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Research Article

Formulation and *In Vitro* Release Studies of Emulgels Containing Shea Butter and Diclofenac Diethylamine

Hermine ZIME DIAWARA[1,2]*, Hyacinthe W. BONKOUGOU [1], Charles B. SOMBIE [1,3], Salfo OUEDRAOGO [4], Luc ZONGO [6,7], Josias B. G. YAMEOGO [1,5], Rasmané SEMDE [1]

1- Laboratoire de Développement du Médicament (LADME)/EDSS/Université Joseph KI-ZERBO

2- Centre Hospitalier Universitaire Yalgado Ouédraogo (CHU YO)

3- Centre Hospitalier Universitaire Pédiatrique Charles De Gaulle (CHUP CDG)

4- Institut de Recherche en Sciences de la Santé (IRSS)

5- Agence nationale pour la sécurité sanitaire de l'environnement, de l'alimentation, du travail et des produits de santé (ANSSEAT)

6- Faculté des Sciences de Santé, Université Saint Thomas d'Aquin (USTA), Ouagadougou, Burkina Faso.

7- Hôpital Saint Camille de Ouagadougou (HOSCO), Ouagadougou, Burkina Faso.

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For Correspondence:

Hermine ZIME DIAWARA, Laboratoire de Développement du Médicament (LADME)/EDSS/Université Joseph KI-ZERBO

Abstract

Shea butter is a raw material widely used in cosmetology. Its use in the pharmaceutical sector is becoming increasingly popular. As it's commonly produced in Burkina Faso, it can help reduce medicine costs. Several dermatological formulations (creams, body milks, ointments) have been developed in our laboratories in Burkina Faso. However, some active ingredients are not compatible with those bases due to their hydrophilic-lipophilic balance. The emulgel form can thus be a solution. Moreover, this type of dermatological base has not yet been reported in the literature on shea butter. The main objective of our study was to develop an emulgel based on shea butter, and diclofenac diethylamine was chosen as the active ingredient. Emulgel formulations were prepared with shea butter, carbomer 980, or arabic gum and diclofenac diethylamine. Physical quality control was performed against the Diclofenac Reference emulgel. The better emulgel formulations were tested for *in vitro* release of diclofenac diethylamine, compared with the Diclofenac Reference emulgel. The formulated emulgel was homogeneous, whitish in colour. The pH ranged from 6.53 to 6.71. The emulgel made with 0.5% carbomer 980 had a viscosity close to that of the Diclofenac Reference emulgel. Their diclofenac diethylamine content conformed to standards (99.47% and 100.55%). The release rate of these formulations after 6 hours ranged from 58.66% to 66.26%. The diclofenac reference emulgel had a lower rate of 44.02%. Locally produced shea butter can thus be used to formulate an emulgel incorporating diclofenac diethylamine as the active ingredient.

Keywords: Diclofenac diethylamine, emulgel, shea butter, carbomer, arabic gum.

1. INTRODUCTION

Topical preparations are preparations for external use with a liquid, semi-solid or fluid consistency containing one or more active pharmaceutical ingredients (APIs) and intended to be applied to skin surfaces. Emulgel is specific type of dermal vehicle. It is an interesting dermatological base because of the dual system composed by gel and emulsion.[1]

Standard fats in topical formulation are petrolatum, paraffin, triglycerides, waxes, fatty alcohols, fatty acids. Shea butter (BK) is a vegetable fat extracted from the kernels of *Vitellaria paradoxa* C. F. Gaertn. (Sapotaceae).[2] Due to its composition rich in unsaponifiable matter, shea butter has moisturizing, anti-inflammatory, healing, regenerative and nourishing properties on the skin.[3,4]

Burkina Faso is one of the main producers of shea butter. This raw material, widely available, can be an excipient in the manufacture of dermatological products.[5]

Several bases with shea butter (cream, milk, ointment) have been developed and successfully used for the incorporation of APIs in our laboratories.[6–8] In fact, shea butter has adequate physicochemical characteristics as a major excipient in the formulation of dermatological forms.

