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Lubricating Properties of Co-processed Coconut Oil in Paracetamol Tablets Formulation

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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 EL 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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ABSTRACT

Objective: Lubricants are additives which reduce friction and so essential components of drug formulation. This piece of work was initiated to evaluate coconut oil as a co-processed lubricant in the formulation and compression of paracetamol tablets in comparison with magnesium stearate-talc as standard lubricant.
Methods: Various concentrations 0.5, 1.5, 2.0 and 2.5% $^{w}/_{w}$ lubricant mixtures of magnesium stearate-talc (MT), coconut magnesium stearate-talc (CMT), magnesium stearate (M), coconut oil alone (C) respectively; and without lubricant (None) which served as control were thoroughly mixed with granules (200 mg) prepared from the basic formula for paracetamol tablets which contained 85% $^{w}/_{w}$, 5% $^{w}/_{w}$ and 10% $^{w}/_{w}$ of paracetamol powder, corn starch and lactose respectively. The mechanical properties of tablets produced were evaluated using crushing strength, friability and crushing strength -friability ratio while the release properties of tablets were evaluated using disintegration and dissolution tests.
Results: Granules lubricated with coconut oil co-processed with magnesium stearate had excellent flow. The crushing strength obtained for all the paracetamol tablets had acceptable

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values ranging from 4.82 to 6.85 kgf except for tablets lubricated with coconut oil alone. Generally, as the crushing strength values increased the friability decreased. Friability values for all the tablets generally decreased with increasing tablet lubricant concentrations of 2.0% $^{w}/_{w}$ and 2.5% $^{w}/_{w}$ though falling within range considered for conventional tablets. The disintegration time increased with increase in lubricant concentration as all the tablets had acceptable values. Tablets lubricated with coconut oil mixed with magnesium stearate-talc showed the highest CSFR/DT ratio. As the concentration of lubricant increased, there was a general decrease in the rate and extent of the drug release from the formulation.

Conclusion: Coconut oil is an effective lubricant which can be processed with magnesium stearate and talc for an effective lubrication of granules before compression into pharmaceutical tablets.

Keywords: Lubricant; coconut oil; magnesium stearate; talc; mechanical properties; release properties.

1. INTRODUCTION

Lubricants are additives which reduce friction and are an essential component of drug formulation. Lubrication is frequently a requisite that ensures the achievement of a good pharmaceutical manufacturing [1].

In the pharmaceutical industry, tribology in drug development has become increasingly important for developing a successful manufacturing process [2]. For pharmaceutical operations such as blending, roller compaction, tablet manufacturing, and capsule-filling, lubrication is essential in order to reduce friction between the surfaces of manufacturing equipment and that of organic solids as well as to ensure the continuation of an operation [3].

Pharmaceutical lubricants as excipients are added to the tablet formulation in a very small quantity (usually 0.25%-5% $^{w}/_{w}$), to prevent sticking of tablets to the die cavity as well as sticking of capsules to dosators and tamping pins [4].

Without lubricants, tablets cannot be produced. However some uncertainty exists in the definition of a lubricant because glidants and anti-adherents perform the same purpose [5]. These inter-related groups of tablet excipients are used in tablet production to promote granule flow and prevent powder adhesion to punch faces and minimize die wall friction respectively [6,7]. Although magnesium stearate and stearic acid are the most frequently used lubricants in the pharmaceutical industry, there are other lubricants in use as well [8]. Lipids (oily and fatty substances) by their nature exert lubricity between surfaces that are in relative motion. It is therefore explicable that when applied in carefully regulated amounts, they could develop the lubricating efficiency of lubricants in general use [9]. They have been studied for their effect on the characteristics of granules and tablets such as moisture content, tablet hardness, disintegration and dissolution, and the stability of active ingredients [10] showed that unlike magnesium stearate, which delays disintegration and dissolution of the active ingredient, the fatty acid esters promotes a reduction in disintegration time. Fatty acid esters have better-quality as lubricant than magnesium stearate because the tablets containing them have better stability.

