9.38, 8.52, 8.67 and 8.67 g/sec respectively. From the results, as the binder concentration was increased, the flow rate also increased up to a limit before it started stabilizing. From the analysis, the flow rate increases significantly with increase in binder concentration. The binder concentrations 4% and 5% had the highest flow rate. The increase in binder concentration created more bridges with the granules decrease the attractive force of cohesion and attraction. It is relatively higher in *Raphia hookeri* gum.

The angle of repose explains flowability, though it has been used as an indirect method of quantifying granule flowability because of the relationship with interparticulate cohesion. Large angle of repose indicates low flowability. Granules below 25° flow better. The angle of repose for the granules formulated with *Raphia hookeri* gum using 1, 2, 3, 4, 5% concentration of the gum were 20.56°,18.97°, 20.55°,19.39° and 20.30° respectively compared to 22.6°, 25.20°, 22.6°, 23.8°, 25.2° respectively obtained for gelatin. As the binder concentration was increased angle of repose increased to a certain level after which it tended to go up again. This happens when the binder has reached its maximum concentration and any additional will have little or no effect on the angle of repose. Comparing the two results, granules formulated with *Raphia hookeri* gum had slightly better flow although the disparity was not much. Concentrations 1% and 3% had the highest angle of repose while concentration 2% had the least angle of repose.

Tapped density explains the density of granules after packing. As the binder concentration is increased the granules size increases forming more void spaces and decreased tapped density [15]. In this work as the binder concentration was increased, the tapped density did not change appreciably. There was no significant difference in the tapped density for concentrations 1%-4%. Granules mixed with 5% of binder had the least tapped density. Granules mixed with 4% and 5%

of binder had the least bulk density while concentration 1% had the highest bulk density. The low bulk and tapped densities of granules formulated with *Raphia hookeri* gum indicates that the granules were highly porous and had acceptable flow properties. Increasing the binder concentration had little or no influence on the bulk density. The low bulk density results when the void spaces created by larger particles are not filled by smaller particles leading to consolidation of powder particles [16].

Hausner ratio describes the compressibility of the granules. The confirmation of the passable flow nature of the granules formulated with *Raphia hookeri* gum were gotten from the fact that the Hausner ratio of the granules formulated using the different binder concentrations of 1, 2, 3, 4, and 5% are 1.23, 1.26, 1.30, 1.33 and 1.33 respectively indicating that they are passable, whereas granules formulated with 5% gelatin gum had Hausner ratio and Carr's index of 1.10 and 9.09 respectively showing an excellent flow. The granules formulated with gelatin gum concentrations of 1, 2, 3 and 4 had their Hausner ratio of 1.17,1.21,1.17,1.17 and Carr's index of 16.67, 17.14, 14.71, 14.71 respectively showing that they have good flow properties. Comparing these two gums, gelatin produces granules with better flow properties than *Raphia hookeri* gum. Granules mixed with 4% and 5% had the highest Hausner's ratio while 1% had the least. Like the flow rate, the Hausner's ratio increases with an increase in the binder's concentration.

Carr's index explains percentage compressibility of the granules. As the binder concentration of the granules was increased up to 4% in *Raphia hookeri* gum and 2% in gelatin the Carr's index increased which explained that at those concentrations enough bridges have been formed giving denser granules [17].

4.2 Evaluation of Tablet Properties

Crushing strength is indicative of the extent of interparticulate bond between the granules. It is the measure of the compressional force which when applied diametrically to the tablet just causes the tablet to fracture [18]. The force is measured in kilogram force or kilogram centimeter; 4 kg force is considered the minimum for satisfactory tablets [19]. There was a significant difference between the difference concentrations of the binders and the mechanical properties of the tablets. From the analysis, as the binder concentration was increased, the crushing strength increased gradually for both tablets formulated with *Raphia hookeri* gum and gelatin BP. Tablets produced with 5% of binder concentration had the highest crushing strength. This means that at the same concentration *Raphia hookeri* gum produced harder tablets. In the study, all tablets formulated with either of the gums fell within the acceptable range of 4-7 kgF. However, batch per batch, as the concentration of the gum increased, the crushing strength also increased. Tablets formulated with *Raphia hookeri* gum had higher crushing strength than those formulated with gelatin. There was a significant difference between the different binder concentrations and the mechanical properties for the tablet prepared with gelatin as binder.