However, certain APIs exhibit incompatibility with conventional dermatological bases due to their

hydrophilic–lipophilic balance. The emulgel form therefore represents a promising alternative. To date, no emulgel formulation incorporating shea butter has been reported or marketed. It is thus of particular interest to explore the feasibility of using shea butter as a lipidic phase in emulgel formulation. Diclofenac diethylamine was selected as the model active ingredient to develop emulgel preparations comparable to the reference diclofenac emulgel, which remains the most commonly dispensed topical anti-inflammatory formulation in Burkina Faso.

2. Materials and Methods

2.1. Materials

The raw materials used are: Diclofenac diethylamine: DDEA (ABC Chemicals), Shea butter (KARIBIO®), Carbomer 980 (Hefei TNJ Chemical Industry), Arabic Gum (COOPER), Propylene glycol (FAGRON), Sorbitan monosterate (Span 60® LUDECO), Polyoxyethylene sorbitan monosterate (Tween 60® MERCK), Nipagin® SIGMA, Nipasol® SIGMA, Diethylamine (Panreac), Distilled water (LADME).

2.2. Methods

2.2.1. Shea butter emulgel formulations

Various proportions of shea butter and gelling agent (carbomer 980 or arabic gum) were then realized. A total of eighteen emulgel formulations were performed. Nine emulgel formulations were prepared using carbomer as the gelling agent (as presented in Table I), while nine additional formulations were developed using gum arabic as the alternative gelling polymer.

Table 1: Qualitative and quantitative composition of emulgel with shea butter and Carbomer 980 (%m/m)

Designations / Components	Proportions of the different constituents (%m/m)									
	$C_{0,5}BK_{2,5}$	$C_{0,75}BK_{2,5}$	$C_1BK_{2,5}$	$C_{0,5}BK_5$	$C_{0,75}BK_5$	C_1BK_5	$C_{0,5}BK_{7,5}$	$C_{0,75}BK_{7,5}$	$C_1BK_{7,5}$	Components function
Diclofenac diethylamine	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	API
Carbomer 980	0.50	0.75	1.00	0.50	0.75	1.00	0.50	0.75	1.00	Gelling agent
Shea butter	2.50	2.50	2.50	5.00	5.00	5.00	7.50	7.50	7.50	Fatty phase
Span®60	0.30	0.30	0.30	0.60	0.60	0.60	0.90	0.90	0.90	Non-ionic surfactant
Tween®60	0.32	0.32	0.32	0.64	0.64	0.64	0.97	0.97	0.97	Non-ionic surfactant
Propylene glycol	7.50	7.50	7.50	7.50	7.50	7.50	10.00	10.00	10.00	Humectant
Diethylamine	qs	qs	qs	qs	qs	qs	qs	qs	qs	Neutralizing agent
Aqua conservans ad	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	Antimicrobial preservative and Solvent

2.2.2. Shea butter emulgel preparations

Dermatological emulgel preparations and packaging

The emulsion was prepared by direct emulsification method.[6–9] Carbomer 980 or arabic gum was dispersed under stirring in aqua conservans at an optimized stirring speed and time. Diethylamine was then added in carbomer gels to adjust the pH at about 6.00.

Finally, emulgel was prepared by mixing the emulsion with the gel base in a weight 1:1 ratio. of. Incorporation of diclofenac into the emulgel base was achieved using the propeller shaker.

Emulgel was packed in transparent low density polyethylene jars and aluminum tubes with varnished interior.

2.2.3. Physical quality control of the shea butter emulgel and Diclofenac reference emulgel

Macroscopic analysis: All the products were visually inspected for appearance, color and macroscopic stability.

pH measurement: The pH was determined using Hanna H 9811 pH meter.

Rheological study: It was carried out at 30°C, using a coaxial cylinder rotary viscometer (Brookfield LVDV, USA) and its S18 moving arm. The emulgel viscosities were measured at arm speeds ranging from 0.3 to 100 rpm.

Granulometric analysis: The droplets size was determined by examining the emulgel under a Karl Zeiss microscope with a 10x magnification objective. Particle

size distribution (µm) and median geometric diameters were determined.

