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# Lubricating Effects of Cocoa Butter and Coconut Oil in Conventional Paracetamol Tablets

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

## Abstract

**Background:** Due to chemical instability of some Active Pharmaceutical Ingredients often caused by magnesium stearate and its impurities, it is expedient to research into some other materials especially of natural origin, which would probably exhibit better lubricating activity, chemically inactive, less bioactive and less prohibitive.
**Objective:** This work is designed to examine the lubricating properties of cocoa butter and coconut oil as alternative lubricants in comparison with conventional lubricant - magnesium stearate at different concentrations in paracetamol tablets.
**Materials and Methods:** Cocoa butter was extracted from the seeds of *Theobroma cacao* and coconut oil from the meat of matured coconuts harvested from the coconuts palm (*Cocos nucifera).* Physicochemical evaluation was carried out on the extracted oils. Thirteen different formulations were prepared using different lubricants; magnesium stearate, cocoa butter and coconut oil at 0 – 4 %w/w concentrations. The prepared granules were evaluated for various pre-compression characteristics (bulk density, tapped density, angle of repose, Hausner's quotient and Carr's index) and post-compression characteristics (weight variation, friability, hardness, disintegration and dissolution times).
**Discussion:** Most of the values obtained from the evaluation of pre- and post- compression characteristics correlate with the pharmacopoeial limits. The values of disintegration time were observed to increase as the lubricant concentration increased but no direct relationship with dissolution time. Tablet hardness values decreased while friability increased as the lubricant concentration increased for all the batches. From the study, cocoa butter and coconut oil at 2 – 4 % exhibited effective lubricating effect in the formulation of paracetamol tablet with respect to their values of weight variation, friability, hardness, disintegration and dissolution times.
**Conclusion:** Cocoa butter and coconut oil could be employed as good alternative lubricants to the conventional ones in pharmaceutical tablet formulation.
**Keywords:** Lubricants, Cocoa butter, Coconut oil, Magnesium stearate.

## INTRODUCTION

Lubricants are agents added in small quantities to tablet and capsule formulations to improve certain processing characteristics thus ensuring the success of pharmaceutical manufacturing (Li and Wu, 2014). An ideal lubricant should have low shear strength which permits the reduction in friction between the formulation and the die wall and on punches during compression and eases ejection of tablets from the die (Patel et al, 2011). This would resultantly minimise the wears on the punches and the dies. The lubricant should also be chemically inert, unaffected by process variables and possess minimal adverse effects on the finished dosage forms. They also improve the flowability of powder mix and aid for example, the blending of active pharmaceutical ingredients (APIs) of small particles with other adjuvants thereby reducing segregation in the hopper (Aoshima et al, 2005; Roberts et al, 2004). This will improve the weight and content uniformities of the formed tablets. The type, mode of incorporation of lubricants, concentration, conditions of mixing, and the efficiency of lubricants had been found to influence many of the quality parameters of the tablets including tablet weight, hardness, friability, disintegration and dissolution times (Otsuka et al, 2001;

Odeniyi and Jaiyeoba, 2009; Adeagbo and Alebiowu, 2009).

Magnesium stearate is perhaps the most common lubricant often incorporated into pharmaceutical formulations. However, this material and its impurities often cause chemical instability of APIs (Li and Wu, 2014). For instance, Gordons and co-workers (1984) reported that ibuprofen formed a eutectic mixture which sublimates with magnesium stearate. Also, commercial magnesium stearate contains several impurities such as magnesium oxide and palmitic acid which often react with APIs in the solid state resulting in instability (Li and Wu, 2014). Also, it has been affirmed that magnesium stearate has more negative effects on the hardness of tablets prepared with more deformable materials than brittle ones (Wang et al, 2010). For instance, when magnesium stearate lubricant was mixed with microcrystalline cellulose, a typical example of plastic material, the tablet strength was weakened significantly as the proportion of the lubricant increased (Morin and Briens, 2013). Incorporation of magnesium stearate lubricant in tablet formulation would therefore prolong disintegration and dissolution times (Alderborn, 2007). The material that would exhibit all the desirable qualities of an ideal lubricant is yet to be found (Alebiowu and Adeagbo, 2009). This work was thus designed to exploit two materials of botanical source (cocoa butter and coconut oil) in search of such a miracle lubricant.

