



FORMULATION AND EVALUATION OF KETOKONAZOLE ANTI-DANDRUFF SHAMPOO

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ABSTRACT

Abstract shampoo is a hair care product that is use for cleansing of hair and nourishing them and making them protective against outer environment. It removes oil, dirt, dandruff and other particles. So basically ketoconazole shampoo helps for the treatment of dandruff and fungus in the scalp which is also called as seborrhoeic dermatitis. So we have made I formulation and compared with the marketed formulation danfree shampoo which is marketed by cipla. With comparison with that product our product shows similar results obtained by marketed product. So we can say our product got satisfactory results and also we have compared the results obtained with available parameters, Basically the ketoconazole shampoo we examined by checking its PH, viscosity, appearance, foam ability and foam stability, surface tension measurement, stability studies, Wetting time, percentage of solid content etc. and the shampoo has been formulated using ingredients like ketoconazole [API], PVP, Sodium metabisulphide, Sodium lauryl sulphate, Stearic acid, Methyl cellulose, EDTA, sodium hydroxide, amaranth color and water. more specifically the product we formulated is sulphate free.

INTRODUCTION

Shampoo is a hair care product use for cleansing of hair, removing dirt, making them strong and nourishing they are applied on the et scalp and and should be rinsed out after sometime. It is in the form of a viscous liquid Dandruff represents one of the most common dermatological skin conditions and is a chronic, non-inflammatory condition of the scalp that is characterized by excessive scaling of scalp tissue. Various antifungal agents are employed in hair care preparations for the treatment of dandruff. These products show many side effects such as loss of hair, increased scaling, itching, irritation, nausea, and headache.

Hence, an attempt was made to formulate synthetic anti- dandruff shampoo which is effective in terms of safety and treating the dandruff condition. Dandruff is apparently caused by a fungus called Malassezia restricted and Malassezia globosa Malassezia formerly called Pityrosporum is a yeast causing infection of skin and scalp. It often causes itching Warm and humid atmosphere, overcrowding, and poor personal hygiene are ideally suited for the growth of Malassezia Dandruff affects 5% of the population and mostly occurs after puberty, between 20 and 30 years and dandruff affects males more than females. Dandruff occurs exclusively on skin in areas with high levels of sebum. Symptoms of dandruff mainly include itching, flakes, and redness of scalp.

Dandruff can be treated in two ways, using herbal-based anti- dandruff shampoo and using chemical-based anti-dandruff shampoo. A shampoo is a preparation containing surfactant (ie, surface active material) in a suitable form - liquid, solid, or powder which when used under the specified conditions will remove surface grease, dirt, and skin debris from the hair shaft and scalp without adversely affecting the user. Most shampoos contain water, a detergent (cleaning agent), surfactant (lather making agent), salt, fragrance (natural and artificial), preservative, and food coloring. With the exception of water and salt (sodium chloride), different chemical compounds are used depending on the desired result of the shampoo. Many shampoos also contain vitamins and moisturizing alcohols to prevent too much of the hair and scalp's natural oils from being stripped away during cleansing