DDEA content : It was performed in the different emulgel by high performance liquid chromatography (HPLC) using the method described in British Pharmacopoeia Volume III 2021.[10]

2.2.4. In vitro DDEA release tests[11–13]

The release of DDEA from the shea butter emulgel was studied through a cellulose acetate membrane filter (pore diameter: 0.45 µm) using a diffusion cell with a 13 mm orifice diameter and a total diameter of 21 mm.

The cell was filled to the brim with emulgel and then covered with a membrane. It was then placed in the flask of paddle dissolution device (SOTAX AT) which is the receiving compartment containing a phosphate buffer of pH 7.4. The tests were carried out at a temperature of 32° C ± 0.5 and a rotation speed of 100 rpm during 6 hours.

The volume of the dissolution medium of 500 mL met the Sink conditions. Samples (5 mL) of the dissolution medium were taken at time intervals of 30 min, 1h, 2h, 4h and 6h with the same amount replaced. The samples were analyzed by HPLC at 280 nm. All tests were performed in triplicate.

3. RESULTS

3.1. Pharmaceutical quality of emulgel

Macroscopic analysis

The nine preparations realized with carbomer 980 as gelling agent were whitish viscous creamy with a smooth homogeneous texture and a shiny appearance. These preparations were stable.

Phase separation between the gel and emulsion components was observed macroscopically in all nine arabic gum–based emulgel. So, they were not used for next steps of this study.

Physico-chemical characteristics of emulgel

The physico-chemical parameters of the Diclofenac emulgel are summarized in Table II.

Table II: Physico-chemical characteristics of prepared shea butter emulgel and Diclofenac Reference Emulgel

Preparations	pH à 25°C	Viscosity at 0.3rpm (mPas)	Median Geometric diameter	Active ingredient content (%)
$C_{0,5}BK_{2,5}$	6.53 ± 0.02	12 750 ± 40	5.49	100.33 ± 0.04
$C_{0,75}BK_{2,5}$	6.54 ± 0.02	20 370 ± 53	5.62	100.31 ± 0.04
$C_1BK_{2,5}$	6.56 ± 0.01	24 875 ± 68	5.75	100.31 ± 0.04
$C_{0,5}BK_5$	6.59 ± 0.02	14 000 ± 56	6.02	100.41 ± 0.18
$C_{0,75}BK_5$	6.61 ± 0.01	20 810 ± 73	6.16	99.39 ± 0.18
C_1BK_5	6.63 ± 0.01	25 415 ± 42	6.30	100.39 ± 0.18
$C_{0,5}BK_{7,5}$	6.66 ± 0.01	14 810 ±86	6.60	100.39 ± 0.18
$C_{0,75}BK_{7,5}$	6.68 ± 0.01	22 440 ±58	7.09	100.26 ± 0.18
$C_1BK_{7,5}$	6.71 ± 0.01	25 690 ±46	7.24	99.47 ± 0.18
Diclofenac reference Emulgel	6,58 ± 0,02	12 910 ±38	5.37	99.89 ± 0.01

The pH values of the prepared emulgel and Diclofenac Reference were 6.53 to 6.71 at 25°C. The viscosity of the preparations at 0.30 rpm increased proportionally with the amount of Carbomer 980 and shea butter. Only the preparations with a carbomer 980 proportion of 0.50% had a viscosity similar to that of Diclofenac Reference Emulgel (Table II). Figure 1 shows the overall rheograms of the emulgel.

