World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

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Evaluation of diclofenac sodium creams formulated using extracted castor oil (*Ricinus communis* L.)

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World Journal of Biology Pharmacy and Health Sciences, 2025, 23(01), 184-191

Publication history: Received on 18 May 2025; revised on 05 July 2025; accepted on 07 July 2025

Article DOI: https://doi.org/10.30574/wjbphs.2025.23.1.0647

Abstract

This study evaluated the formulation and physicochemical properties of diclofenac sodium cream using castor oil (Ricinus communis L.) extracted from seeds cultivated in Abraka, Nigeria. Diclofenac sodium, a non-steroidal anti-inflammatory drug (NSAID), is commonly used for managing pain and inflammation but is associated with gastrointestinal side effects when administered orally. Topical formulations, such as creams, can mitigate these adverse effects while providing targeted drug delivery. Castor oil, known for its high viscosity and unique chemical profile rich in ricinoleic acid, was extracted via solvent extraction and utilized as the oil phase in various cream formulations. The creams were assessed for pH, viscosity, spreadability, homogeneity, emolliency, and stability. Results indicated that all formulations exhibited shear-thinning behavior, with viscosity decreasing as shear rate increased. The pH values (4.30–6.15) were within the normal skin range, suggesting suitability for topical application. The creams demonstrated good spreadability (28–46 g·cm/s), were non-greasy, easily washable, and left no residue. All formulations were stable under accelerated conditions, with no phase separation or degradation observed. Notably, creams containing castor oil had higher viscosity compared to those formulated with arachis oil at equivalent concentrations. These findings demonstrate that locally sourced castor oil is a suitable pharmaceutical excipient for topical diclofenac sodium creams, offering desirable physicochemical properties and stability, and supporting its potential for commercial and therapeutic use in dermatological preparations.

Keywords: Castor oil; Diclofenac Sodium; Cream; Extraction; Viscosity

1. Introduction

Diclofenac is a phenylacetic acid derivative non-steroidal anti-inflammatory drug (NSAID) that is used in the management of conditions associated with pain and inflammation, such as arthritis and sports injury. Diclofenac is commonly available in two salt forms: potassium and sodium. Diclofenac potassium is known for its rapid onset of action and is primarily used for acute conditions, whereas diclofenac sodium acts more slowly and is typically prescribed for chronic conditions such as rheumatoid arthritis [1, 2]. While diclofenac is effective, it can cause side effects like gastric irritation and bleeding. Using diclofenac in topical formulations—such as creams, ointments, and gels—helps minimize these gastrointestinal side effects.

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Creams are topical preparations applied to the skin. They are viscous liquid or semi-solid emulsions of either oil-in-water (O/W) or water-in-oil (W/O) type, with consistency varying based on their oil and water content [3, 4]. They serve cosmetic purposes—such as cleansing, beautifying, enhancing appearance, and providing protection—as well as therapeutic functions. These formulations are designed for localized drug delivery into the underlying skin layers or mucous membranes, ensuring targeted treatment for skin disorders [3]. The raw materials which are used in the manufacturing of skin creams include water, oil/fats/waxes, humectants, preservatives, emollients, and colours but the two most important ingredients are water and oil/fats/waxes. Among the oils, mineral oils (hydrocarbon oils) and glyceride oils (vegetable oils) are used. Examples of vegetable oils include arachis oil, almond oil, olive oil, castor oil, and coconut oil [3].

Ricinus communis, commonly known as castor, is a soft-wooded, perennial flowering shrub belonging to the spurge family, Euphorbiaceae. Although its seed is referred to as the castor bean, it is not a true bean. Castor is cultivated globally on a commercial scale, primarily for its seeds, which are rich in ricinoleic acid and contain about 40% oil [5]. Oil can be extracted from castor beans by mechanical pressing, solvent extraction, or a combination of pressing and extraction. Castor oil, extracted from the seeds, is a nearly colorless or slightly yellow, viscous liquid with little to no odor. Initially, it has a bland taste that later becomes sharp and unpleasant. The oil is non-volatile and dries very slowly, with a specific gravity of 0.958. Its refractive index ranges from 1.4790 to 1.4805, and it solidifies at temperatures between 10°C and -18°C. The oil's acidity, present as oleic acid, is about 1.5 percent [5]. Castor oil holds unique global importance in the specialty chemical industry as the sole commercial source of hydroxylated fatty acids, primarily ricinoleic acid. The hydroxyl groups within ricinoleic acid impart distinct chemical properties, including high viscosity and polarity, setting it apart from other vegetable oils [6, 7].

