



Formulation And Evaluation Of Luliconazole Cream: As A Topical Use”

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Abstract:

A topical medication is a medication that is applied to a particular place on or in the body. Most often topical administration means application to body surfaces such as the skin or mucous membranes to treat ailments via a large range of classes including creams, foams, gels, lotions, and ointments. Luliconazole is a novel topical antifungal imidazole with broad-spectrum and potent antifungal activity used in treatment of superficial mycoses. To formulate luliconazole cream by using different excipients and evaluate the luliconazole cream through chemical and physical properties. Manufacturing procedure: aqueous phase preparation- oil phase preparation- drug phase preparation - final mixing. No any physical change found by visual observation. But some variation found in ph. Short-term stability study was carried out (due to shortage of time) for optimized formulation. Formulation was exposed to different conditions of temperature as well as relative humidity 25°c/ 60% rh and 40°c/ 65% rh for a period of 1 month. After 1 month no any physical change found during visual observation, but some variation found in pH.

Key word: Topical, Luliconazole, pH and Formulation etc.

1. Introduction:

A **topical medication** is a medication that is applied to a particular place on or in the body. Most often topical administration means application to body surfaces such as the skin or mucous membranes to treat ailments via a large range of classes including creams, foams, gels, lotions, and ointments(1). The definition of the topical route of administration sometimes states that both the application location and the pharmacodynamic effect thereof are local (2).

1.2 Classification (5):

There are many general classes-



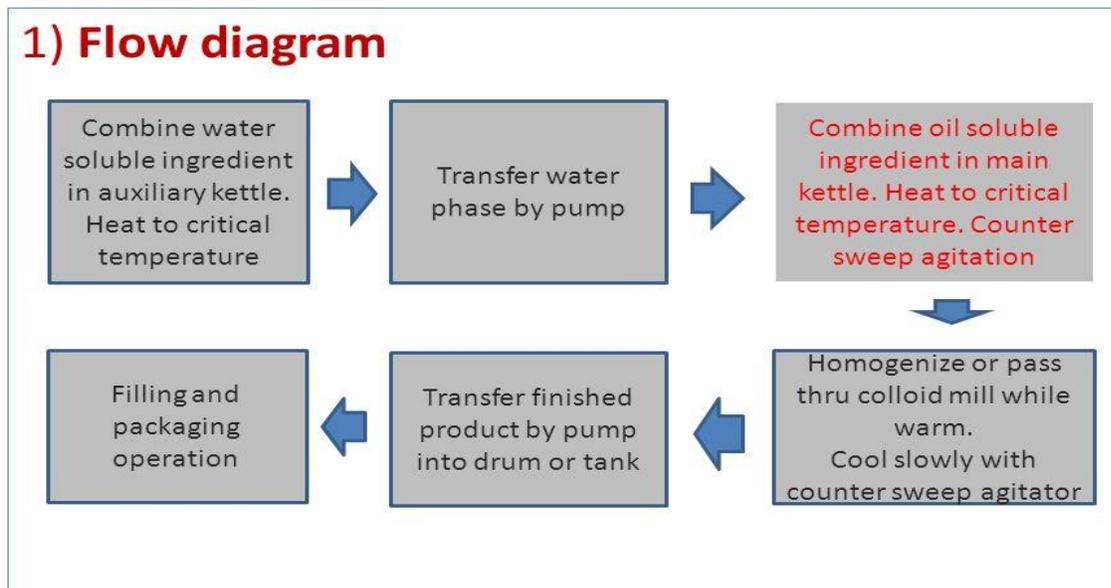
Fig 1. Classification of topical dosage forms.

1.3 Cream (6, 7):

It is a semisolid emulsion formulation for application to the skin or mucous membranes. Water in oil (w/o) emulsion type creams is less greasy and good spread ability as comparison to ointments whereas oil in water (o/w) emulsion creams readily rub into the skin is termed as vanishing cream and is readily removed by water. A **cream** is a preparation usually for application to the skin. Creams for application to mucous membranes such as those of the rectum or vagina are also used. Creams may be considered pharmaceutical products as even cosmetic creams are based on techniques developed by pharmacy and unmedicated creams are highly used in a variety of skin conditions (dermatoses). The use of the finger tip unit concept may be helpful in guiding how much topical cream is required to cover different areas.

Semisolids manufacturing consideration

1) Flow diagram



1.3.1 Classification of Creams (7):

All the skin creams can be classified on different basis:

1. According to function, e.g. cleansing, foundation, massage, etc.
2. According to characteristics properties, e.g. cold creams, vanishing creams, etc.
3. According to the nature or type of emulsion.

