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# Formulation and Evaluation of Fluconazole Antidandruff Gel

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## Abstract

Dandruff is a common scalp disorder , it is a flaking of dead skin and over activity of the oil glands, known as seborrhea. Fluconazole is an imidazole derivative used for the treatment of local and systemic fungal infection .So, the formulation of fluconazole antidandruff gel. The present study was designed to formulate and evaluate different formulae of antidandruff gel containing fluconazole for treatment of dandruff. The gel was formulated by using different polymers with different concentration as Carbopol 940, methyl paraben, polyethylene glycol, triethanolamine, glycerine, ethanol.Six different formulae were prepared and characterized physically in term of color, spreadability, pH, drug content and rheological properties. FT-IR study confirmed the purity of drug and revealed no interaction between the drug and excipient. In-vitro drug release in phosphate buffer pH 7.4 and permeation study through cellophane membrane. The results of in vitro drug release and its permeation studies showed that the highest values were from F3. Also F3 shows the highest antifungal activity and best fitted to the korsmayer peppas release.

Key-Words: Fluconazole, Antidrandruff, Gel

## Introduction

The Etiology of Seborrheic Dermatitis remains unidentified, though many factors, including hormonal, have been occupied. This chronic inflammatory disorder is normally limited to area where the sebaceous glands are present like head. In this condition of skin, the skin becomes crumbling. This type of dermatitis on scalp is harsh type of dandruff. When this type of dermatitis affect the scalp various people call it as dandruff. Seborrheic dermatitis occurs when in the neonatal period, it generally disappears by six to twelve months , suggesting that it possibly a respond to maternal hormone stimulation. Seborrheic dermatitis often affects people in post puberty. Further facts of hormonal influence is provided by research indicating that the human sebocyte responds to androgen stimulation. Although specific details remain unknown Pityrodporium Ovale is mainly found to take part in the demonstrating of the Seborrheic dermatitis. The migration rate of occupied skin by this organism may be lesser than of normal skin. (Janniger C.K. *et al.*1995)

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Classified Common sites of dandruff distribution: The distribution is naturally symmetric and general sites of distribution are Hairy areas of head, Fore head, The external ear canals, Post auricular creases.Its affect not just on the scalp but also affect the ears, eyebrows, side of nose, beard, and less commonly the central part of the chest. Dandruff may cause in any hairy area with even very small hair follicles .Dandruff is seen in all ages from baby to the elderly .In efficiency scalp, "Cradle cap" is another term using for dandruff. Dandruff is commonly known as seborrheic dermatitis. Severe dandruff may be very difficult and frustrating condition. On going combination treatment of multiple shampoo, washes, cream and lotion may be required to treat resistance condition. Overall, dandruff treatment is safe and effective . The best shampoo choice include zinc pyrithione, selenium sulfide, tar based shampoo. Prescriptions shampoo of dandruff such as ketoconazole have no over over-the-counter brands.(Alai N. 2014) .

**Causes Of Dandruff**

The cause of dandruff is undefined. Now there are so many experts who think that the dandruff is not caused by the poor cleanliness .

Persons who are highly sensitive to yeast having higher probability of having dandruff. That's why we can say that the yeast may play an important part in causing dandruff. *Malassezia* is a type of fungi and its sensitive people who get dandruff find that it gets lost

during the warmer season and higher in cold.. UV light from the sun interacts with the yeast. Several say, that during winter skin becomes dried due to cold air and hot area temperature,that causes dandruff more liable. Fungi Malassezia is generally present on everyone's scalp. Normally, thisfungi doesnot show any problem .Though, it can grow uncontrol. It nourished by the oils and by the hair follicles secretion. When it occurs, the scalp can become irritated and produces extra skin cells. After that the extra skin cells die and fall off. Then they mix with the oil of the hair and scalp, and turn into a flaky scale which we can say as dandruff..

**Seborrheic dermatitis** – Person who suffers from seborrheic dermatitis are more sensitive to dandruff. Seborrheic dermatitis affects various areas of the skin, include the back of the ears, the breastbone, eyebrows, and the sides of the nose, not only on the scalp. The patient who suffers with this disease will have red, greasy, itchy, irritates skin covered with flaky white scales.

