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FORMULATION, DEVELOPMENT AND EVALUATION OF ANTIOXIDANT HERBAL CAPSULE

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ABSTRACT

Patients at the Centre for Plant Medicine Research (CPMR) in Ghana are prescribed and given an encapsulated combination of powdered Cassia sieberiana stem and root bark to relieve their gastric ulcer discomfort and dysmenorrhea. The absence of standardisation in the actual quantities of extracts obtained from product consumption poses substantial hurdles for the manufacturing process and the optimisation of therapeutic effects. The goal of the study was to use the stem and root bark to create and assess Cassia sieberiana capsules. Two distinct solvents were used for the extraction process: 70% ethanol (F2) and 100% ethanol (F1). CPMR compared these two formulations to the current product (MP1). Wet granulation was used to create the encapsulating granules, and MP1 was used to compare the granules' flow characteristics. The study of drug-excipient compatibility using TLC, UV, and FT-IR techniques. The MP1, F1, and F2 capsules underwent quality control testing utilising pharmacopoieal techniques. The organoleptic and physicochemical characteristics of the extracts indicated from the results that they were suitable for use in the production of oral capsules. The λmax values for MP1, F1, and F2 were 278 nm, 278 nm, and 276 nm, in that order. The results showed that for F1 and F2, the extract per dose of capsules was 27.84 ± 0.11 mg and 36.65 ± 0.03 mg, respectively. While MP1 showed a fair flow property, the granules of F1 and F2 had good flow qualities. Possible interactions between extracts and excipients were shown by FT-IR spectra. Nonetheless, TLC studies showed that the extracts and granules contained comparable components.

Since the percentage medication contents of the F1 and F2 capsules were found to be 98.0% ± 1.40 and 98.90% ± 2.80, respectively, the UV marker analysis also revealed no interaction. With the exception of MP1, which failed the uniformity of weight test, all three formulations passed the disintegration test. MP1 capsules had the lowest dissolve efficiency (22%), whereas F1 capsules had the highest (99%). The release of Cassia sieberiana between the three formulations varied significantly ($p < 0.0001$). This investigation has shown the potential

1. Introduction

Human beings have used microorganisms, marine organisms, animals, plants and other natural products to treat and alleviate diseases throughout ages. The use of plants as medicines can be traced back to 60,000 years ago [1,2]. It is highly possible that, early humans might have consumed plants which might have led to either

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therapeutic and / or toxic effects in their attempt to develop their knowledge in edible, medicinal and poisonous plants [3]. There has been increasing attention on natural products in the search for novel drugs for treating human diseases for decades due to the undesirable side effects, high cost and ineffectiveness of existing medications. [3]. A major challenge for herbal products is their lack of standardization which is necessary to provide optimum therapeutic outcomes during their use as well as in the provision of convenient dosage forms for patients [4].

Capsules are solid dosage forms which help to mask the bitter taste of drugs. In Ghana, most locally produced herbal capsules are formulated using the raw powdered plant material without any extraction [5]. This process may cause suboptimal therapeutic outcomes in some instances due to lack of consistency and standardization [4].

Cassia sieberiana commonly known as Africa laburnum is a woody shrub belonging to the family Fabaceae. It is a native African shrub distributed across the continent [6,7]. Cassia sieberiana is widely used especially across Africa in traditional medicine and as food [8]. The root of Cassia sieberiana is also used as chewing stick to improve dental health [9]. The root bark is used as analgesic and gastric cytoprotective agents [6]. Currently, a herbal product containing Cassia sieberiana on the Ghanaian market is produced by the Centre for Plant Medicine Research (CPMR), Mampong-Akuapem. This product is used for the management of dysmenorrhea and pain due to peptic ulcer. These two conditions are amongst the top ten conditions managed at the out patients clinic of CPMR [10]. The formulation is done by the encapsulation of the powdered plant parts; mostly a blend of the powdered stem and root bark. The challenges with the current formulation is the lack of standardization of the dosage and dosage regimen, the high quantity of chaff present and non-acceptability of the product by some patients, all these necessary to ensure the achievement of an improved therapeutic outcome. The current process of the capsule preparation also causes challenges such as poor flow during encapsulation of the powder blend. The study sought to formulate capsules of Cassia sieberiana using a combination of the stem and root barks by extracting with different solvents and comparing with the existing formulation available on the market. Extracts were obtained from the powdered materials using absolute and 70%v/v ethanol. The quantity of extract per dose available in the existing product was also determined. Formulated granules for encapsulation was assayed for its flow properties, extract-excipient compatibility and general qualitative assessment.

