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Development and Evaluation of Shea Butter-Based Povidone-Iodine Ovules for the Treatment of Vaginal Infections

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ABSTRACT

Povidone-iodine ovules, semi-solid forms used for the prevention and treatment of vaginal infections. However, their current excipients, such as gelatin or synthetic lipids, face limitations such as high costs, fluctuating availability, allergy risks, limited stability, and insufficient emollient properties. This study aimed to develop and evaluate a povidone-iodine ovule formulation using shea butter as a natural excipient.

The methodology included the characterization of shea butter and povidone-iodine according to the European Pharmacopoeia. Various ovule formulations were then developed, and the optimal formulation underwent physicochemical, pharmacotechnical, and microbiological evaluations. The in vitro antimicrobial efficacy of the formulation of interest was verified using the Kirby-Bauer method.

The results showed that shea butter exhibited optimal properties, including a melting point of 34.5°C, acid values (9.72 mg KOH/g) and peroxide values (14.96 meq O_2/kg) consistent with the European Pharmacopoeia, and the absence of pathogens. Povidone-iodine was also identified with an iodine content of 9.98%, consistent with the European Pharmacopoeia. The optimal formulation (F2), composed of povidone-iodine (8.33%), shea butter (80%), beeswax (10%), lecithin (1%), and vitamin E (0.67%), demonstrated satisfactory properties, including a melting point of 36.7°C (adapted to vaginal temperature) and microbiological cleanliness. Furthermore, its in vitro antimicrobial efficacy test revealed zones of inhibition equivalent to those of BETADINE®, the ovules.

In conclusion, the combination of shea butter and beeswax constitutes a natural, pharmaceutical-grade excipient, allowing for optimal formulation of povidone-iodine ovules. This advance represents a promising solution for more accessible management of vaginal infections.

Keywords
Ovules, Povidone-iodine, Shea butter, Excipient, Formulation, Vaginal infections.

Introduction

Povidone-iodine ovules, semi-solid forms used for the prevention and treatment of vaginal infections, allow targeted release of the active ingredient, which reduces adverse systemic effects [1]. However, their current excipients, such as gelatin or synthetic lipids, face limitations such as high costs, fluctuating availability, allergy risks, limited stability, and insufficient emollient properties [2]. Faced with these constraints, shea butter (Figure 1) presents itself

as a promising natural alternative. This plant-based raw material, traditionally used in Africa for skin and mucosal care [3], has relevant pharmacological properties: emollient, anti-inflammatory, healing, and anti-infectious effects [4]. Its economic accessibility and sustainable supply reinforce its interest. This study aims to evaluate the potential of shea butter as a lipid base for povidone-iodine ovules to overcome the limitations of synthetic excipients, improve local acceptability and tolerance, and potentiate the antimicrobial effect of iodine through the synergistic properties of this natural excipient [5,6].

Figure 1: Shea butter and Shea fruit [6].

Materials and Methods

Materials

Raw Material

We used: 10% povidone-iodine (CAS batch 25655-41-8); shea butter; vitamin E (CAS batch 7695-91-2); soy lecithin (CAS batch 58-95-7); as well as beeswax (*Apis mellifera*).

Biological Material

The biological material consisted of clinical strains from the Bacteriology Laboratory of the Yaoundé University Hospital (CHU): *Candida albicans*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus*.

Culture Media

The media used were: cetrimide agar, MacConkey agar (MCA), Mannitol agar (MSA), Mueller Hinton agar (MHA), Plat Count Agar (PCA), and Sabouraud chloramphenicol agar.

Equipment

The list of equipment used is recorded in table 1.

Methods

Raw Material Characterization

Shea Butter Characterization

Organoleptic Characteristics: Color, odor, and texture were examined according to the requirements of the European Pharmacopoeia [7].

Physicochemical Characteristics: Melting point, acid value, iodine value, saponification value, peroxide value, and saponification value were determined using standard methods [8-13].

Microbiological Control: To ensure the microbiological cleanliness of shea butter, total aerobic organisms, yeasts and molds, Staphylococcus aureus, Pseudomonas aeruginosa, and Escherichia coli were investigated using the methods of the European Pharmacopoeia and ISO 6579-1 [8,14]. The preparation of the 10^{-4} shea butter stock solution is summarized in figure 2.

Table 1: Equipment Used.

Équipment	Role	Brand
Magnetic Stirrer	Stirring and Homogenizing Solutions	DRAGON MS-H-Pro+®
Platinum Loop	Aseptic Collection of Bacterial Colonies	Socimed®
Water Bath	Uniform and Controlled Heating of Substances	Memmert®
Precision Analytical Balance	Accurate Weighing of Reagents	BK-JA5003B®
Conical Flask	Titration	SARTORIUS®
Mortar and Pestle	Grinding and Homogenizing Solid Matrices	KERAMIK MORSER®
Ovules Molds	Ovules Molding Production	LGA®
pH-meter	pH Measurement	ATC NEUFTECH®
Hot plate	Controlled Heating of Substances	LABINCO®
Refrigerator	Storage of Thermolabile Reagents	BIOBASE®
Thermometer	Melting Point Measurement	BD-NOVA®
Vortex	Homogenizing	DRAGON MS®

