Focus On the Use of Shea Butter as Excipient For Ointment

Oumar Thioune*, Ahmedou Bamba Koueimel Fall, Sidy Dieng, Moussa Diop.
Laboratory of Galenic Pharmacy and Pharmaceutical Legislation, Faculty of Medicine, Pharmacy and Odontology, Cheikh Anta Diop University of Dakar, Dakar, Sénégal.

ABSTRACT

Shea butter is a fat produced from the seeds of Vitellaria paradoxa (Sapotaceae). It can exist under different qualities which depend on several factors such as the region of origin, the method of production, treatments performed, etc. Its use as ointment excipient was the subject of several work that has raised issues that need further discussion. In this study, certain aspects relating to the adequacy between the main properties required for the ointment excipients and the characteristics of the different qualities of shea butter were analyzed. The data collected showed that for some properties, namely organoleptic characteristics such as color and odor, it may be necessary to perform discoloration or deodorization operations to ensure the comfort of the user. Similarly, it has sometimes been necessary to add peanut oil to the butter to reduce its consistency in order to facilitate its spreading. Concerning the release of the active ingredients, the qualities of the butter seem to have no influence because whatever the butter used, the results obtained were satisfactory. As regards inertia and long-term stability, the composition could have a great influence, but the refined shea butter obtained by chemical extraction seems more apt to act as an excipient. However, for such a product, it is still necessary to standardize industrial procedures for obtaining it, with a view to propose a standard shea butter, specifically for use as ointment excipient.

Keywords: refined shea butter, unrefined shea butter, excipient for topical forms, ointment

*Corresponding Author Email: oumar.thioune@ucad.edu.sn
Received 04 April 2019, Accepted 16 April 2019

Please cite this article as: Thioune O et al., Focus On the Use of Shea Butter as Excipient For Ointment. American Journal of PharmTech Research 2019.
INTRODUCTION

Shea butter is a fat produced from the seeds of Vitallaria paradoxa (Sapotaceae). It is widely used in various sectors such as cosmetology (1-5) but especially in food industry (6-8) which would consume about 90% of world production (9, 10).

One of its peculiarities is the great variability of its quality. Indeed, there are several types of shea which are distinguished by different physicochemical profiles. This variability depends on several factors such as the area of origin, method of production, treatment implemented or storage conditions (11-16).

Its use in the pharmaceutical field, although being quantitatively less important, nevertheless attracts much interest. This is justified, in large part, by its pharmacodynamic properties, in particular anti-inflammatory properties associated with its unsaponifiable fraction (17-22). But apart from its therapeutic properties, shea butter has other potentialities that have interested researchers. Indeed, its excipient properties have been the subject of numerous works, some of which date back several decades (23-26). Subsequent studies have confirmed such properties (27, 28). It should be noted, however, that in these studies, some aspects have been little or not addressed. These concern in particular, questions relating to the adequacy between the properties required for the excipients for topical forms and the quality of the butter used; the present work aims to analyze these issues in order to provide elements to better guide the choice of shea butter to use as an excipient when formulating ointments.

Some reminders about the required properties of excipients for topical use

The excipients used in topical forms, especially for ointments are defined on the one hand by physicochemical characteristics described in detail in the pharmacopoeias and, on the other hand by technological characteristics to meet the requirements for the production and the conditions of use of such forms.

They must have certain qualities, the main ones of which are set out below (29-32):

- A consistency allowing an easy spreading on the skin.
- Organoleptic characteristics (odor and color) that do not bother the user
- Absence of irritation, good tolerance and weak allergenicity
- Miscibility to the aqueous or fatty secretions of the skin. Thus, it can influence, according to its nature, the speed of penetration of an active principle capable of crossing the cutaneous barrier,
- Sufficient stability to allow good preservation
- Inertia towards the active ingredient (the excipient must not inhibit or increase the activity of the active ingredient), the packaging material (the excipient must neither dissolve the packaging material nor be absorbed by it), the body (in principle, the excipient must have no own activity or at least a pharmacological action compatible with that of the active ingredient).
- The ability, if possible, to be washable with water and not stain the laundry
- The possibility of being sterilized in the case of ointments to be applied to wounds.