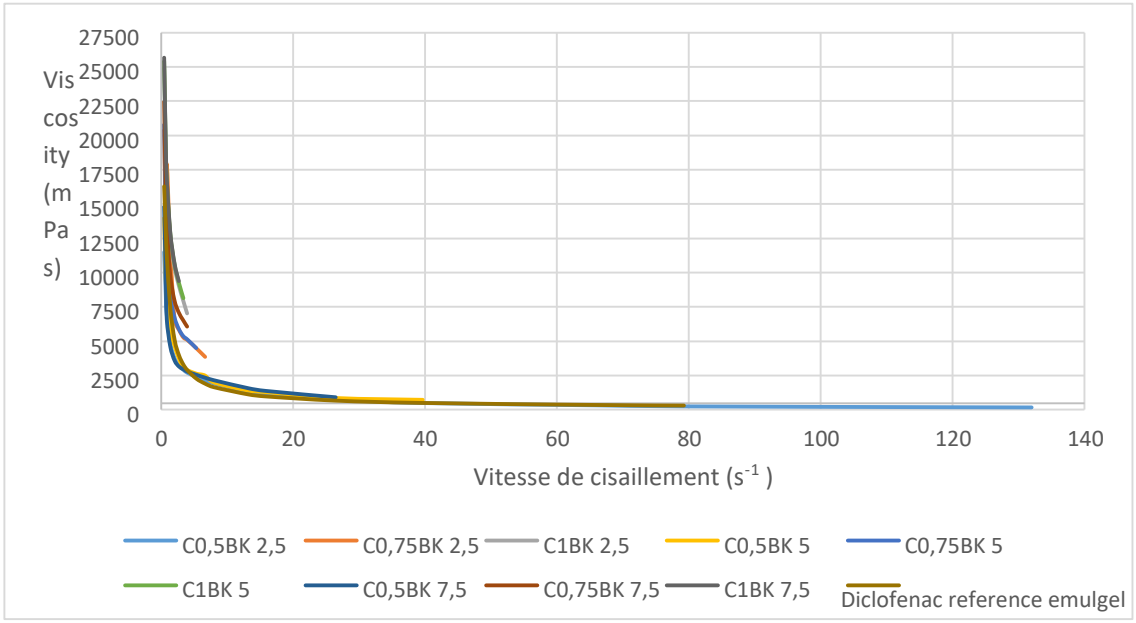

Figure 1: Rheograms of the shea butter emulgel and Diclofenac Reference emulgel.

Granulometric analysis

The increase of median geometric diameter for the prepared emulgels was proportional to the increase in the amounts of carbomer 980 and shea butter (table II).

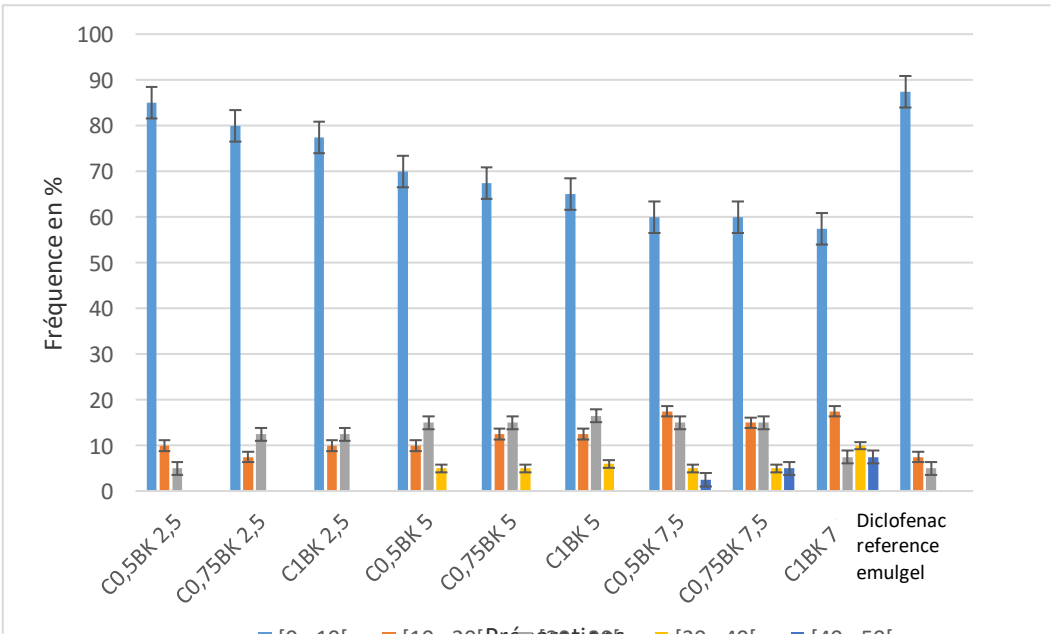

Figure 2: Particle size distribution of shea butter emulgel containing DDEA and Diclofenac reference emulgel

Determination of DDEA content

The content of DDEA in the prepared shea butter emulgel ranged from 99.39% to 100.41% (Table II).

