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FORMULATION AND EVALUATION OF EMULGEL OF LULICONAZOLE AS TOPICAL DRUG DELIVERY SYSTEM

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ABSTRACT

The present studies are aimed to formulate and characterized emulgel of selected antifungal drugs luliconazole for the rapid easy onset of action in the treatment of acne vulgarises or skin disorder and to improve the bioavailability of the drug. Luliconazole being a BCS Class II drug has a low solubility and high permeability hence to increase the solubility of drug an emulgel was formulated which also ensures patient compliance. Formulation of better product than the currently marketed product, having better penetration and ultimately the efficacy of the final formulation when compared with marketed product. Hypothesis of Polymeric emulsifiers will be evaluated to convert unstable emulsion to a stable formulation with lower level of surfactant concentration. Formulation of emulgel with incorporation of maximum concentration of oil phase up to 50%w/w with lowest concentration of surfactants in aqueous phase can be done. The aim behind carrying out this research work is to formulate a stable emulgel of a hydrophobic drug Luliconazole of 1.0 % for the treatment of Fungal Infections which enhance the solubility and stability of Luliconazole.

KEYWORDS: Antifungal, luliconazole, solubility, permeability, emulgel.

INTRODUCTION

The skin is the primary mechanical defense against penetration of many pharmacological compounds, and it also serves as an ideal site for local and systemic drug delivery. Over the last few decades, the topical route of medication delivery has been increasingly popular. Despite the limitations of traditional topical medication delivery techniques, such as poor retention and bioavailability. This disadvantage is resolved through intensive research aimed at developing novel topical drug delivery technologies that increase safety, effectiveness, and side effects.[1,2]

Gel is a “high to low viscosity semisolid formulation made up of a dispersion of either big organic molecules or small inorganic particles, or of both”. It can also be enclosed and penetrated by liquid phase. The diluted cross-linked polymer system prevents the gels from flowing in steady state. The gel is a highly liquid-rich system. When continuous structure is present, solid-like qualities result.[3,4]

Emulgels are emulsions, either of the oil-in-water or water in oil type, which are gelled by mixing with a gelling agent. Emulsified gel is stable one and superior vehicle for hydrophobic or poorly water-soluble drugs. In short emulgels are the combination of emulsion and gel. In spite of many advantages of gels a major limitation in the deliveryof hydrophobic drugs. So to overcome this limitation an emulsion based approaches being used, so that even a hydrophobic therapeutic moiety can enjoy the unique properties of gels. In recent years, there has been great interest in the use of novel polymers which can function as emulsifiers and thickeners because the gelling capacity of these compounds allows the formulation of stable emulsions and creams by decreasing surface and interfacial tension and at the same time increasing the viscosity of the aqueous phase. In fact, the presence of a gelling agent in the water phase converts a classical emulsion into an

emulgel. Emulgels for dermatological use have several favorable properties such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, water-soluble, greater shelf life, bio-friendly, clear & pleasant appearance.[5,6]

METHODOLOGY

Formulation of Emulgel of Luliconazole

Different formulations were prepared using varying amount of gelling agent. The method only differed in process of making gel in different formulation. The preparation of emulsion was same in all the formulations. The gel bases were prepared by dispersing Carbopol 934, xanthun gum and HPMC in distilled water separately with constant stirring at a moderate speed using mechanical shaker. As gelling agent. The gel prepared by dispersing the gelling agent in heated distilled water and the dispersion was cooled and left overnight. The pH of all the formulations was adjusted to 5.5 to 6.5 using tri ethanol amine (TEA) The oil phase of the emulsion was prepared by dissolving methyl and propyl parabens in ethanol and it was added to oleic acid. Then luliconazole was added to oil phase. The aqueous phase was prepared by incorporating Tween-80 into distilled water, then both phase were mixed using constant stirring to get micro emulsion. The obtained emulsion was mixed with the gel in 1:1 ratio with gentle stirring to obtain the emulgel.[7,8]

Table 1: Composition of different formulation batches (%w/w).

Ingredients(% w/w)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Luliconazole	1	1	1	1	1	1	1	1	1	1	1	1
Oleic acid	6	6	6	6	6	6	6	6	6	6	6	6
Tween 80	20	20	20	20	20	20	20	20	20	20	20	20
Ethanol	10	10	10	10	10	10	10	10	10	10	10	10
Methanol	1	1	1	1	1	1	1	1	1	1	1	1
Methyl paraben	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Propyl paraben	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Carbopol 934	0.5	1.5	-	-	-	-	0.5	0.75	-	-	0.5	0.75
Xanthum gum	-	-	1	1.5	-	-	0.5	0.75	0.5	0.75	-	-
HPMC K15M	-	-	-	-	1	1.5	-	-	0.5	0.75	0.5	0.75
Triethanolamine	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Characterization of emulgel

i) Determination of Drug Content

The concentration of luliconazole in emulgel was determined by sonicating a known amount of emulgel in solvent (ethanol). A UV spectrophotometer was used to determine absorbance after an appropriate dilution at 296 nm.[9,10]

ii) Drug Release Studies

A modified Franz diffusion (FD) cell was used in the in-vitro drug release tests, firstly the formulation was applied to a dialysis membrane sand wiched between the donor and receptor compartments of the Franz diffusion cell (which had previously been soaked in phosphate buffer pH 7.4 for 24 hours). By putting the cell in the water bath, the temperature was kept at 37°C. This "entire assembly was placed on a magnetic stirrer, and the solution was continually stirred at 50 rpm using a magnetic bead, after adequate dilutions, the samples (2ml) were withdrawn at a sufficient time interval and examined for drug content using a UV visible spectrophotometer. The percent drug release was estimated.[11,12]