Castor bean plant is grown in many states in southern Nigeria but the seeds are mainly utilized as a probiotic food seasoning for making soups. It is essential to explore its commercial usage so as to improve the economy of the farmers and the communities in general. This study intends to evaluate the use of castor oil extracted from castor oil bean seeds cultivated in Abraka, Nigeria as pharmaceutical oil used in the preparation of creams.

2. Materials and Methods

2.1. Materials

Stearic acid, Cethyl Alcohol, Methyl paraben (Central Drug House(P) Ltd, New Delhi, India), Propyl paraben (Kermel chemicals, India), Diclofenac Sodium (Alpha Lab, Germany), Glycerol (Guangdong Guanghua Sci-Tech Co. Ltd., Guanghua, China). Other materials used were of analytical grade.

2.2. Collection and identification of plant material

Castor beans were collected from the farm attached to the botanical garden of the Department of Pharmacognosy and Traditional Medicines, Faculty of Pharmacy, Delta State University, Abraka, Nigeria. It was identified by Dr. Akinnibosun Henry Adewale of the Department of Plant Biology and Biotechnology, Faculty of Life Sciences, University of Benin, Nigeria. It was assigned voucher number UBH-R391.

2.3. Extraction of castor oil

The solvent extraction method was used for the extraction of castor oil. The shell of the castor bean seeds were removed, revealing the white portion (endosperm). These were pulverized using a blender and were macerated in sufficient amount of hexane for 72 hours with frequent agitation. Thereafter the supernatant layer was decanted and passed through a filter cloth. The filtrate was poured into a wide mouthed stainless-steel pan and left overnight so as to allow the hexane to evaporate. The oil obtained was poured into a container and labelled appropriately.

2.4. Characterization of the extracted castor oil

The extracted oil was characterized based on pH, viscosity, density, refractive index and organoleptic properties.

2.5. Preparation of creams

The creams were prepared following the formula in Table 1. The oil phase was prepared by transferring 6 g of stearic acid into a clean dry 100 ml beaker. It was then melted at 70°C with agitation over a water bath. A 6 g quantity of cetyl alcohol was added to the melted stearic acid in the beaker and stirred properly. A 0.02 g of propyl paraben was added, followed by required quantity (8, 9 or 10 ml) of the extracted castor oil and stirred properly. Diclofenac sodium (2 g) was poured into the mixture and stirred until a homogenous mixture was formed. The aqueous phase was prepared by

transferring 10 ml of glycerol into a beaker. A 0.08 g of methyl paraben was weighed and carefully dispersed in the glycerol. A 9 ml of water was added and stirred with a glass rod until a homogenous dispersion was formed. The mixture was heated in a water-bath at 70 °C. The oil phase was gradually poured into the aqueous phase while stirring with a glass rod. The heat was turned off and the stirring continued until a homogeneous cream was formed.

Table 1 Composition of diclofenac sodium cream formulations

Ingredient	**F1**	**F2**	**F3**	**F4**	**F5**
Diclofenac sodium (g)	2	2	2	2	-
Stearic acid (g)	6	6	6	6	6
Cetyl alcohol (g)	3	3	3	3	3
Castor oil (ml)	10	8	9	-	9
Glycerol (ml)	8	11	10	10	10
Methyl paraben (g)	0.08	0.08	0.08	0.08	0.08
Propyl paraben (g)	0.02	0.02	0.02	0.02	0.02
Arachis oil (ml)	-	-	-	9	-
Water (ml)	9	9	9	9	9

3. Evaluation of the diclofenac sodium creams

The physicochemical parameters such as colour, pH, homogeneity, washability, solubility and stability are usually evaluated to ensure satisfactory results for the formulated creams [8]. The following quality control test were conducted on the formulated cream: determination of pH, viscosity test, determination of wetness, type of smear, and emolliency, determination of cream type, determination of spreadability and accelerated stability testing.

3.1. Physicochemical tests

3.1.1. Viscosity test

The viscosity of the formulated oil-in-water cream was measured using spindle 4 of a Brookfield viscometer (model NDJ-5S, Shinghai, Nirun) at ambient temperature (28°C) [9, 10].

3.1.2. Homogeneity

The homogeneity of the formulated creams was evaluated by visual inspection [11, 12].

3.1.3. Determination of pH

A 5 g of the formulated cream was weighed and put into a calibrated beaker. Upon calibration of pH meter with a buffer solution, the pH of the emulsion was determined at 27.3°C using the OHAUS starter 2100 bench pH meter [13].