3.2. *In vitro* release testing of DDEA

The percentage release of DDEA from the 03 selected emulgel after 6 hours was respectively: 66.26 ± 1.40 ($C_{0,5}BK_{2,5}$), 62.78 ± 0.90 ($C_{0,5}BK_5$), 58.66 ± 0.70 ($C_{0,5}BK_{7,5}$) and 44.02 ± 1.40 for Diclofenac Reference Emulgel. A statistically significant difference ($p<<0.05$) was found between the shea butter emulgel and Diclofenac Reference emulgel. P-value ($C_{0,5}BK_{2,5}$ vs Reference emulgel) = 0.0148; ($C_{0,5}BK_5$ vs Reference emulgel) = 0.0046; ($C_{0,5}BK_{7,5}$ vs Reference emulgel) = 0.0191.

Figure 3 shows that Diclofenac Reference Emulgel release was less compared to release from realized emulgel. The comparison of DDEA quantities of release from the differents shea butter emulgels after 6h was in the order: $C_{0,5}BK_{2,5}$ >$C_{0,5}BK_5$ >$C_{0,5}BK_{7,5}$ >Diclofenac Reference emulgel.

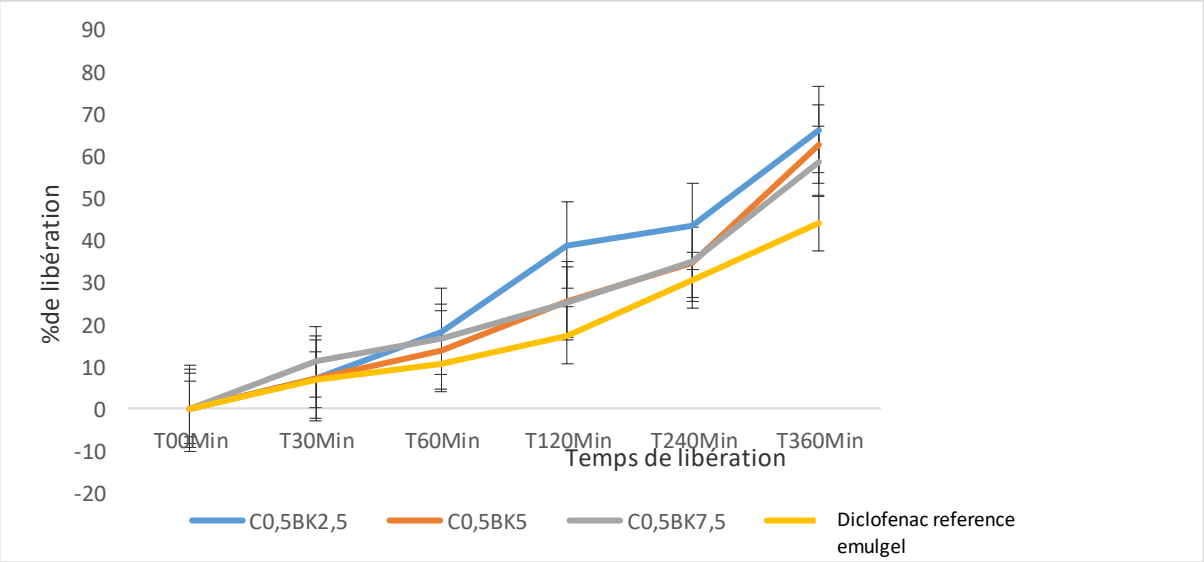

Figure 3: Comparative *in vitro* DDEA release from shea butter emulgel formulations and Diclofenac reference emulgel.

4. DISCUSSION

Emulgel formulations represent an optimal system for dermal drug delivery. In this study, emulgel containing diclofenac diethylamine (DDEA) were formulated using varying concentrations of shea butter as the lipid phase and different gelling agents to optimize topical performance.