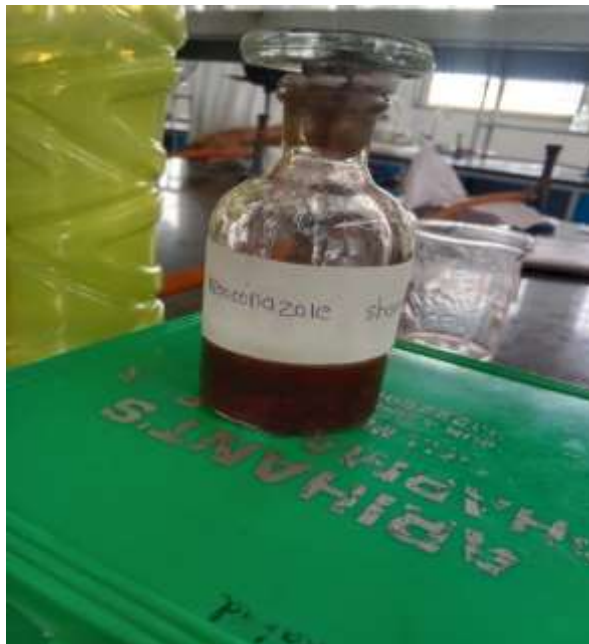


Fig.1. Ketokonazole Shampoo

Dandruff is a common scalp disorder affecting almost half of the population at the pre- pubertal age and of any gender and ethnicity. No population in any geographical region would have passed through freely without being affected by dandruff at some stage in their life. [2] The word dandruff (dandruff, dandriffe) is of Anglo-Saxon origin, a combination of 'tan' meaning 'tetter' and 'drof' meaning 'dirty'. Dandruff affects aesthetic value and often causes itching. It has been well established that keratinocytes play a key role in the expression and generation of immunological reactions during dandruff formation. [3] The severity of dandruff may fluctuate with season as it often worsens in winter. (4) Dandruff is a common scalp condition that occurs when dead skin is shed, producing irritating white flakes and possibly an itchy scalp. Ordinarily, dandruff results from excessive drying of skin and over.

Any substance which destroys or prevents the growth of fungi. It is one of the antibiotic groups. There are several classes of antifungal drugs: Polyenes, which cause an increase in fungal cell wall permeability leading to its death.

Examples: amphotericin B, natamycin, nystatin. Azoles, which act either by inhibiting the synthesis of ergosterol, a component of fungal cell wall or by causing direct wall damage. Examples: clotrimazole, econazole, fluconazole, itraconazole, ketoconazole, miconazole. Pyrimidines, which interfere with the normal function of fungal cells. Example: flucytosine. Syn antimycotic agent, 10-32]

• **CLASSIFICATION OF DANDRUFF**

Depending upon the symptoms the dandruff is classified into two main types

A] Dry Dandruff

- It is also called as pityriasis simplex characterize by excessive formation of minute scales which accumulate on the scalp area.
- In this type of dandruff there is no excessive hair loss. The inflammation on the skin is not observed.
- The scales are first found in middle of the scalp and then spread to frontal, parietal and occipital areas.

B] Oily Dandruff

- It is also called as pityriasis steatites.
- It arrives on the scalp with sebum production.
- It is mostly found in young men following puberty.
- Inflammation of varied intensity developed on the scalp along with oily scales of dirty yellow color.
- Hair fall is most commonly found in this condition.
- The most common site affected by this type of dandruff is scalp, behind the ears, over breast bone, armpits



ADVANTAGES

- Anti-dandruff shampoos often contain an activating moisturizer. These effective moisturizers work regularly to combat dryness while keeping the scalp healthy and hair beautiful.
- Anti-dandruff shampoo contains a zinc-based activator that can slightly relieve itching. They make your scalp brighter and give you complete comfort.
- Anti-dandruff shampoo has a sedative formula that gently relieves irritation while providing healthy hair without dandruff
- In addition to relieving irritation, anti-dandruff shampoo reduces redness. It makes a person's scalp feel great and their appearance is awesome.
- .Anti-dandruff shampoo is very suitable for controlling the oiliness of the scalp.

IDEAL PROPERTIES OF SHAMPOO

- Make your hair smooth and shiny.
- Produces a large amount of foam.
- 3 Do not irritate the scalp, skin or eyes.
- Dirt needs to be removed completely and effectively.
- Gives hair a pleasant scent.
- **Shampoo Features**
- Dirt and dirt need to be removed effectively and completely.
- You need to wash your hair effectively.
- It should not have any side effects or causes irritation to the skin and eye.

CLASSIFICATION OF SHAMPOO:

1. Based on Appearance

- Powder shampoo, Liquid shampoo or lotion shampoo, Gel shampoo or Solid shampoo, Oil shampoo, Cream shampoo

2. Based on Use or Function

- Conditioning shampoo Antidandruff shampoo.
Therapeutic shampoo Balancing shampoo, Baby shampoo 12-4
- Dandruff is a skin condition that mainly affects the scalp. Symptoms include flaking and sometimes mild itchiness. A more severe form of the condition, which includes inflammation of the skin, is known as seborrheic dermatitis

FACTORS THAT CAUSES DANDRUFF

- Skin oil, commonly referred to as sebum or sebaceous secretions
- The metabolic by-products of skin micro-organisms (most specifically Malassezia yeasts)
- Individual susceptibility and allergy sensitivity
- Scalp conditions
- Yeast overgrowth
- Less shampooing
- Underlying medical conditions
- Allergy)
- An antifungal medication, also known as an antimycotic medication, is a pharmaceutical fungicide or fungistatic used to treat and prevent mycosis such as athlete's foot, ringworm, candidiasis, serious systemic infections such as Cryptococci meningitis, and others.
Ketoconazole is antifungal of azole group it is a imidazole derivative of antifungal Agent .