Coconut oil or copra oil (common name) (*Cocos nucifera*), (Fam. Arecaceae), Isip Mbakara in Ibibio, idi-agbon in Yoruba, Aku-Oyinbo in Igbo, Mosara in Hausa [11], belongs to the class of the fixed oil, is an edible (vegetable) oil extracted from the kernel or meat of matured coconuts harvested from the coconut palm. Chemical composition of coconut oil includes lauric saturated C12 (46.64-48.03), myristic saturated C14 (16%), palmitic saturated C16 (9.5%), Oleic monounsaturated C18 (6.5%), free fairly low fatty acid content (0.15-0.25). All chemical compositions are within the limit of official standard for edible coconut oil [12]. Coconut oil has various applications in food, medicine, and industry. Coconut oil also contains lipid-oily and fatty substances with a high percentage of saturated hydrocarbons mainly glyceride of caprylic acid and glyceride of lauric acid - by their nature exert lubricity over surfaces encountered with [12]. It is therefore that when applied in carefully regulated amount they will improve the lubrication efficiency in lubricants used in tableting. Thus, this piece of work was investigated to evaluate coconut oil as a co-processed lubricant in the formulation and compression of paracetamol tablets.

2. MATERIALS AND METHODS

2.1 Materials

The materials used were paracetamol powder BP, corn starch BP(BDH Chemicals Ltd, Poole, UK), Lactose BP (AB Knight and Co., London, UK), Coconut (*Cocos nucifera*), oil obtained from the meat of coconut in Uyo. Magnesium stearate and talc; Acetone (BDH Chemicals Ltd., Poole, UK) and 95% Ethanol. All other reagents were of analytical grade.

2.2 Methods

2.2.1 Extraction of coconut oil

Fresh matured coconut meat was comminuted to smaller sizes and then further blended into a paste. Afterwards, the paste was subjected to wet rendering by maceration using freshly boiled water and was allowed to stand for 24 hours. The oily layer was then separated from the mixture with a separating funnel. The oily cream was heated with dry heat until it melted at its melting point and the pure oil was collected, cooled and stored in a screw capped bottle until needed.

2.2.2 Preparation of processed powdered lubricant mixture

Equal amount of magnesium stearate and talc (MT) were triturated together using a porcelain mortar and pestle to ensure uniform mixing of the two powder lubricant. This was then passed through a 150 µm sieve and stored in a screw-capped bottle until required. Coconut oil (1.2 g) was co-processed with magnesium stearate-talc mixture (50:50) by mixing the coconut oil with MT mixture (38.8 g) in a beaker placed in a desiccator for 72 hours. The remaining powder mix contained about 3% $^{w}/_{w}$ of coconut oil. The processed powder mix was then stored in a screw-capped bottle until needed.

2.2.3 Preparation of granules

Batches (200 mg) of the basic formula of paracetamol tablets: 85% $^{w}/_{w}$, 5% $^{w}/_{w}$ and 10% $^{w}/_{w}$ of paracetamol powder, corn starch and lactose respectively were triturated together for 10mins in a porcelain mortar and pestle by geometric dilution and then moistened with the prepared binder mucilage which was added to the formulation by wet massing. Massing continued for 5 min and the wet mass was then screened with a 2.0 mm sieve mesh leading to the formation of granules which was then dried in a hot air oven. The dried granules were further screened using a 1.0 mm sieve mesh to obtain the coarse granules (180 g). The coarse granules were further passed through a 0.25 mm sieve mesh to obtain the fines (20 g). Batch granules (12 g), (1.2 g for fines and 10.8 for coarse granules), were then weighed for 17 batches of equal parts before the addition of the lubricant into each part.

2.2.4 Addition of lubricants to the granules

Varying concentrations of 0.5, 1.5, 2.0 and 2.5% $^{w}/_{w}$ of the lubricant mixtures of magnesium stearate-talc (MT), coconut magnesium stearate-talc (CMT), magnesium stearate (M), coconut oil alone (C) were thoroughly mixed with the granules. One batch of granules did not contain lubricant (No Lubricant) and so served as control. The granule-lubricant mixtures were then shaken for 10 mins to ensure proper mixing.