iii) Rheological Study

The viscosity was measured with a cone and plate viscometer with spindle 7 (Brookfield rheometer) andthe viscosity-to-be-measured formulation was placed in a beaker and allowed to settle for 30 minutes, before the measurement, the temperature was set to the assay temperature (250°C) and the spindle was lowered perpendicularly into the centre of the emulgel, making sure it did not touch the jar's bottom, and rotated at 50 rpm for 10 minutes, further, the spindle was moved up and down, resulting in viscosities at various locations along the path. The viscosity of the gel was calculated as the average of values made over a 10-minute period.[13,14]

iv) Spreadability

A pulley is fastened to one end of a wooden block that makes up the device. Using the 'Slip' and 'Drag' characteristics of the emulgel, the spreading coefficient was computed. On the wood block, a glass slide was set in the ground. On this ground slide, there was an extra 1 g of emulgel. Between this one and the emulgel was a second glass slide that was the same size as the fixed ground slide. The hook is included with the second glass slide. To remove air from the area between the two slides and produce a uniform layer of emulgel, a 100 g weight was placed on top of them for five minutes. The measured weight (35g) was dropped into the pan fastened to the pulley using a hook. "Time in seconds it takes for two slides to separate" from the emulgel and be put in between them under the influence of a specific force. The spreadability improves as the time it takes to separate two slides decreases.[15,16]

v) Drug release kinetic models

The zero-order rate describes the systems where the

drug release rate is independentof its concentration. The first order which describes the release from systems where the release rate is concentration dependent. While the log cumulative percent drug remaining vs time illustrates the Higuchi square root kinetics, showing the cumulative percent drug release vs the square root of time. The regression coefficients (R^2) of each plot were determined using their corresponding plot. The release data are fitted in different kinetic molel.[17,18]

RESULT

Drug content determination

1gm of emulgel was dissolved in 10 ml of ethanol. The volumetric flask was kept for 1 hour and shaken well in a shaker to mix it properly and the solution was passed through the filter paper and filtered, further, withdrawn 1ml was diluted up to 10 ml with PBS 7.4 the absorbance was measured spectrophotometrically and finally the drug content was determined using a standard plot. Following data shown in the table.

Table 2: Drug content of formulations.

Sr no.	Formulation code	%drug content
1	F1	76.69
2	F2	96.83
3	F3	77.19
4	F4	93.69
5	F5	82.59
6	F6	76.59
7	F7	92.45
8	F8	71.71
9	F9	91.54
10	F10	83.21
11	F11	78.54
12	F12	83.90

Rheological study

Rheological behavior of the emulgel formulations exhibited non-Newtonian shear thinning pseudo plastic type of flow, i.e. decreases in viscosity at increasing shear rates. As the shearstress is increased, the disarranged molecules of the gelling material are caused to align their long axes in the direction of flow.

Table 3: Viscosity values of formulations.

Sr.No.	Formulation code	Viscosity(cps)
1	F1	5050
2	F2	5250
3	F3	5120
4	F4	5010
5	F5	4800
6	F6	4375
7	F7	5150
8	F8	3270
9	F9	4902
10	F10	4289
11	F11	4890
12	F12	5100

Spreadability

Table 4: Spreadability values of formulation F1-F12.

Sr no.	Formulation code	Spreadability g.cm/sec
1	F1	18.14±0.12
2	F2	21.96±0.34
3	F3	19.15±0.22
4	F4	17.67±0.61
5	F5	18.44±0.15
6	F6	17.76±0.29
7	F7	16.06±0.19
8	F8	19.07±0.27
9	F9	20.05±0.85
10	F10	18.67±0.43
11	F11	15.89±0.27
12	F12	16.97±0.39

In vitro release of emulgel

Drug release studies were performed in Franz diffusion cell applied on dialysis membrane which is used in diffusion media of phosphate buffer solution 7.4 withdrawn 2ml sample diluted in PBS 7.4 at 10 min time interval absorbance measured by UV spectrophotometer in all formulation. The in vitro test was performed to ensure the uniform and accurate permeability of the drug. A good drug permeability was observed in F2 emulgel formulations and was found to be 87.45±0.66 in six hrs.

Table 4: Drug release of formulations.

Formulation code	% Drug release
F1	56.15±1.61
F2	87.45±0.66
F3	59.93±1.96
F4	73.7±1.37
F5	75.36±0.89
F6	75.36±1.68
F7	74.53±1.49
F8	51.01±2.40
F9	56.21±1.53
F10	52.37±2.15
F11	48.30±2.41
F12	46.51±1.29

Drug release kinetic models

The zero-order rate describes the systems where the drug release rate is independent of its concentration. The first order which describes the release from systems where the release rate is concentration dependent. While the log cumulative percent drug remaining vs time illustrates the Higuchi square root kinetics, showing the cumulative percent drug release vs the square root of time. The regression coefficients (R2) of each plot were determined using their corresponding plot. It was found that the in vitro drug release was followed by by zero order (R2 = 0.985).

Table 5: Results of Different models in terms of R^2 slope and intercept.

Model name	Formulation		
	R^2	Slope	Intercept
Zero order	0.985	0.247	0
First order	0.931	379.7	80.82
Higuchi	0.894	37.35	13.68

CONCLUSION

The goal of this study was to make formulation and assess Luliconazole transdermal gels. Luliconazole's identity and purity were verified as part of our preliminary investigation. Additionally, the produced gel has acceptable physical characteristics. The drug concentration in optimized F2 gels made using the cold mechanical technique was in the range of 96.83, in vitro diffusion release of 87.45%, viscosity was found 5250 cps and spreadability was found to be 21.96. The formulation F2 follows all parameters of stable and acceptable emulgel. The post-formulation parameters and in vitro drug release indicate no obvious alterations according to the stability investigation and this shows that under storage conditions, the gels are quite stable.

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