- COMPOSITION OF SHAMPOOS**



The following are the ingredients used for the preparation of shampoos. They include three anti-dandruff agents such as ketoconazole, sodium lauryl sulfate as solubilizing agent, sequestering agent, sodium ethylenediaminetetraacetic acid (EDTA) as chelating agent, guar gum as foam stabilizing agent and thickening agent, tween 80, and distilled water as vehicle.

- FORMULATION:**

| Ingredients | F1 |
|------------------------|-------|
| Ketoconazole | 1 gm |
| Pvp | 5gm |
| Sodium lauryl sulphate | 40gm |
| Stearic acid | 1.25g |
| Methyl cellulose | 0.9g |
| EDTA | 0.1g |
| Sodium hydroxide | 0.5g |
| Rose water | 1ml |
| Amaranth colour | 0.3ml |
| Water | Qs. |

- MATERIAL AND METHODS**

METHOD: Firstly methyl cellulose to be taken which is used as a thickener and heating them by mixing it with deionised water, then it should be mixed with sodium lauryl sulphate stearic acid with the above solution. Then to the above solution sodium meta bisulfide were added, finally API Ketoconazole drug is mixed with above prepared solution, then the solution were allowed to cool for sometime at room temperature after that remaining ingredients i.e., EDTA, PVP, Fragrance, colourant were added. To balance the p^H sodium hydroxide was added, finally water was added to make upto 100ml



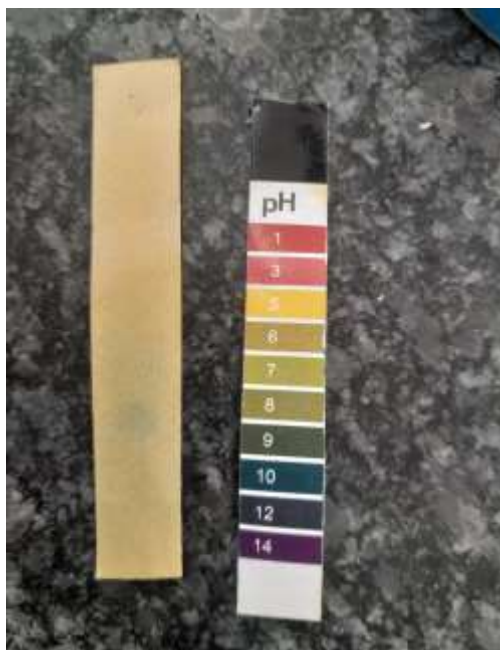
- **EVALUATION OF KETONAZOLE SHAMPOO**

- 1. **ORGANOLEPTIC PROPERTIES**

- i) colour: pink
- ii) Fragrance: sweet
- iii) Clarity: No greedy particle present
- iv) Physical appearance: No aggregate

- **pH DETERMINATION**

The ph of formulated anti-dandruff shampoo was determined using ph paper. Required amount of shampoo was added to 10ml of distilled water in this solution PH paper was dipped and colour change was noted/



- **DETERMINATION OF PERCENT OF SOLIDS**

Clean dry evaporating dish were taken & 4gms of shampoo was added & then dish was kept on hot plate to evaporate the liquid solution. After that solid contents were weighed & percent of solid were calculated A good shampoo will be between 20-30% solids





• **DIRT DISPERSION**

2 drops of shampoo were added to the test tube which was containing 10ml of distilled water, to this 1 drop of indian ink were added & shaken for ten times.