2.3 Evaluation of Physicochemical Properties of Granules

2.3.1 Angle of repose

Granules (10 g) were allowed to flow through a funnel and fall freely on to a surface. Further addition of powder was stopped as soon as the pile touches the tip of the funnel. A circle was drawn around the pile without disturbing it. The height and diameter of the resulting cone were measured. The same procedure was repeated three times and the average value was taken. Angle of repose was calculated by using the following equation [13]:

$$\text{Tan } \theta = 0.5 \text{ (h) height / (r) base} \quad (1)$$

Where,

h = height of the powder cone;
r = radius of the powder cone

2.3.2 Bulk density

Each granule batches (10 g) were transferred to a 100 ml measuring cylinder. The volume was measured as Vo (g/ml).
Thereafter, the bulk density was calculated using the following formula:

$$\text{Bulk density} = \frac{\text{Mass of the granule}}{\text{Bulk volume}} \quad (2)$$

2.3.3 Tapped density

Accurately weighed quantity of powder is introduced into a measuring cylinder. Mechanically the cylinder was tapped containing the sample by tapping the cylinder on the workbench 500 times and the tapped volume (Va) was measured. The operation was repeated for an additional 750 tappings and again the tapped volume as (Vb) was measured as the final tapped volume, and then the tapped density can be calculated using the following formula:

$$\text{Tapped density} = \frac{\text{Mass of the granule}}{\text{Tapped volume}} \quad (3)$$

2.3.4 Carr's index

The compressibility index of granules was determined using Carr's compressibility index, and can be determined by the following formula [13]:

$$\text{Compressibility Index} = 100 \times \frac{\text{Tapped density-bulk density}}{\text{Tapped density}} \quad (4)$$

2.3.5 Hausner ratio

The Hausner ratio was determined using the following formula [13]:

$$\text{Hausner ratio} = \frac{\text{Tapped density}}{\text{Bulk density}} \quad (5)$$

2.3.6 Determination of the moisture content and particle density

The moisture content of the granule formulations was determined by the pycnometer method with liquid paraffin as the displacement fluid [14].

2.4 Preparation of Tablets

Granules (600 mg) from each batch were compressed into tablets using a Manesty F3 single punch tableting machine (Model SSF -3, Cadmach Machine Co. PVI, LTD., India). A set of 17 batches of tablets was produced from a pressure of 9KN. After ejection, each tablet batches were stored in airtight containers to allow for elastic recovery and hardening [5].

2.5 Evaluation of Mechanical Properties of Tablets

2.5.1 Weight variation

Ten tablets were selected at random, weighed individually and collectively using Ohaus balance (Model: TP 2005, Serial No 1673: 200 g, Ohaus Corporation, Florham Park, New Jersey, USA) and the average weight determined for each batch. The percentage deviation was then calculated from the average weight.

2.5.2 Friability

For each formulation, pre-weighed tablet samples (3 tablets) were placed in the friabilator, which is then operated for 100 revolutions. The tablets were then dusted and reweighed. Conventional compressed tablets that lost less than 0.5–1.0% of their weight were considered acceptable.

2.5.3 Crushing strength

Tablet crushing strength of each formulation was determined using a Monsanto hardness tester MHT-20 (Hindustan Apparatus Mfg. Company. India). Results were calculated from the average results of five tablets.

2.5.4 Thickness

Tablet thickness was determined using Vernier calipers. Five tablets were evaluated to determine the average thickness.

2.5.5 Evaluation of release properties of tablets

2.5.5.1 Disintegration test

Disintegration test was carried out in an Erweka GmbH ZT320 Disintegration tester. One tablet was introduced into each tube and a disc was added to each tube. The assembly was suspended in the beaker containing the specified liquid and the apparatus was operated for a specified period of time.

