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Formulation and evaluation of antibacterial herbal formulations containing the aquatic ethanol extract of *Kigelia africana* fruits

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Abstract
Kigelia africana (*Bignoniaceae*) possess various pharmacological activities like antibacterial activity.
Objective: The aim of the present study was to formulate and evaluate the aquatic ethanol extract of *Kigelia africana* fruits as efficient antibacterial therapy.
Methods: Topical formulations were prepared by incorporating the extract in two aqueous cream formulations and two emulgel formulations (1%, 2%, 3%, 5%, 7% and 10% w/w) and evaluated for organoleptic characteristics, melting point, pH, viscosity, spreadability, extrudability, microbial limit, *in vitro* activity, *in vitro* release, *ex vivo* diffusion and stability.
Results: The study showed that the formulated creams and emulgels had acceptable organoleptic properties, melting point, pH, viscosity, spreadability, extrudability and microbial limit. The *in vitro* activity, release rate and diffusion rate was higher in emulgels than creams. Among cream formulations one formula (10%) exhibited significant *in vitro* activity, release and diffusion rate while one emulgel formula (7% and 10%) provide significant *in vitro* activity, release and diffusion rate. The effective aqueous cream and one formula of emulgels exhibited stability while another emulgel showed physical instability.
Conclusion: The present study concludes that the formulated cream and emulgel were safe, effective and stable antibacterial formulations for the topical delivery of the aquatic ethanol extract of *Kigelia africana* fruits.

Keywords: Herbal formulations, *Kigelia africana*, cream, emulgel, antibacterial

Introduction
Acquired antimicrobial resistance is a growing global problem due to the increasing use of antimicrobials in humans, animals, and agriculture [1]. Today, bacterial resistance has become far more serious, escalating to crisis proportions [2]. It has compromised the effectiveness of conventional antimicrobials; thus, the development of new antibiotics represents a must in today's world [3]. The most commonly reported resistant bacteria were *Escherichia coli*, *Klebsiella pneumonia*, *Staphylococcus aureus* and *streptococcus pneumonia* followed by *Salmonella* spp [4]. Among them *Staphylococcus aureus* is one of the most common bacteria causing skin infections such as impetigo, folliculitis, erythrasma, and rosacea [5]. Hence, there is a pressing need to develop a natural formulation, which can act against the microorganisms causing skin diseases [6].
It is known that for treating topical disorders, topically applied drug products are preferred over their systemic counterparts for the several advantages they offer. Topical treatments elicit no systemic side effects because there is no systemic absorption. They are also easy to manufacture, convenient to administer and impart greater patients' compliance [7].
Out of the numerous topical drug delivery systems, creams and emulgels have shown their superiority over present systems [8, 9]. They have several favorable properties for dermatological use such as being greaseless, easily spreadable and easily removable. Moreover, they are emollient, non-staining, bio-friendly and have long shelf life [8, 10].
There is a wide range of plant derivatives in use for the manufacture of drug products such as extracts, fresh and dried plant materials, acellular products, pure and *in vitro* biotechnology derived individual compounds, in addition to several others [11]. *Kigelia africana* Lam (Benth) belongs to the family *Bignoniaceae*, commonly known as the sausage tree, has a wide distribution in Africa, America, India and Australia. *Kigelia africana* is of medicinal value in most parts of Africa; the fruits are collected and traded locally in market places as local

medicine. Commercial value is attributable to industrially produced pharmaceutical products, for which fruits are harvested from naturally occurring trees [12]. In Sudan, the fruits of this plant are largely used in the southern and south western parts for treating many local infectious diseases such as wounds and abscess [13]. The fruits are also used in Africa to treat other infectious diseases including leprosy, impetigo and dermal complaints and infections, such as whitlows, cysts, acne and boils [12].

To compose this herb into a pharmaceutically useful dosage form, the aim of the present study was set to formulate effective, safe and stable cream and emulgel of *Kigelia africana* fruits as antibacterial topical therapy.

Materials and Methodology

Materials

The materials used include: Emulsifying wax (Medex, England), white soft paraffin (Bogdany, Hungary), liquid paraffin (Surechem, England), propylene glycol (S. D. Fine-Chem, India), tween 20 (Surechem, England), span20 (Surechem, England), xanthan gum (Xi'an Le Sen Biotechnology, China), hydroxy propyl methyl cellulose (HPMC) from (Tama-Tokyo, Japan), triethanolamine (VMP Chemiekontor, Germany), methyl paraben (Mallinckrodt Specialty Chemicals Co, Paris) and propyl paraben (Mallinckrodt Specialty Chemicals Co, Paris).

