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The Potential of *Allanblackia floribunda* Butter as a Suppository Base

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Abstract

The rectal route for drug administration is becoming attractive to drug formulators because there are no hepatic first-pass effects, it decreases gastrointestinal side effects, and it avoids undesirable food effects on drug absorption. Suppositories are recognized as an alternative to the oral dosage forms in situations such as when the patient is comatose, unable to swallow, nauseous, or vomiting. Effective drug delivery with appropriate pharmaceutical excipients is critical to producing clinically valuable preparations. The high cost of available excipients and other disadvantages have led to exploring potential excipients from natural sources. *Allanblackia floribunda* butter, a naturally occurring lipid, is used for medicinal, culinary, and cosmetic purposes. The butter was used as a base to formulate Paracetamol and Diclofenac suppositories. Quality control tests were conducted on the formulated suppositories, such as the Weight variation, hardness, disintegration time, and content uniformity. The suppositories passed all the quality control tests as the parameters assessed were within the acceptable range. The melting point ranges for all the suppositories were found to be satisfactory. The cumulative drug release (%) of the suppositories at 45 minutes was 90.19±0.00 (Hot water extract), 93.75±0.00 (Cold press extract), and 98.16±0.00 (Hexane extract) for Paracetamol suppositories. Diclofenac sodium suppositories had a cumulative percentage release of 81.60±0.00 (Hot water Extract), 95.33±0.00 (Cold press extract), and 99.20±0.00 (Hexane Extract). However, the release profiles of the drugs from the bases were similar (f2 > 50). The suppository formulation was successful, and the quality control tests conformed to Pharmacopoeia standards.

Keywords: *Allanblackia floribunda* butter, Suppositories, Extracts

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1. Introduction

The drug delivery system is a formulation or device that enables a therapeutic substance to selectively reach its site of action without reaching the non-target cells, organs, or tissues. Examples include tablets, capsules, suppositories, emulsions, liposomes, micelles, dendrimers, pessaries, self-emulsifying drug delivery systems (SEDDS), nebulizers, nasal sprays, eye drops, and transdermal patches (1). Drugs are rarely administered alone and are almost always formulated with excipients to enhance the process of drug preparation and delivery. These additives impact active pharmaceutical ingredients' efficacy, stability, quality, manufacture, and safety (2). Excipients range from inert and simple to active and complex substances that can be difficult to characterize. Traditionally, excipients, such as corn, wheat, sugar, and minerals, were often structurally simple, biologically inert, and of natural origins. Many complex excipients have been developed as novel drug delivery systems emerge and evolve. Many of these excipients are potentially toxic at high doses in ani-

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mals, though safe in humans at therapeutic doses, including commonly used ones such as cyclodextrins, dextran, and polyethylene glycol (3).

Drug administration by rectal route is appealing to drug formulators because it avoids hepatic first-pass effects, gastrointestinal side effects, and food-related adverse effects on drug absorption. As a result, attempts are now being made to produce a variety of medications in suppository form (4).

Suppositories are prepared using bases as vehicles. The bases are of two types: oleaginous/fatty bases (theobroma oil or cocoa butter and hydrogenated vegetable oils) and water-miscible or soluble (glycerinated gelatin and polyethylene glycol polymers, also known as Macrogols). Commercially available fatty bases that are considered cocoa butter substitutes include Dehydag®, Hydrokote®, Suppocire®, and Witepsol® (5, 6). Although many suppository bases are used in the pharmaceutical manufacturing of suppositories, most are synthetic and semi-synthetic and are very expensive. Nature presents a wide range of naturally occurring lipids that can be exploited for drug delivery properties. Examples are cocoa butter, shea butter, and Allanblackia floribunda butter. Shea butter has, over the years, gained significant attention as one of the essential vegetable fats. It has been used as a substitute for cocoa butter in cosmetics (7), but the fat is soft at room temperature. It is helpful for skin care because it has sun-screening properties and acts as an emollient and moisturizer. Bartels *et al*. applied shea butter to formulate suppositories of alum but had to add beeswax as a hardening agent due to the low melting point of the Shea butter (8).