2.5.5.2 Dissolution studies / in vitro release profile

Dissolution test was carried out in an Erweka DT-820 Dissolution tester. Hydrochloric acid (0.1N)

was used as the dissolution medium. Hydrochloric acid was prepared by dissolving 150 ml of acid in 18L of water. Dissolution apparatus was set at 100 rpm for 60 minutes using one tablet per batch. The amount of paracetamol released was determined by measuring the absorbance of the sample withdrawn at 244 nm in comparison with a standard solution having a known concentration of USP paracetamol reference standard (RS) in the same medium.

2.6 Statistical Analysis

Statistical analysis was done using the one way ANOVA followed by Duncan's test. The other data were evaluated using Graph Pad Prism software. Data were expressed as mean ± SD. A p-value < 0.05 was considered significant.

3. RESULTS

3.1 Physiochemical Properties of Granules

The results of the particle density (PD), bulk density (BD), Hausner ratio (HR), Carr's index (CI), angle of repose (AR), moisture content (MC) and percentage porosity (%P) are presented in Table 1.

3.2 Crushing Strength, Friability and Disintegration Test

The results of the crushing strength (kgf), friability and disintegration test are presented in Table 2. The representative plot of relative density for the lubricant batches (MT, CMT, CM & C) of various concentrations (0.0 - 2.5%) are presented in Fig. 1, while the representative plot of crushing strength (kgf) versus lubricant concentration (%) for paracetamol tablet containing 0.0% $^{w}/_{w}$ lubricant, 2.5% $^{w}/_{w}$ MT, 2.5% $^{w}/_{w}$ CMT, 2.5% $^{w}/_{w}$ CM, and 2.5% $^{w}/_{w}$ C are presented in Fig. 2. The representative plots of friability (%) versus lubricant concentration (%) for paracetamol tablets containing 0.0% $^{w}/_{w}$ lubricant; 2.5% $^{w}/_{w}$ MT, 2.5% $^{w}/_{w}$ CMT, 2.5% $^{w}/_{w}$ CM and 2.5% $^{w}/_{w}$ C are presented Fig. 3, while the effects of lubricant concentration (%) on disintegration time for paracetamol tablets containing different concentration of lubricants 0.5% $^{w}/_{w}$, 1.5% $^{w}/_{w}$ 2.5% $^{w}/_{w}$ MT, and 0.5% $^{w}/_{w}$, 1.5% $^{w}/_{w}$, 2.5% $^{w}/_{w}$ CMT; 0.5% $^{w}/_{w}$; 1.5% $^{w}/_{w}$, 2.5% $^{w}/_{w}$ CM, .5% $^{w}/_{w}$, 1.5% $^{w}/_{w}$, 2.5% $^{w}/_{w}$ C are presented in Fig. 4. The representative plots of CSFR/DT versus lubricant concentration (%) for paracetamol tablets containing 0.0% $^{w}/_{w}$ of lubricant; 2.0% $^{w}/_{w}$ of MT, 2.0% $^{w}/_{w}$ CMT, 2.0% $^{w}/_{w}$ of CM and 2.0% $^{w}/_{w}$ of C are presented in Fig. 5.

Table 1. Values of physicochemical evaluation of granules

Lubricant	% $^{w}/_{w}$	PD (+SD)	BD (+SD)	HR (+SD)	CI (+SD)	AR (+SD)	MC (+SD)	% Porosity (+SD)
None	0.0	1.26	0.50	1.17	14.96	40.06	1.20	60.22
MT	0.5	1.26	0.46	1.06	6.25	24.22	1.38	63.89
	1.5	1.29	0.50	1.06	5.66	20.53	1.41	61.24
	2.0	1.31	0.46	1.11	10.00	27.50	1.38	65.16
	2.5	1.35	0.46	1.15	13.50	28.23	1.36	66.19
CMT	0.5	1.30	0.50	1.06	5.66	21.08	1.30	61.53
	1.5	1.36	0.44	1.04	4.44	17.73	1.36	68.06
	2.0	1.38	0.48	1.10	9.43	21.30	1.37	65.56
	2.5	1.40	0.44	1.12	10.42	22.89	1.42	68.82
CM	0.5	1.31	0.46	1.06	6.25	25.95	1.35	65.32
	1.5	1.38	0.50	1.06	5.66	17.02	1.38	63.87
	2.0	1.36	0.46	1.11	10.00	31.10	1.39	66.50
	2.5	1.37	0.46	1.15	13.50	32.58	1.38	66.84
C	0.5	1.32	0.53	1.06	5.36	24.77	1.39	60.15
	1.5	1.34	0.48	1.04	4.00	24.22	1.44	64.37
	2.0	1.36	0.50	1.06	5.66	26.31	1.44	63.18
	2.5	1.37	0.48	1.10	9.43	28.24	1.50	65.35