Formulation

Aquatic ethanol extract of *Kigelia africana* fruits was prepared in different concentration 1%, 2%, 3%, 5%, 7% and 10% (w/w) in two cream formulations and two emulgel formulations.

Formulation of creams

The required quantities of the oily phase constituents, namely, emulsifying wax, white soft paraffin, and liquid paraffin were accurately weighed, heated up to 70 – 75 ºC and stirred continuously. Propylene glycol, tween 20, methyl paraben and propyl paraben were also weighed accurately and dissolved in purified water to form the aqueous phase. The latter was added to the oily phase constantly until homogenous product was attained. The extract was then incorporated into the cream base [14, 15]. The composition of the different cream formulations are given in Table 1.

Formulation of emulgels

The oily phase of the cream was prepared by adding span 20 to liquid paraffin whereas the aqueous phase was formed through the addition of propylene glycol and tween 20 to purified water. Afterwards, the aqueous phase was added constantly to the oily phase. The gel was prepared by soaking xanthan gum and HPMC overnight in purified water containing methyl paraben, propyl paraben and triethanolamine. Both phases, cream and gel were mixed in 1:1 ratio until homogenous product was obtained. The extract was then incorporated into the already prepared vehicle [16, 17]. The composition of emulgel formulations are given in Table 2.

Table 1: Composition of cream formulations (F1 and F2) of aquatic ethanol extract of *Kigelia africana* fruits prepared in various extract concentrations into two cream formulations differing in their constitution.

No.	Constituent	Formulation 1	Formulation 2
		% w/w	% w/w
1	Extract	1,2,3,5,7,10	1,2,3,5,7,10
2	Emulsifying wax	9	9
3	White soft paraffin	15	15
4	Liquid paraffin	6	6
5	Propylene glycol		10
6	Tween 20		1
7	Methyl paraben	0.3	0.3
8	Propyl paraben	0.03	0.03
9	Purified water	q.s*	q.s

* q.s: sufficient quantity

Table 2: Composition of emulgel formulations (F3 and F4) of aquatic ethanol extract of *Kigelia africana* fruits prepared in various extract concentrations into two emulgel formulations differing in their constitution.

No.	Constituent	Formulation 3	Formulation 4
		% w/w	% w/w
1	Extract	1,2,3,5,7,10	1,2,3,5,7,10
2	Xanthan gum	1	2
3	HPMC	1.5	3
4	Liquid paraffin	5	7.5
5	Tween 20	0.4	1
6	Span 20	0.6	1.5
7	Propylene glycol	5	5
8	Triethanolamine	q.s	q.s
9	Methyl paraben	0.3	0.3
10	Propyl paraben	0.03	0.03
11	Purified water	q.s*	q.s

* q.s: sufficient quantity

Evaluation of the formulations

The prepared formulations were evaluated for their physical characteristics, microbial limit, *in vitro* activity, release, diffusion and stability:

Organoleptic characterization

The formulations were inspected for their color, odor, texture and homogeneity. A trace amount of each formulation was spread between two glass slides and examined visually. The results of texture and homogeneity were presented as: (+++) = excellence, (++) = very good, (+) = good and (-) = poor [18].

pH

The pH was measured using a digital pH meter (Jenway, UK). 1g of each formulation was mixed in 100 ml distilled water (1% w/v), then warmed, vigorously shaken and stored for two hours. The electrode was inserted thrice into the sample for pH recording [19].

Viscosity
The viscosity of the formulations was checked via a Brookfield Viscometer (Fungilab, Spain). The spindle was immersed in the sample and viscosity near to 100% torque was recorded at 10 revolutions per minute (rpm) and 25 °C [20].

Spreadability
Spreadability of the formulation was determined by the apparatus suggested by Muttimer *et al.*, 1956 after suitable modifications. An excess amount of the formulation was placed between two glass slides of uniform thickness and 500 g weight was placed on these glass slides to compress them. Additional weight of 200 g was added and the time required to move the upper slide a distance of 50 mm was noted [21]. slides under the direction of a certain load. Spreadability was calculated using the formula:

S = M.L / T Where:
M = Weight tied to upper slide, L = Length of glass slides. T = Time taken to separate the slides.