Cocoa butter, also known as theobroma oil is a pale yellow edible vegetable fat obtained from the seed of cocoa tree (*Theobroma cacao*). Nigeria is the third largest cocoa producer in Africa and about the sixth of the total world output (Amao et al, 2015). The lipid possesses characteristic flavour and is used to prepare chocolate, as well as some ointments. The main constituent of cocoa butter is triglyceride (fat) derived from palmitic acid, stearic acid and oleic acid. Cocoa butter is readily soluble in ether, chloroform and light petroleum, slightly soluble in 95% alcohol but insoluble in water. Its melting point is between 34 - 38 $^0$C.

Coconut oil is edible fixed oil extracted from the kernel or meat (endocarp) of matured coconut palm - *Cocos nucifera*. The plant is a member of the family Arecaceae found throughout the tropical and subtropical areas. Philippines and Indonesia are the world's largest producers of coconut according to Shashikumar and Chandrashekar (2014). Coconut oil is highly stable: Because of its high saturated fats content, it is slow to oxidize and thus, resistant to rancidification, lasting up to six months at 24 $^0$C (75 F) without spoiling.

This study was aimed at designing and formulating oral tablets of paracetamol using cocoa butter and coconut oil lubricants. Tablet properties such as weight variation, hardness, friability, disintegration and dissolution times were then assessed and compared with those obtained for tablets formulated with a conventional lubricant, magnesium stearate. Paracetamol is used worldwide for its analgesic and antipyretic activities (British Pharmaceutical Codex BPC, 1979; Benkhassi et al, 2013; British Pharmacopoeia BP, 2015) but possesses poor fluidity and thus requires a lubricant to form tablets of acceptable quality.

# MATERIALS AND METHODS

The materials used for the formulation of the paracetamol tablets are Paracetamol B.P (PCM) (FCC/Ph Eur F. Merck Darmstadt), Polyvinylpyrrolidone (PVP), Corn starch, Talc (BDH Chemicals Ltd Poole, England), N-hexane, 95% Ethanol (Sigma-Aldrich Chemical Company, France). Other reagents amd chemicals were of analytical grade. Fresh matured cocoa pods and coconuts were purchased from Ikono Local Government Area of Akwa Ibom State and authenticated in the herbarium facility of the Faculty of Pharmacy, University of Uyo, Nigeria. The voucher numbers of authentication are UUPH31(g) and UUPH8(b), respectively.

## Methods

**Extraction of fixed oils from cocoa seeds and coconuts**

The cocoa pods were opened and the seeds were collected, air-dried and de-shelled to remove the inner nib. The seeds were powdered using mortar and pestle. Cocoa oil was extracted from 480 g of cocoa powder by maceration using 1.5 L of N- Hexane at room temperature for 72 hrs. It was filtered using funnel sealed with glass wool. The filtrate was concentrated using rotary evaporator at 35 $^0$C. The yielded oil, 86.60 g was stored in an air tight container in the refrigerator at 2.8 $^0$C to convert the oil to fat and to avoid rancidity.

The coconuts were de-shelled using a machete; the meat (white content) was removed with a knife, washed thoroughly with cold distilled water, then chopped into chunks and grinded using an Osterizer blender (Model 857,Willamette Industries, USA) until the mixture becomes visibly thick. The mixture was placed into a bigger bowl and hot water was added. The coconut mixture was strained through a clean cotton fabric into a large bowl. The top of the fabric was twisted to squeeze out the "milk" which was allowed to stand for 24 hours. Little bubbles, an indication of fermentation, started to form throughout the milk the next day. The thick cream (milk) was heated at 80 $^0$C for about 5 hours to extract the oil which was drained off from the bottom layer and then transferred into a clean air tight container and stored at room temperature.

The specific gravity of each of the lipids was determined using established procedure (AOCS, 1973).

**Physicochemical Properties of the Oils**

*Organoleptic properties*

The colour, odour, taste and physical appearance of the extracted oils were observed.