Table 2. Evaluation of tablet properties

Lubricant	% $^{w}/_{w}$	CS (Kgf)	FR (%)	DT (min)	RD	CSFR/DT
None	0.0	6.64 ± 0.22	2.94 ± 0.13	1.28 ± 0.04	0.84 ± 0.12	1.76 ± 0.15
MT	0.5	6.60 ± 0.13	1.51 ± 0.17	1.87 ±0.04	0.88 ± 0. 11	2.34 ±0.36
	1.5	6.46 ± 0.08	1.33 ± 0.27	2.55 ±0.05	0.90 ± 0.22	1.88 ±0.24
	2.0	6.26 ± 0.10	1.00 ±0.29	3.70 ±0.22	0.82 ± 0.13	1.69 ±0.35
	2.5	6.14 ± 0.10	0.80 ±0.28	5.68 ±0.45	0.81 ± 1.02	1.35 ±0.26
CMT	0.5	6.50 ± 0.09	1.01 ±0.72	1.84 ±0.04	0.87 ± 0. 32	3.50 ±0.15
	1.5	6.44 ± 0.10	1.00 ±1.30	1.94 ±0.04	0.97 ± 0.21	3.32 ±0.27
	2.0	6.26 ± 0.10	0.88 ±0.30	2.05 ±0.03	0.98 ± 0.34	3.47 ± 0.34
	2.5	6.04 ± 0.12	0.86 ±1.43	2.13 ±0.03	0.76 ± 0.23	3.30 ± 0.13
CM	0.5	6.10 ± 0.09	1.40 ±0.11	3.66 ±0.37	0.75 ± 0.2 4	1.19 ± 0.34
	1.5	5.86 ± 0.15	1.40 ±0.29	6.03 ±0.20	0.84 ± 0.32	0.69 ± 0.43
	2.0	5.48 ± 0.07	0.98 ±0.36	7.60 ±0.43	0.84 ± 0.43	0.74 ± 0.25
	2.5	4.82 ± 0.16	0.80 ±0.34	9.54 ±0.76	0.82 ± 0.24	0.40 ± 0.24
C	0.5	3.78 ± 0.13	2.64 ±0.10	1.18 ±0.40	0.89 ± 0.3 1	1.21 ± 0.36
	1.5	3.64 ± 0.15	1.01 ±0.71	1.24 ±0.04	1.14 ± 0.43	2.91 ± 0.12
	2.0	3.46 ± 0.12	1.01 ±0.28	1.37 ±0.05	1.01 ± 0.42	2.50 ± 0.36
	2.5	3.30 ± 0.09	0.85 ±0.24	1.66 ±0.05	0.96 ± 0.35	2.40 ± 0.21

