

FORMULATION AND EVALUATION OF ANTIFUNGAL CREAM SHAMPOO USING
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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 seborrheic dermatitis. So, we have made 3 formulation and optimized the composition and compared with the marketed formulation (dan free) 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 metabisulfite, Sodium lauryl sulphate, Stearic acid, Methyl cellulose, EDTA, sodium hydroxide, amaranth colour and water. More specifically the product we formulated is sulphate free. Hence the prepared antifungal shampoo suits human scalp and can be therapeutic to alternative fungal infections.

KEYWORDS: Antifungal, ketoconazole, antifungal shampoo, fungal infections.

INTRODUCTION

- **Fungus:** any member of the group of eukaryotic organisms that includes organisms such as yeasts and molds, as well as the more complex mushrooms. These organisms are classified as one of the traditional eukaryotic kingdoms, along with Animalia, Plantae and either Protista^[4] or Protozoa and Chromista.
- **Seborrheic dermatitis (SD):** is a chronic skin condition that causes only, flaky, and sometimes itchy patches of skin. These patches often appear on the face, scalp, and chest, and are accompanied by dandruff-like flakes. Other symptoms include red skin, greasy skin, and sometimes inflammation, SD is non-infectious and is more common in men than women.
- **Alopecia:** also known as hair loss or baldness, is the loss of hair from the head or body. typically affecting the head. Hair loss can be temporary or permanent and can affect the entire body or just the scalp. It can be caused by heredity, hormonal changes, medical conditions, or aging.

Shampoo is a hair care product used for cleansing of hair, removing dirt, making them strong and nourishing they are applied on the scalp and should be rinsed out after some time. It is in the form of a viscous liquid. Shampooing is the most common form of hair treatment. Shampoos have primarily been products aimed at cleansing the hair and scalp.

- **Aim:** To prepare antifungal cream shampoo using ketoconazole anti-fungal drug.

ADVANTAGES

- Antifungal shampoos can treat fungal infections on the scalp and skin. They can help with conditions like dandruff, seborrheic dermatitis, psoriasis, tinea, versicolor, and ringworm.
- Antifungal shampoos can also help with folliculitis, which is a condition that causes inflamed hair follicles on the scalp.
- Antifungal shampoos work by killing or slowing the growth of the fungi that cause infections. They can

also help relieve symptoms like itching, flaking, and burning sensations.

DISADVANTAGES

- Skin irritation: Pimple-like bumps, burning, stinging, swelling, or redness.

- Hair changes: Discoloration, abnormal texture, loss of curl in permed hair, or hair loss
- Other: Itching, hives, hypersensitivity, dry skin, or alopecia

MATERIALS AND METHODS

DRUG PROFILE

Cytochrome P450 3A4, Cytochrome P450

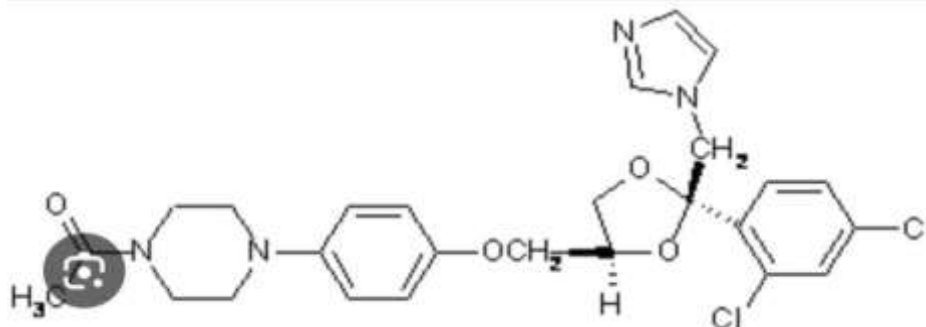


Figure No. 1: Ketoconazole.

KETOCONAZOLE

NATURE: Weak dibasic compound

MOLECULAR WEIGHT: 531.43

MELTING POINT: 146 DEG

BOILING POINT: 760 DEG

PH: 6.5-6.8

ORGANOLEPTIC PROPERTY

COLOR: Colorless crystal or powder

ODOUR: Fresh meadow

TASTE: extremely bitter

CHEMICAL CONSTITUTENTS

Ketoconazole is a synthetic antifungal agent with the chemical formula $C_{26}H_{28}Cl_2N_4O_4$ and the systematic name 1-(4-(4-(((2R,4S)-2-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl)methoxy)phenyl)-1-piperazinyl)ethanone.

It's synthesized from 2,4-dichlorophenacyl bromide and glycerol through a process called metallization. Ketoconazole is an imidazole derivative that inhibits the biosynthesis of ergosterol, a key component of fungal membranes. It's also an azole antifungal that works by inhibiting 3A5, and P-Glycoprotein.

USES

Ketoconazole is used to treat serious fungal or yeast infections, such as candidiasis (thrush, oral thrush), blastomycosis (Gilchrist's disease), coccidioidomycosis (Valley fever, San Joaquin Valley fever), histoplasmosis (Darling's disease), chromoblastomycosis (thrombocytosis), or Para coccidioidomycosis.