2. Materials and methods

Materials The stem and root bark of Cassia sieberiana were collected from Ago Meda, Ghana (6°07 20.3 ’N, 0°14 36.2 W) and was authenticated by the Head of Plant Development Department of CPMR. The plant parts have been deposited in the herbarium of the Centre for Plant Medicine Research, Mampong-Akuapem with the identification code (CPMR 4978). The Maize starch (Anhui Sunhere Pharmaceutical Excipients Co.

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Ltd, Huainan), Talc (Multi Mineral Industries, Jodhpur) and ethanol (Shandong Pulisi Chemical Co. Ltd., Zibo) were obtained from the chemical store of Centre for Plant Medicine Research. All reagents and chemicals used in this study were of analytical grade.

Methods Processing and extraction of plant material The plant material was sorted to remove all foreign matter. The materials were then chopped into smaller pieces, washed under clean running tap water, dried and milled into powder. An amount of 200 g of a mixture of powdered stem and root barks of Cassia sieberiana was cold macerated using 2 L of absolute ethanol for 7 days and filtered. The volume of filtrate and the total solid residue obtained were determined. The filtrate was concentrated at 60 °C under reduced pressure using a rotary evaporator. The ethanol free extract was then freeze dried and stored in cellophane bag at room temperature until required for analyses. This procedure was repeated for the 70%v/v extract.

Organoleptic and physicochemical characterization The color, odor, texture, taste, total ash, water soluble ash, acid insoluble ash and moisture contents were determined using official methods [11]. The pH of 1%w/v powdered plant material (MP1), absolute ethanol extract (F1) and 70%v/v ethanol extract (F2) of C. sieberiana was determined using pH meter (PL-700PV from Nickel-Electro Ltd, UK) at 25 °C.

Determination of UV absorption of powdered plant material blend (MP1), absolute ethanol (F1) and 70% v/v ethanol extracts (F2) The maximum wavelength of absorption (λmax) was determined by scanning various concentrations (0.0001–0.1%w/v) of the test materials in phosphate buffer (pH 7.2) using a UV-Visible spectrophotometer (Shimadzu UV-1700 PharmaSpec, Japan) through a range of 190 nm – 500 nm using quartz cuvettes over a path length of 1 cm. The phosphate buffer (pH 7.2) was prepared by using method stated in the BP [12].

UV-vis calibration plot of MP1, F1 and F2 The absorbance values of various concentrations of the test samples were determined at 278 nm (λmax) for both MP1 (0.004–0.0075%w/v) and F1 (0.0025–0.006%w/v) and 276 nm for F2 (0.002–0.005%) from which a calibration plot was obtained for subsequent estimation of extracts released from formulated capsules.
Preparation of MP1 powder, F1 and F2 granules Powder for preparation of MP1 was prepared directly from a blend of the stem and root of Cassia sieberiana using proprietary formula. A volume of the filtrate obtained from the extraction process and equivalent to the amount of F1 and F2 per encapsulated plant material were determined. The required volume of the filtrate was concentrated using the rotary evaporator. The concentrated extracts were mixed thoroughly with the starch using the wet granulation method. The damp masses were screened through a sieve with mesh size 2000 µm to form the wet granules. The wet granules were then dried at 60 °C for an hour. The dried granules were passed through another sieve of mesh size 841 µm to produce

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granules of uniform size suitable for encapsulation.