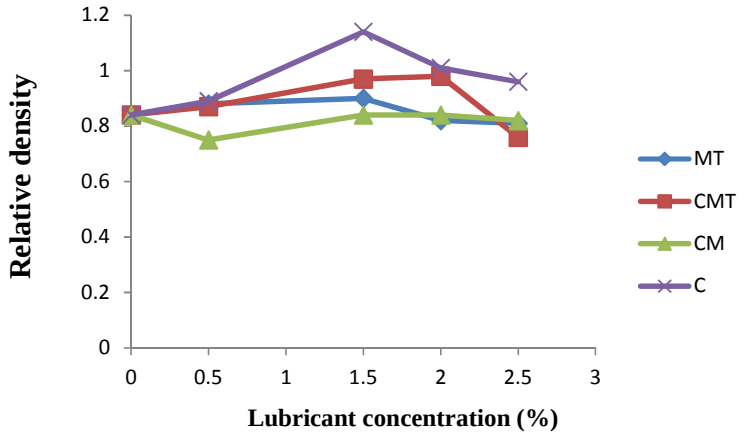

Fig. 1. Representative plot relative density versus lubricant concentration

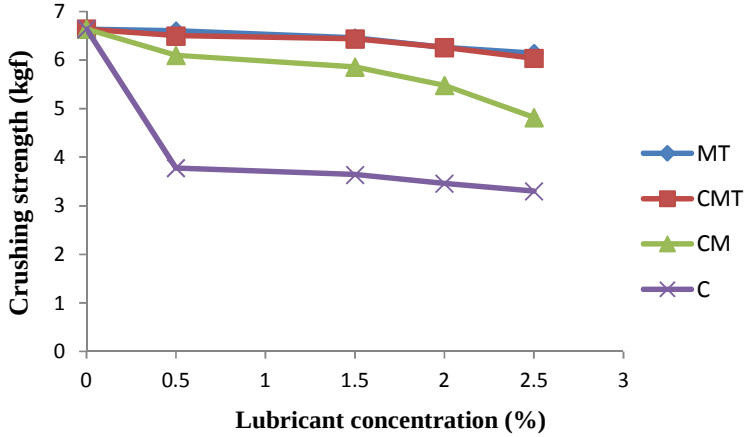

Fig. 2. Representative plot of crushing strength (kgf) versus lubricant concentration

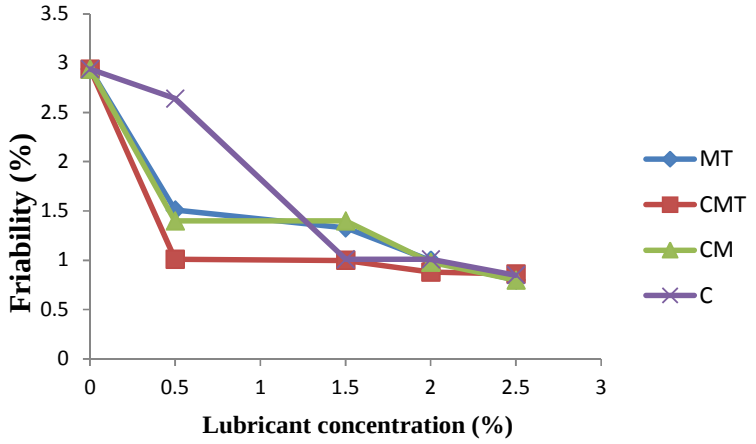

Fig. 3. Representative plot of % friability versus lubricant concentration

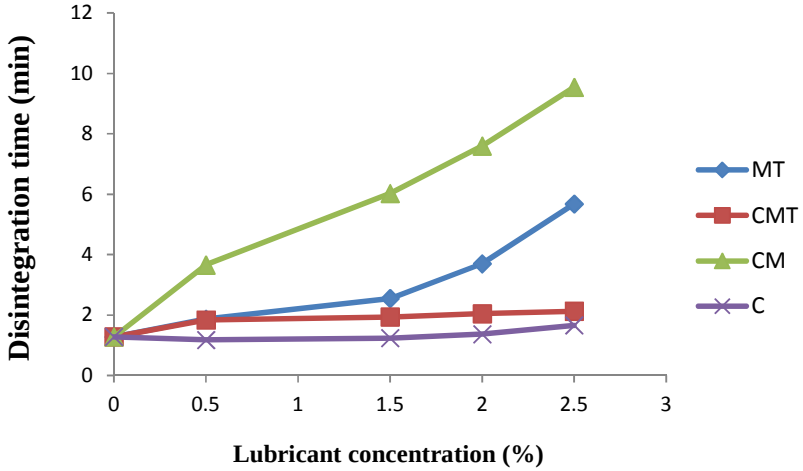

Fig. 4. Representative plot of disintegration time versus lubricant concentration