Amount of ink in the foam was noted Shampoo that causes the ink to concentrate in the foam is considered as of poor quality, the dirt should stay in water. The amount of ink in the foam was indicated by the rubric such as none, moderate, light or heavy



• **FOAM ABILITY & FOAM STABILITY**

Foam ability was determined using cylinder shake method. Briefly, 50 mL of the 1% commercial or formulated shampoo solution was placed into a 250 mL. graduated cylinder; it was covered with one hand and shaken 10 times. The total volume of the foam content after 1 min of shaking was recorded. Foam stability was evaluated by recording the foam volume after 1 min and 4 min of shake test





VISCOSITY MEASUREMENT

Viscosity was measured by using Brookfield viscometer



• SURFACE TENSION MEASUREMENT

It is measured using stalagnometer, 10% (10ml of shampoo in 100ml of distilled water) of shampoo solution was prepared thoroughly cleaned the stalagnometer with chronic acid & purified water (because surface tension is highly affected with grease & other lubricants)

Data was calculated by the following equation

$$R^2 = \frac{(W_3 - W_1)n_1}{(W_2 - W_1)n_2}$$

Where,

$W^* 1$ = Weight of empty beaker

$W^* 2$ = 1 Weight of beaker with distilled water

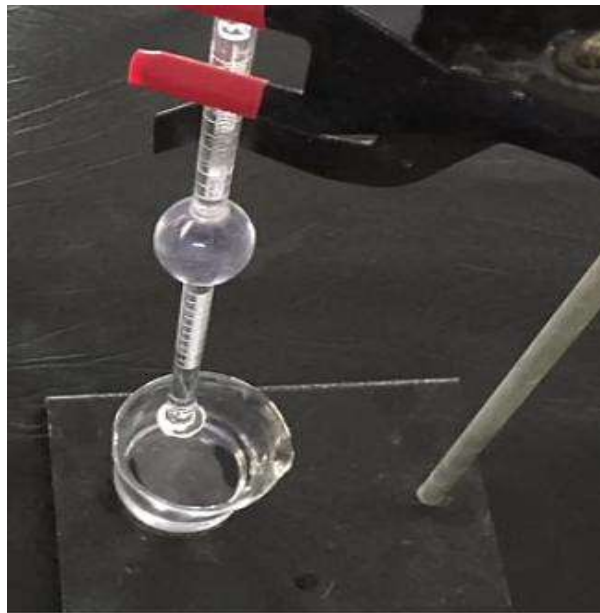
$W^* 3$ = Weight of beaker with shampoo solution

$n^* 1$ = number of drops of distilled water

$n^* 2$ = number of drops of shampoo solution

$R^* 1$ = surface tension of distilled water

$R^* 2$ = surface tention of shampoo solution





• WETTING TIME DETERMINATION

The canvas paper was cut into 1-inch diameter discs having an average weight of 0.44g. The smooth surface of disc was placed on the surface of 1% shampoo solution & the stop watch started. The time required for the disc to begin to sink was noted as wetting time



• STABILITY STUDIES

Stability studies is performed to check physical & chemical integrity of the formulation. The thermal stability of the formulated product studied by placing them in glass tubes in humidity chamber at accelerated 40 - 2 deg * C / 60 - 5% * Rh room temperature 25 - 2 ^ o * C / 75 - 5% * Rh the sample kept for stability was evaluated for their appearance, physical stability for a period of 1 month.

RESULT & DISCUSSION

The topical ketoconazole shampoo and conditioner was formulated using different ingredients such as Sodium metabisulphide, Sodium lauryl sulphate, Stearic acid, Methylcellulose, EDTA, Sodium hydroxide, Rosewater, Amaranth colour, Water & pvp was added as a conditioner. Stability studies were performed. The excipients along with the pure drug was found to be compatible when evaluated. Finally ketoconazole shampoo and conditioner were evaluated for PH, Dirt dispersion, percent of solid content, surface tension, foam ability & stability

CONCLUSION

Ketoconazole isazole group of drug used for treating fungal drug and treat dandruff caused by fungus. 1 formulations were prepared and characterization of formulation were carried out and compared with marketed (danfree) shampoo and shows similar results.

The PH values for ketoconazole shampoo formulation was found to be 8.5

The percent of solids contents was found to be 22% foam ability & foam stability was determined i.e., 70ml after and wetting time was observed as 30secs and Stability studies were carried out for a period of 1 month & it shows no significance changes in the characteristics of ketoconazole formulation.

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