Evaluation of the flow properties of MP1 powder, F1 and F2 granules for encapsulation The flow properties (angle of repose, Carr's index, Hausner's ratio) of the formulations were determined using Pharmacopoieal methods [12]. Determination of bulk and tapped densities: An amount of 10 g of F1 granules was weighed and poured through a funnel into a 100 mL tarred measuring cylinder. The cylinder was then lightly tapped twice to collect all the granules sticking on the wall of the cylinder. The initial volume, Vo was recorded. The cylinder was tapped from a height of 2.5 cm 50 times on a wooden bench top to attain a constant volume reading from the cylinder, Vf The initial density was calculated as the initial bulk density or fluff or paired bulk density, Do,

$$\text{ie } D_o = {}^{\text{mass}}/_{V_o}$$

The final density was also calculated as the final bulk density or equilibrium or tapped or consolidated bulk density, Df

$$\text{i.e. } D_f = {}^{\text{mass}}/_{V_f}.$$

The ratio Df/ Do was calculated as the Hausner's ratio. Carr's index also known as percentage compressibility was calculated as Df − Do/ Df × 100. The same was repeated for MP1 powder and F2 granules [13]. Angle of repose: This was determined by using the fixed height method. F1 granules was allowed to flow freely from the funnel at a distance of 2 cm from the tip of the funnel to the horizontal surface to form a cone. The base of the cone was marked and the pile of granules was also poured off. The average of the two diameters were also determined. The angle of repose was then calculated from the height of the cone (h) and the radius (r) from the relation; θ=tan−1 (h/r) [13]. The same was repeated for MP1 powder and F2 granules.

Drug-excipient compatibility studies FTIR analysis: To ensure the extracts and the excipients are compatible, the FTIR analysis of the powdered blend extracts and formulated granules were carried out to obtain a spectrum between 400 and 4000/cm. The IR spectra of the granules were superimposed with the IR spectra of their corresponding extracts to determine whether or not the principal bands present in the extracts and plant materials were still present in the mixture of extracts and excipients. Thin layer chromatography (TLC): Thin layer chromatography was carried out to determine the Rf (retardation factor) values of the extracts and extract-excipient systems. Respective samples were extracted with petroleum ether. Samples were spotted on the TLC plate with solvent system, hexane/ethyl acetate (7:0.5). The plate was then developed with 10%v/v H2SO4 and heated at 110 °C for visualization. The Rf values were calculated using the formula, Rf = Distance traveled by sample/Distance traveled by solvent front

UV content analysis: Ten capsules were randomly selected from formulation F1 and F2. Each capsule was emptied and crushed. The active ingredient was extracted with phosphate buffer (pH 7.2)

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in 100 mL volumetric flask. The amount of Cassia sieberiana extract in each capsule was determined using a UV spectrophotometer at wavelength of 278 nm and 276 nm for formulations F1 and F2 respectively. This was done in triplicate.

Encapsulation of MP1 powder, F1 and F2 granules The preparations were encapsulated after addition of 1% w/w talc in size '0 capsule shell using encapsulation machine (GMP Industries, India).

Assessment of quality of capsules Uniformity of weight test of capsules: The capsules MP1, F1 and F2 were evaluated for uniformity of weight. For each formulation, twenty (20) capsules were randomly selected and weighed individually with an analytical balance (Adams Equipment, UK). Each capsule was carefully opened and the content removed totally. The difference between the weight of the intact capsule and the empty shell was calculated for each capsule. The mean weight and percentage deviations of the twenty capsules were calculated [12]. Capsule disintegration test: Disintegration test on capsules were carried out using a disintegrating apparatus (Type: ZT3/1, Erweka

R GmbH, Heusenstamn, Germany) at 37 ± 2 °C. The disintegration medium used was distilled water. A disk was placed on each capsule to prevent it from floating. The time taken for all six capsules to disintegrate leaving only remnants of gelatin shell on the mesh was recorded [12].

In vitro drug release studies This study was carried out using USP Dissolution Apparatus 2 (Veego, India) in 900 mL of phosphate buffer of pH 7.2 at a speed of 100 rpm and temperature of 37 ± 0.5 °C. Three capsules from each formulation were introduced into the consecutive round bottom beakers at 5 min intervals and the procedure conducted under sink conditions. At 0, 5, 15, 30, 45 and 60 min, 20 mL of each sample were withdrawn and replaced with fresh dissolution medium maintained at 37 ± 0.5 °C. The samples withdrawn were then filtered through whatman filter paper (No. 5) and assayed using the UV Spectrophotometer (Shimadzu UV – 1700 PharmaSpec, Japan) at wavelengths of 278, 278 and 276 nm for MP1, F1 and F2 capsules respectively using the data obtained from the calibration plots. The cumulative drug release was calculated and plotted against time.