**Methods of obtaining and variations of the quality of shea butter**

Shea butter can be produced by several methods (traditional, artisanal, industrial); these may have many modalities in their implementation and can be followed or not by complementary operations such as refining.

However, despite these numerous parameters which constitute factors of variation in their quality, the butters obtained can be classified into two types essentially: butter extracted with or without solvent and butter refined or not after extraction. According to these criteria, the composition of the butter may sometimes vary significantly. Table I shows the difference in composition which may exist between two butters which have been extracted with hexane but one was subsequently refined and the other not (33).

**Table I: Characteristic of unrefined and refined shea butter (33)**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Crude oil (not refined)</th>
<th>Refined oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saponification value (mg KOH/g)</td>
<td>389.89</td>
<td>162.61</td>
</tr>
<tr>
<td>pH</td>
<td>4.38</td>
<td>4.58</td>
</tr>
<tr>
<td>Free fatty acid (%)</td>
<td>4.28</td>
<td>1.68</td>
</tr>
<tr>
<td>Acid value (mg KOH/ g)</td>
<td>8.42</td>
<td>3.36</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>0.86</td>
<td>0.89</td>
</tr>
<tr>
<td>Moisture content (%)</td>
<td>2.29</td>
<td>0.12</td>
</tr>
<tr>
<td>Peroxide value (meq/kg)</td>
<td>15</td>
<td>9.40</td>
</tr>
<tr>
<td>Refractive index</td>
<td>1.472</td>
<td>1.467</td>
</tr>
</tbody>
</table>

In another study (34), two unrefined butters, one of which was extracted with water and the other with hexane, were compared and the results also showed differences for most measured parameters (Table II)
Table II: Physico-chemical Properties of SBT and SBS (34) (SBT: Shea butter extracted using traditional method; SBS: Shea butter extracted using solvent (hexane) extraction method.

<table>
<thead>
<tr>
<th>Properties</th>
<th>SBT</th>
<th>SBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative density</td>
<td>0.908</td>
<td>0.851</td>
</tr>
<tr>
<td>Kinematic viscosity (mm²s⁻¹)</td>
<td>30.68</td>
<td>44.84</td>
</tr>
<tr>
<td>Melting point (°C)</td>
<td>33.0</td>
<td>40.5</td>
</tr>
<tr>
<td>Free fatty acid (%)</td>
<td>9.0</td>
<td>23.89</td>
</tr>
<tr>
<td>Peroxide value (mg/100 g)</td>
<td>29.5</td>
<td>44.01</td>
</tr>
<tr>
<td>Acid value (mgKOH/g oil)</td>
<td>21.85</td>
<td>48.63</td>
</tr>
<tr>
<td>Iodine value (gI₂/100 g oil)</td>
<td>21.43</td>
<td>13.19</td>
</tr>
<tr>
<td>Saponification (mgKOH/g oil)</td>
<td>167.4</td>
<td>202.9</td>
</tr>
<tr>
<td>pH value</td>
<td>6.09</td>
<td>5.02</td>
</tr>
</tbody>
</table>

The unrefined butter itself may have several qualities which are distinguished by different physicochemical properties.

Thus, the West African Regional Standard (35) defined three grades of unrefined shea butter (Table III)

Table III: Quality Characteristics and Grading System for Unrefined Shea Butter (35)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Max – Min</td>
<td>Max-Min</td>
<td>Max-Min</td>
</tr>
<tr>
<td>Moisture content (%)</td>
<td>0 - 0.05</td>
<td>&gt; 0.05 - 0.2</td>
<td>&gt; 0.2 - 2.0</td>
</tr>
<tr>
<td>Free fatty acid (%)</td>
<td>0 - 1.0</td>
<td>&gt; 1.0 - 3.0</td>
<td>&gt; 3.0 - 8.0</td>
</tr>
<tr>
<td>Peroxide value (meq/kg)</td>
<td>0 - 10.0</td>
<td>&gt;10.0 - 15.0</td>
<td>&gt; 0.2 - 2.0</td>
</tr>
<tr>
<td>Insoluble impurities (%)</td>
<td>0 - 0.09</td>
<td>&gt; 0.09 - 0.2</td>
<td>&gt; 0.2 - 2.0</td>
</tr>
</tbody>
</table>

Organisms such as the American Shea Butter Institute (ASBI) have proposed other classification criteria that define five qualities of butter: A (raw or unrefined, extracted using water), B (refined), C (highly refined and extracted with Solvents such as hexane), D (lowest uncontaminated grade), E (with contaminants) (36).