Types of creams according to function, characteristic properties and type of emulsion:

1. Make-up cream (o/w emulsion):

- a) Vanishing creams.
- b) Foundation creams.

1. Cleansing cream, cleansing milk, cleansing lotion (w/o emulsion)
2. Winter cream (w/o emulsion)
3. 4. All-purpose cream and general creams
4. Night cream and massage creams.
5. Skin protective cream.
6. Hand and body creams

Advantages of topical drug delivery system:

- i. It is the easiest way to deliver a drug.
- ii. It avoids first pass metabolism.
- iii. Topical formulation is very useful for delivery of rectal, vaginal drug delivery.
- iv. It is non-invasive.
- v. It gives a high level of patient satisfaction.
- vi. Easily medicaments can be terminated when required.
- vii. Avoidance of gastro-intestinal incompatibility. viii. It is safe and effective delivery of drug molecules with lower doses as compared to conventional system

Disadvantages of topical drug delivery system:

- i. Skin irritation or dermatitis may occur due to the drug or excipients.
- ii. Most drugs have a high molecular weight and are poorly lipid soluble, so are not absorbed via skin or mucous membranes.
- iii. Very slow absorption.
- iv. It can be used only for those drugs which need very small plasma concentration for action.

1.4. Luliconazole:

Luliconazole is a novel topical antifungal imidazole with broad-spectrum and potent antifungal activity used in treatment of superficial mycoses. Superficial mycoses are not fatal, but they constitute a serious problem for patients 'quality of life in view of the considerable discomfort and/or cosmetic deformity they cause. These diseases are found worldwide and affect 20 to 25% of the world's population (9, 10).

2. Material and Method :

2.1 Materials:

Luliconazole was obtained from HIS Pvt. Ltd. And all other chemicals used were of analytical grade and were used without any further chemical modification.

Table 1 Formulation (% W/W)

Sr. No.	Ingredients	F1	F2	F3
01	Luliconazole	1	1	1
02	Cetostearyl Alcohol	6	5	6
03	Cetomacrogol	1.5	1.5	2
04	Liquid Paraffin	4	4	5
05	Propylene Glycol	18	15	18
06	Di sodium Edetate	0.01	.02	.01
07	Butylated hydroxy Toluène	0.1	0.1	0.2
08	Benzyl Alcohol	1	1.5	1
09	Purified Water	QS	QS	QS

2.2 Method:

Take Purified water and dissolve Disodium Edetate and heat it to a temperature 70-80°C. Add Paraffin, CetostearylAlcohol, Cetomacrogol, Heat the material to a temperature 70-80°C. Filter the above preparation and maintain the temperature. Transfer the filter oil phase to the Aqueous Phase in vessel slowly under stirring. Mix the above preparation at the fast speed and kept in water bath for cooling at mix at slow speed.

Take Propylène Glycol and dissolve Luliconazole by heating the mixture to a temperature 70-75°C. Then add drug solution to under stir it. Dissolve Butylated hydroxy Toluène by heating to a temperature 70-80°C then cool the solution. Add remaining purified water, under Stirring. Continue mixing till cream reaches a temperature around 30°C and stand for cooling.

3. Evaluation Method

3.1. Description:

Transfer a portion of sample into a clean glass plate and observe color and appearance.

3.2 pH:

Take specified amount of cream in 200ml glass beaker and add water and mix properly. Then determine pH through digital pH meter.

3.3 Stability Study: Short-term stability study was carried out.

4. Results and Discussion

Table 2.-

S.NO.	PARAMETERS	RESULTS
1.	pH	5.9(F1),5.7(F2),5.9(F3)
2.	Color and Appearance(F1,F2,F3)	White
3.	Homogeneity(F1,F2,F3)	Homogeneous cream(by touch)

Stability Study: Short-term stability study was carried out (due to shortage of time) for optimized formulation. Determine-

- **Physical appearance-** No any physical change found during visual observation (after 1 month).
- pH- 5.7(F1),5.6(F2),5.8(F3) through digital pH meter.

No any physical change found by visual observation. But some variation found in pH. Short-term stability study was carried out (due to shortage of time) for optimized formulation. Formulation was exposed to different conditions of temperature as well as relative humidity 25°C/ 60% RH and 40°C/ 65% RH for a period of 1 month. After 1 month no any physical change found during visual observation, but some variation found in pH.

We develop stable cream of luliconazole by using different emulsifying agent through various phase preparation. Advantages of topical drug delivery system are safe and effective delivery of drug molecules with lower doses as compared to conventional system. Its development is multifactorial, including skin wetness, friction, skin irritants, and pH change.

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