Extrudability
Formulations containing 10% of *Kigelia africana* extract were filled in aluminum collapsible tubes with 5 mm tips. Weights of 200g, 300g and 400g were applied separately for 5 minutes on each tube using modified Burrell-Server Rheometer-like apparatus. The amount of formulation extruded -in grams- was recorded.

Microbial limit
Microbial count and detection of microorganisms was carried out according to the United States Pharmacopeia (USP 2010) and European Pharmacopeia (PhEur 2011) [22, 23].

Microbial count
The test sample was prepared by suspending 1g of the formulation in 9 ml of buffered sodium chloride peptone solution then shaking it for 15 minutes in a vortex mixer (ICEN, China).

Total aerobic bacterial count (TABC)
1 ml of test fluid was removed from the supernatant layer aseptically by a sterile pipette and spread on solid soybean-casein digest agar medium plates containing Amphotericin B (2 ml/L of medium) for prevention of the fungal growth and incubated at 37 °C for 24 hours. The colony forming unit (CFU) of each plate was counted using the colony counter and the CFU/g of the formulation was recorded**.**

Total yeast and mould count (TYMC)
1 ml of test fluid was spread on solid Sabouraud dextrose agar medium containing chloramphenicol antibiotic (50 mg/L of medium) for prevention of the bacterial growth. The plates were then incubated at 25 °C for 72 hours and the CFU of each plate was counted using colony counter and CFU/g of formulation was noted**.**

Detected Microorganisms
Staphylococcus aureus
1 g of the test specimen was enriched in 9 ml fluid casein-soybean digest medium and incubated at 37 °C for 24 hours. Next, a portion of the incubated media was spread on mannitol salt agar as selective media and incubated for 24 hours at 37 °C. The growth of yellow colonies indicated the presence of *Staphylococcus aureus*.

Pseudomonas aeruginosa
The sample was spread on cetrimide agar and incubated for 24 hours at 37 °C. The green colonies would indicate the presence of *Pseudomonas aeruginosa*.

***In vitro* antibacterial activity**
In vitro antibacterial activity was evaluated using the agar well diffusion technique. Muller-Hinton agar was used as the medium. The sterile agar was inoculated with the bacterial culture (10^8 CFU/ml of *S. aureus* and *P. aeruginosa*, separately). 6 mm-Wells were bored using a sterile cork borer and 0.1 g of each formulation was filled in each well using a sterile syringe. Plates were kept for 2 hours at room temperature for the extracts to diffuse into the agar. Afterwards, the plates were incubated overnight at 37 °C. The plain bases were used as negative control and the following antibiotics topical formulations were used as standard reference products: Fusidic acid cream 2% w/w (LEO, Ireland), Mupirocin ointment 2% w/w (Glenmark, India), Ciprofloxacin cream 0.5% w/w (Cipla, India), Tetracycline ointment 3% w/w (Zhejiang Shenghua, China) and Povidone iodine ointment 10% w/w (Pharaonia, Egypt). The mean diameter of inhibition zones (MDIZ) was determined from a duplicate value for the test samples, control and standard reference products [24]. Formulations exhibited significant *in vitro* activity (MDIZ >18mm) were considered for further tests.

***In vitro* release**
Fabricated apparatus similar to Franz diffusion cell was used, where one gram of formulations was applied on egg shell membrane tied up with polyethylene stopper as donor cell. The acceptor cell was 50 ml of phosphate buffer pH =7.4. One ml sample was removed for analysis at intervals 0.5, 1, 1.5, 2, 3, 4, 5 and 6 hours using UV/Visible spectrophotometer (Lasany, India) at 236 nm as ʎ max of extract. The cumulative released amount per time interval was calculated [25].

***Ex vivo* diffusion**
It was conducted using similar apparatus to the one used in *in vitro* release test, but the membrane was freshly excised intact Swiss albino rats' skin. The cumulative amount of the extract diffused through the rats' skin was estimated using UV/Visible spectrophotometer and the remaining amount of the extract in the formulation was determined using a biological assay technique of cup plate agar diffusion method to estimate the percent of extract diffused into the rats skin [26].

% of extract diffused into the skin throughout 6 hours =
% of extract in the formulation – % of cumulative amount of extract in the acceptor cell – % of extract remained in the formulation after 6 hours.