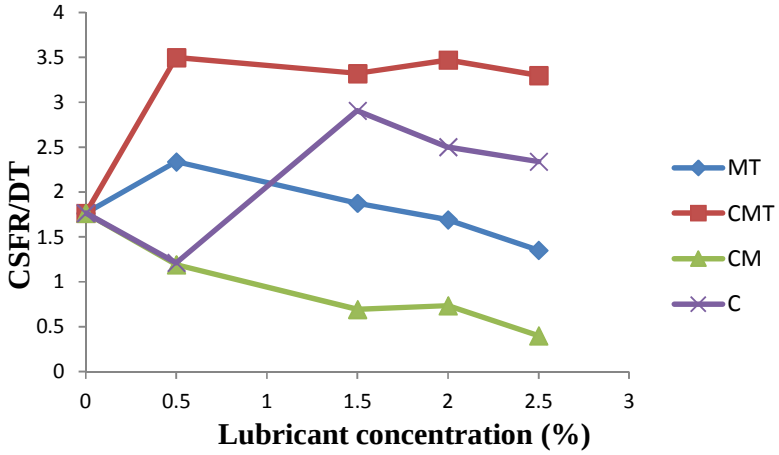

Fig. 5. Representative plot of CSFR/DT versus lubricant concentration

4. DISCUSSION

4.1 Powder Flow Properties

The flow properties of the powder are essential in the determination of the suitability of a material as a direct compressible excipient. The flow rates of granules produced using different concentration of the lubricant were adequate (with range of values between (8.10-12.98) and thus exhibited significantly ($p < 0.05$) (better) flow properties than the batch without lubricant with 7.50 value.

The useful guide given by Hausner's ratio i.e values less than 1.25 indicate good flow while values greater than 1.25 indicate poor flow (BP, 2004) [15]. In this work all the granules have values less than 1.25 (which range from 1.06-1.16) indicating good flow. The empirical guide given by Carr's index values of 5-10 show excellent flow, 12-16 for good flow, 18-21 fair, 23-28 as poor flow, 35-38 very poor and greater than 40 as extremely poor flow. From Table 1, it was observed that granules had a compressibility index from 5.36 to 14.96 indicating good flow with batch without lubricant having the highest values. Angle of repose has been used as an indirect method of quantifying granules flowability because of relationship with inter-particulate cohesion. It is possible that different angles of repose could be obtained for some powder owing to differences in the handling of the sample prior to measurement. For this reason, angle of repose tend to be variable and are not always representative of the flow under specific conditions [16]. Thus it was observed that the granules without lubricant had a value of (40.16°) indicating a passable type of flow. While the granules that were lubricated with different concentrations of the lubricant (MT mixture) had a good flow with values ranging from (24.22 – 28.23) the granules lubricated with the co-processed lubricant (CMT) had significantly ($p < 0.05$) excellent flow (17.73°-22.89°). The ranking of the angle of repose was None > CM > C > MT > CMT.

The percentage moisture content for granules with (CMT) is higher than that of granules with (MT) and granules without lubricant having the least percentage of moisture content. This could be due to the hygroscopic nature of coconut oil.

4.2 Evaluation of Mechanical Properties of Tablets

4.2.1 Uniformity of weight

Weight uniformity refers to the average weight of tablets in each sample. Weight and appearance of tablets are essential properties of a tablets formulation since it guarantees the provision of an adequate dosage of the medication and facilitates patient acceptability. The tablets showed some variations in weights, though complied with the standard weight uniformity, which is, not more than two tablets should deviate from the mean by more than 5% and none should deviate by more than 10% for a tablet containing more than 250mg of active ingredient [15].

4.2.2 Crushing strength

The mechanical strength of tablet dosage forms is an important property and it plays a significant role in product development and manufacturing control [16]. Tablet hardness is affected by the type and concentration of binder, lubricant and compression force. Force (4 kgf) is considered minimum for satisfactory tablet [17]. Crushing strength results obtained for all the seventeen batches of tablet produced had acceptable hardness values with mean ranging from 4.82-6.85 kgf (Table 2) except for batches lubricant with coconut oil alone. The ranking of crushing strength was None > MT >CMT > CM > C.