Cocoa butter is also of natural origin and is included in chocolate and other food products. It can also be found in over-the-counter skin products such as lotions, creams, and bars to maintain skin softness due to its moisturizing properties (9). Despite these properties, cocoa butter crystallizes into six polymorphic forms with different melting points due to many unsaturated triglycerides (10, 11). It is susceptible to oxidation, has poor water-absorbing ability, and can leak from the body. Above all, it is expensive. Cocoa butter has been used to formulate suppositories by including agents such as Polyethylene glycols, Tweens, and Cyclodextrins to improve its hydrophilicity and sometimes with beeswax as a hardener (12).

Allanblackia floribunda butter has a unique blend of fatty acids with melting properties that are excellent for structuring fat products such as margarine. Konadu (2022) investigated the physicochemical properties of Allanblackia butter using three different methods of extraction (cold press, hexane, and hot water). The study revealed that butter comprises prominent fatty acids such as palmitic and stearic (Saturated fatty acids), oleic, linoleic, and linolenic (Polyunsaturated fatty acids). It concluded that the presence of these constituents and the favorable physicochemical properties of the butter could make it ideal as a drug delivery excipient for formulations such as suppositories, ointments, creams, emulsions, solid-lipid nanoparticles, and liposomes (13). Other researchers have investigated the physicochemical properties of butter for food and cosmetic purposes (14, 15). However, there is no drug-delivery application of this butter in the literature. In this regard, this study investigated the use of *Allanblackia floribunda* butter as a base in the formulation of suppositories using paracetamol and diclofenac as active pharmaceutical ingredients. Either hexane, hot water, or cold press extracted the butter. The fusion and incorporation techniques were employed in the suppository formulation, and the quality was assessed using pharmacopeia standards such as Uniformity of weight, content uniformity, disintegration time, hardness, melting range, and drug release. Its successful use will provide a natural, cheap, and readily available alternative suppository base.

2. Materials and Methods

2.1. Materials

Allanblackia floribunda fruits were collected from the Council for Scientific and Industrial Research (CSIR) forest at Fumesua in the Ashanti region of Ghana, Kumasi. Diclofenac sodium and Paracetamol powders were obtained as a gift from Danadams Pharmaceutical Industry, Ghana. All other chemical reagents were obtained from the Department of Pharmaceutics, KNUST, Kumasi

2.2. Methods

2.2.1. Extraction of Allanblackia floribunda Butter

The butter was extracted by three meth-

ods and stored until use, as described by Konadu (2022) (13).

2.2.2. Determination of displacement value of Paracetamol and Diclofenac in Allanblackia floribunda butter

The method by Bartels et al. was slightly modified (8). The method used 40 % of alum as the active pharmaceutical ingredient. In this work, however, 15 % of medicament was used due to the bulk of the drugs. Six suppositories of *Allanblackia floribunda* butter extracted by the different methods were formulated, and the weight was recorded as A mg using a 2g suppository mould (method explained in detail under section 2.2.3). These are referred to as blank suppositories. Six medicated suppositories containing 15% paracetamol or 15% diclofenac were also prepared using Allanblackia floribunda butter extracted by either hexane, hot water, or cold press, and the weight was recorded as B mg. The amount of Allanblackia floribunda butter (C mg) and diclofenac or paracetamol (D mg) in the medicated suppository was determined (16). The displacement value of each medicament in a given base was computed using Equation 1 below.

$$Displacement\ value = \frac{D(mg)}{A - C(mg)} \quad \text{(Eq. 1)}$$

2.2.3 Preparation of the suppositories

The suppositories were prepared using the Active Pharmaceutical Ingredient (API) amounts and the butter indicated in Table 1.