Stability study
The formulations showed significant release and diffusion [$F2_{(10\%)}$, $F3_{(10\%)}$, $F4_{(7\%)}$ and $F4_{(10\%)}$] were packaged in aluminum collapsible tubes and placed in an accelerated stability chamber (Remi, India) at 40 °C and 75% relative humidity (RH) for six months according to the international conference on harmonization (ICH) guidelines [27]. Samples

were removed after 1, 2, 3 and 6 months storage for evaluating the following parameters:

- **Physical stability:** Clarity, pH and viscosity.
- **Chemical stability:** For this, the *in vitro* release using the cup plate agar method was adopted. *S. aureus* was chosen as a test bacteria and the degraded extract -if any- was assumed to show less inhibition zone than the one noted at zero time.
- **Microbiological stability:** Was assessed using microbial limit test (2.3.7) results to ensure the efficiency of the preservative used and the packaging efficiency.

Results and Discussion

Organoleptic characterization

The cream and emulgel formulations showed similar organoleptic characteristics (Table 3) as the distinct constituents in cream and emulgel formulations has no significant effect on the organoleptic properties. Generally, the results obtained for all characteristics were acceptable as all have brownish consistent color, agreeable odor, highly homogenous and excellent texture [26]. The intensity of color increased with increasing of concentration of extract because the extract was brownish colored while the vehicles were white colored. The odor was not distinctive because neither the extract nor the excipients had distinctive odor.

pH

All formulations pH ranged between 5.5 and 7.5 as displayed in Table 3. Such values would ensure their physiological compatibility with human skin because pH of the human skin is ranged between 4 and 7 and below or above this range will adversely affect the human skin [28, 29, 30, 31].

Rheological properties

The viscosity of emulgels were less than that of creams because of the high solid content in the latter which was represented by the emulsifying wax. The cream formulation that contained propylene glycol (F2) was slightly more viscous the one didn't (F1). That was attributed to the viscosity of the propylene glycol and the effect of the tween 20 which reduced the droplet size of the oily phase that further increase the formulation viscosity [11].

Table 3: Organoleptic properties and pH of cream (F1 and F2) and emulgel (F3 and F4) formulations containing different percentages of *Kigelia africana* extract.

F		Extract Conc. w/w	Color	Odor	Texture	Homogeneity	pH
Cream	F1	1%	Light brown	ND*	+++	+++	6.6
		2%	Light Brown	ND	+++	+++	6.5
		3%	Brown	ND	+++	+++	6.3
		5%	Brown	ND	+++	+++	5.8
		7%	Brown	ND	+++	+++	5.6
		10%	Dark brown	ND	+++	+++	5.5
	F2	1%	Light brown	ND	+++	+++	6.1
		2%	Light Brown	ND	+++	+++	6.0
		3%	Brown	ND	+++	+++	5.9
		5%	Brown	ND	+++	+++	5.7
		7%	Dark brown	ND	+++	+++	5.4
		10%	Dark brown	ND	+++	+++	5.3
Emulgel	F3	1%	Light brown	ND	+++	+++	6.1
		2%	Light Brown	ND	+++	+++	6.1
		3%	Brown	ND	+++	+++	6.0
		5%	Brown	ND	+++	+++	5.9
		7%	Dark brown	ND	+++	+++	5.9
		10%	Dark brown	ND	+++	+++	5.7
	F4	1%	Light brown	ND	+++	+++	6.0
		2%	Light Brown	ND	+++	+++	5.9
		3%	Brown	ND	+++	+++	5.9
		5%	Brown	ND	+++	+++	5.8
		7%	Dark brown	ND	+++	+++	5.7
		10%	Dark brown	ND	+++	+++	5.6

ND: Not Distinctive

For the emulgels, F3 was less viscous than F4 due to the lower percent of gelling agent (HPMC1% and xanthan gum1.5%) that the former had.

Viscosity is known to affect release rate, diffusion rate, application on skin and stability of creams and emulgels [7]. Viscosity test results revealed that as the concentration of the extract increased, the viscosity slightly increased, because the solid nature of extract which increase the total solid content of the formulation, as the solid contents in the formulation increased its viscosity increased [32].

The spreadability and extrudability of the various formulations were affected by their viscosity. They were inversely related to it; as the viscosity increased, the spreadability and extrudability decreased because the latters are rheological properties depend on viscosity of formulation i.e. lower viscosity means lower resistance to flow and deformation and the spreading of formulation on skin and its extrusion from tubes are flow and deformation processes [33]. The rheological properties of all formulations are tabulated in Table 4.

