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Inclusion of Hydrophilic-Lipophilic Balance (HLB) in the treatment of Psoriasis - A new approach

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Abstract

The present study highlights the importance of Hydrophilic-Lipophilic value of the base cream for the dermatological purposes beyond formulation stability. Hydrophilic- Lipophilic Balance (HLB) is largely considered for attaining stability of the base cream by the chosen emulsifier/ surfactants. However the base formulation (cream or ointment) also must act as an emulsifier to balance the hydrophilic- lipophilic ecosystem of the skin besides the formulation acts as the drug dispensing mechanism. Psorolin ointment for the treatment of psoriasis is being formulated with due diligence to HLB value due to the skin conditions of psoriasis. Details are presented in the paper.

Keywords: Hydrophilic – Lipophilic Balance (HLB), Surfactant, emulsifier, Stratum corneum, Psorolin.

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1. Introduction

HLB value refers to the hydrophilic- lipophilic property of the emulsifiers/surfactants. The HLB value of various surfactants differs greatly and there property also changes such as non-ionic and ionic. The ionic surfactants are further classified as anionic, cationic and amphoteric (zwitterionic). [1-3]

For making a stable emulsion system with different proportions of oil and water phases, a suitable choice of an emulsifier with appropriate HLB value is necessary. The proportion of water in oil or oil in water can be calibrated and stabilized only with the help of the emulsifiers having appropriate HLB value. [4, 5]

In most occasions the HLB of the finished product is seldom considered or given any importance. The finished product is although meant to deliver the oil soluble and water soluble constituents, therefore the importance of HLB value of the finished product for the overall benefit of the skin is given least thrust.

The dermatological products must consider the HLB of the finished product (base cream or ointment) from the context of the moisture and oil equilibrium of the skin. Due consideration therefore must be given to the formulations to have the appropriate HLB value with reference to the skin conditions, especially for psoriasis. Lower the HLB value, the product would tend to behave more as an emollient and higher the HLB value the product would exhibit greater hydrophilic property.

The treatment of Psoriasis requires a product with great emolliency and hydration. The products with lower HLB may occlude and provide hydrophobic barrier to the skin but such products cannot provide the required hydration to the epidermal cells. Providing hydration and emolliency to the epidermal cells would increase the viability of epidermal cells. Further, a proper hydration of the cells alone will ensure the cyclic process of stratum corneum turnover without deposition. [6]

Most of the anti-psoriatic preparations are largely made as moisturizers to provide hydration that is essential for the psoriatic skin. The base formulations of most of the dermatological products have been formulated only for the purpose of delivering the active pharmaceutical agent (s) than balancing the micro-ecosystem of skin which is constituted predominantly by water and lipid.

The topical dermatological drugs with balanced HLB would essentially act also as an emulsifier to hold the hydrophilic-lipophilic balance of the skin, while delivering the active pharmaceutical agent (s).

The present study reports the HLB value of Psorolin ointment and its importance in the treatment of psoriasis.

2. Materials and methods

Description of the products/formulations studied

1. Psorolin ointment

Psorolin ointment is the proprietary Siddha product of Dr. JRK's Research and Pharmaceuticals Pvt. Ltd. The formulation is oil in water emulsion with hydrophilic dominance. Psorolin ointment contains 3.3% *Wrightiatinctoria*, 3.3% *Cynodondactylon*, ointment base q.s

2.1 Experiment to determine water retaining capacity of the formulations

Following products were used for the study

1. Psorolin ointment
2. Petroleum jelly with 5% water without any emulsifier
3. Petroleum jelly with 5 % water with 2 % glycerin as emulsifier

50gm of all the above products were taken separately in a pre-weighed identical containers and micropore film was used to cover the container. The experimental products were filled in the containers in triplicate and then were incubated at 100⁰ C for 6 hours. After 6 hours, weight of each container was noted. The percentage of water loss in different products were averaged and then calculated.

2.2 Calculation of HLB

HLB values of the individual ingredients were multiplied with the fraction of the given ingredient in the total oil phase. The obtained values of all ingredients in the oil phase were added and from the above, the HLB of the mixture/formulation was derived as below

For example a formulation contains the following ingredients at different proportions such as

- Light liquid paraffin - 5 %,
- Cetyl alcohol-1 %
- Emulsifier- 3 %
- Water to 100.

The percentage of the oil phase is 6 and the proportion of each is:

Light liquid paraffin - $5/6 \times 100 = 83.3\%$, Cetyl alcohol $1/6 \times 100 = 16.6\%$

The required HLB number for the formulation to remain stable is 11.23

(Liquid paraffin (HLB 10.5) $83.3/100 \times 10.5 = 8.74$, Cetyl alcohol (HLB 15) $16.6/100 \times 15 = 2.49$)

2.3 HLB of Psorolin ointment vis-à-vis the test formulations

The HLB value of Psorolin ointment is 11.7 whereas the petroleum jelly does not have HLB value.

