

Evaluation of Binding Properties of *Phoenix dactylifera* (Date Palm) in Tablet Production

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ARTICLE INFO

Article history:

Received 11th March 2024
Revised 27th April 2025
Accepted 30th April 2025
Online
Published

Keywords:

Tablets,
Phoenix dactylifera,
acacia,
binding

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ABSTRACT

Background *Phoenix dactylifera* (Date Palm) is one of the earliest fruit crops growing in the Arabian Peninsula, North Africa, and the Middle East. PD is important as it is a high-energy food. It has chemical constituents which have medicinal purposes including antioxidant, anti-mutagenic, anti-inflammatory, anti-cancer activities, anti-analgesic, antipyretic, and protection against colds, sore throat and fever. Most times, natural products are also used for pharmaceutical excipients apart from medicinal purposes.

Binders are dry powders or liquids incorporated into powders during the process of wet granulation to produce granules. It gives the tablet tensile stability. Binders can be applied to the powder in a variety of methods prior to wet agglomeration to ensure equal distribution. There are many sources of natural binders such as starch, pre gelatinized starch, gelatin, acacia, tragacanth and gums. Hence, this study is aimed at evaluating the binding effect of PD mucilage in granules and tablet and comparing it with binding effect of acacia.

Methods: Granules containing dried PD and acacia at various concentrations (2, 4, 6 and 8 %) as a binder were prepared by wet granulation method. Corn starch and lactose were mixed in a mortar and the Sodium salicylate was then added as active pharmaceutical ingredient. The mixtures were moistened with the appropriate amount of binder solution prepared in distilled water. The granules were prepared by the conventional method. Evaluation of granules including physical examination, flow rate, angle of repose, bulk density, tapped density, Carr's compressibility index and Hausner ratio (HR) were carried out. Tableting of the granules were carried out. Evaluation of tablets for various properties such as weight uniformity, disintegration time test and dissolution test were also done.

Results: Angle of repose of all batches of granules of PD and acacia was 25 - 40 °. The optimal concentration of PD granules was 4% which has Carr's compressibility index as 9.25% and HR as 1.10 while acacia granules was 8% with Carr's compressibility index as 15.51% and HR as 1.18. All the batches of PD and acacia gum tablets passed weight uniformity and friability tests. All the PD had disintegration time above 15 min which is contrary to Acacia tablets. All the PD tablets had slow drug release when compared with acacia tablets.

Conclusion: Based on the findings from investigation carried out, granules containing PD of 4% concentration showed good flow property which is better than acacia granules of 8%. However, all the PD tablets at various concentrations had good tableting properties with exception of long disintegration times and slower drug release when compared with acacia tablets.

1. INTRODUCTION

Phoenix dactylifera (Date Palm) is a major food supply and source of revenue for local inhabitants throughout the Middle East and North Africa. It is also available in northern Nigeria. PD are packed and processed in a variety of ways, in addition to serving as a direct food source, other

portions of the tree are utilized for a variety of reasons. PD fruit juice, vinegar, wines, alcohol, sugar, molasses, honey, chutney, pickle, paste, dip, and food seasoning can all be prepared from PD fruit^{1,2}. PD could also be used in cereal, porridge, toast, compressed baked goods, pastries, chocolate bars, ice cream, and date shakes e.t.c (a California

specialty). PD was reported to possess many medicinal values. It gives protection against a variety of chronic diseases, including cancer and heart disease, due to their antioxidant and antimutagenic characteristics^{3,4,5,6,7}. Aqueous extracts of PD have also been demonstrated to reduce lipid peroxidation and protein oxidation, as well as to have strong superoxide and hydroxyl radical scavenging properties⁵. It has also been suggested that the extracts of PD flesh and pits can reverse the carbon tetra chloride (CCl₄)-induced liver damages in rats⁸. PD products are used to treat sore throats, colds, and bronchial catarrh. This is possible when used in the form of infusion, decoction, syrup, or paste for inflammation of mucus membranes^{7,9}. There is no clinical evidence yet to support such assertions for the antioxidant and anti-inflammatory properties of dates⁴.