3.1.4. Determination of spreadability

In this evaluation method, 3 g of cream was placed between two-glass slides and pressed by placing 100 g weight for 5 min to obtain a film of constant density. A 10 g of weight was added to it, and the plate was subjected to pull. The upper glass slide moved over the lower plate and the distance covered was noted [14, 15].

The spreadability (S) can be calculated by using the formula

$$S = m \times L/t$$

Where, S – spreadability, m – weight tied to the upper glass slide (g), L – length moved on a glass slide (cm), t – the time is taken (s).

3.1.5. Determination of cream (emulsion) type

To determine the emulsion type, the formulated emulsions underwent a dilution test. Specifically, the emulsion was diluted with the external phase (water in this case). This was done by adding 10 ml of distilled water to 1 g of the cream in a beaker. This was stirred properly and was observed for separation [16, 17, 18].

3.1.6. Determination of wetness, type of smear, and emolliency

The evaluation was performed by applying the cream to the skin surface. After application, the formation of films or smears was assessed [14, 19]. Additionally, emolliency, slipperiness, and residual amounts were measured following the application of fixed cream quantities. The ease of removal was examined by washing the treated area with tap water [3, 14, 19].

3.2. Accelerated stability testing

It was performed by observing the formulations at 40°C ± 1 °C for 7 days. And afterwards the formulations were observed at 28 °C ± 1 °C for 20 days [14]

4. Results and Discussion

4.1. Physical appearance of the extracted castor oil

The extracted castor oil had a pale yellow colour, nauseous taste, mild odour and was very viscous.

4.2. Physicochemical properties of castor oil

The extracted castor oil has a pH of 5.90, density of 0.93 g/ml and refractive index of 1.4754. These values were close to that reported by Akpan *et al* [20]; pH of 6.16, density of 0.959 g/ml and refractive index of 1.472 at 30ºC. This also agrees with density (0.9664 g/ml) and refractive index of 1.46 reported by Deshamukh *et al* [21] at 28ºC but pH (6.86) differed.

The viscosity of castor oil measured at 28°C, reduced from 10,906 mPas (6 rpm) to 1930.1 mPas (60 rpm), showing a shear-thinning property that is typical of pseudoplastic materials. The viscosity of arachis oil reduced from 10727 mPas (6 rpm) to 3179.5 mPas (60 rpm).

4.3. Physicochemical properties of the formulated creams

4.3.1. Viscosity

As illustrated in Figure 1, the viscosity of cream formulation F1 decreased from 791.7 mPas at 6 rpm to 473.6 mPas at 12 rpm. For formulation F2, viscosity dropped from 9830.7 mPas at 6 rpm to 873.3 mPas at 60 rpm, while formulation F3 showed a reduction from 23,078 mPas to 718.2 mPas at 60 rpm. Similarly, F4's viscosity declined from 9999.1 mPas at 6 rpm to 1205.6 mPas at 60 rpm, and F5 decreased from 6369.6 mPas to 879.8 mPas at 60 rpm. The consistency of a semisolid formulation is largely determined by its viscosity. The viscosity of a cream is crucial for determining its flow characteristics; higher viscosity indicates greater resistance to flow [22]. Products with lower viscosity spread easily across surfaces, whereas those with higher viscosity tend to have difficulty spreading [22]. All the creams demonstrated shear-thinning behavior, as their viscosity decreased with increasing shear rate. Notably, the viscosity of formulation F4, which contains castor oil, was higher than that of F5, which was prepared with the same concentration of arachis oil.