*Determination of Acid Value and Percentage free fatty acid*

Standard Methods for the Analysis of Fats and Oils in Official Methods of Analysis of Association of Official Analytical Chemists (AOAC) International (2005) was used: Quantities of 25 ml of alcohol (95 %), 25 ml of diethyl ether and 1 ml of phenolphthalein solution were mixed together. The solution was neutralized by the addition of alkali drop-wise until a pale pink colour was obtained. A 10 g quantity (*W*) each of cocoa butter (melted) and coconut oil was weighed into a 250 ml

conical flask and the prepared solvent was added. After complete dissolution of the oil, it was then titrated with 0.1 N potassium hydroxide (KOH), with constant shaking until the pink colour which persisted for over 30 seconds was obtained. The volume in ml of KOH (*V*) required was noted. The determination was repeated and acid value calculated as follow:

Acid value = $VN \times M/W$ ..... (1)
*N* = normality of KOH
*M* = molecular weight of KOH = 56.11

**Determination of Saponification and Ester Values**

Saponification value is the number of mg of potassium hydroxide required to neutralize the free acids and saponify the esters in 1 g of test substance. A 2.0 g quantity each (*W*) of cocoa butter and coconut oil was accurately weighed into a tarred 250 ml flask, 25 ml of approximately 0.5 N alcoholic KOH was added from a burette. The flask was heated on a steam bath, under a suitable condenser to maintain reflux for 30 min, frequently rotating the contents. Five millilitres of phenolphthalein solution was poured down the condenser. The flask was cooled for exactly 5 minutes under tap water. The content was finally titrated with 0.5 N hydrochloric acid (HCl). A blank determination without the oil was performed under exactly similar conditions. Values of *A* and *B*, volume of HCl required for the titration of the blank and of the sample, respectively were thus obtained and the saponification value was calculated thus:

Saponification value = [56.11 × N (A - B)] / W..... (2)
N is normality of the HCl
Ester value = Saponification value - acid value.

**Determination of Iodine Value**

Approximately 0.25 g each of cocoa butter and coconut oil (*W*) was weighed into 250 ml conical flask and 10 ml of chloroform was added. Then 30 ml of Hanus solution was added and the flask was closed completely. The solution was shaken constantly for 30 minutes with 10 ml of potassium iodide, followed by 10 ml of distilled water. The iodine solution was titrated against 0.I N sodium thiosulphate solution till yellow colour was formed. Two to three drops of 1 % starch solution was added and a blue solution was formed and titration was continued till the blue colour disappeared. The volume (ml) of sodium thiosulphate at end point (*V*) was recorded. The process was repeated without the sample and volume of sodium thiosulphate at end point (*B*) was noted

Iodine value = $A[V - B]N/10.W$
*A* = atomic weight of iodine, 126.90
*N* = normality of sodium thiosulphate

***Preparation of Powdered Lubricant Mixture***

A quantity of 4 g each of the extracted cocoa butter and coconut oil was weighed and placed inside a dry beaker containing 200 ml of 95 % ethanol. Each beaker was placed in a water bath set at 60 $^0$C to allow the materials to dissolve in the ethanol. A quantity of magnesium oxide (absorbent) was weighed and added in aliquots to each ethanol solution of cocoa butter and coconut oil and thoroughly mixed each time. Mixing was continued to achieve homogeneity. This happened after adding 36 g of the adsorbent to each of the mixtures. The mixture was stored over silica gel at 100 $^0$C for 72 hours prior to use (the silica gel was first charged in an oven (P- Selecta 00384635, China) to allow for the ethanol to evaporate completely. The processed powdered lubricant mixture was then stored in a screw-capped bottle.

***Granule Preparation***

The formula used for the preparation of each paracetamol tablet is presented in Table 1. A total of 13 batches of the tablets were produced with a target weight of 600 mg per tablet. That is a batch containing no lubricant (0 %) and four batches each containing 1, 2, 3 and 4 %w/w of magnesium stearate, cocoa butter or coconut oil, respectively. Appropriate quantities of PVP mucilage, talc, lactose and corn starch were weighed and mixed thoroughly with the paracetamol powder in a clean mortar. The resultant wet mass was screened through a 2.0 mm sieve. The granule from each batch was dried in an oven at a temperature of 60 $^0$C for 3 hours and dry-screened using 1.0 mm sieve and the final dry granule was sealed in an air-tight container.