All the emulgel has homogeneous appearance which is desired characteristic in dermatology as it allows a good spreading of the preparation thus favoring a better compliance to the treatment.[14–16]

For pH evaluation, the results were similar to the findings of Bhanu P V *et al* in 2011 on emulgel containing diclofenac diethylamine (6.52 to 6.86).[17] These values are consistent with the physiological pH of the skin[18]. These values were also within the stability range of diclofenac diethylamine (6.4 to 8.4) and parabens (2 to 7). According to the results obtained, the pH seems to increase with increasing carbomer 980 and shea butter content.

The viscosity results were closed to the findings of Toé *et al* in 2007 with creams and milks made with shea butter. An increase in viscosity was recorded as the amount of shea butter increased.[6]

All the emulgel prepared as well as Diclofenac Reference showed a rheofluidic type of profile since the viscosity decreased with increasing shear rate.[15] This type of behavior is similar to that observed by Sah K. *et al* in 2017 on tioconazole emulgels.[16] Only the preparations with a carbomer 980 content of 0.5% ($C_{0,5}BK_{2,5}$ $C_{0,5}BK_5$ and $C_{0,5}BK_{7,5}$) had similar rheograms to Diclofenac Reference Emulgel.

For the granulometric evaluation, only the $C_{0,5}BK_{2,5}$ emulgel had a particle size distribution close to that of Diclofenac Reference (Figure 2). These observations can lead us to affirm that the $C_{0,5}BK_{2,5}$ emulgel could have a similar physical stability with Diclofenac Reference emulgel.

The content of DDEA in shea butter emulgel ranged from 99.39% to 100.41% (Table II) and was in accordance with the British Pharmacopoeia standards (95-105%).[10] The prepared emulgel contain the appropriate content for therapeutic use.

The diffusion study results for formulations **$C_{0,5}BK_{2,5}$**; **$C_{0,5}BK_5$**; **$C_{0,5}BK_{7,5}$** was higher than **Diclofenac Reference Emulgel** one.

The higher release rate of shea butter emulgel realized in this study compared to control emulgel could be due to the enhanced penetration effect of shea butter. The shea butter present in our formulations acted as a release enhancer, thus improving the diffusion characteristics across membrane of our emulgel. However, this release is found to be delayed when the quantity of shea butter increases and therefore the viscosity of our formulations increases.

The lower release rate of Diclofenac Reference could be explained by greater retention of DDEA within the matrix of preparation. This would be due to a molecular interaction between the excipients and the active ingredient. Karin Gobel *et al* [19] and by Silva J. A. *et al* reported in their studies that molecular interactions of DDEA with the system interface could delay its release[20] in the case of DDEA emulgel containing caprylic glyceride, polyglyceryl and isopropyl. These components are used as fatty phase in Diclofenac reference emulgel.

5. CONCLUSION

Emulgel containing local shea butter with Diclofenac diethylamine as active ingredient have been prepared. This study shows that all the emulgel prepared with shea butter and carbomer as gelling agent had adequate physical appearance, pH values, and diclofenac

diethylamine content. However, only the emulgel with a carbomer 980 proportion of 0.5% ($C_{0,5}BK_{2,5}$; $C_{0,5}BK_5$; $C_{0,5}BK_{7,5}$) had a viscosity close to the reference: Diclofenac Reference® emulgel.

The finding results indicate that the release rates of diclofenac diethylamine from these three candidate emulgel were higher than from Diclofenac reference Emulgel.

These results highlight the influence of excipients on the performance of topical products. We put forward various hypotheses, in particular: improved release of diclofenac diethylamine by the shea butter contained in our emulgel and delayed release of diclofenac diethylamine by molecular interactions due to the presence of caprylic glyceride and polyglyceryl, combined with isopropyl containing in Diclofenac reference emulgel.

Conflict of Interest: The authors declare no potential conflict of interest concerning the contents, authorship and/or publication of this article.

Author Contributions: H. Hermine G. ZIME DIAWARA and Hyacinthe W. BONKOUGOU contribute in conceptualization, manipulation, data curation, writing initial draft. Charles B. SOMBIE, Salfo OUEDRAOGO, Luc ZONGO, Josias B. G. YAMEOGO performed experiments and wrote manuscript. Rasmané SEMDE contribute in conceptualization and supervision. All authors have equal contributions in revising and editing the manuscript and approve the final version.

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Ethical approval: Not applicable

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