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A Review on Formulation and Evaluation of Luliconazole Emulgel

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Abstract: *The present study was undertaken with an intention to develop a stable and effective topical formulation containing luliconazole. Luliconazole belongs to a class of drugs called Antifungals. Luliconazole exhibits highest antifungal activity against Trichophyton spp. Candida albicans, Malassezia spp., and Aspergillus fumigatu, which are major causative agents of dermatophytosis. However, luliconazole suffers from drawbacks such as lesser skin retention, low aqueous solubility and poor skin penetration because it comes under BCS Class*

Materials and methods: Luliconazole emulgel was prepared by hot melt emulsification technique. The formulation of emulgel includes three steps; first step is to prepare O/W emulsions in which the API is included, and then in second step the preparation of the gel base using carbopol 934 and eventually in the third step emulsion is added to the gel by constant stirring to produce an emulgel. The presence of a gelatinizing agent in the water phase converts a classical emulsion into an emulgel. This strategy is suitable to enhance the permeability of luliconazole and deliver to the target site in a controlled release system. The luliconazole emulgel was evaluated for the physical appearance, pH, spreadability, viscosity, extrudability and drug content. Result and discussions: the drug content was found to be maximum in formulation F3 with 72.21%.

Keywords: Luliconazole, antifungal, emulgel, BCS class II, controlled release system

I. INTRODUCTION

Emulgels are the combination of gel and emulsion. Both oil-in-water (o/w) and water- in-oil (w/o) type of emulsion are used as a vehicle to deliver various drugs to the skin. Emulgels represents the dosage form having high skin permeability. The presence of the gelling agent in water phase converts a classical emulsion into an emulgel. Emulgel for dermatological use has several advantages such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, water- soluble, longer shelf life, bio-friendly, transparent and pleasing appearance.[1-3]

Luliconazole:

Luliconazole has anti-fungal activity. Luliconazole is inhibiting the enzyme lanosterol demethylase. Lanosterol demethylase is needed for the synthesis of ergo-sterol, which is a major component of the fungus cell membranes. For skin care and the topical treatment of dermatological diseases, a wide choice of vehicles including solid, semisolids and liquid Preparation is available to physician and patients. Within the major groups of semisolid preparations, the use of transparent emulgel has expanded, both in cosmetics and pharmaceuticals. Emulgel or jellified emulsion is stable one and better vehicle for hydrophobic or water insoluble drugs as Luliconazole. Also emulgel has a high patient acceptability since they possess the advantages of both emulsions and gels. Therefore, they have been recently used as vehicles to deliver various drugs to the skin.

Formulation of Emulgel:

- **Vehicle-** Comply with the ideal characteristics given in the Pharmacopeias.
- **Aqueous material-** The aqueous phases used is water, alcohol, etc.
- **Oil-** Oils used for preparation of emulsion includes mineral oils and paraffin, either alone or in combination.[5]

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- **Emulsifiers-** Emulsifiers are used for preparation of emulsion. Classical examples are span 80, tween 80, stearic acid, sodium stearate.
- **Gelling agents-** Gelling agents are used to prepare gels, which enhances consistency and provides thickness to the preparation.
- **Penetration enhancers-** Penetration enhancers help to absorb drug to the skin. [6]

II. MATERIALS AND METHODS

Luliconazole, methyl paraben, liquid paraffin, ethanol, carbopol 934, tween 20, propylene glycol and span 20 were obtained from the laboratory of Samarth institute of pharmacy, Belhe. All chemical solvents were of analytical grade and used without further purifications.

Preformulation studies:

- **Melting point determination:** The melting point of the sample is done to check the purity of the sample. Melting point is defined as the temperature at which a solid substance transits its state from solid to liquid. [10] Melting point of luliconazole was found by using the digital melting point apparatus.
- **Solubility analysis:** Solubility is defined as the ability of a solute to dissolve in a liquid (solvent) to form a homogeneous solution. Factors affecting solubility are; type of solvent used, temperature and pressure. [11] Solubility analysis was primarily performed in order to find out a suitable solvent to dissolve the API, lipid and excipients used for formulation preparation.
- **Partition Coefficient of the Drug:** Partition coefficient is the measure of the lipophilic and hydrophilic nature of a drug substance. It is defined as the extent to which a substance is distributed between two liquid phases, one being the aqueous phase and other being the oily phase. The majorly used phases are water and n-octanol (oil phase) in the ratio 1:1. [12]

$$P\ o/w = C\ (n\text{-octanol}) / C\ (water)$$

Preparation of luliconazole emulgel:

- **Preparation of emulsion:** In this o/w emulsion, the oily phase was prepared by dissolving Span 20 in light liquid paraffin while the aqueous phase was prepared by dissolving Tween 20 in purified water. Methyl paraben was dissolved in propylene glycol whereas drug was dissolved in methanol and both solutions were mixed with the aqueous phase. Both the phases were heated separately to 70° to 80°C; then the oily phase was added to the aqueous phase with continuous stirring until cooled to room temperature.
- **Preparation of gel:** The gel was prepared by dispersing Carbopol 940 in purified water with constant stirring at a moderate speed and then the pH was adjusted approximately to 6 using tri-ethanol amine. Finally, the emulgel was prepared by mixing both the gel and emulsion in 1:1 ratio. The composition of different formulations has been discussed in Table 1:

Table.1: Composition of Different Formulation Batches (%w/w).