**Disease conditions** - People with psoriasis, eczema and some other skin disorders have a tendency to get dandruff much more often than other people. Adults with Parkinson's disease and some other neurological disease are more prone to having dandruff and seborrheic dermatitis. Patients who having heart disease and they recover from heart attack having dandruff more than the other persons.

**Types of dandruff**

**Oil-Related Dandruff**

This kind of dandruff is commonly found due to the gathering of oils in the skin and scalp. It may resulting because of irregular cleanliness practices. This type of dandruff is generally occurred by improper washing of hair and not enough shampooing. Sebaceous glands are found in the scalp which secretes oil. This production and release of Sebum oil is a natural incident in human beings and it make an important part of healthy hair. Alternatively, if this sebum is not cleared regularly, it can bined with dead skin and dirt which foremost to the formation of dandruff.

**Yeast-Related Dandruff**

As its named, this is occurred due to the yeast/fungus known as Malassezia that is found in everyone's scalps. However, this kind of yeast is growing normally in a limited quantity but in dandruff condition the growth becomes uncontrolled.

Fluconazole is a triazole anti-fungal agent having wide range of activity than Ketoconazole. It is used in treatment of cryptococcal meningitis, systemic and mucosal candidiasis in both normal and immune-compromised patients, coccidioidal meningitis and histoplasmosis. The bioavailability (oral) is not affect by gastric pH and food. Long term fluconazole maintenance therapy is needed in AIDS patients with fungal meningitis. (Tripathi K.D. 2009).

Fluconazole remains the drug of choice in the treatment of oropharyngeal candidiasis. Fluconazole has also been used for prophylaxis in those at high risk for invasive fungal infections. After induction therapy with AMB and flucytosine, fluconazole is used for suppression of cryptococcosis. Fluconazole is also useful for infections caused by *Coccidioides immitis*(R.T. George *et al*., 2009)

## Material and Methods

Fluconazole was a gift sample from Alembic Pharma Vadodra .Carbapol, glycerine, ethanol was obtained from Mapromax, Life Science Pvt. Ltd.,Dehradun Polyethylene glycol, methyl parabene, triethanolamine was obtained from Thomas Baker chemicals Pvt. Ltd., Mumbai.

**Formulation and Evaluation**

**(**Niyaz Basha *et al*.,2011**)**In this formulation, polyethylene glycol, glycerine and methyl parabene were used in weighed quantity and six different formulation are prepared and their different quantity is shown in table no.6.2.2 and dissolved in 35 ml of water in beaker and were stirred at high speed using mechanical stirrer (or sonicator). Then Carbopol 940 of different quantity for different formulation shown in table no.6.9 was added slowly in to the mixture with continous stirring. Neutralized the preparation by adding triethanolamine n to the preparation with constant stirring until the gel is formed. Carbopo 940 – Gelling Polymer, Triethanolamine- gelling agent, pH Adjusting agent, Neutralizer, Methyl Paraben – Preservative, Distilled Water, Ethanol, Glycerin and Polyethylene Glycol-solvents**.**

**Evaluation of fluconazole gel:**

**Appearance and consistency:** (Waghmare Nilkamal *et al.*,2011) Physical appearance was cheked visually for texture of transdermal gel formulations and observed.

**Washability** The designed formulation was applied on skin surface and then wash the drug and check the ease of wash manually and was observed.

**Extrudability determination of formulations (**Kumar Lalit *et al.,* 2010**)**

The hair gel formulations were filled into collapsible metal tubes or aluminium collapsible tubes. The tubes were pressed to extrude the material and the extrudability of the formulation was checked.

**Determination of Spreadability (**Niyaz Basha *et al*.,2011**)**

**Method:** Two glass slides of standard dimensions (6×2) were selected. The hair gel formulation whose spreadability has to be determined was placed over one of the slides. The second slide was placed over the slide in such a way that the formulation was sandwiched between them across a length of 6 cms along the slide. 100 grams of weight was placed up on the upper slide so that the hair gel formulation between the two slides was traced uniformly to form a thin layer.