**Granule Evaluation**

***Determination of some Density and Flow parameters***

Values of bulk and tapped densities, Hausner's quotient, Carr's compressibility index, flow rate and angle of repose were determined by employing established procedures (Adedokun and Itiola, 2010, 2013). The determinations were carried out in quadruplicates and the mean values presented in Table 4.

***Preparation of Tablets***

To the granules mix, appropriate quantity of the talc as indicated in the formula in Table 1 was added and triturated thoroughly. This batch contains no lubricant and was assigned code number PWL (that is, paracetamol tablets without lubricant). Also, either magnesium stearate which served as control conventional lubricant), processed cocoa butter or coconut powder (1 – 4 $\%^w/_w$) was added to the granule mix with the appropriate amount of talc in each batch and mixed thoroughly for at least 3 minutes. The granule was then compressed to a target weight of 600 mg under the compression force of 4.5 KgF. The tablets were wrapped in Aluminum foil and packed in an airtight container.

**Paracetamol Tablets Evaluation**

***Weight Variation***

Twenty tablets were selected randomly from each of the batches and were weighed individually and the average weight was determined. The percentage deviation of each tablet weight from the mean weight was computed, to establish the conformity or otherwise of the tablet batch to official weight uniformity standards (Lund, 2002; Adedokun et al, 2014).

**Table 1: Formulae for the preparation of paracetamol tablets containing magnesium stearate, cocoa butter and coconut oil lubricants**

| **Ingredients (mg) Batches** | **PWL** | **PMS1** | **PMS2** | **PMS3** | **PMS4** | **PCB1** | **PCB2** | **PCB3** | **PCB4** | **PCO1** | **PCO2** | **PCO3** | **PCO4** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PCM | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 | 500 |
| PVP | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| Corn starch | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 |
| Lactose | 49 | 43 | 37 | 31 | 25 | 43 | 37 | 31 | 25 | 43 | 37 | 31 | 25 |
| Magnesium stearate | 0 | 6(1%) | 12(2%) | 18(3%) | 24(4%) | - | - | - | - | - | - | - | - |
| Cocoa butter | 0 | - | - | - | - | 6(1%) | 12(2%) | 18(3%) | 24(4%) | - | - | - | - |
| Coconut oil | 0 | - | - | - | - | - | - | - | - | 6(1%) | 12(2%) | 18(3%) | 24(4%) |
| Talc | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

PWL - paracetamol tablet formulated without lubricant

PMS - paracetamol tablet formulated with magnesium stearate

PCB - paracetamol tablet formulated with cocoa butter

PCO - paracetamol tablet formulated with coconut oil

**Table 2: Solubility of cocoa butter and coconut oil**

| Solvent | Solubility | |
|---|---|---|
| | **Cocoa butter** | **Coconut oil** |
| Distilled water | insoluble | Insoluble |
| Ethanol | slightly soluble | slightly soluble |
| Chloroform | soluble | soluble |
| N – Hexane | soluble | soluble |
| Hydrochloric acid | insoluble | slightly soluble |

**Tablet Hardness Test**

Tablet hardness tester (Monsanto, India MHT - 20) was used to determine the hardness of ten tablets from each batch. The mean hardness was then calculated.

**Friability Test**

Twenty tablets each from all the tablet batches were selected, de-dusted, weighed and placed in the compartment of a Roche friabilator (DT-2D, India) and made to tumble for 4 minutes at a speed of 25 revolutions per minute. The tablets were then removed, de-dusted and reweighed. The friability was then computed (Adedokun and Itiola, 2013).

**Determination of Release Properties**

The British Pharmacopoeia (BP) apparatus consisting water at 37(2 $^0$C was used to determine the disintegration time of the tablets (BP, 2002). Also, the in-vitro dissolution test of the tablets was carried out using the USP basket method in the tablet dissolution test apparatus (United States Pharmacopoeia USP, 2014).