4.2.3 Friability

Tablet must be strong enough to withstand the agitation and stress that occur during manufacturing, coating, packaging, shipping and during use; but must be friable enough to break-up when swallowed. Tablets that remain intact without cracking or chipping e.g. (less than 1% weight change) typically have sufficient strength to withstand fewer processing and packaging stresses. From the graph in Fig. 3, it can be seen that as the concentration of the lubricants increased, the tablet's percentage friability for all the different batches of co processed lubricants decreased.

Tablets lubricated with coconut oil and magnesium stearate mixture and coconut oil alone showed a decrease in friability with increase in lubricant concentration. However, it was observed that the friability values for all tablet batches generally decrease with increasing tablet lubricant concentration showing values that

are considered acceptable at 2.0% $^{w}/_{w}$ and 2.5% $^{w}/_{w}$ and fall within the range of conventional compressed tablets that loose less than 0.5-1.0% of their weight. This result was also observed as well in the remaining tablet batches. This observation could be due to the influence of force of attraction in the tablet mass. The ranking of friability was None > CM > MT > CMT > C.

4.2.4 Disintegration time

The disintegration time of the paracetamol tablet obtained in Table 2 increased with an increase in lubricant concentration as tablets lubricated with coconut oil-magnesium stearate mixture having a higher disintegration time than other tablet batches, but still falls within the acceptable limit of 15 minutes. Fig. 3 shows the representative plots of disintegration time against relative density [18]. This could be due to the fact that most lubricants are hydrophobic and they are usually added in smaller concentrations than any other excipient in tablet formulations. When they are added and mixed, lubricant particle may adhere to the surface of the other particle. Thus, hydrophobic coating inhibits the wetting and consequently tablet disintegration. The ranking of the disintegration time was CM > MT > CMT > None > C.

4.2.5 Crushing strength-friability/ disintegration ratio

The crushing strength-friability/disintegration time ratio (CSFR/DT ratio) has been suggested as latter index in the monitoring of tablet strengths and weaknesses as well as determining the quality and bioavailability profiles of the tablet. A significant ($p < 0.05$) higher value of CSFR/DT ratio indicates a better balance between binding and disintegration properties thus, the higher the CSFR/DT value, the better the disintegration time of the tablets as shown in Table 2, where the CSFR/DT for all batches decreases with an increase in lubricant concentration. Tablet batches lubricated with various concentrations of coconut oil with magnesium stearate-talc mixture showed the significantly ($p < 0.05$) highest CSFR/DT ratio. This result showed that incorporation of coconut oil in small quantities will improve the quality of pharmaceutical formulations. The ranking of CSFR/DT was CMT > C > MT > None > CM.

4.2.6 Dissolution test

Dissolution was carried out using 0.IN HCL acid as the dissolution medium and an absorbance wavelength of paracetamol at 244 nm to explore the effect of amount of lubricants. Sixteen formulations in four groups were compared. Batches of tablet which contained 0.5% $^{w}/_{w}$, 1.5% $^{w}/_{w}$, 2.0% $^{w}/_{w}$ and 2.5% $^{w}/_{w}$ of lubricants were compared. It was observed that the total percent release of paracetamol from the various formulations were between 65-75% for batches lubricated with MT; 45-70% for batches with CMT; 43-60% for batches lubricated with CM; and 40-55% for batches lubricated with C. It was also observed that increasing the concentration of the lubricants, the rate and extent of drug release from the formulation was decreased. This effect was due to the increase of concentration of lubricant.

The rate and extent of drug release versus time shows the zero order release profile of paracetamol from various batches lubricated with lubricant at the concentration of 1.5% $^{w}/_{w.}$

5. CONCLUSION AND RECOMMENDATIONS

The study on the use of coconut oil as co-processed lubricant with magnesium stearate and talc (CMT) in the formulation of paracetamol tablets has shown that coconut oil, an inexpensive and readily and commercially available lipid, enhanced the packaging and flow properties of the paracetamol granules to produce strong and quality tablets and could be useful in reducing lamination and capping in tablets. Though further work such as the brittle fracture index is needed.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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