Table 4: Viscosity, spreadability and extrudability of different cream (F1 and F2) and emulgel (F3 and F4) formulations of *Kigelia africana* fruits extract.

F		Extract conc. (w/w)	Viscosity (Cp)	Spreadability (sec)	Extrudability (g)		
					200 g	300 g	400 g
Cream	F1	1%	37000	25	NA	NA	NA
		2%	37000	25	NA	NA	NA
		3%	38000	26	NA	NA	NA
		5%	39000	28	NA	NA	NA
		7%	40000	29	NA	NA	NA
		10%	41000	31	0.025	0.037	0.055
	F2	1%	46000	38	NA	NA	NA
		2%	46000	39	NA	NA	NA
		3%	46000	38	NA	NA	NA
		5%	47000	40	NA	NA	NA
		7%	48000	42	NA	NA	NA
		10%	49000	44	0.022	0.033	0.056
Emulgel	F3	1%	16000	12	NA	NA	NA
		2%	16000	13	NA	NA	NA
		3%	16000	13	NA	NA	NA
		5%	17000	15	NA	NA	NA
		7%	18000	17	NA	NA	NA
		10%	20000	17	0.59	0.77	1.07
	F4	1%	20000	15	NA	NA	NA
		2%	21000	15	NA	NA	NA
		3%	21000	15	NA	NA	NA
		5%	22000	16	NA	NA	NA
		7%	23000	17	NA	NA	NA
		10%	26000	20	0.56	0.74	1.05

Microbial limit

All formulations of creams and emulgels exhibited TABC < 10^2 CFU/g, TYMC < 10 CFU/g and showed absence of *S. aureus* and *P. aeruginosa*. The obtained results met the PhEur requirements and indicated the good hygienic preparation, good microbial limit of raw materials and efficient preservation.

***In vitro* activity**

It was observed that as the concentration of extract increased, the MDIZ increased indicating better *in vitro* antibacterial activity. It was also noted that emulgels exhibited better activity than creams which was reasoned by the lower viscosity of emulgels compared to creams that affected the release rate of the extract from the creams. Among the cream formulations, F2 showed better antibacterial activity than F1. That was attributed to the to the higher solubility of the extract in the aqueous phase of F2 which contained propylene glycol as cosolvent and tween 20 was suggested to reduce the droplet size and subsequently promote the release of the extract from the lipophilic phase [34]. Moreover, between the F2 formulations, $F2_{(10\%)}$ exhibited significant activity against *S. aureus* and *P. aeruginosa* with inhibition zone 23 mm and 20 mm, respectively which mean 10% w/w was the extract concentration in the formulation exhibiting significant *in vitro* activity, so it selected for further investigation.

Additionally, the F4 emulgel formulations was found to have higher activity than the F3 ones; because of the high oil and emulsifier percentages which promoted the solubility of the extract and reduced the droplet size in the former formulations and resulted in attaining better results.

The formulations that showed best results in the creams and emulgels (Table 4) were $F2_{(10\%)}$ and $F4_{(10\%)}$, respectively. $F2_{(10\%)}$ cream was comparable to ciprofloxacin activity against *S. aureus*, higher than the tetracycline but less than povidone iodine, mupirocin and fusidic acid. Nevertheless, $F4_{(10\%)}$ had similar activity to povidone iodine, was better than the tetracycline and ciprofloxacin and less than mupirocin and fusidic acid.

***In vitro* release**

Emulgel formulations recorded faster release rate than creams as depicted in Figure 1 and that was accredited to the lower viscosity of the emulgels. The highest release rate was with $F4_{(10\%)}$ emulgel due to higher solubility of extract in oily phase due to larger oily phase ratio and smaller droplet size due to high percent of emulsifier which increase surface area of oily phase droplets permitting faster release of extract.

Table 5: *In vitro* antibacterial activity cream (F1 and F2) and emulgel (F3 and F4) formulations of *Kigelia africana* extract determined using cup plate method.