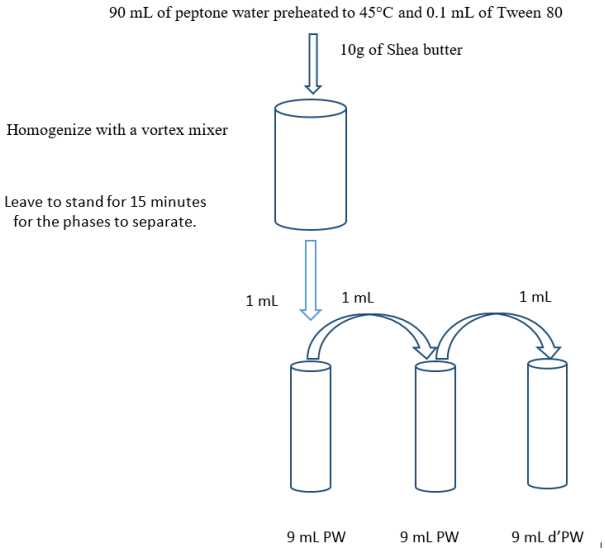

Figure 2: Shea butter sample preparation step.

Characterization of povidone-iodine [15]

Povidone-iodine was identified by colorimetric assay.

Development of ovule formulations [16]

Determination of the quantity of excipient

To determine the quantity of excipient to be added, the following formula was applied:

Q=N.E-N.F.S

Q: Quantity of excipient to be added to the ovule,
N: Number of ovules per mold,
E: Mass of one ovule in pure excipient,
F: Displacement factor

The displacement factor is the quantity (in grams) of excipient displaced by one gram of active ingredient. Given the densities of the raw materials, the displacement factor is determined as follows:
F = (Density of shea butter) / (Density of povidone-iodine)

Selection of excipients

The excipients and their proportions were chosen to ensure physicochemical stability: resistance to oxidation, preservation of the lipid structure (Table 2).

Table 2: Ingredients used for the formulation.

Components	Role	Proportions (%)
Povidone iodine	Active ingredient	8,3
Soy lecithin	Émulsifier	1
Shea Butter	Base	45 - 85
Beeswax	Consistency agent	5 - 45
Vitamine E	Antioxidant	0,5 - 2

Ovules Production

Melting and Homogenization of the Lipid Base

Variable amounts of shea butter and beeswax were melted separately in a water bath (50–60°C). The molten lipid mixture was combined under magnetic stirring (500 rpm). Vitamin E and soy lecithin were incorporated for 5 minutes, then povidone-iodine was dispersed into the base with prolonged homogenization (10 minutes).

Molding and Solidification of the Ovules

The homogeneous mass was poured into preheated molds (37°C) to prevent premature crystallization. The ovules were solidified by controlled cooling at 4°C for 2 hours.

Packaging of the Ovules

The packaging of the ovules was carried out according to the requirements of the European Pharmacopoeia [17].

Quality Control of Formulated Ovules

Physicochemical and microbiological parameters were assessed using standard methods. The parameters determined were: melting point, organoleptic parameters (color, uniformity, odor), mass uniformity, and microbiological cleanliness.

In Vitro Antimicrobial Efficacy of Formulated Ovules

The Kirby-Bauer agar diffusion method was used to assess the antimicrobial activity of povidone-iodine ovules [18]. The positive control was performed using a solution of BETADINE® ovules. Pure shea butter diluted in sterile water served as the negative control. Inhibition diameters were recorded.

Results

Characterization of the Raw Material

The characterization of the shea butter revealed an optimal melting point (34.5°C), acid values (9.72 mg KOH/g) and peroxide values (14.96 meq O_2/kg) consistent with the European Pharmacopoeia, and the absence of pathogens (Table 3).

Table 3: Characteristics of Shea Butter.

Parameter	Value	Standard
Melting Point	34,5 °C	31–40 °C
Acid Value	9,72 ± 0,54 mg KOH/g	≤ 15mg KOH/g
Iodine Value	32,51 ± 0,83 g I_2/100g	30–75 g I_2/100g
Peroxyde Value	14,96 ± 0,12 meq O_2/kg	≤ 26 meq O_2/kg
Saponification Value	138,59 ± 0,55 mg/g	160–195 mg/g
Pathogens	Absent	Absent

The identification and determination of povidone-iodine revealed an iodine content of 9.98%, also consistent with the standard.

Development of Ovule Formulations

The optimal formulation (F2), containing 8.33% povidone-iodine, 80% shea butter, 10% beeswax, 1% lecithin, and 0.67% vitamin E, demonstrated satisfactory properties, including a melting point of 36.7°C (adapted to vaginal temperature) and microbiological cleanliness (Table 4).

Table 4: Different ovule formulations.