**Statistical Analysis**

For validity of statistical analysis, all experiments were performed in replicates (n = 3). Results were expressed as mean ± SD. Statistical analysis was carried out on all the tablet quality parameters determined in assessing the influence of the lubricants on the formulations. Two-way Analysis of Variance (ANOVA) on a computer software GraphPad Prism® 4 (GraphPad Software Inc., San Diego, USA) was employed as statistical tool. Post-hoc (Turkey-Kramer multiple comparison) test was employed to compare the individual differences between the samples. At 95% confidence interval, probability, *p* values greater than 0.05 were considered insignificant.

## RESULTS AND DISCUSSION

Percentage yields of cocoa butter from cocoa beans and coconut oil from coconut pulp were 16.15 %w/w and 40.00 %w/w, respectively. The solubility of the experimental lubricants in different solvents was recorded in Table 2. The values of specific gravity of the cocoa butter and coconut oil determined were 0.94 and 0.92 respectively (Table 3). These and other physicochemical properties in Table 3 are within the range of the values recorded for industrially established vegetable oils such as sesame, soya bean, cotton seed, sunflower and corn oils (Salanke and Desai, 1986). The pH value of 7.65 for cocoa butter and 7.67 for coconut oil indicates that the oils are somewhat neutral.

The angle of repose values obtained for the thirteen granule batches as presented in Table 4 indicated excellent to good flow properties (Reddy et al, 2003). However, this parameter is not an intrinsic property of the powder; that is, it is very much dependent upon the method used to form the cone of powder. During tablet manufacturing, the flow of powder from the hopper into the die often determines the weight, hardness and content uniformity.

**Table 3: Organoleptic and physicochemical properties of Cocoa butter and Coconut oil lubricants**

| Lubricants | Properties | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Colour | Odour | Taste | Appearance | Acid value (mg KOHg-$^1$ oil) | Specific gravity | Saponificaiton value | Iodine value |
| Cocoa butter | pale yellow | characteristic and pleasant | bland | Fatty | 1.65 | 0.94 | 193.54 | 33.14 |
| Coconut oil | light brown | characteristic and pleasant | bland | viscous liquid | 1.64 | 0.92 | 190.74 | 10.12 |

**Table 4: Powder Density and flow properties of paracetamol granules formulated with magnesium stearate, Cocoa butter and Coconut oil lubricants**

| Batches | Bulk density ($g/cm^2$) | Tapped Density ($g/cm^2$) | Angle repose ($^0$) | Flow rate (sec) | Hausner's ratio | Carr's index (%) |
|---|---|---|---|---|---|---|
| **PWL** | 0.500 | 0.576 | 26.56 | 8.57 | 1.15 | 13.28 |
| **PMS1** | 0.483 | 0.545 | 21.37 | 10.34 | 1.13 | 11.37 |
| **PMS2** | 0.500 | 0.550 | 23.46 | 10.56 | 1.11 | 9.00 |
| **PMS3** | 0.500 | 0.576 | 23.96 | 10.71 | 1.19 | 15.00 |
| **PMS4** | 0.441 | 0.545 | 25.01 | 11.19 | 1.23 | 19.00 |
| **PCB1** | 0.484 | 0.577 | 23.75 | 10.00 | 1.19 | 16.11 |
| **PCB2** | 0.500 | 0.550 | 25.30 | 10.71 | 1.11 | 9.90 |
| **PCB3** | 0.568 | 0.556 | 21.80 | 10.00 | 1.80 | 15.00 |
| **PCB4** | 0.484 | 0.576 | 23.96 | 10.71 | 1.19 | 15.97 |
| **PCO1** | 0.500 | 0.555 | 24.54 | 10.00 | 1.11 | 12.00 |
| **PCO2** | 0.500 | 0.555 | 21.37 | 10.56 | 1.11 | 9.00 |
| **PCO3** | 0.490 | 0.555 | 24.57 | 10.56 | 1.11 | 9.00 |
| **PCO4** | 0.483 | 0.545 | 21.37 | 10.34 | 1.13 | 11.37 |

