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IMPORTANCE OF THERMO, HYDRO AND LIPID CHEMISTRY OF PSOROLIN B AND ITS TREATMENT SIGNIFICANCE IN PSORIASIS

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ABSTRACT

The formulation Psorolin B is formulated by strictly following the principle of hydro-lipid chemistry that is essential for the psoriatic skin. Under elevated temperature the lipid and non-lipid moiety separates fast and thereby the lipid constituents permeate through skin in a staggered manner whereas the hydro moiety acts fast and when the temperature is low the separation of hydro-lipid moieties are relatively poor which in turn favors the succulent property of epidermis that has been impaired due to severe low external weather. Psorolin B is organized not only from hydro-lipid principle alone but also the siddha herbal formulations are also placed based on their polar preferences. Details are presented in the paper.

KEYWORDS: Hydro-lipid chemistry of creams, Le chatelier's, Psoriasis cream, Boswellia serrata, Psorolin B.

INTRODUCTION

The treatment products for psoriasis require robust formulation architecture i.e., a balanced hydro and lipid chemistry vis-à-vis thermal response. More often the treatment products often focus on the active pharmaceutical agent(s) than to the delivery mechanism and the associated cybernetic requirements of the formulation to the psoriatic skin.[1, 2, 3, 4, 5] Unless the formulation architecture is adequately balanced in the above matrix, treatment success cannot be achieved with such formulations despite the use of superior therapeutic agent(s).

Psorolin B is a proprietary siddha formulation comprised of traditionally well accepted and documented herbs such as *Wrightia tinctoria, Cynodon dactylon, Boswellia serrata and Hydnocarpus igdhiana*. Besides the above, red ochre, the rich source of Vitamin D, Vitamin E and salicylic acid are also used in Psorolin B.

The complex active pharmaceutical agents in Psorolin B is bound to have a fractionated or fragmented dermal absorption and release and hence the formulation architecture needs to be devised in such a way to achieve sustained release and timed absorption of all the constituents of Psorolin B.

The basic premise of the formulation architecture requires for the above is not only lipo and hydro chemistry but also thermochemistry in order to ensure the release and absorption of the actives through the skin at wide range of temperature differences.[6, 7. 8]

At the well regulated temperature of the skin as well as the extreme temperature variability of the environment, the backbone effect should adjust accordingly and must facilitate the timely release and provide congenial ecosystem for their absorption through skin.[9]

We, in the present paper, for the first time examined the importance of thermo, hydro and lipo chemistry of the formulation and how that is directly linked with the release and absorption of the active constituents. The details are presented in the paper.

MATERIALS AND METHODS

Percentage of separation of lipid and hydro moiety vis-à-vis temperature

A given quantity of cream was stored at different temperatures for 15 minutes and then the percentage removal of hydro-lipid portion was estimated.

Percentage of separation of lipid and hydro moiety vis-à-vis time

A given quantity of cream was stored at different temperatures at varying time points and then the percentage removal of hydro-lipid portion was estimated.

Half- life of cream Vs time in days

2mg of cream per $2cm^2$ was applied over a pre-identified surface and left the experiment undisturbed for different days and the percentage removal of hydro-lipo portion from the sample was estimated.

Ingredients vis-à-vis solvent system

Different ingredients used in the formulation were tested for their percentage solubility either in water or in lipid (coconut oil) and based on their miscibility the preference quotient of different ingredients for lipid or water was estimated.

RESULTS

At the temperature of 50°C, about 95% of lipid and about 95% of water moieties could be separated from the formulation. When the temperature was lower than the above, the level of recovery increases to the level they were present in the formulation. At 0°C, the separation of both lipid and hydro moieties was the least with reference to their percentage of presence in the formulation. Table- 1.

Percentage of separation of lipid and hydro moiety vis-à-vis temperature.

Temperature	Percentage quantified	
	Lipid (from 45%)	Water (from 54%)
50°C	44	52
33°C	45	54
26°C	45	54
0°C	10	5

At the skin temperature (33°C), in 15 minutes, only 15% of lipid constituent could be separated and the percentage of lipid that could be separated increases to 22% by 120 minutes. When the temperature of 26°C was applied, the proportion of lipid separation declined significantly. Table- 2.

Table 2: Percentage of separation of lipid and hydro moiety vis-à-vis time.

Temperature	% of separation of lipid vs time in minutes			
	15	30	60	120
33°C	8	14	18	22
26°C	7	11	15	17

At 33°C (skin temperature), when 2mg of cream per $2cm^2$ was applied over a membrane showed the presence of 80% of the formulation on day 2 and the same was declined to 45% on day 8. Table- 3.

Table 3: Half- life of cream vs time in days.

Details	Presence of residual effect in % / days			
	2	4	6	8
At 33°C, 2mg of cream per $2cm^2$	80	78	50	45

The majority of the drug ingredients used in the formulation were greatly lipid soluble and sparingly water soluble. The red ochre is dispersible in water but not soluble either in lipid or water. Similarly the source of vitamin D, vitamin E and salicylic acid were hydrophobic.Table-4.