Formulation	Povidone iodine (%)	Shea Butter (%)	Beewax (%)	Soy lecithin (%)	Vitamine E (%)	Melting point (°C)
F1	8,33	85	5	1	0,67	35,4
F2	**8,33**	**80**	**10**	**1**	**0,67**	**36,7**
F3	8,33	75	15	1	0,67	38,1
F4	8,33	70	20	1	0,67	38,9
F5	8,33	65	25	1	0,67	39,3
F6	8,33	60	30	1	0,67	39,6
F7	8,33	55	35	1	0,67	40,2
F8	8,33	50	40	1	0,67	41
F9	8,33	45	45	1	0,67	41,1

Figure 3 shows the regularly oval, smooth, and crack-free yellow-brown ovules (a), as well as the secondary packaging (b).

Figure 3: a) Formulated ovules, b) Secondary packaging.

In vitro antimicrobial efficacy tests demonstrated that this formulation had zones of inhibition equivalent to those of BETADINE® for *P. aeruginosa* (13±1 mm vs. 15±1 mm), *S. aureus* (19±1 mm vs. 17±1 mm), *E. coli* (16±1 mm vs. 16±1 mm), and *C. albicans* (15±1 mm vs. 15±1 mm) (Table 5).

Table 5: Inhibition Diameters.

Microorganism	Formulation F2 (mm)	BETADINE® ovule (mm)	Pure Shea Butter (mm)	Standard
Pseudomonas aeruginosa	13 ± 1	15 ± 1	6	≥ 14
Escherichia coli	16 ± 1	16 ± 1	6	≥ 15
Staphylococcus aureus	19 ± 1	17 ± 1	6	≥ 16
Candida albicans	15 ± 1	15 ± 1	6	≥ 14

Discussion

Shea butter (*Vitellaria paradoxa*) was analyzed according to the standardized methods of the European Pharmacopoeia and ISO 6579-1. The results reveal a melting point of 34.5 °C, optimal for release at vaginal temperature as found by Maranz et al. [19]. This thermal property contrasts with semi-synthetic glycerides, whose melting range (33–37 °C) may lead to instability in tropical climates. The acid value (9.72 ± 0.54 mg KOH/g), determined by potentiometric titration, and the peroxide value (14.96 ± 0.12 meq O_2/kg), measured via the iodometric method, confirm minimal lipid oxidation, in accordance with the standards for excipients [16]. However, the saponification value (18.59 ± 0.55 mg/g), lower than typical values (160–195 mg/g), suggests a reduced content of short-chain fatty acids as shown in the studies of Bettahar et al. [20]; This is probably due to the type of soil used for shea cultivation. Microbiologically, the tests carried out did not detect any contamination by Staphylococcus aureus, Pseudomonas aeruginosa or yeasts and molds in 10g of sample, validating its suitability to the criteria of the European Pharmacopoeia [8].

Nine formulations (F1–F9) were evaluated. Formulation F2 (80% shea butter, 10% beeswax, 1% soy lecithin, 0.67% vitamin E) has sufficient rigidity for storage, and complete melting in 7 ± 1 min at 37°C±1°C. Beeswax, composed of esters of fatty acids and long-chain alcohols, acts as a structuring agent while inhibiting oxidation via the formation of a dense crystalline network [21]. Soy lecithin (1%), rich in phosphatidylcholine, stabilizes the oil-water interface via its polar phosphate group, reducing lipid droplet coalescence. Integrated vitamin E (0.67%), reduces lipid peroxidation [22].

The melting point of the suppositories, important for their stability at room temperature and their efficacy, varies from 35.4°C to 41.1°C depending on their composition. Formulation F2 (80% shea butter, 10% beeswax) has an optimal melting point of 36.7°C. Close to vaginal temperature (37°C), this value ensures rapid in situ melting and homogeneous release of povidone-iodine, while guaranteeing stability at 25°C during storage. Formulations rich in beeswax (F7–F9, >40°C) are reported to delay the release of the active ingredient. Shea butter, rich in unsaturated fatty acids, naturally lowers the melting point, while beeswax, composed of long-chain esters, increases it. The 80:10 ratio optimizes this balance, avoiding the problems of extreme formulations (too early or delayed melting). These results are consistent with the literature: In 2007, Attama et al. demonstrated the impact of wax content on the melting point in shea bases [21]. The selection of F2 is based on this validated compromise: melting in 7 min ± 1 min (limiting leaks) and thermal stability in tropical climates (25–30°C), demonstrating the feasibility of using local excipients for forms adapted to hot regions.

Agar diffusion tests (Kirby-Bauer) made it possible to evaluate the efficacy against several germs. For Pseudomonas aeruginosa, the F2 ova produced a zone of inhibition of 13 ± 1 mm, a result lower than that of the BETADINE® ovule (15 ± 1 mm). This discrepancy suggests possible resistance, due to the origin of the strain tested, which is clinical. This result is consistent with the work of Chantefort et al. [22]. Regarding the other germs, the diameters were identical; this suggests that the excipients used are compatible with povidone-iodine, which remains active as in the BETADINE® specialty.

Conclusion

Shea butter, in combination with beeswax, proves to be a natural, pharmaceutical-grade excipient suitable for the optimal formulation of povidone-iodine ovules. This innovation represents a significant advance in the development of accessible and effective treatments for vaginosis.

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