Statistical analysis Data was analyzed with Excel and Graph Pad Prism for windows version 5 (Graph Pad Software Inc., San Diego, CA, USA) using one-way ANOVA. A p value < 0.05 was considered significant. All measurements were done in triplicates and results stated as mean ± standard deviation.

3. Results and discussion

Organoleptic and physicochemical properties The organoleptic and physicochemical properties of a plant material or its extracts may affect the choice of its formulation. From the results shown in Table 1, all the preparations had bitter taste hence

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formulation of capsules from these extracts and plant material will help to mask their bitter taste. The moisture contents of the powdered plant parts and extracts represent their water contents. The rate and kinetics of decomposition increases with increasing moisture content. Moisture content also influences the physicochemical properties of plant materials and extracts [11]. High moisture content in plants increase drug decomposition and subsequent spoilage, hence it is desirable that plant materials to be used in formulation development have very low moisture content. The results as seen in Table 1 were below 10%w/w which is within the limits stated (8–10% w/w) in African Pharmacopoeia for vegetable drugs [14]. F1 and F2 recorded lower moisture contents as compared to the MP1. This could be as a result of the high fiber content in the MP1 as compared to the F1 and F2. Plant fibers are known to have a strong hydrophilic behavior. The

Table 1

Organoleptic and Physicochemical properties of extracts (F1 and F2) and powdered plant material (MP1).

Color	Organoleptic properties			Physicochemical properties					Volume of filtrate (2 L solvent (L))	TSR of extracts (%)
	Texture	Color	Smell	Taste	Total ash (%)	AIA (%)	WSA (%)	Moisture content (%)	pH at 25°C		
MP1	Coarse	Brown	citric	Bitter	2.48 ± 0.04	0.58 ± 0.04	1.55 ± 0.07	8.40 ± 1.35	5.15 ± 0.01	10	10
F1	Smooth	Dark brown	citric	Bitter	1.50 ± 0.07	0.02 ± 0.05	0.91 ± 0.02	5.83 ± 0.91	4.51 ± 0.02	1.79	0.89 ± 0.11
F2	Smooth	Brown	citric	Bitter	1.68 ± 0.04	0.05 ± 0.07	0.59 ± 0.36	4.33 ± 2.21	4.57 ± 0.01	1.68	1.36 ± 0.03

citric represents characteristic; AIA-Acid insoluble ash; WSA-Water soluble ash; ND-Not determined; P values for comparison of pH of Plant material and extracts ($p < 0.05$) for absolute ethanol extract and 70%v/v ethanol extracts, respectively.

Table 2

Flow properties of MP1 powder, F1 and F2 granules ($n = 3$).

Properties	MP1 powder	F1 granules	F2 granules
Bulk density (g/mL)	0.45 ± 0.00	0.45 ± 0.02	0.44 ± 0.01
Tapped density (g/mL)	0.56 ± 0.00	0.53 ± 0.00	0.52 ± 0.01
Carr's index (%)	18.20 ± 0.00	14.78 ± 4.55	15.43 ± 1.89
Hausner's ratio	1.22 ± 0.00	1.18 ± 0.06	1.18 ± 0.03
Angle of repose (°)	38.59 ± 0.85	33.99 ± 0.39	33.73 ± 0.46
Flow	Fair flow	Good flow	Good flow

strengthening of this behavior in humid conditions leads to the absorption of high levels of moisture in wet environments [15]. The pH of any active ingredient is known to influence the nature and type of its formulation, delivery, stability and other physiological activities [16,17]. For the same concentration, 1%w/v at 25 °C, the F1 and F2 recorded lower pH as compared to MP1 (Table 1). A statistical analysis also shows a significant difference ($p < 0.05$) in the recorded pH values. The higher pH of MP1 could be due to its high fiber content resulting to its high moisture content. Thus, hydrogen ions of the film surrounding the MP1 particles originates not only from the ionization of acid salts and acids in the MP1 solution but also from micellar hydrogen ions held in the absorbed state on the surface of MP1 particles. As a result, there is a fluctuation of the hydrogen ion concentration with moisture content, temperature and others [18]. The ash content of MP1, F1 and F2 is the measure of the total amount of minerals present in them while mineral content is the total quantity of specific inorganic components such as sodium, calcium, zinc etc. present in them. The measure of both the ash and mineral contents is salient in determining their microbial stability, quality and nutritional benefits [19]. MP1 reported the highest water soluble and total ash but the lowest acid insoluble ash values (Table 1). Thus, MP1 contains the lowest level of sand as acid insoluble contaminant whereas F1 and F2 contain lower contents of water soluble contaminants. The low ash values of water soluble ash, acid insoluble ash and total ash shows that