Granulation is a size-enlargement process that transforms fine or coarse particulates into bigger and more powerful agglomerates with excellent flow properties, compressive characteristics and homogeneity. There are two types of granulation process namely dry granulation and wet granulation. Dry granulation is carried out without the use of a liquid solution. Dry powder particles can be mechanically compressed into slugs or rolled into flakes in this technique. However, wet granulation entails adding a liquid solution (with or without binder) to powders to make a damp mass¹⁰. The screened wet substance is dried before being sized into granules. During repeated drying, more persistent connections are created, resulting in the creation of agglomerates¹¹.

In wet granulation process, binder which comes as a dry powder or liquid is incorporated to produce granules or cohesive compact during direct compression. Binder is known as a liquid binder when utilized as an aggregation of liquid in wet granulation¹². Binder can be formed from natural and synthetic polymer. Natural polymers are available as a gum and mucilage. Gum results as a pathological product that can be created by three separate ways while mucilage results from intercellular development generated by a typical by-product of metabolism and created without causing any significant damage to the plant¹³. Examples of natural gum and mucilage include acacia, tragacanth, Guar gum, xanthan gum, dextrin, alginic acid, pectin, karaya gum, chitosan and chitin. Natural gum and mucilage have many advantages such as biodegradable, local availability, low production cost, biocompatible and nontoxic. Acacia and tragacanth gum are used commercially as a binder in 10-20% concentration. Researches have been done on use of PD as

excipients.

A study investigated the use of date syrup as a tablet binder for granulation of sodium bicarbonate and calcium carbonate¹⁴. Another study developed co-processed PD sugar and Manihot esculent starch for preparation of ketoconazole dry suspension which gave good release characteristics and other acceptable suspension properties¹⁵. A study use biocompatible date palm mucilage for encapsulation with silver nano particles for sustained drug release so as to provoke an immune response. Nano formulated mucilage delayed the onset exposure of drug in gastric medium giving recommendations as value added bio binder for drug to the target organ¹⁶. Akin *et al* studied co-processing of this novel mucilage with microcrystalline cellulose using co-grinding and co-fusion methods so as to improve disintegration properties of metronidazole tablets¹⁷. Also a study was carried on PD as a binder for paracetamol tablets formulation¹⁸. However, this study focused on preparation and evaluation of Sodium salicylate granules and tablets using PD mucilage as a binder. The binding effect was compared with acacia.

Materials: Sodium salicylate (Burgoyne Laboratory, India), Acacia (Molychem, India), Lactose (Molychem, India), Magnesium Sterate (Qualikems, India), Corn starch, Distilled water prepared from the distiller.

Sourcing and Preparation of the *Phoenix dactylifera*(PD)

The fresh PD fruits were obtained from Masaka Market, Masaka, Nasarawa State. Fresh PD were dried, blended and stored until usage.



Figure 1: Date Fruit

PREPARATION OF GRANULES

Granules were prepared by wet granulation method using formula in Tables 1 and 2. Various Acacia and PD granules were prepared at different concentrations of 2%, 4%, 6%, and 8%^{w/w}. Weighed Corn starch and lactose which act as disintegrant and filler respectively were added to the mortar and mixed properly.. Sodium salicylate which served as the active pharmaceutical ingredient (API) was also added to the mixture. The mixtures were then moistened with the appropriate amount of binder solution prepared in distilled water. The screening of the homogenous wet mass was

carried out with sieve No 2.0mm placed in hot air oven at 60°C for 40 min. Thereafter the dried granules were screened through a 1.4 mm sieve to obtain fine granules which was mixed with weighed magnesium stearate (a lubricant). Talc was excluded from the formula to reduce number of excipients present in the formula which may have interactions with PD when compared to previous study¹⁸. Though talc can be used as lubricant and glidant, magnesium stearate was used in-place of talc for its role of a lubricant for easy of tableting.