**Table 5: Physical and release properties of paracetamol tablets formulated with magnesium stearate, Cocoa butter and Coconut oil lubricants**

| Batches | Weight Variation (g) Mean ± SD | Hardness (KgF) Mean ± SD | Friability (%) mean ± SD | Disintegration time (seconds) mean ± SD | Dissolution time $t_{80}$ (minutes) mean ± SD |
|---|---|---|---|---|---|
| **PWL** | 0.607 ± 0.031 | 9.18 ± 0.48 | 3.30 ± 0.05 | 180.2 ± 8.0 | 82.7 ± 2.6 |
| **PMS1** | 0.605 ± 0.028 | 8.29 ± 0.43 | 0.83 ± 0.04 | 300.0 ± 6.1 | 105.1± 4.1 |
| **PMS2** | 0.605 ± 0.016 | 7.49 ± 0.19 | 0.60 ± 0.02 | 347.9 ± 7.9 | 60.4 ± 2.2 |
| **PMS3** | 0.606 ± 0.021 | 7.49 ± 0.22 | 0.60 ± 0.02 | 420.4 ± 5.4 | 108.4± 5.2 |
| **PMS4** | 0.617 ± 0.026 | 6.51 ± 0.19 | 0.33 ± 0.01 | 485.6 ± 7.2 | 75.4 ± 4.3 |
| **PCB1** | 0.577 ± 0.024 | 8.07 ± 0.23 | 1.77 ± 0.03 | 312.3 ± 8.3 | 111.1± 4.0 |
| **PCB2** | 0.588 ± 0.032 | 7.60 ± 0.26 | 1.00 ± 0.03 | 359.7 ± 7.8 | 75.4 ± 2.2 |
| **PCB3** | 0.606 ± 0.021 | 6.61 ± 0.19 | 0.83 ± 0.02 | 372.0 ± 5.9 | 111.4± 2.1 |
| **PCB4** | 0.514 ± 0.024 | 5.80 ± 0.17 | 0.67 ± 0.05 | 456.4 ± 8.1 | 90.0 ± 4.0 |
| **PCO1** | 0.592 ± 0.018 | 8.04 ± 0.22 | 1.00 ± 0.03 | 300.2 ± 6.3 | 117.1± 3.0 |
| **PCO2** | 0.582 ± 0.024 | 7.04 ± 0.39 | 0.67 ± 0.02 | 348.4 ± 7.3 | 105.4± 3.2 |
| **PCO3** | 0.594 ± 0.030 | 6.62 ± 0.21 | 0.53 ± 0.07 | 336.1 ± 6.4 | 91.9 ± 2.7 |
| **PCO4** | 0.614 ± 0.025 | 5.63 ± 0.12 | 0.48 ± 0.01 | 396.1 ± 7.2 | 75.2 ± 2.0 |

Other flow and density parameters also presented in Table 4 show that the granules exhibited low inter-particulate friction and hence good flow. The bulk and tapped densities are used to compute the compressibility index and Hausner's quotient of the granules. The latter as determined for the formulations (Table 4) indicated good flow and compaction properties (Panda et al, 2008). Low values of tapped and bulk density, indicating high porosity, will result in a high deformation potential during compression, which will cause more intimate contact between the particles within the tablets, resulting in harder and probably less friable tablets (Momoh et al., 2012). In most cases, hardness is a direct function of disintegration and dissolution times. Good flowability generally promotes tablet weight uniformity thus reducing variation in drug content and thereby affecting the overall API's bioavailability (Onyishi et al, 2013).

Representative plots of weight variation, friability, mean hardness, and disintegration time against concentration for the paracetamol tablets formulated with magnesium stearate, cocoa butter and coconut oil lubricants are presented in Figs. 1 – 4. Generally, as shown in Table 5, tablets produced using different concentrations of the lubricants compared favourably with the standard for tablet weight uniformity, that is, not more than 2 tablets should vary by more than 5 % deviation for tablet containing an average weight of 250 mg tablet or more (Ofoefule, 2006). It is also indicated in Table 5 that the higher the concentration of lubricant, the higher the value of friability, and vice versa for hardness. Tablets friability measures the resistance of tablet to surface abrasion (Ofoefule, 2006).