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MP1, F1 and F2 have more organic contents than inorganic contents. This demonstrates a low level of contamination during collection, extraction and handling of Cassia sieberiana and its extracts.

The UV calibration plots for MP1, F1 and F2 The UV calibration plot for the phosphate buffer solution of MP1, F1 and F2 were linear with R2 of 0.9931 (Supplementary data Fig. 1A), R2 of 0.9967 (Supplementary data Fig. 1B) and R2 of 0.9959 (Supplementary data Fig. 1C) respectively. This indicates a good linear relationship between the concentrations of the extract solutions and the absorbance and as such the absorbance values of the solutions at λ max 278 nm for both MP1 and F1 solutions and 276 nm for F2 solution could be used to quantify marker in subsequent dissolution studies.

Flow properties of powdered MP1, F1 and F2 granules The flow properties of the formulated F1 and F2 granules as well as the powdered MP1 were investigated to avoid problems of irregular flow and flow obstruction during encapsulation. The results as reported in Table 2 shows that while F1 and F2 granules have good flow property, MP1 powder has a fair flow [20]. This means that, F1 and F2 granules would flow better than MP1 powder during encapsulation. In addition, they would not require vibration, agitation or any mechanical aid to flow during their manufacture [20].

FTIR analysis The FT-IR analysis of F2 exhibited absorption in the range of 3283.39 cm−1 to 416.04 cm−1 (Fig. 1). The spectrum exhibited a broad band at 3283.39 cm−1 (O–H Stretch) assigned to alcohol and hydroxyl group. A long, sharp peak at 1602.39 cm−1 is attributed to amines (N–H bending). Other major peaks were observed at 1514.41 cm−1 assigned to a nitro group (N–O stretching), a band at 1346.64 cm−1 corresponding to O–H stretch of phenols. The peaks observed at 1220.54 and 1060.93 cm−1 also indicates the presence of amines (C–N stretch). Also, the FT-IR of F1 (Fig. 2) proved the presence of alcohol or hydroxyl group at 3277.40 cm−1 (O–H stretch). A sharp long band at 1602.48 cm−1 corresponding to (N–H Stretch) of amines, a nitro group at 1514.40 cm−1, O–H (stretch) of phenols at 1350.62 cm−1. Other bands at 1092.21 and 1061.21 cm−1 indicate amine C–N (stretch). These bands were similar to that observed in F2. The extracts and excipients showed the shifting and shortening of the peak at 1602 cm−1 in both formulations. Also, the peaks within the range of 1600 and 1350 cm−1 were significantly shortened indicating some form of interaction between the extracts and the excipient. Again, the appearance of an elongated peak at 995.21 and 996.37 cm−1 in F2 and F1 granules respectively, indicate some kind of interaction. This interactions occurring at the fingerprint region may not negatively affect the drug. Herbal extracts are made up of several phytochemical constituents, of which only a few are

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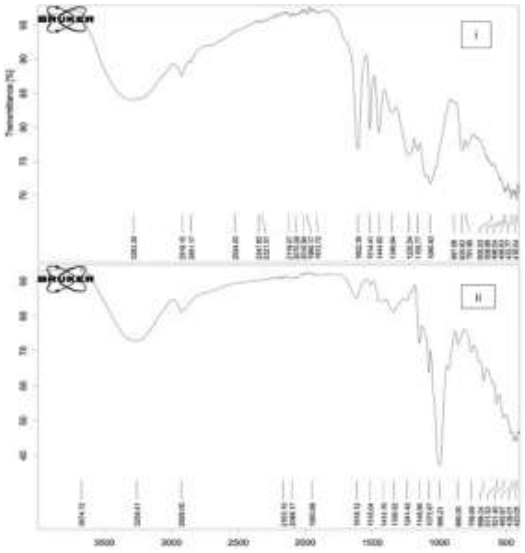

involved in a particular activity. Also, since the two excipients used in this study are inert (starch and talc) and are compatible with herbal extracts, the observed incompatibility may be as a result of some intermolecular interactions between the phytochemical constituents and the excipients and / or intramolecular interactions within the Phytoconstituents during the formulation [21].