Critical analysis of the use of butter in the formulation of ointment

Whatever the standard of classification, the different types of butter defined therein are characterized by physicochemical properties that justify their use in specific areas. According to the Regional Technical Committee, grade 1 unrefined shea butter is intended for the cosmetics and / or pharmaceutical industries and for direct consumption, the second category (grade 2) is intended for the food industries (confectionery, chocolate factories, kitchen and margarine ...), while the third category (grade 3) is for soap and direct consumption after refining (35)
However, as regards its use as excipient for ointment, a well-defined quality does not seem to be specified. It is therefore legitimate to ask the following questions: do all types of butter possess the main properties required for topical excipients? If not, for which properties would one or the other type be more apt to play the role of excipient?

**Color and odor**

Color varies according to the region of origin, the quality of the nuts and the conditions of production (37); It can thus vary from pale yellow to yellow (38, 39, 40) which is considered as that of unrefined butter. The refinement loses this original color which becomes whitish (41, 42).

Raw shea butter has a characteristic odor that some find unpleasant. The latter, which is more pronounced for shea butter in West Africa compared with that from East Africa, can however be corrected by various deodorization and aromatization processes (43).

**Consistency and release of active ingredients**

In publications where shea butter was used as excipient, the main objectives of the authors were the possibility of preparing an ointment whose consistency allowed, on the one hand, good spreading and on the other hand the release of the active ingredients according to the desired profile. Raw unrefined shea butter has a relatively hard consistency which does not favor a good spreading power, whereas the latter is an essential quality required for ointments.

Thus, to meet such a requirement, the use of shea butter as an excipient for ointment required the addition of a more fluid substance such as peanut oil at a concentration between 10% and 20% (23, 24, 26, 28) to have a suitable consistency capable of ensuring good spreading.

Its ability to release active ingredients has been studied in many works where shea butter has been compared with various other conventional ointment excipients. The results showed that the release profiles obtained with the shea butter were comparable to those observed with the reference excipients.

The release of Aureomycin from an ointment made with shea butter proved to be greater than when lanolin or petroleum jelly were used as excipients (28). Similar results were obtained when the release profiles of Metronidazole (44) and Sulfur (45) from shea butter based ointments and from Simple Ointment (BP) were compared. Similarly, salicylic acid was released faster from an ointment using shea butter as excipient than from the British Pharmacopoeia's reference ointment (26). In another study where shea butter was used as a base for an ointment containing Griseofulvin as active (46), the results showed a release of the latter with satisfactory profiles.

It should be noted that to meet these two criteria (good spreading and good release of the active ingredients with which it is associated), the type of butter used does not seem to be of particular
importance. Indeed, some have used butter purchased at the local market and then treated with different purification methods (28, 33). Sometimes there is no clarification of the treatment of butter before use (45, 47). In other cases, studies have focused on a comparison between purified butter and raw butter (46). But whatever the butter that was used, the technological qualities of the latter allowed the preparation of ointments which have been tested successfully.

**Inertia**

**With respect to the active ingredient**

A reaction with the active ingredient could result in degradation of the latter leading to its inactivation or toxicity for example (48-52). Publications where shea butter has been used as an excipient for various active ingredients do not mention such a phenomenon (26, 28, 44, 45).