Ingredients	F1	F2	F3	F4
Luliconazole	0.5	0.5	0.5	0.5
Carbopol 934	0.5	0.5	0.5	0.5
Liquid Paraffin	12.5	12.5	18.75	18.75
Tween 20	2.5	5	2.5	5
Span 20	2.5	3.75	2.5	3.75
Propylene Glycol	12.5	12.5	12.5	12.5
Methanol	6.25	6.25	6.25	6.25
Methyl Paraben	0.075	0.075	0.075	0.075
Purified Water	q.s.	q.s.	q.s.	q.s.

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Evaluation of prepared luliconazole emulgel:

Physical appearance: The prepared gel was examined for clarity, colour, homogeneity, odour, feel upon application (greasiness, grittiness) and texture.

- **pH:** For pH measurements, freshly prepared solutions were kept at 25±2°C for a period of 30 min. After pH measurement, each solution was placed in a water bath and heated gradually up to 60 °C. The pH was determined using digital pH meter.
- **Drug Solubility:** [13] The shake-flask method was employed for the drug solubility experiment. The drug was solubilized in each solvent by stirring at room temperature. The sample solutions were filtered (0.45µm, Millipore, MA) before they attained the maximum solubility of Luliconazole in varying solvents.
- **Viscosity:** The viscosity of the prepared gel was carried out using a Brookfield viscometer using T-bar spindle (spindle-L4). The speed of 6 rpm was maintained for spindle rotation and the values were measured when the gel level was stabilized.

  Viscosity (mPa.S) = Dial Reading x Factor
- **Spreadability:** [14] 5 g emulgel was placed within a circle of 1 cm diameter premarked on a glass plate over which a second glass plate was placed. A weight of 500 gm was allowed to rest on the upper glass plate for 5 minutes. The increase in the diameter due to spreading of the emulgel was noted from the formula:

  $$S = M. L / T$$

  Where, S is the spreadability (gm.cm/sec), M is the mass placed on the pan, L is the length of the slide (cm), and T is the time (in seconds) required to move the upper slide.
- **Extrudability:** [15] The test was performed using a clean aluminum collapsible tube (20 g capacity) with a tip opening diameter of 1 cm. The extrudability was evaluated in by measuring the weight of gel sample ejected from the tube opening upon pressing with fingers, while holding the tube in hands.

III. RESULT AND DISCUSSION

Physical appearance, pH, viscosity, spreadability and extrudability of the prepared gel: All the prepared formulations were homogenous in appearance and smooth in texture and none of the formulation displayed any sort of phase separation. The pH of all was found to be in range of 5.5-6.5, which suit the skin pH indicating the skin compatibility.

Table.2: Result and discussion.

Formulation	Appearance	Phase Separation	pH	Viscosity (mPa.S)	Extrudability (gm)	Spreadability (gm.cm/sec)
F1	White	None	5.9±0.5	32000±0.54	5.4± 0.11	20.01±2
F2	White	None	6.1±0.5	25000±0.98	6.8± 0.21	22.40±2
F3	White	None	6.3±0.5	39000±0.65	9.0± 0.15	28.31±2
F4	White	None	5.8±0.5	26000±0.75	4.4 ± 0.3	23.26±2

IV. CONCLUSION

The main goal of the study was to formulate an antifungal luliconazole emulgel for topical route of administration to treat patients suffering from Candida albicans, Malassezia spp., and Aspergillus Luliconazole has been concluded to be a drug of BCS Class II (low soluble and high permeable drug). The present work focused on preparing luliconazole emulgel by employing varied concentrations of methanol, propylene glycol, liquid paraffin, span and tween to form an appropriate formulation.

As resulted all the preparations, F1-F4 was found to be suitable in all preparations and formulation F3 was most stable. All the formulations were stored at room temperature 25-35°C and then observed for 1 month. Stored formulations were observed for phase separation and related substances (bacterial growth). None of the formulation showed phase separation and bacterial growth. According to the findings, it can be concluded that that luliconazole emulgel can prove to be an effective and more efficient system for topical fungal treatment as compared to the traditional luliconazole systems that are commercially available.

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