The weight was removed and the excess of the hair gel formulation adhering to the slides was scrapped off. The lower slide was fixed on the board of the apparatus and one end of the upper slide was tied to a string to which a plastic jar/bottle is placed and dropwise water is added. The time taken for the upper slide to travel the distance of 6 cms and separate away from lower slide under the direction of the weight was noted. The experiment was repeated and the average of 6 such determinations was calculated for each hair gel formulation.

$$\text{Spreadability} = \frac{m.l}{t}$$

Where, S=Spreadability (gcm/sec)
m = weight tied to the upper slide (20 grams)
l= length of glass slide (6cms).
t = time taken is second.

**Determination of pH** (Helal A. Doaa *et al.,* 2012)

The pH of the transdermal gels were determined by digital pH meter. One gram of gel was dissolved in 25 ml of distilled water and the electrode was then dipped in to gel formulation until constant reading obtained. And constant reading was noted. The measurements of pH of each formulation were replicated two times.

**Viscosity (**Niyaz Basha *et al.*,2011**)**

Viscosity of the prepared gel was measured by using Brookfield viscometer . The viscosity was measured by using spindle no. 64 at 10rpm at $25^0$C . The sufficient quantity of gel was filled in appropriate wide mouth container. The gel was filled in the wide mouth container in such way that it should sufficiently allow to dip the spindle of the Viscometer.

Samples of the gels were allowed to settle over 30 min at the constant temperature ($25\pm/1^0$C) before the measurements.

**Drug content** (Helal A. Doaa *et al.,* 2012)

The drug content was determined by taking approx. 1 g of gel (equivalent to 10 mg of Fluconazole) was accurately weighed and dissolved in 10 ml volumetric flask diluted with Phosphate buffer 7.4PH. The above solution was suitably diluted and determined using UV – Visible spectrophotometer at 235.0 nm.

***In-vitro* Drug Release Studies Using the Prehydrated Cellophane Membrane**

**(**Waghmare Nilkamal *et al.*,2011***)***

**1. Preparation of cellophane membrane for the diffusion studies:**

The cellophane membrane approximately 25 cm x 2cm was taken and washed in the running water. It was then soaked in distilled water for 24 hours, before used for diffusion studies to remove glycerin present on it and was mounted on the diffusion cell for further studies.

**2. Diffusion Studies:**

*In-vitro* diffusion study of the drug from different formulation were studied by using classical standard cylindrical tube in laboratory , a glass tube of about 15mm diameter and 100mm in height. The diffusion cell membrane was tied in which 1gm of gel was placed at one end of the tube, the other end kept open to required conditions which acted as donor compartment. The cell was inverted and dipped slightly in 250 ml of beaker containing neutralizing Phosphate buffer, freshly prepared (7.4 pH as a receptor base and the system was maintained for 2 hrs at 37± 0.5º C. The media was stirred using magnetic stirrer. Aliquots, each of 5 ml volume were withdrawn periodically at predetermined time interval of 15, 30, 45, 60, 90, 120, 180, 240, 300, 360 min and replaced by an equal volume of the receptor medium. The aliquots were suitably diluted with the receptor medium and analyzed by UV-Visible spectrophotometer at 252 nm using neutralizing Phosphate buffer 7.4pH as blank.

## Results and Discussion

In the present study various parameter of Preformulation study performed for Fluconazole like Physiochemical Properties, Organoleptic property, Solubility, Identification Test by IR and melting point, Flow properties of fluconazole also performed like Bulk density, Compressibility index, Hausner ratio and Angle of Repose the result of flow properties fund satisfactory.

Solubility studies of Fluconazole have been done in various solvent such as water, Chloroform, Ethanol, Methanol, and 0.1N HCL solution. We were found that a solubility of Fluconazole is good in a Methanol solution.

On the basis of solubility results methanol select as a diluents because of drug is freely soluble in methanol. The drug obey the beers law between 50 to 90 µg/ml with correlation coefficient value 0.990 and regression equation found to be y = 0.002x + 0.006.