Table 4: Ingredients vis-à-vis solvent system.

Ingredients	Solvent system	
	Lipid	Water
Wrightia tinctoria	+++	+
Cynodon dactylon	+++	+
Hydnocarpus igdhiana	+++	+
Boswellia serrata	+++	+
Source of Vitamin D (Cheese)	+++	---
Vitamin E	+++	---
Salicylic acid	+++	---
Red ochre	---	+++

DISCUSSION

We are the first to report the importance of hydro, lipid and thermo chemistry aspects of the formulation for the treatment of psoriasis. A cream formulation with equi-proportional of lipid and hydro moieties are bound to behave differently at different temperature and therefore the active constituents used in such formulation also may get separated fragmentally according to the behavior of the solvent vis-à-vis temperature.

Psorolin B has been formulated according to the Le chatelier's principles where the hydro and lipid moieties are made to auto adjust to minimize or maximize the release of the other according to the temperature difference.

At 50°C, the separation of hydro-lipid constituents was near the actual whereas at 0°C the separation of hydro-lipid constituents was extremely low. At higher temperature, the rate of transpiration lead sweating over skin will be high as well as the dermal permeability also would increase.[10] Therefore, at this temperature the separation of hydro-lipid constituents needs to be high in order to aid the rapid absorption of the actives.

At low temperature the skin is tend to lose its moisture content and become dry. Under such circumstances the separation of hydro-lipid constituents of the formulation needs to be very low only then sustained humectancy and emolliency such formulation can offer to the skin besides the sustained release and absorption of the actives.

Our experiment on time kinetics of the formulation has revealed that at constant temperature (26 or 33°C) the separation of hydro-lipid constituents increased over time suggesting the possibility of both the slow release and time release of the actives.

In an undisturbed condition, the half-life of the formulation was found to be 8 days when 2mg of the formulation was applied evenly over $2cm^2$ area revalidating our earlier findings on the time kinetics of the formulation.

In psoriatic condition, the skin is irregularly thickened and may be partly inflamed. The formulation therefore needs to have very low 'break-point' between the hydro and lipid moiety and if necessary the 'link' between the above must act like 'plasmodesmata' in supporting the release of hydro and lipid constituents.

In psorolin B formulation the active constituents are classified under 3 categories such as.

1. Greatly lipid soluble, sparingly hydro soluble
2. Hydro-dispersible
3. Hydro insoluble

Due to the above complexity of the active pharmaceuticals ingredients in Psorolin B the formulation has been interiorly and exteriorly designed to harmonize both the dermal requirements at the larger scope as well as to achieve the slow and sustained release of the actives.

We have formulated Psorolin B fitting well into Le chatelier's principles where according to the deviation in temperature the hydro-lipid constituents may get separated completely or may exhibit elastic property or may form further more rigid bondage to meet the advantage of skin as well as to achieve timed release of the actives.

REFERENCES

1. Handjani-Vila RM, Ribier A, Rondot B, Vanlerberghie G. Dispersions of lamellar phases of non-ionic lipids in cosmetic products. *Int J Cosmet Sci*, 1979; 1: 303-14.
2. Cevc G. Drug delivery across the skin. *Exp Opin Investig Drugs*, 1997; 6: 1887-937.
3. Elias PM, Friend DS. The permeability barrier in mammalian epidermis. *J Cell Biol*, 1975; 65: 180-91.
4. National Psoriasis Foundation. *Topical treatments for psoriasis*. Available from: http://www.psoriasis.org/about-psoriasis/treatments/topicals.
5. Vincent N, Ramya DD, Vedha HB. Progress in Psoriasis Therapy via Novel Drug Delivery Systems. *Dermatol Reports*, 2014; 6(1): 5451. Published 2014 Sep 8. doi:10.4081/dr.2014.5451.
6. Soundharya R, Aruna V, Amruthavalli GV, Gayathri R, Inclusion of Hydrophilic-Lipophilic Balance (HLB) in the treatment of Psoriasis- A new approach. International Journal of Advances in Pharmaceutics, 2019; 08(01): e5150. DOI: 10.7439/ijap.v8i1.5150.
7. Caio P. Fernandes, Manuela P.Mascarenhas, Fiorella M.Zibetti1Barbara, G.Lima et al., HLB value, an important parameter for the development of essential oil phytopharmaceuticals. Revista Brasileira de Farmacognosia, 2013; 23(1): 108-114.
8. Masanori Takenouchi, M.S., Hiroyuki Suzuki, and HachiroTagami, M.D. Hydration Characteristics of Pathologic Stratum Corneum-Evaluation of Bound Water. The Journal of Investigative Dermatology, 1986; 87(5): 574-576.
9. Hao J, Ghosh P, Li SK, Newman B, Kasting GB, Raney SG. Heat effects on drug delivery across human skin. *Expert Opin Drug Deliv*, 2016; 13(5): 755-768. doi:10.1517/17425247.2016.1136286.
10. Hadgraft J, Lane ME. Skin permeation: The years of enlightenment. *Int J Pharm*, 2005; 305: 2–12.