TLC analysis In the TLC studies, Rf values of the two extracts were compared with the Rf values of their corresponding extractexcipient systems [22,23]. TLC profile of F1 (1), F1 granules (2), F2 (3) and F2 granules (4) is shown in Supplementary data Fig. 2. Three distinct common marker bands (spots) at Rf = 0.85, 0.21 and 0.12 were observed in the case of F1 and F1 granules and this may indicate that, there was no significant interaction between the extract and excipients [23]. Similar trend was observed for the TLC profile of F2 and F2 granules being two marker bands (spots) at Rf = 0.11 and 0.20. This results is in contradiction to that obtained from the FT-IR analysis.

UV content analysis The UV marker analysis also indicated no interaction since the percentage Cassia sieberiana extract contents were 98.0% ± 1.4 and 98.90% ± 2.80 in F1 and F2 capsules respectively. This is within the BP stipulated range [12]. Quality assessment of formulated capsules Disintegration time and uniformity of weight of capsules One important quality control test for capsules is the disintegration test that determines if formulated capsules break up within a specified time when placed in an immersion medium [12]. In order for the active ingredient in formulated capsules to go into solution for subsequent absorption to occur, the capsule must first disintegrate [24]. The results as shown in Table 3 conformed to Pharmacopoeia standards which stipulates a maximum of 30 min for capsule products formulated using hard gelatin capsules [12]. F1 capsules recorded the lowest disintegration time of 5.03 min. The results from Table 3 also demonstrates that, F1 and F2 capsules passed the uniformity of weight test while MP1 capsules failed. Therefore, it is expected that, for F1 and F2 capsules, there will be a uniform dose of Cassia sieberiana between individual capsules. This means that, there is a high possibility of producing a desired drug concentration as well as the attainment of therapeutic goals. The failure of MP1 capsules could be as a result of its fair flow properties and irregular particle sizes caused by the presence of too much fibers in powdered plant material causing uneven feeding of

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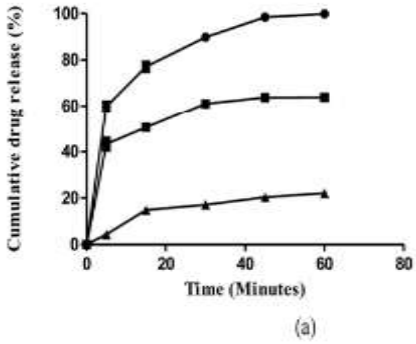
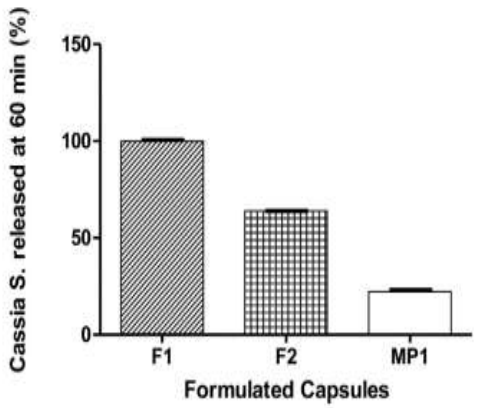


(a)



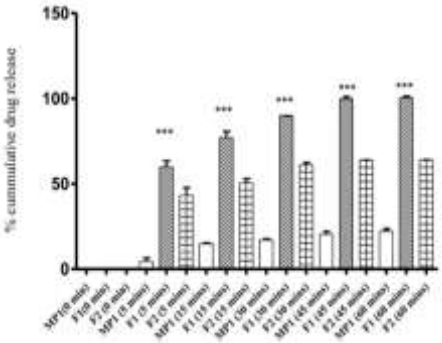
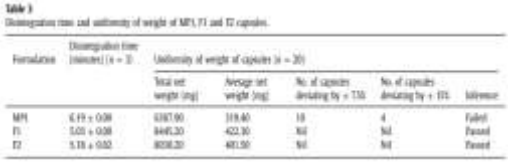