Forty suppositories (40) of each of the bases extracted by either hexane, hot water, or cold press (Table 1) were prepared using the hot melt and trituration methods. A blank suppository using, for example, hexane-extracted butter was prepared using the 2 g mould and weighed. The displacement value indicated in Figure 1 for paracetamol in hexane-extracted butter was used to calculate the total amount of base required for the formulation of the forty suppositories by using equation (2).

$$Amount\ of\ base\ required = (N \times w) - (N \times D/DV) \quad \text{(Eq. 2)}$$

Where N is the number of suppositories to be formulated, w is the weight of the blank suppository (2.06 g), D is the amount of drug in one suppository (0.25 g), and DV is the displacement value of the base (1.52). A 2 g suppository mould (D-7166, Erwema Pharmatechnik, Germany) was disassembled, washed, cleaned, and dried. The mould was lubricated with the help of cotton wool and soap spirit. The paracetamol powder was weighed using an analytical balance (SN: AE 436647 Adam Equipment, UK). The hexane-extracted butter was shredded, and the required amount was weighed on the balance. It was heated in a stainless steel container in a water bath (Sanyo, OMT Oven, Gallenkamp, UK) at 37 °C until liquefied. Care was taken to prevent the butter from overheating. The paracetamol powder was incorporated into a small amount of the base on a warm tile. The rest of the base was added geometrically with stirring until a homogeneous mixture was obtained. The molten mass was left to set and poured into the mould until overfilled. The mould was then refrigerated for about 30 minutes for solidification. A warm spatula scraped the excess base from the top of the mould. The mould was disassembled, and the suppositories were removed, packed, and stored until further use (8). The procedure was repeated with the other extracted butter and medications.

2.3. Quality evaluation of formulated suppositories

The suppositories were evaluated according to the requirements of the British Pharmacopoeia (17).

Table 1. Amount of Allanblackia floribunda butter and APIs used for the formulation.

Butter	(API)	Amount of API(g)	Amount of base (g)	Weight of blank suppository (g)
Hexane	Paracetamol	10	75.84	2.06
Hexane	Diclofenac	4	77.32	2.02
Hot water	Paracetamol	10	73.92	2.03
Hot water	Diclofenac	4	79.68	2.06
Cold press	Paracetamol	10	75.28	2.03
Cold press	Diclofenac	4	78.80	2.04

2.3.1. Sensory evaluation

The prepared suppositories were evaluated for colour and surface factors such as texture, look, feel, and shape to guarantee product-to-product Uniformity.

2.3.2. Visual characterization

The suppositories were randomly selected and evaluated for the absence of fissuring, pitting exudation, and fat blooming. The suppositories were observed as a complete unit as a whole. It was then split longitudinally to evaluate the physical characteristics. The observed characteristics were recorded.

2.3.3. Weight Variation Test on Suppositories

Twenty (20) randomly sampled suppositories were taken from each formulation indicated in Table 1. They were weighed, and the average was calculated as (A). The suppositories were then weighed individually (B), and the deviation from the average was calculated as (A-B). The percentage deviation was determined using Equation 3 (BP, 2013).

$$Percentage\ deviation\ = \frac{IA - BI}{A} x\ 100\% \quad \text{(Eq. 3)}$$

The pharmacopeia states that not more than two suppositories must deviate from the mean weight by more than 5%, and none must deviate by more than 10% for all weights of suppositories (17).

2.3.4. Breaking strength (hardness) Test of Suppositories

The hardness test was conducted on the formulated suppositories using a Copley hardness tester (BFG 200 N). The breaking strength was recorded at the weight where the suppository lost its structure or collapsed. Hardness test values were determined by an average of six suppositories (18).