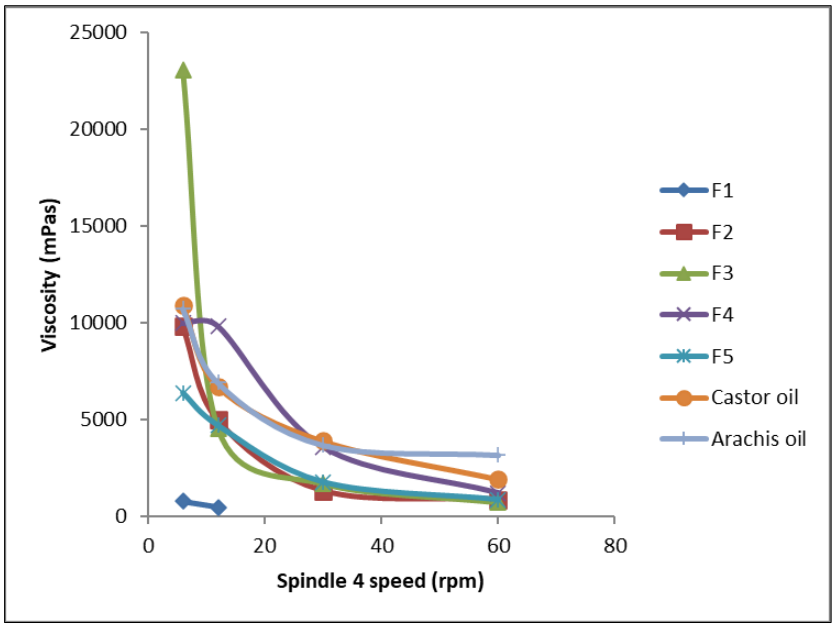

Figure 1 Viscosity versus shear rate (Speed in rpm) of cream formulations F1-F5

4.3.2. Homogeneity

As shown in Table 2, all the cream formulations were homogenous.

4.3.3. Determination of pH

As shown in Table 2, the pH of the formulated creams ranged from 4.30 (F5) to 6.15 (F4). The normal skin pH range falls between 4.0 and 6.8 [23]. All the cream formulations-maintained pH (4.30-6.15) within the normal skin pH range and therefore, may not cause skin irritation. Creams that have pH value within the normal skin pH range could be applied on the skin without any irritating effect [24]. Hence castor oil would be suitable for formulation of dermatological products. Also, the cream formulated with arachis oil (F4) was less acidic (pH = 6.15) and would be less effective in fighting off bacterial infection on the skin and maintaining the normal skin flora than products with castor oil (pH = 5.40-5.49).

4.3.4. Determination of Spreadability

The spreadability of the cream formulations as shown in Table 2 ranged from 28 to 46 $gcms^{-1}$. The formulations were found to express good spreadability. Spreadability refers to a cream's ability to distribute evenly across the skin surface. This property is essential for ensuring uniform application and ease of use in dermatological formulations. It also significantly influences patient compliance, as a cream that spreads effortlessly enhances comfort during application. Moreover, the therapeutic efficacy of the cream depends on its ability to cover the skin adequately. A cream with optimal spreadability exhibits minimal resistance ("drag") while providing smooth gliding ("slip"), improving user experience [22, 25]. It is reported that the viscosity range of cream or gel determines its spreadability [26].

4.3.5. Determination of cream (emulsion) type

No phase separation or cracking was observed upon dilution, confirming that the formulated emulsion is an oil-in-water (O/W) type. When an O/W type of emulsion is diluted with water, it will remain stable as water is the dispersion medium or continuous phase, but if it is diluted with oil, the emulsion breaks or crack. Also**, t**he W/O type of cream remains stable when diluted with oily liquid and separates upon addition of water. O/W emulsion can easily be diluted with an aqueous solvent, whereas water in oil emulsion can be diluted with an oily liquid [16, 17].

4.3.6. Determination of wetness, type of smear, and emolliency

As shown in Table 2, the formulated creams were non-greasy, moisturize the skin and did not leave any residue on the skin [19]. reported that oil-in-water type creams are usually non-greasy and easily washable.

Table 2 The physicochemical properties of formulated creams

	F1	**F2**	**F3**	**F4**	**F5**
pH	5.49	5.40	5.47	6.15	4.30
Spreadability (g.cm/s)	32	36	28	46	30
Type of cream	O/W	O/W	O/W	O/W	O/W
Ease of removal	Easily washable	Easily washable	Easily washable	Easily washable	Easily washable
Homogeneity	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous
Wetness	Moisturises skin surface	Moisturises skin surface	Moisturises skin surface	Moisturises skin surface	Moisturises skin surface
Type of smear	Non-greasy	Non-greasy	Non-greasy	Non-greasy	Non-greasy
Emolliency	No residue left	No residue left	No residue left	No residue left	No residue left

4.3.7. Accelerated stability testing

Upon observation of formulations at 40°C for 7 days and then at 28°C for 20 days, there was no separation or physical degradation that was observed. Therefore, the cream formulations would be considered to be stable.

5. Conclusion

Creams prepared using castor oil showed good physicochemical properties comparable to those formulated using arachis oil. Therefore, castor oil could serve as a suitable alternative to arachis oil in the production of diclofenac creams and other dermatological products.

Compliance with ethical standards

Acknowledgement

The authors are grateful to the Department of Pharmaceutics and Industrial Pharmacy, Madonna University, Elele, Nigeria for providing their laboratory for the research.

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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