Table 1: Composition of Sodium Salicylate granules using Acacia and PD as a binder at various concentration

INGREDIENT	QUANTITY (g)							
	ACACIA BINDER				PD BINDER			
Binder Concen. (% w/w)	2	4	6	8	2	4	6	8
Sodium Salicylate (19.7%)	8.9	8.9	8.9	8.9	8.9	8.9	8.9	8.9
Magnesium Stearate (1%)	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45
Corn Starch (10%)	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Lactose	qs	qs	qs	qs	qs	qs	qs	qs

Evaluation of Granule Properties

Physical Examination: The granules from different batches were examined virtually for colour and odour.

Bulk densities: Weighed granule was placed in a 100ml measuring cylinder. The volume occupied by the granule was recorded as the bulk volume. The density of the bulk (D) was calculated as stated in Equation 1.

$$D = \frac{M}{V} \text{----- Equation 1}$$

where

D= Bulk Densities

M_ Mass of granules

V_ volume of granules

Tapped density: The measuring cylinder with known mass of granules was tapped on a smooth, flat surface by dropping the cylinder from a height of one inch '100 times'. This was done till there was no significant change in the volume of the granules and the volume was then recorded as the tapped volume. The tapped density was calculated as stated in Equation 2.

$$T = \frac{M}{V_{\text{(tap)}}} \text{----- Equation 2}$$

where

T= Tapped Density

M= Mass of granules

V_(tap)= Volume of tapped granules

Hausner ratio and Compressibility Carr's index: The flow properties of the granules were evaluated by calculating the Hausner ratio and Carr's index. Hausner ratio was calculated as stated in Equation 3, while Carr's index was calculated as stated in Equation 4.

$$\text{Hausner ratio (HR)} = \frac{\text{tapped density}}{\text{bulk density}} \text{----- Equation 3}$$

$$\text{Carr's index} = \frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} \times 100 \text{----- Equation 4}$$

Flow rate and angle of repose: The flow rate and angle of repose were also measured. A 5 g quantity of each granule batch was poured into a glass funnel fixed to the retort stand with its funnel orifice closed. The glass funnel with a constant known efflux tube length and orifice was used. The time taken for the entire granule to flow through the orifice was recorded. The flow rate was obtained by dividing the mass of the sample by the time of flow in seconds^{19,20}. A cone of granules was formed on a flat base. The height of the cone was measured and the angle of repose was calculated as stated in Equation 5. Determinations were done in triplicates.

$$\theta = \tan^{-1} \frac{h}{r} \text{-----Equation 5}$$

Where

θ = angle of repose

h = height of the conical powder heap

r = radius of the circular base.

Preparation of Tablets

The sodium salicylate granules were then passed through sieve 0.25 to separate the fines from the coarse. Finally, magnesium stearate was added first to the fines and mixed for 5 mins after which the coarse granules were incorporated and mixed. The different batches of the sodium salicylate granules in the size range of 250-300 mg were compressed into tablets using a 16 punch tableting machine. The tablets were stored for 24 h after compression to allow for elastic recovery and hardening before evaluation. The earlier formula in Table 1 was enlarged to get 80 tablets per batch. The ingredients were reduced to fine particle size using the porcelain mortar and pestle.

Evaluation of Tablets

Physical Examination: The different batches of the tablets were physically examined.

Weight Uniformity Test: Twenty tablets of each batch were randomly selected and weighed individually with a sensitive analytical weighing balance. The percentage weight deviation was calculated using Equation 6..

$$\text{Weight Percentage Deviation (\%)} = \frac{X_1 - X_2}{X_1} \times 100 \text{----- Eqn 6}$$

Where X1 is each Tablet weight and X2 is Average of twenty tablets

Disintegration Time Test: Disintegration time was determined using USP disintegration apparatus. A tablet was placed in each tube and the basket rack positioned in distilled water that was maintained at temperature of 37 degrees. The mean time taken for six tablets of each batch to disintegrate was recorded.