2.3.5. Disintegration Test of Suppositories

A disintegration test for the variously formulated suppositories was performed using the suppository disintegration apparatus (Erweka Type ZT 3/1, GmbH, Heusenstamm, Nr 68318, Germany). Six suppositories were randomly selected from each formulated group as indicated in Table 1 and placed in the rack of the disintegration apparatus containing 900 ml of water in a vessel maintained at 37±0.5 °C. The disintegration time was noted when there was an appreciable change in shape with no solid core offering resistance to pressure with a glass rod (19).

2.3.6. Melting Range Determination of Suppositories

A glass beaker filled with 50ml of distilled water with an immersed thermometer was placed in a water bath. Individual suppositories were placed inside the water, and the temperature at which the suppositories began to melt and wholly melted was recorded as the melting range (20). Three (3) suppositories of each were used.

2.3.7. Uniformity of content of the suppositories

2.3.7.1. Assay of Paracetamol

Ten (10) Paracetamol suppositories were randomly selected and accurately weighed. They were carefully chopped into little bits and uniformly blended. A portion of the fragments containing about 75mg of paracetamol was weighed accurately into a 100 ml volumetric flask. 25 ml of 0.1 M Sodium hydroxide solution was added, sonicated for 15 minutes, and then topped up to 100 ml with deionized water. It was then warmed to dissolve and mix. After allowing the mixture to cool, it was filtered using Whatman filter paper. 1 ml of the filtrate was pipetted into a 100 ml volumetric flask, followed by 10 ml of 0.1M Sodium hydroxide, and the volume made up to 100 ml with distilled water (sample solution).

10 ml of 0.1M Sodium Hydroxide was pipetted into a 100 ml volumetric flask and topped up to the mark with water as the blank. The absorbance of the sample solution was measured with a UV spectrophotometer (Jenway 7315, UK) at 257nm. The content of paracetamol was determined at the maximum wavelength of 257nm using a predetermined calibration curve ($y = 607.1x - 0.032$, $R2 = 0.9962$) (21).

2.3.7.2. Assay of diclofenac sodium

Ten (10) Diclofenac Sodium suppositories were accurately weighed, cut carefully into small pieces, and mixed uniformly. An amount containing 50 milligrams of Diclofenac sodium was carefully weighed into a 100 ml volumetric flask. 5 ml

Tetrahydrofuran was added and dissolved using a sonicator. A combination of methanol and water (3:2) was added to the 100 ml mark and filtered using Whatman filter paper. 5 ml of the filtrate was pipetted into a 50 ml volumetric flask. It was topped up to the mark with the same solvent. The absorbance was determined with a UV spectrophotometer (Jenway 7315, UK) at a wavelength of 254 nm using a predetermined calibration curve (y = 261.54x + 0.081, R2 = 0.9942).

2.3.8. In vitro release of paracetamol from suppository (dissolution)

The drug release profile of Paracetamol suppositories formulated with hexane extract of Allanblackia floribunda butter was analyzed using the USP Apparatus II. In this analysis, the dissolution medium employed was 900 ml of phosphate buffer (pH 5.8), and the temperature was kept constant at 37±0.5 ºC throughout the experiment. Six suppositories were placed in the dissolution vessel, and the paddle speed was set at 50 rpm. At time intervals (5, 10, 15, 30, 45, and 60 minutes), 10 ml of the medium was withdrawn from the vessel, and the same amount of fresh medium was used to replace it to maintain the sink condition. Each sample was filtered and then diluted with 0.1M NaOH to provide a solution containing roughly 0.00075 % w/v paracetamol. Using the UV spectrophotometer, 0.1M NaOH was used in the reference cell to measure the absorbance of the solution at its maximum wavelength of 257 nm (21). The amount of paracetamol in each sample was determined with a calibration curve. The cumulative percentage amount of paracetamol released was then calculated, and a graph of the cumulative percentage amount against time was plotted.

The above procedure was repeated for hot water and cold press extracts.