**With respect to the organism**

This is one of the most important properties for an excipient. Nowadays, the activity of certain excipients towards the organism is increasingly mentioned, but in general reference is made to excipients with a known effect (53-55). For topical products, allergic or irritation reactions (54, 55) can sometimes occur but with shea butter-based ointments, such reactions have not been reported. On the contrary, with unrefined shea butter, there is rather a beneficial effect that is noted. Indeed, apart from its importance in the agro-food industry, unrefined shea butter owes its current popularity to the many cosmetic and therapeutic virtues attributed to its unsaponifiable fraction that is rich in active principles, in particular anti-inflammatory (17-22). Therefore, if unrefined shea butter is to be used, the activity of the active ingredient to which it is to be combined must be different from that of the principles contained in the unsaponifiable. If this is not the case, the evaluation of the active ingredient could be biased. For example, it would be difficult to distinguish between the activity of an anti-inflammatory active ingredient and that due to the unsaponifiable. Ointments prepared with the barks of Khaya senegalensis (Meliaceae), an anti-inflammatory plant, using shea butter as a carrier (56-58), could be cited to illustrate such a phenomenon. Indeed, the anti-inflammatory activity of such ointments can not be attributed only to the barks of the plant.

As regards refined shea butter, the treatments which led to its obtaining destroyed most of the active ingredients contained in its unsaponifiable fraction (59, 60); thus, it would better meet the criterion of inertia required vis-à-vis the organism.

**Long-term stability**

Various parameters such as moisture content, insoluble impurities, free fatty acids and peroxides can lead to fatty alteration reactions and thus, limit their shelf life. Among these reactions, the
oxidation, which is responsible for the rancidity phenomenon, represents one of their principal degradation pathways (61-66).

The substrates of the oxidation reactions consist essentially of the free fatty acids. Unrefined shea butter being much richer in free fatty acids (see Table I), would therefore be more sensitive to such reactions.

It should also be noted that these oxidative phenomena are accompanied by a deterioration of the organoleptic characteristics such as the occurrence of an unpleasant odor (63). However, when stored in good conditions, these reactions can be delayed by, in part, the natural antioxidants found in the unsaponifiable fraction (7, 3). But this would only be possible if unrefined shea butter is obtained in the absence of a high temperature capable of destroying these antioxidants. In order to improve its stability, it would therefore be necessary to associate it with antioxidants (24, 67).

As for refined shea butter, the operations allowing its obtaining lead to the elimination of a large part of the free fatty acids and thus constitute a factor of stability (3, 67, 68) favorable to better conservation over time. However, what is important is the maintenance of the stability of the ointment using the shea butter (refined or not). A dosage of the various components just after the preparation of ointments and after a defined time could allow an objective judgment.

In total, when comparing unrefined butter and refined butter, it can be seen that both can be used indifferently if one considers the spreading power and the ability to release the active ingredients. However, as regards the other properties required for excipients for topical use, such as the ability to ensure user comfort, inertia to the body and long-term stability, refined shea butter seems more apt to play the role of excipient. The availability of such a product, however, comes up against a difficulty often found in the world of excipients, namely the lack of industry that is specifically intended for them (69, 70). In general, the excipients used in the pharmaceutical formulation are also produced for other purposes. Shea butter most suitable for use as an ointment excipient is that produced by the food industry because it has the essential properties required for topical application (moisture content, free and unsaponifiables fatty acids are low, the color is stable and there is no odor) (3). However, the procedures used should be adapted to the requirements for a pharmaceutical use (71).

CONCLUSION

This analysis has shown that it is possible to use different types of shea butter as an excipient for ointment but in some cases it has been found necessary to modify certain characteristics of the
butter in order to make them conform to the properties required for such use. These modifications are justified by the fact that there is not on the market a standard shea butter especially intended for use as an excipient in the pharmaceutical formulation of ointment. Nevertheless, it may be noted that the characteristics of refined shea butter seem more suited to the properties required for the excipients for topical use. However, the procedures for preparing and distributing such a butter should be standardized in order to solve the problems associated with the choice of the butter to be used and, moreover, to ensure the reproducibility of the formulations in which it is to be incorporated.

REFERENCES

10- BEURRE DE KARITÉ : Comprendre la différence entre un beurre de karité naturel et un beurre de karité raffiné ; Guide Technique COSMEBIO, September 2014.


47- Dembélé DL. Formulation de pommade antalgique et anti-inflammatoire à base de *Securidaca longipedunculata* Fresen. Thèse de Pharmacie 2010-2011. Université de Bamako (Mali).