Hardness Test. The hardness was measured using Mosanto hardness tester. The tablet was placed between the anvil and spindle of the tester, and the knurled knob turned until the tablets fits into space and adjusted to zero. The force (kg) taken to

break the tablet was read and the mean of triplicate determination of each batch was recorded.

Measurement of Tablet Thickness and Diameter; The thickness and diameter of ten randomly selected tablets from each batch were determined using a digital vernier caliper (4Cr13 stainless steel digital caliper, China).

Friability test: The percentage friability was determined using a friabilator. Ten tablets were selected randomly from each batch, weighed together and recorded (w1). The tablets were then placed in the friabilator and rotated at a set speed of 25rpm, after 100 resolutions i.e 4mins, the machine was stopped and the tablets were dusted and re-weighed (w2).The percentage friability of each batch was determined and recorded.

$$\text{Friability \%} = \frac{W_1 - W_2}{W_2} \times 100 \text{ ----- Eqn 7}$$

Where W1 is original weight and W2 is final weight

In vitro Dissolution Studies

The *in vitro* study was performed in an improvised USP type-II Paddle apparatus at 50 rpm using distilled water as a dissolution medium at a temperature of 37°C +_ 1°C . The 5 mL samples were drawn periodically (every 5 min) and replaced with distilled water. The withdrawn samples were filtered and filtrate diluted to 50 ml with 0.1 M NaOH. Absorbance of each solution was measured with the aid of UV-spectrophotometer (T90 UV/VIS Spectrophotometer, PG Instruments Ltd UK) at wavelength of 345 nm .

$$\% \text{ release} = \frac{\frac{A}{K} + D.F}{\text{Absolute drug content}} \times 100 \text{ ----- Equ8}$$

Where A = Absorbance

K = Slope of the Beer's plot

D.F = Dilution factor

RESULTS

Two batches of granules containing Acacia and PD as a binder in various concentrations were prepared. Figure 1 shows the granules of PD while Figure 2 shows the PD mucilage.



Figure 1: Granules of PD



Figure 2: Mucilage of PD

The micromeritic properties of PD and acacia granules were evaluated and presented in Table 2 and Table 3.

Table 2: Flow Characteristics of Acacia granule batch at various concentrations

	F1	F2	F3	F4
Micromeritic properties/ Acacia Conc	2%	4%	6%	8%
Angle of repose(°)	33.42	37.65	33.10	33.12
Bulk density	0.46	0.49	0.45	0.49
Tapped density	0.59	0.57	0.55	0.58
Carr's index(%)	22.03	14.03	18.18	15.51
Hausner ratio (HR)	1.28	1.16	1.22	1.18
Flow rate(g/s)	2.80	1.26	3.61	3.81

As shown in Table 2 granules of acacia at all concentrations had a good angle of repose which is within the good flow range of angle of repose (25 - 40 °) that depicts fairness to excellent flow. Only 2% acacia granule batch had Carr's index of 22.03 which was above the normal range for good flow (< 10 to 20). Similarly, only 2% of acacia granules had highest Hausner ratio of 1.28 that is above the value for fair flow which is 1.25. Formula 4 (F4) granules with 8% concentration of acacia is the optimized formula which gave good flow when all the parameters are considered holistically. Granules of PD as a binder at all concentrations had a good angle of repose which is within the range of angle of repose (25 - 40 °) that depicts good to excellent flow (Table 3).