2.3.9. In vitro release of diclofenac sodium from the suppositories

The same procedure described in section 2.3.8 was used to release the diclofenac from the suppositories, except that the medium used was phosphate butter (pH 6.8). The filtrate from each sample was diluted with 0.1 M HCl to give a solution containing about 0.0294 mg/ml of diclofenac and analyzed at 276 nm using a UV spectrophotometer. The cumulative percentage of the diclofenac released was calculated and plotted against time.

2.4. Statistical analysis

Statistical analysis and graph plots were performed using Statistical Package for the Social Sciences (SPSS v.20, IBM). Data are presented as the mean ± standard deviation. The f2 values were calculated using the equation below:

$$f_2 = 50 \times \log\left\{\left[1+1/n\sum\left(R_t - T_t\right)^2\right]^{-0.5} \times 100\right\} \quad \text{(Eq. 4)}$$

Where n = number of sampling times t (t = 1 to n), Rt = cumulative percent dissolved at time t for the reference, and Tt = cumulative percent dissolved at time t for the test.

3. Result

3.1. Displacement value of Paracetamol and Diclofenac in Allanblackia floribunda butter

Medicated suppositories are formulated by adding an active pharmaceutical ingredient (API) and other excipients to a suppository base. Adding APIs and the excipients displace a certain amount of the base. The displacement value measures how much of the base is displaced by the API. The amount of base displaced depends on the API and the base used. The displacement value has to be determined by experiment unless known in the literature. The displacement values of paracetamol and diclofenac in the *Allanblackia floribunda* but-

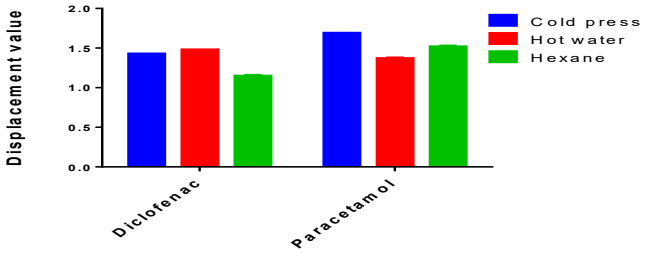

Figure 1. Displacement value of Diclofenac and Paracetamol in the *Allanblackia floribunda* butter extracted by different methods.

Table 2. Sensory parameters of the formulated suppositories.

Formulation	Sensory parameter				
	Color	Texture	Appearance	Feel	Shape
Hexane-paracetamol	Pale yellow	Smooth	Oily	Plastic	Torpedo
Hexane-diclofenac	Pale yellow	Smooth	Oily	Plastic	Torpedo
Hot water-paracetamol	Yellow	Smooth	Oily	Plastic	Torpedo
Hot water-diclofenac	Yellow	Smooth	Oily	Plastic	Torpedo
Cold press-paracetamol	Pale yellow	Smooth	Oily	Plastic	Torpedo
Cold press-diclofenac	Pale yellow	Smooth	Oily	Plastic	Torpedo

Plastic means a soft palpable mass

ter extracted by the different methods are shown in Figure 1. There was no correlation between the butter extraction method and the type of API used.

3.2. Sensory Evaluation of the Suppositories

The sensory characteristics of the paracetamol and diclofenac suppositories using Allanblackia floribunda butter, such as the colour, texture, appearance, feel, and shape, are summarised in Table 2. The solvent used in the butter extraction for the formulation development influenced the colour of the prepared suppositories. The hexane and cold press butter were pale yellow, while the hot water was yellow. The yellow is due to the high carotenoids extracted from boiling water (13, 22). The complete suppository unit showed no fissures, pits, fat blooming, or exudation. The same observation was made when the suppositories were split longitudinally into two halves. By the British pharmacopeia standard, the suppositories are satisfactory in appearance and sensory characteristics (17).