F	Extract Concentration (w/w)	Mean diameter of inhibition zones ± Standard deviation		F	Extract Concentration (w/w)	Mean diameter of inhibition zones ± Standard deviation	
		Staphylococcus aureus	*Pseudomonas aeruginosa*			*Staphylococcus aureus*	*Pseudomonas aeruginosa*
F1	1%	-	-	F3	1%	-	-
	2%	-	-		2%	-	-
	3%	-	-		3%	11.0±2.1	-
	5%	11.0±1.4	-		5%	13.0±2.1	11.5±0.7
	7%	13.0±0.0	10.5±0.7		7%	16.0±1.4	14.0±0.0
	10%	15.0±1.4	12.0±2.1		10%	21.0±0.0	18.0±1.4

F2	1%	-	-	F4	1%	-	-
	2%	-	-		2%	-	-
	3%	14.0±2.1	10.0±0.0		3%	13.0±2.1	12.5±0.7
	5%	17.0±0.0	12.0±1.4		5%	17.0±0.0	15.0±2.1
	7%	19.0±0.7	16.0±1.4		7%	21.0±1.4	19.0±1.4
	10%	23.0±1.4	20.0±0.0		10%	25.0±1.4	22.0±1.4
Standard products	Fusidic acid cream	29.0±2.1	-	Standard products	Tetracycline ointment	17.0±1.4	24.0±0.0
	Mupirocin ointment	27.5±0.7	25.0±2.1		Povidone iodine ointment	26.0±2.1	25.5±0.7
	Ciprofloxacin cream	22.0±1.4	27.0±2.1				

MDIZ < 14 mm = Inactive, MDIZ 14 - 18 = Moderately active, MDIZ > 18 mm = Active

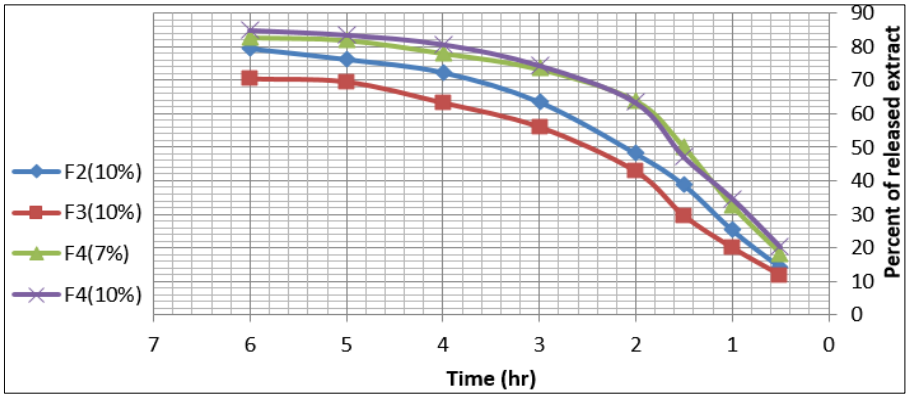

Fig 1: Release rate profile of various cream and emulgel formulations of *Kigelia africana* extract using egg shell membrane method. Emulgel formulations showed faster release rate than creams with the best one being the highest in the extract content.

Ex vivo diffusion

Ex vivo diffusion was influenced by the release rate of the extract which was in turn affected the concentration gradient at the diffusion surface and the product viscosity as stated by Fick's law [7].

The highest diffusion profile was of F4 $_{(10\%)}$ which exhibited the fastest release rate of the incorporated extract and the low viscosity. The diffusion rate of drugs increased with increasing the release rate of drug, decreasing of viscosity and increasing of partition coefficient [35]. *Ex vivo* diffusion pattern for all investigated formulations is depicted in Figure 2.

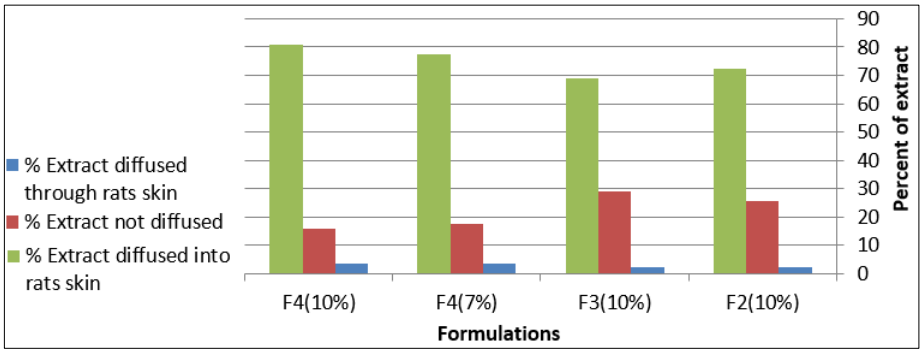

Fig 2: *Kigelia africana* extract *ex vivo* diffusion in creams and emulgels using Wistar rats skin membrane method. The formulations considered for this experiment are the cream formulation with 10% extract [F2 $_{(10\%)}$] and the emulgels with 7% and 10%; [F3 $_{(10\%)}$, F4 $_{(7\%)}$ and F4$_{(10\%)}$, respectively].