Values of 0.8 – 1 % friability are often regarded as the upper level of acceptance for pharmaceutical tablets (BP, 2015). All the tablets except those without lubricant exhibited good ability to resist abrasion. The hardness test result obtained from all the batches complied with the minimum hardness for uncoated tablets as indicated in the official compendia (BP, 2002). This is an indication that this tablet possesses an acceptable resistance to breakage and chipping. Batches with low level concentration of lubricant (1 – 2 %) were observed to exhibit high tablet hardness but batch PWL exhibited the highest value of hardness most likely due to the absence of lubricant in the formulation. Disintegration time test is a measure of the time required under standard condition for a group of tablets to disintegrate into particles. Specified disintegration time for various tablet types are provided in the official compendia (BP, 2002; USP, 2014). All the tablet batches complied with the standard disintegration time for uncoated tablets. An increase in disintegration time was generally observed as lubricant concentration increased as seen in Table 5. No clear cut influence of lubricant concentration on dissolution time was observed. Representative plots of percentage drug released against time for formulations containing 2 % lubricants (Fig. 5) however showed that, $t_{80}$ (time required for 80% of paracetamol to be released) increased in the order: coconut oil > cocoa butter > magnesium stearate.

Statistically, significant differences ($p < 0.05$) existed between the values of weight variation, friability, hardness, disintegration and dissolution times, for the three lubricants. Interrelationships between all the parameters also showed different levels of significance ($p < 0.05$).

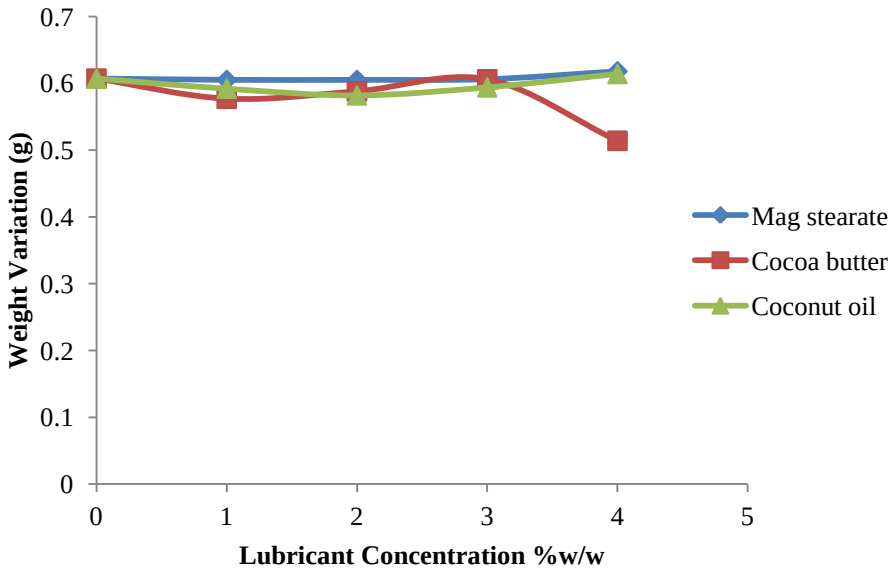


**Figure 1: Plots of weight variation against concentration for paracetamol tablets formulated with magnesium stearate, cocoa butter and coconut oil lubricants**

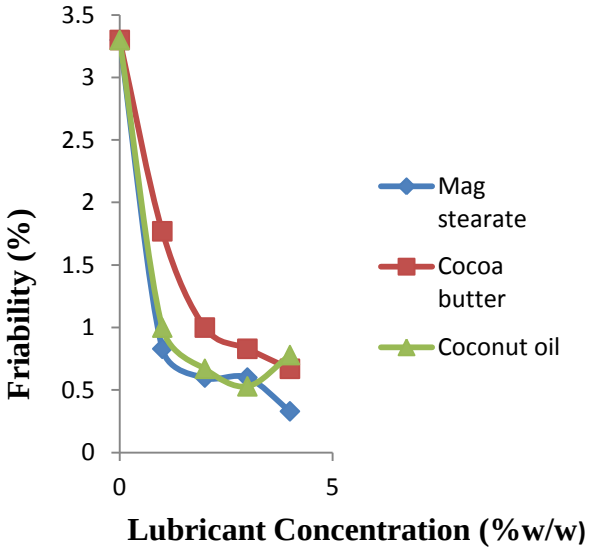


**Figure 2:Plots of friability against concentration (%w/w) for paracetamol tablets formulated with magnesium stearate, cocoa butter and coconut oil lubricants**