Table 3: Flow characteristics of PD granule batch at various concentration

	F1	F2	F3	F4
Micrometric properties/PD Conc.	2%	4%	6%	8%
Angle of repose (*)	38.28	37.94	37.77	32.67
Bulk density	0.51	0.49	0.45	0.44
Tapped density	0.58	0.54	0.58	0.59
Carr's index (%)	13.79	9.25	22.41	25.42
Hausner ratio	1.16	1.10	1.28	1.34
Flow rate(g/s)	2.79	3.06	2.79	3.04

F3 and F4 granules of 6 and 8 % concentration of PD had Carr's index of 22.41 and 25.42% which were above the normal range for good flow (< 10 to 20%). Similarly, 6 and 8 % of PD granules had highest Hausner ratio of 1.28 and 1.34 which is above the value for upper limit for fair flow (1.25). Among the different formula, F2 with 4% PD concentration had the granules optimized formula for having excellent flow property with Carr's index 9.25 and HR of 1.10. This is good for tableting of the drug due to excellent flow property. For this reason the 4% concentration clearly showed excellent flow properties that will make tableting process easy.

Tablet Parameters Results.

Physical Properties: All the various batch of PD tablets were light brown tablets with no discolouration

Weight Uniformity: The results showed that all PD and acacia tablets of various batches had percentage deviation of less than $\pm 10\%$.

Table 4: Tablet official and non-official properties of PD tablets batch at various concentration

Concentration	2%	4%	6%	8%
Mean Weight (g) \pm SD	0.705 \pm 0.008	0.696 \pm 0.014	0.698 \pm 0.015	0.690 \pm 0.009
Mean Diameter (mm)	0.964	0.966	0.970	0.980
Mean Thickness (mm)	0.27	0.27	0.28	0.28
Hardness (kg)	7.00	8.50	8.70	10.00
Friability (%)	0.67	0.54	0.50	0.40
Disintegration (min)	19.24	23.0	25.60	30.20

The hardness of the all the PD tablets batches ranged from 7.00 to 10.00 kg. The highest friability was 0.67 % for 2% PD concentrations tablet as shown in Table 4. The disintegration time of all PD batches were high for uncoated tablets at all the concentrations.

Table 5: Tablet official and non-official properties of Acacia batch at various concentration

Conc/Tablet Parameters	2%	4%	6%	8%
Mean Weight (g) \pm SD	0.683 \pm 0.007	0.701 \pm 0.004	0.693 \pm 0.01	0.698 \pm 0.008
Mean Diameter (mm)	0.983	0.984	0.988	0.990
Mean Thickness (mm)	0.28	0.27	0.28	0.29
Hardness (kg)	7.78	6.50	6.00	5.32
Friability (%)	0.79	0.81	0.83	0.89
Disintegration (Min)	14.55	12.22	10.60	10.00

Table 5 clearly showed that all the acacia tablets at varying concentration had good friability, hardness and disintegration for highest value were 0.89 %, 7.78 kg and 14.55 min respectively.