Stability study

In general cream formulation ($F2_{10\%}$) showed stability while one formulation of emulgels ($F3_{10\%}$) was physically unstable.

Physical stability

Physical stability of emulsified systems was enhanced with reduction of droplet size of internal phase and increasing of viscosity of external phase according to Stoke's law [10]. F2 $_{(10\%)}$ cream showed physical stability because of presence of tween 20 beside of emulsifying wax as emulsifying system which reduce the droplet size of oily phase retarding the coalescence. F4$_{(7\%)}$ and F4$_{(10\%)}$ emulgel were physically stable formulations because of high percent of gelling agents (2% for xanthan gum and 3% for HPMC) and emulsifying system (7.5%) compared to the F3 formulations which was physically unstable due to low percent of gelling agents (xanthan gum 1% and HPMC 1.5%) and emulsifying system (5%).

Chemical stability

All formulations exhibited chemical stability because of chemical compatibility between extract and excipients, thermo stability of the extract and excipients and chemical stability of extract at the pH of the formulations.

Microbiological stability

All formulations were microbiologically stable due to preservative efficiency, good microbial quality of raw materials and hygienic preparation.

Table 5: Stability of creams and emulgels of *Kigelia africana* extract at 40 °C and 75% relative humidity for six-month storage in an accelerated stability chamber. The formulations considered for this experiment are the cream formulation with 10% extract [F2 (10%)] and the emulgels with 7% and 10%; [F3 (10%), F4 (7%) and F4 (10%), respectively].

F	Physical stability			Chemical Stability (MDIZ±SD)[a]	Microbiological stability				Stability
	Clarity	pH	Viscosity (cp)		TABC[b] (CFU[d]/g)	TYMC[c] (CFU/g)	*S.a*[e]	*P.a*[f]	
1st month									
F2 (10%)	+++	5.3	47,000	23±2.1	<100	<10	(-)	(-)	Stable
F3 (10%)	-	NA	NA	NA	NA	NA	NA	NA	Unstable
F4 (7%)	+++	5.8	23,000	21±1.4	<100	<10	(-)	(-)	Stable
F4 (10%)	+++	5.3	26,000	25.5±0.7	<100	<10	(-)	(-)	Stable
2nd month									
F2 (10%)	+++	5.4	46,000	23±1.4	<100	<10	(-)	-)(	Stable
F4 (7%)	+++	5.8	22,000	22±0.0	<100	<10	(-)	(-)	Stable
F4 (10%)	+++	5.2	26,000	25 ±1.4	<100	<10	(-)	(-)	Stable
3rd month									
F2 (10%)	+++	5.4	45,000	22.5±0.7	<100	<10	(-)	(-)	Stable
F4 (7%)	+++	5.7	23,000	21±1.4	<100	<10	(-)	(-)	Stable
F4 (10%)	+++	5.3	25,000	24±2.1	<100	<10	(-)	(-)	Stable
6th month									
F2 (10%)	+++	5.3	45,000	22±0.0	<100	<10	(-)	(-)	Stable
F4 (7%)	+++	5.6	23,000	22±2.1	<100	<10	(-)	(-)	Stable
F4 (10%)	+++	5.2	24,000	25±1.4	<100	<10	(-)	(-)	Stable

a. MDIZ ± SD: Mean diameter of inhibition zones ± Standard deviation
b. TABC: Total aerobic bacterial count
c. TYMC: Total yeast and mould count
d. C.F.U: Colony forming unit
e. *S. a*: *Staphylococcus aureus*
f. *P. a*: *Pseudomonas aeruginosa*

Conclusion

Kigelia africana fruits are used widely in Sudan and Africa in treatment of different infectious diseases among them are skin infections like abscess and wound infections. The drugs are administer as drug products to deliver the active constituents to the site of action. Creams and emulgels have favorable properties over other semisolid dosage forms. The aquatic ethanol extract was formulated as cream and emulgel preparations for topical delivery of extract. The cream (10%w/w) and emulgel (7% and 10% w/w) showed elegant appearance, convenient pH, appropriate rheological properties, significant *in vitro* activity, considerable release and diffusion and physical, chemical and microbiological stability.

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