In the present research Fluconazole gel were prepared using various ingredient Carbapol 940, PEG, Ethanol, Preservative (Methyl paraben, Propyl Paraben), Smoothing agent (Glycerin), along with

trientholamine in different proportion. The prepared Fluconazole gel was evaluated for various parameters like Viscosity, pH, Spreadability, Washability, immobilization capacity and *in vitro* drug release. At last, the selected preparation was used as gel for topical use.In all the formulations washability and extrudability was found good and Spreadability found between 13 to 15 gcm/sec in all formulation.

pH of the prepared formulation was identified by using pH meter ,take 1gm of gel and dissolved in 100ml distill water and stand for two hours. Now the ph electrode was dipped in the prepared solution and measured the pH in triplet and finaly the average value is calculated.The pH of the fluconazole gel was found to be in the range of 7.0-7.3. This clearly indicates that the gel could mimic the pH of the skin and will not contribute to the irritation of skin.

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**Table No. 1.FormulationDevelopment**

| Ingredients (gm) | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|
| Fluconazole | 0.250 | 0.250 | 0.250 | 0.250 | 0.250 | 0.250 |
| Carbopol 940(gm) | 0.25 | 0.30 | 0.35 | 0.40 | 0.45 | 0.5 |
| PolyethyleneGlycol(gm) | 10 | 10 | 10 | 10 | 10 | 10 |
| Methyl Paraben(gm) | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 |
| Triethanolamine(ml) | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |
| Glycerin(ml) | 5 | 5 | 5 | 5 | 5 | 5 |
| Ethanol(ml) | 10 | 10 | 10 | 10 | 10 | 10 |
| Distilled Water(ml)(q.s) | 50 | 50 | 50 | 50 | 50 | 50 |

**Table No.2: Appearance and consistency, washability, extrudability of different formulation**

| S. No. | Formulation | Colour | Clogging | Homogenity | Texture | Washability | Extrudability |
|---|---|---|---|---|---|---|---|
| 1 | F1 | Clear | Absent | Good | Smooth | Good | Average |
| 2 | F2 | Clear | Absent | Good | Smooth | Good | Average |
| 3 | F3 | Clear | Absent | Good | Smooth | Good | Average |
| 4 | F4 | Clear | Absent | Good | Smooth | Good | Average |
| 5 | F5 | Clear | Absent | Good | Smooth | Good | Average |
| 6 | F6 | Clear | Absent | Good | Smooth | Good | Average |

**Table No. 3: Result Spreadability, pH, viscosity, drug content of Different Formulation**

| S. No. | Formulation | Spreadability (gcm/sec) | pH | Viscosity (cps) | % Drug Content* |
|---|---|---|---|---|---|
| 1 | F1 | 13.00±0.5 | 7.2±0.1 | 2560±0.52 | 84.7±0.21 |
| 2 | F2 | 13.00±0.4 | 7.0±0.1 | 3050±026 | 80.5±0.52 |
| 3 | F3 | 14.00±0.6 | 7.3±0.1 | 3565±0.49 | 89.3±0.36 |
| 4 | F4 | 15.00±0.4 | 7.2±0.2 | 4530±0.51 | 80.8±0.45 |
| 5 | F5 | 15.00±0.5 | 7.3±0.1 | 5431±0.86 | 80.1±0.25 |
| 6 | F6 | 15.00±0.21 | 7.0±0.2 | 6589±0.61 | 75.7±0.78 |

***Mean of three reading**

**Table No. 4: In vitro drug Drug release of optimized formulation**

| S. No. | Time (inhrs.) | Abs. | %DR | Correction Factor | %CDR |
|---|---|---|---|---|---|
| 1 | 0.5 | 0.121 | 28.4038 | 1.70423 | 28.4038 |
| 2 | 1 | 0.155 | 36.385 | 2.1831 | 38.0892 |
| 3 | 1.5 | 0.201 | 47.1831 | 2.83099 | 51.0704 |
| 4 | 2 | 0.255 | 59.8592 | 3.59155 | 66.5775 |
| 5 | 4 | 0.289 | 67.8404 | 4.07042 | 78.1502 |
| 6 | 6 | 0.355 | 83.3333 | 5.0000 | 94.8826 |

**Table No. 5: Correlation coefficient of Model fitting ($R^2$)**
**Results of Comparative Parameters of release study:**

| Formulation code | Correlation coefficient of Model fitting ($R^2$) | | | | Best fit model |
|---|---|---|---|---|---|
| | Zero order | First order | Higuchi matrix | Pappas kinetics | |
| F3 | 0.910 | 0.961 | 0.965 | 0.970 | (Pappas) |

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