Fig. 3. a: In-vitro dissolution profiles of MP1, F1 and F2 capsules in phosphate buffer (pH of 7.2). b: Percentage release of Cassia sieberiana extract from MP1, F1 and F2 capsules (mass ± SD, n = 3). c: Comparative analysis of the in-vitro drug release from MP1, F1 and F2 capsules at different times using one-way ANOVA followed by Newman–Keuls multiple comparison Test. *** is $p < 0.0001$ Significance.



the material into the shell of the capsules during the encapsulation process. The difference between the expected weight (500 mg for capsule size 0) and the actual weights as seen in Table 3 could be as a result of the use of manual encapsulation machine, differences in density and particle size distribution of MP1 powder, F1 and F2 granules. The net weight of the encapsulated powdered blend of plant material using capsule size '0 was found to be 320.00 ± 20 mg. The equivalent weight of extracts of absolute and 70% v/v ethanol from 320.00 ± 20 mg dose of powdered blend of plant material were determined to be 27.84 ± 0.11 mg and 36.65 ± 0.03 mg respectively

In-vitro Cassia sieberiana release from MP1, F1 and F2 capsules In vitro dissolution testing is important for providing information on the rate and extent of drug release from oral dosage forms [25]. Not only does it form the basis for selecting a suitable batch amongst other batches but it also represents an important quality control tool in assessing the suitability of a formulation in the drug development process [26]. For a desired therapeutic effect of an oral formulation to be achieved, dissolution must occur. Dissolution efficiency is not only for making quantitative comparison among batches of capsules but also, it gives information about the consistency in each batch. However, it is not a

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parameter for a comparative dissolution kinetics, it only characterizes the release of drugs. Results from the dissolution studies shows MP1 capsules gave the least labeled drug content release of 22% whereas formulations F1 and F2 released 99% and 63.9% of the labeled drug content respectively at the end of the 60 min dissolution study as shown in Fig. 3a and b. Thus, F1 and F2 capsules released 77% and 41.9% of Cassia sieberiana extract respectively higher than MP1. This results shows that, capsules formulated from F1 and F2 released higher amounts of the Cassia sieberiana extract within the same time frame as compared to the capsules on the market. A study by Costa et al. [27] demonstrated a similar occurrence in the dissolution of total flavonoids in Passiflora sp capsules. Dissolution of capsules prepared with its dried extract was 12% higher than that of the product containing the powdered plant material in the final 30 min. These different drug release profiles may be associated with extraction techniques employed, extraction solvents, particle size, moisture, drug manufacturing processes and the presence or absence of excipients [28,29]. The different drug release profiles represent different bioavailabilities which may subsequently cause variations in the therapeutic outcome of the formulation [30]. It is therefore important to standardize plant materials used in herbal product manufacture. A comparison of the dissolution profiles of the formulated capsules gave an indication as to whether the formulated capsules from different extracts affected the release of Cassia sieberiana extracts from the capsules. This is relevant in determining the similarity or difference in Cassia sieberiana release from the different formulations which could be an indication of their bioequivalence. This will help manufacturers identify the possible formulations which could be substituted to attain similar Cassia sieberiana release in place of existing product MP1. Analyses from obtained results indicate significant differences between the drug release profiles of the three formulations ($p < 0.05$) as shown in Fig. 3c, with only formulation F1 passing the dissolution test (not less than 80% release of active substance in 45 min) [12].

4. Conclusion

Oral capsules for the conventional release of Cassia sieberiana has been successfully formulated from the absolute and 70% ethanol extracts of the powdered blend of stem and root bark found on the Ghanaian market. Formulation F1 passed all pharmacopeia tests and had a better release profile as compared to MP1. Further studies are needed to determine the extent and nature of drug-excipient interaction during the manufacturing process. The introduction of these capsules will aid in the administration of the right dose to achieve the desired therapeutic outcome from its use.

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