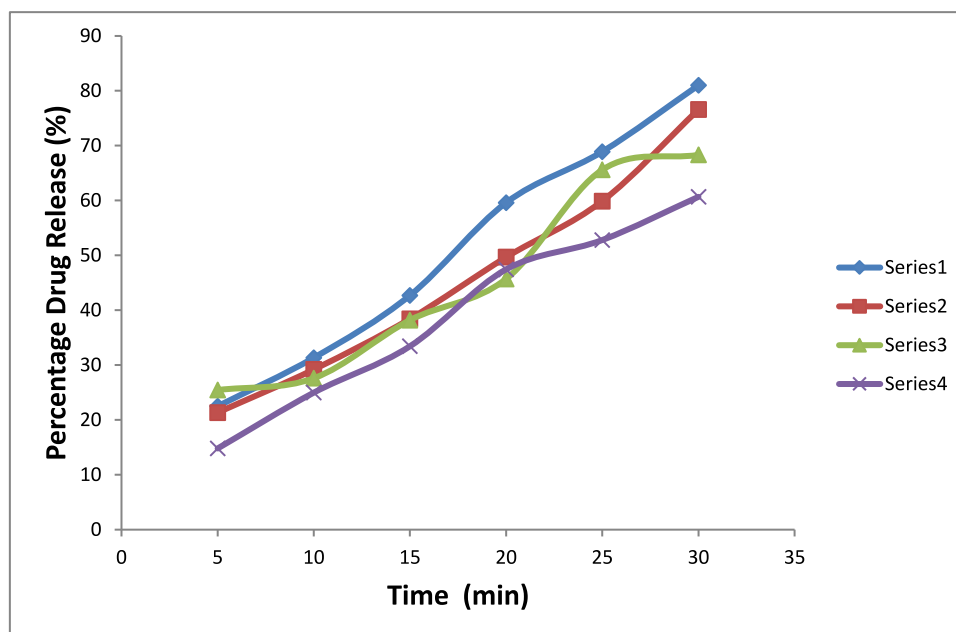


Figure 3: Drug Release Profile for PD Tablets

Key: Series 1: 2% Series 2: 4% Series 3: 6% Series 4: 8%

Figure 3 showed that none of the PD batches released drug up to 90% after 30 min.

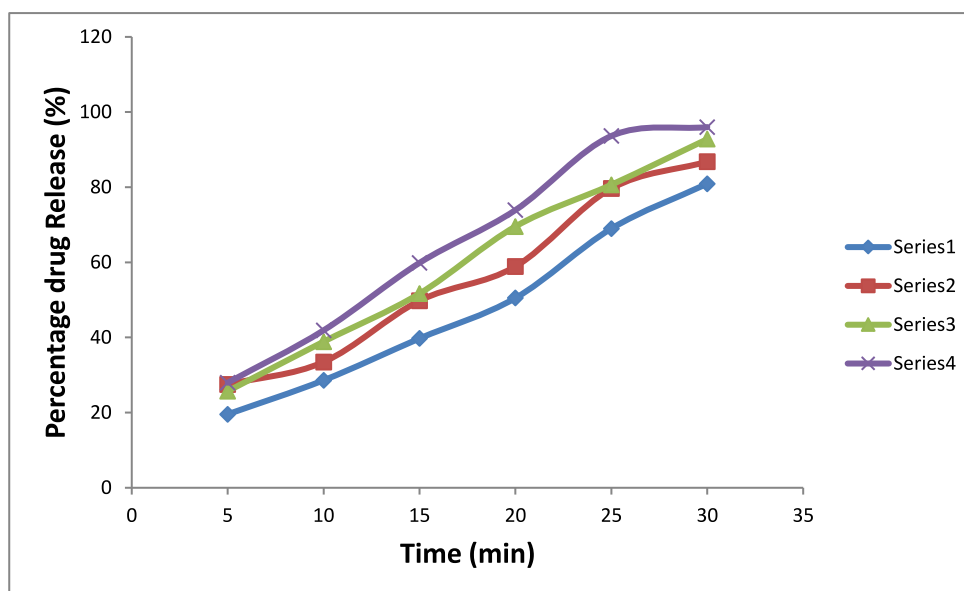


Figure 4: Drug release profile for various concentrations of Acacia powder tablets used.

Key: Series 1: 2% Series 2: 4% Series 3: 6% Series 4: 8% (Conc of gum)

Figure 4 clearly showed that only 8% concentration acacia powder tablets released 93.62 at 25 min.