3.3. Quality control tests for the formulated suppositories

The quality control tests on the formulated suppositories were Uniformity of weight, hardness, disintegration, and content uniformity. The results are shown in Table 3. All the formulated paracetamol and diclofenac suppositories passed the Uniformity of content test as the values were within 90% to 110% (21). The uniform content suggests a uniform dose of the active drug within the suppositories and an expected similar treatment outcome. The melting point of the raw butter extracted by either hexane, hot water, or cold press was between 40 and 42 °C (13). The melting point of the formulated medicated suppositories was similar to the raw butter. There is no chemical interaction between the butter and the medicaments. This high melting point is ideal for including butter in solid products such as lip balms and body moisturizers and as an alternative to cocoa and shea butter (23).

Suppositories are supposed to be hard enough to enable packaging, transportation, and handling. The results indicate that the formulated suppositories can be transported and stored under normal conditions without breaking. A suppository with a breaking strength of at least 1.8 kg is considered ideal (21). The hardness and melting range indicate that the suppositories can be stored at room temperature and temperatures that pertain to the tropic and subtropical regions.

Table 3. Sensory parameters of the formulated suppositories.

S/ No	Suppository	Uniformity of content (%) (n = 10)	Melting Range (oC) (n = 3)	Hardness (kg)(n = 6)	Disintegration (minutes) (n = 6)	Uniformity of weight (n = 20)
1	Cold press- diclofenac	97.00 ± 0.90	39-58 ± 1.0	3.83 ± 0.15	6. 08 ± 0.01	Passed
2	Cold press – paracetamol	90.57 ± 1.3	41-58± 1.0	3.88 ± 0.15	7.12 ±0.00	Passed
3	Hot water- diclofenac	102.00 ± 2.8	41-59 ± 1.5	4.72 ± 0.15	8.15 ± 0.02	Passed
4	Hot water-paracetamol	99.07 ± 0.85	40-58 ± 0.6	4.78± 0.15	9.23 ±0.02	Passed
5	Hexane- diclofenac	95.00 ± 0.00	41-64 ± 0.6	4.86 ± 0.07	9 .9 ±0.03	Passed
6	Hexane- paracetamol	106.34 ± 3.4	42-64 ± 1.0	4.78 ± 0.15	8.37 ±0.01	Passed

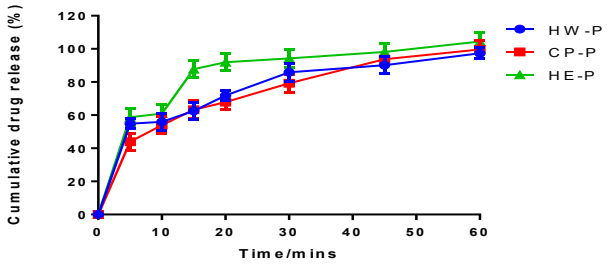

Figure 2. A plot of the cumulative percentage release of paracetamol with time from suppositories (HW-P: hot water – paracetamol; CP-P: cold press – paracetamol; HE-P: hexane – paracetamol).

The disintegration of suppositories occurs when the sample softens or dissolves completely or has dispersed into its components parts, which may collect on the surface (melted fatty substances), sink to the bottom (insoluble powder), or dissolve or become soft, which may involve an appreciable change in shape, without necessarily separating into its components, and the mass has no solid core offering resistance to pressure with a glass rod.

For suppositories formulated using fatty bases, the British Pharmacopoeia (BP) recommends a disintegration time of below 30 minutes (24). All the formulated suppositories using the butter extracted by either hexane, hot water, or cold press disintegrated below ten (10) minutes, satisfying the BP requirement.

3.4. In vitro release of diclofenac and paracetamol from suppositories

Dissolution of drugs is the rate-determining step in the absorption of drugs either by the oral or rectal route and subsequent pharmacological activity. For suppositories, the dissolution of medicaments in the rectal fluid precedes absorption, which can be tested *in vitro*. According to the British Pharmacopoeia, the release of drugs from non-modified dosage forms into the dissolution medium should be at least 70 % at 45 minutes (24). The release profiles for paracetamol and diclofenac from the formulated suppositories with Allanblackia floribunda butter are shown in Figures 2 and 3. From the graphs, all the formulated suppositories passed the dissolution test, with more than 70 % of the drug released at 45 minutes.