The percentage of water loss from petroleum jelly without any emulsifier was 100 %. Whereas when 2% glycerin was added along with 5 % water and then mixed with 45 gm of petroleum jelly, showed a lesser water loss which was 68.5 %. The water loss from Psorolin ointment was 8.75 %. Table- 1

Table 1: HLB and its relation to hold water

Products	HLB Value	% water loss
Psorolin ointment	11.7	8.75
Petroleum jelly with 5% water without any emulsifier	0	100
Petroleum jelly with 5 % water and 2 % glycerin	0	68.5

3. Results and Discussion

Our present study has clearly revealed that the importance of HLB value of the emulsifiers/surfactants should not be limited only to attain formulation stability alone but also for the purpose of balancing both the humectancy and oiliness of the skin.

Based on the proportion of water or oil soluble constituents that are used in the formulation, a suitable emulsifier with different hydrophilic-lipophilic value needs to be chosen and only then a proper emulsification can be achieved. So far, HLB value is considered more for the formulation and the formulation base is always treated as a mere vehicle or dispensing mechanism for several drug actives. Considering the proportion of drug actives vis-à-vis the base, always the base overweighs the drug actives in physical terms. For example, a 1% steroid cream will have only 1% of the steroid and the balance 99% is constituted by the base. The steroid although may function as the active pharmaceutical agent, the residual effect of the balance 99% base cannot be seen in a miniscule way.

Skin is composed of keratinous protein which essentially constitutes lipid and water [7]. Any damage to intact skin will result in the dryness of the skin due to loss of water and or lipid. Further the water present in the skin can be either free or bound form. The formulation base must be made in such a way to balance the proportion of

water and moisture of the skin so that besides offering the desired therapeutic benefit through the active pharmaceutical agent, the macrocosm of the skin also can be taken care of through balancing the HLB value of the base cream.

In the case of formulation engineering, the emulsifier (s) is used to harmonize the water and the oil phase whereas in the case of skin, the entire cream/ointment base must be treated as an emulsifier/surfactant by itself and hence must balance the water and the oil of the skin.

By adopting such strategy in formulating various drugs, the total benefit can be maximized both from the drug as well as the base.

Skin contains about 25 -35% of water in the bound form. The human stratum corneum contains 15 to 20 % of water to the total tissue dry weight and that may vary with different environment to which the skin is exposed.

It is reported that when the tissue hydration is increased, it would in turn increase the transdermal permeation of both hydrophilic and lipophilic drugs. Contrary to this, some reports have stated that occlusion may not enhance the percutaneous transport and transdermal delivery of polar permeants *in vivo*. By elevating the fluxes of polar molecules under occlusive conditions or by the hydration induced absorption of the lipophilic steroids clearly explains how the moisture balance would increase the trans epidermal absorption. All the above findings clearly points towards balancing/increasing the moisturizing value of the skin is far more important than increasing the emolliency of the skin.

The HLB value of Psorolin ointment is 11.7. It means, the Psorolin ointment base is predominantly a hydrophilic formulation. Psorolin ointment is prescribed to the patients who suffer from psoriasis mainly for the purpose of intense moisturization and to improve the remission phase. Due to an un-programed keratinocyte division and differentiation in the case of psoriasis, leads to poor or inefficient epidermal barrier effect. To improve the epidermal barrier effect and to minimize the aggressive progression of senescent stage of stratum corneum cells, the ointment base must have hydration dominance i.e., the HLB of 11 and above.

It has been proven that cholesterol loss is taking place heavily through the psoriatic skin due to the increase in the cell multiplication. It is reported that 85mg of cholesterol is secreted through healthy skin every day. In the case of psoriasis, the percentage of cholesterol loss can be several folds higher due to the high number of cell multiplication and shortening of cell cycle turn over time [8, 9].

Psorolin ointment with high HLB is therefore known to bind and would likely to increase the trans-epidermal permeation of the drugs which is essentially a downward movement into the skin. On the contrary the loss of moisture and lipid are basically an upward process. Therefore we presume that Psorolin ointment with HLB of 11.7 would increase the hydrophilicity of the skin and thereby retard the cholesterol loss as cholesterol may not find that easy to move through water rich environment which is required for the psoriatic patients.

We are the first to consider the HLB value of the dermatological formulations outside the purview of formulation stability and have extended its role to maintain the macrocosm of the skin.

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