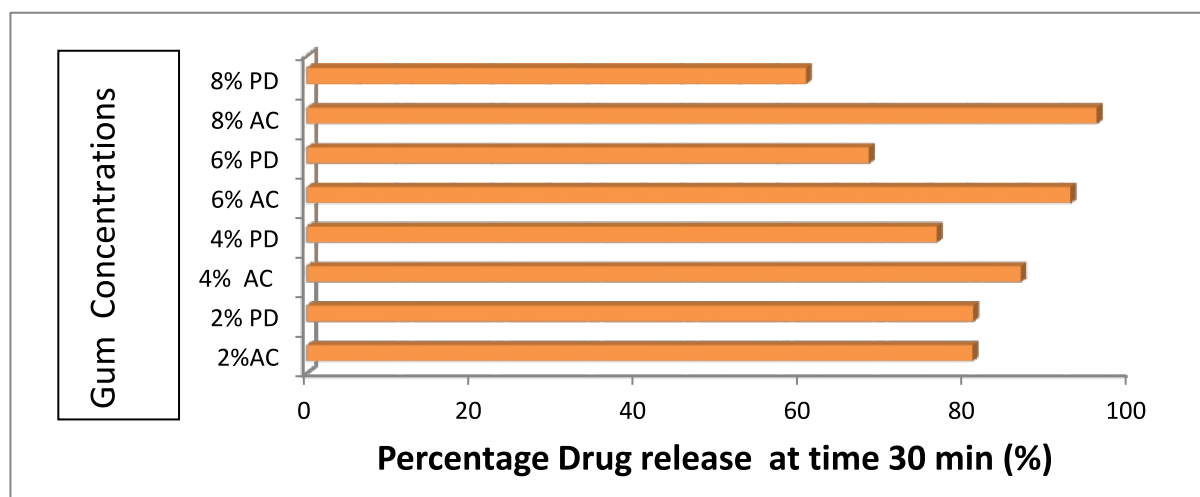


Figure 5: Comparative percentage drug release of tablets at various concentrations of the gum. AC: Acacia, PD: *Phoenix dactylifera*

As shown in Figure 5, 8% Acacia tablet had the highest drug release of 95.8 % while 2% PD tablet had highest of 80 % drug release at 30 min.

DISCUSSION

Wet granulation is a pharmaceutical process of granulation which modifies the properties of formulation ingredients to overcome their tableting deficiencies. Granules formed are relatively more spherical than the powders and have better flow properties. The flow properties of granules were improved when the particle sizes are large, and the particle size distribution is narrow. Granules produced using dried fruit of *Phoenix dactylifera* (PD) showed slight brown color change compared to the granule of the acacia batch. Micromeritic properties are the fundamental and derived properties of individual and collection of particles. It is the study of various characteristics like particle size and particle size distribution, particle shape and surface area, densities, flow property^{20,21,22,23,24}.

This study aimed at producing and evaluating the binding tablet property of the PD and acacia granules. The evaluation of flow property of granules was done by carrying out angle of repose, flow rate, bulk density, tapped density, Carr's compressibility and Hausner ratio determination. The evaluation of the tablets was done by carrying out weight uniformity, hardness, friability disintegration time and *in-vitro* dissolution test.

The PD and acacia granules produced were spherical

without odour. The PD granules were lighter brown in colour when compared to acacia granules. They all have aesthetics appearance which is in agreement with previous studies^{23,24}.

Granules of acacia at various concentrations had a good angle of repose which is within the range of angle of repose (25 - 40 °) that depicts good to excellent flow¹⁹. Only 2% acacia granule batch had Carr's index of 22.03 which was above the normal range for good flow (< 10 to 20) inferring poor flow. Similarly, only 2% of acacia granules had highest Hausner ratio of 1.28 that is above the value for fair flow which also depicts poor flow^{19,25,26}.

Compressibility index is the measure of the propensity of the granules to be compressed. Carr's (compressibility) index is a direct measure of the potential powder/granule arch or bridge strength and stability. Powder with Carr's (compressibility) index < 20 % indicate good flow²¹. This depict that out of F1--4 batches of acacia granules only F1 (the 2% concentration) will not compact well during tableting process. For the PD granules batch, only F1&F2 with 2% and 4% concentration of PD showed excellent-good compressibility while both F3&4 with 6% and 8% concentration showed possible/passable flow character, this maybe as a result of an increase in the PD mucilage. This is contrary to acacia, for increased concentration of

acacia (8%) had good flow with better compressibility.