These results corroborate a study by Bartels et al. on alum suppositories formulated with cocoa butter and shea butter modified with different amounts of beeswax. The beeswax was used to improve the hardness of the suppositories. Despite the beeswax, the suppositories released more than 70% of the incorporated alum (8). The allanblackia butter was hard enough and required no hardening agent. All the formulated suppositories were found to be within the acceptable limit. Generally, the cold press suppositories had a low hardness value and the fastest disintegration time compared to the hexane and hot water suppositories. The heat generated during cold press is not as much as using solvents and hot water. Hence there would be less chemical modification and reaction of constituents. This effect could account for the low hardness and fast disintegration time. The melting range of the butter, disintegration, and hardness influence the dissolution of suppositories. There was no correlation between these factors and the release of the medicaments from the formulated suppositories. The only exception was diclofenac formulated

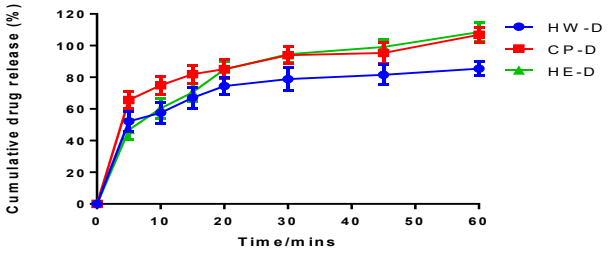

Figure 3. A plot of the percentage cumulative release of diclofenac with time from suppositories (HW-D: hot water – diclofenac; CP-D: cold press – diclofenac; HE-D: hexane – diclofenac).

Table 4. Similarity factor for the dissolution profiles of the suppositories.

Suppositories	f2 value (%)	Similar or Different
Cold press - diclofenac	65.25	Similar
Hot water – diclofenac	73.61	Similar
Hexane – diclofenac	92.76	Similar
Hot water – paracetamol	79.42	Similar
Cold press – paracetamol	96.27	Similar
Hexane - paracetamol	85.64	Similar

with cold press butter (Table 3 and Figures 2 and 3).

The paracetamol and diclofenac dissolution profiles from the suppositories formulated with butter extracted by hexane, hot water, or cold press were compared to assess their equivalence. In the literature, different methods that can be used to compare dissolution profiles have been reported (25-28). The most essential and widely engaged method in this study has been used: the fit factors. The fit factors can be expressed by f1 (the difference factor) and f2 (the similarity factor). For two dissolution profiles to be considered similar and bioequivalent, f1 should be between 0 and 15, whereas f2 should be between 50 and 100 (28). The results for the similarity factor (f2) are indicated in Table 4.

It is evident from the data that the release of paracetamol and diclofenac from the suppositories is similar, as they all have f2 values of more than 50%. The release of the medicaments from the butter is independent of the extraction method and the type of medicament incorporated. The formulations are deemed similar and could be bioequivalent.

4. Conclusion

The suppositories were successfully formulated with the Allanblackia floribunda butter extracted by either hexane, hot water, or cold press and had satisfactory sensory parameters. The suppositories passed all the pharmacopeia tests required for rectal application. The high melting point of the suppositories suggests that they can be stored at room temperature and other higher temperatures. The release of medicaments from the butter is independent of the extraction method and the type of drug incorporated. Allanblackia floribunda butter is an ideal suppository base and a better alternative to cocoa and shea butter. The Pharmaceutical manufacturing industry should research the commercial production of suppositories using Allanblackia floribunda butter, a cheaper alternative.

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Data Availability

The data used to support the findings of this study are included in the article. It is available from the corresponding author upon request.

Conflict of Interest

The authors declare no conflict of interest.

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