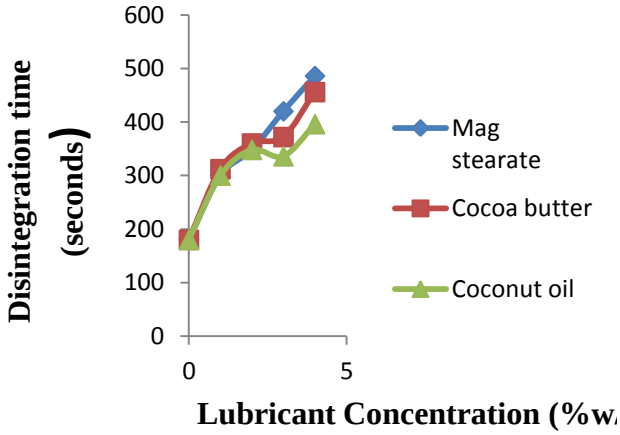


**Figure 4: Plots of disintegration time (seconds) against concentration (%w/w) for paracetamol tablets formulated with magnesium stearate, cocoa butter and coconut oil lubricants**

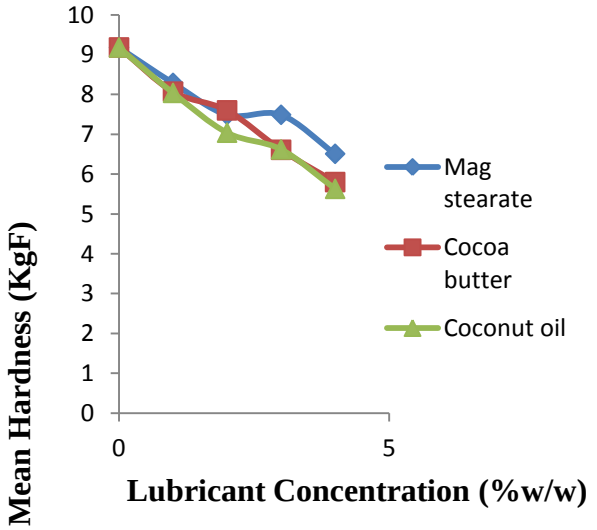


**Figure 3: Plots of mean hardness against concentration (%w/w) for paracetamol tablets formulated with magnesium stearate, cocoa butter and coconut oil lubricants**

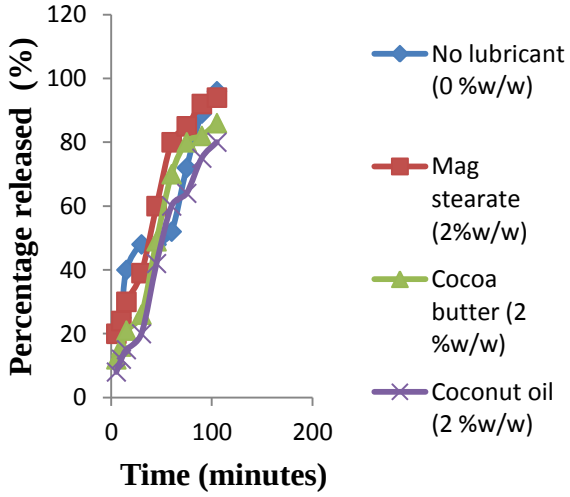


**Figure 5: Plots of dissolution time (minutes) against concentration (%w/w) for paracetamol tablets formulated with magnesium stearate, cocoa butter and coconut oil lubricants**

**CONCLUSION**

Generally, cocoa butter and coconut oil lubricants yielded paracetamol tablet formulations with good flow properties. Due to their cost effectiveness, ready availability and the properties exhibited in the paracetamol tablet formulations, cocoa butter and coconut oil may be considered as potential substitutes for the conventional lubricants like magnesium strearate.

**RECOMMENDATIONS**

Further characterisation of the oils is recommended. Also, detailed studies on release profile of tablets formulated with these natural lubricants should be carried out on both conventional and controlled release formulations. Evaluation of these materials as lubricants in an effervescent tablet formulation is on-going.

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