The test for the friability of tablets measures the ability of the tablet to withstand abrasion in packaging, handling and shipping. In the test for friability of pharmaceutical tablets, the test is rejected if any tablet caps, laminates or breaks up in the course of the test. Values of 0.8-1% are frequently quoted as the upper level of acceptance for pharmaceutical products. As the binder concentration increased there was an decrease in tablet's friability. The increase in binder's concentration increased the binding bridges in between the granules thereby giving additional bonds which increased the tablet's crushing strength. From the results obtained, the percentage friability of *Raphia hookeri* for 1-5% are 0.8, 0.795, 0.595, 1.0, and 0.39% respectively compared to that of gelatin 0.8, 0.99, 0.59, 0.60, 0.59% respectively. Though the values all fell within the acceptable range, tablets formulated with *Raphia hookeri* are less friable. Tablets prepared with 1% had the highest friability profile while concentrations 5% had the least. Generally, the friability profile increased with a decrease in binder concentration.

Apart from the crushing strength, the mechanical strength of tablets can also be measured by the crushing strength and friability ratio (CSFR). Generally, the higher the CSFR values, the stronger the tablet. The values of CSFR for the tablets are included in Table 2. The CSFR increased with increased binding agent concentration with tablets containing *Raphia hookeri* gum having higher values than tablets containing gelatin BP. This means that *Raphia hookeri* gum produced tablets that are generally stronger than gelatin BP. Tablet prepared with 5% binder concentration had the highest CSFR profile while the tablets prepared with 4% binder concentration had the least. Generally, the CSFR

profile increased with an increase in binder concentration with a deviation in tablets prepared with 4% binder concentration.

The tablet disintegration test is a useful means of assessing the potential significance of formulation and process variables on the biopharmaceutical properties of the tablet, and as a control procedure to evaluate the quality reproducibility of the tablet during production. The disintegration test is an *in vitro* procedure and does not necessarily bear a relationship to the *in vivo* action of solid dosage forms. Specified disintegration time for various tablet types in official compendia stipulates 15 minutes for uncoated tablets, 2 hours for coated tablets and 3 minutes for sublingual tablets. In this study, only tablet formulated with 1% concentration of the *Raphia hookeri* gum passed the disintegration test. Generally, the disintegration time increased with an increase in the binder concentration. Tablets prepared with 5% binder concentration had the highest disintegration time while tablets prepared with 1% had the least. All the tablets formulated with gelatin except 5% binder concentration passed the disintegration test. Generally, *Raphia hookeri* gum produced tablets having higher disintegration time than tablets prepared with gelatin as binder. The much higher demonstration of disintegration time of tablets produced by *Raphia hookeri* gum coupled with its high mechanical strength corroborated with the work of Majekodunmi and Udemudo [4] who concluded in the characterization of *Raphia hookeri* gum that it could be useful in controlled release formulations.

There was a marked decrease in dissolution times when the concentration of *Raphia hookeri* gum and gelatin BP were increased to 5%. There was a significant difference in dissolution profile between tablets prepared with RH gum and those prepared with gelatin. Tablets prepared with *Raphia hookeri* gum showed slower dissolution times compared to formulations containing gelatin BP. This suggests that *Raphia hookeri* gum at certain concentrations could be useful in controlled release dosage forms where slower dissolution is required.

5. CONCLUSION

The results of this investigation show that tablet formulations containing *Raphia hookeri* gum as a binding agent demonstrated a stronger mechanical strength and longer disintegration time and slower dissolution times than tablets formulated with gelatin as a binding agent. This proved/indicated that *Raphia hookeri* gum could be useful as a binding agent especially when higher mechanical strength and slower dissolution rates are desired.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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