PD granules of 2 and 4 % had low Hausner ratio (HR) of 1.16 and 1.10 while 6 and 8 % had highest HR of 1.28 and 1.34 which is above the value for upper limit for fair flow (1.25). On the other hand, only 2% of acacia granules had the highest HR of 1.28. Hausner ratio is the measure of the flow ability of a powder or granular material. It assesses the suitability of powders for tableting and encapsulation. HR is related to inter-particulate friction. Powders with low interparticulate friction have ratios of < 1.2, which indicate good flow; whereas more cohesive, less free-flowing powders have HR greater than 1.5²¹. The HR of 4% concentrations PD depicts excellent flow character which explains that it can be employed in tableting and capsule production. An increase in concentration of PD will negatively affect the flow property of the granule. F2 with PD granules of 4% concentration had the optimized formula for tableting of the drug due to good flow property. The angle of repose of acacia granules were of good value for all the concentrations since the values were below 40°C. This infers that the concentrations of acacia (2, 4, 6, 8%) had good flow property when only angle of repose is considered. While for the PD granules F1 - 3 showed more of fair flow with reference to angle of repose with exception of 8% concentration of PD²⁰.

In the view of above discussion, F4 and F2 granules of Acacia and PD with 8 and 4% concentration respectively is the optimized binding concentration which will yield granules that will exhibit good flow properties. In comparison, 4% concentration of PD had an excellent flow property with Carr's Compressibility value of 9.25 and HR of 1.10 which is better than flow property of 8% acacia granules that has Carr's compressibility value of 15.51 and HR of 1.18. This indicates that granules of PD can be preferably used to produce tablets and capsules in large scale with their optimized concentration of 4%^{20,26}.

The tablet weight uniformity results showed that all percentage deviation were less than 10% hence it depicts content uniformity. The disintegration time test showed that all the batches of PD disintegrated at time more than 15 min which is stipulated for uncoated tablet^{21,27}. This infers that all the drugs will break into particles and become bioavailable at time above 15 min which does not conform to BP specifications. On the other hand all the acacia tablets disintegrated within 15 min which is official acceptable. The Hardness results showed that the different batches of PD and acacia had the mean force up to 4 kg and lesser than 10kg as specified hence they passed the test. The binder concentration of the PD and Acacia tablets batches are

appropriate. All the batches of PD and Acacia tablets at various concentrations had friability values ranging from 0.4 to 0.89. The accepted range of percentage friability according to BP should be within 0.5% - 1% of weight. Therefore all PD and Acacia batches passed the friability tests hence will withstand abrasion during transportation. This infers that lubricant concentration is appropriate. However, only 8% concentration of acacia released 95.9 % of drugs after 25 min. PD profile had a slow drug release profile when compared with acacia gum this depicts poor dissolution efficiency. This depicts that 100% of drug would be released tentatively from 40 min upward. Disintegration and drug release of PD is not appropriate when compared to Acacia though they showed good flow properties.

Conclusion

Granules of PD were produced at various concentrations (2, 4, 6 & 8%). Micromeritics of the PD granules showed that at 4% concentration of PD had an excellent flow property with Carr's Compressibility value of 9.25 and HR of 1.10. Tablets of 4% PD passed Physical examination, mean diameter, weight uniformity, hardness and friability evaluation. However, did not pass disintegration time of uncoated tablet and showed slow drug release rate of 76.8 % at 30 min when compared to acacia tablets of 8% at 95.8%. Further studies should be done in formulation of PD to improve disintegration and dissolution for it to be used in pharmaceutical industry as a local raw material. The compatibility of PD with sodium salicylate, and other excipients should be carried out. They were not carried out for there is no functional Fourier Transform Infrared (FTIR) spectrophotometer in South East for carrying out the compatibility study. Stability study is also required to be carried out on the tablets.

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