EXCIPIENTS PROFILE

1. GLYCERINE

Glycerine, also called glycerol, is a sugar alcohol used in foods, soaps, medicines, and skin products. You can get

pure glycerine from either plant or animal sources. This article explains some of the uses and benefits of glycerin and where you can get it. In food and beverages, glycerol serves as a humectant, solvent, and sweetener, and may help preserve foods. It is also used as filler in commercially prepared low-fat foods (e.g., cookies), and as a thickening agent in liqueurs. Glycerol and water are used to preserve certain types of plant leaves.^[15] As a sugar substitute, it has approximately 27 kilocalories per teaspoon (sugar has 20) and is 60% as sweet as sucrose. It does not feed the bacteria that form a dental plaque and cause dental cavities.[citation needed] As a food additive, glycerol is labeled as E number E422. It is added to icing (frosting) to prevent it from setting too hard.



Figure No. 2: Glycerine.

2. COLOR

Color plays a vital role in cosmetics marketing and can be used to achieve a variety of purposes:

- **Choice**

Color can give consumers a wide selection of shades to choose from, especially for products like nail polish and lipstick.

- **Attractiveness**

Color can make a product more appealing and help it stand out from the competition. For example, brands might use color-coding to differentiate their products from each other or from their competitors' products.

- **Packaging**

Color can complement the packaging of a product.

- **Coloring**

Colorants can be added to cosmetics to color the product itself or to tint the skin of the user.



Figure No 3: Colors.

3. PRESERVATIVES



Figure No. 04.

Preservatives in cosmetics and personal care products help prevent contamination and the growth of harmful bacteria in products ranging from sunscreens, lotions and shampoos to cleansers, toothpaste and makeup.

Antimicrobial preservatives in cosmetics and personal care products help prevent the growth of molds, yeasts and bacteria, guarding against contamination that can cause irritation or infections. Antioxidant preservatives also can help keep personal care products from spoiling

by suppressing reactions that can occur when certain ingredients in a cosmetic or personal care product combine with oxygen in the presence of light, heat and some metals.

Table no. 01: Preparation of Antifungal Cream Shampoo Using Ketoconazole.

SNO	INGREDIENTS	QUANTITY
1.	Sodium lauryl sulphate	3.8gm
2.	Acetyl alcohol	0.7g
3.	Water	50ml
4.	Glycerine	2ml
5.	Ketoconazole	3gm
6.	Color, perfume, preservatives	Q.s

METHOD OF PREPARATION

- Firstly SLS was to be taken and weighed and it was in a powder form.
- Take acetyl alcohol, weighed it accordingly to the given quantity
- Add 50ml of water to make the quantity of the shampoo.
- Take glycerine as required and add the drug used which is ketoconazole
- Dissolve it in a glycerine and some essential oils if you want
- Dissolve the Ketoconazole in a glycerine by keeping it on the water bath at a given temperature
- Add Ketoconazole in the above mixture and the consistency of the shampoo should be in a cream base
- Then add color, perfume, preservatives and stir it until smooth
- After the shampoo is ready to go for the evaluation and required quality control test.

EVALUATION OF ANTIFUNGAL CREAM SHAMPOO (KETOCONAZOLE)

1. ORGANOLEPTIC PROPERTIES

Colour: faint orange

Fragrance: sweet

Clarity: smooth & cream

2. PH

The pH of shampoos has been shown to be important for improving and enhancing the qualities of hair, minimizing irritation to the eyes and stabilizing the ecological balance of the scalp 10. The current trend to promote shampoos of lower pH is one of the ways to minimize damage to the hair.

3. FOAM AND FOAM STABILITY

Ross-Mile's foam column test is accepted. 200 ml of surfactant solution is dropped into a glass column containing 50ml of the same solution. The height of the foam generated is measured immediately and again after a specified time.

4. ISCOSITY

Viscosity of the liquid shampoo is determined using a Brookfield viscometer 100 mL of the shampoo is taken in a beaker and the spindle is dipped in it for about 5 min and then the reading is taken.

5. DIRT DISPERSION

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

Amount of ink 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

6. WETTING TIME DETERMINATION

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

7. 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 \pm 2°C/60 \pm 5% Rh, at room temperature 25 \pm 2°C/ 75 \pm 5% Rh. the sample kept for stability was evaluated for their appearance, physical stability for a period of 1 month.

RESULT AND DISCUSSION

1. ORGANOLEPTIC PROPERTIES

COLOR: FAINT ORANGE ODOUR: PLEASANT
APPEARANCE: CREAM AND SMOOTH

2. MEASUREMENT OF PH

The ph. of antifungal cream shampoo was near to neutral ph. that is 5.5 this would not cause any irritation to hairs, reduces dandruff.

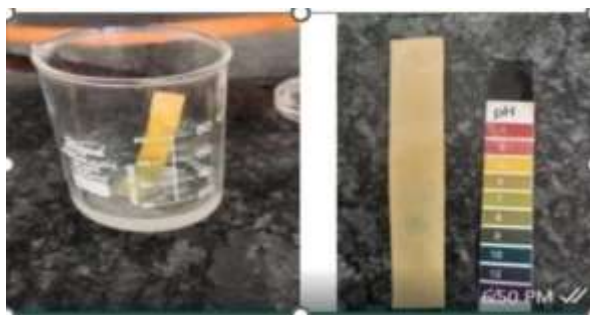


Figure No. 05.

3. FOAM AND FOAM STABILITY

Foam ability was determined using cylinder shake method. Briefly, 50 mL of the 1% commercial or formulated shampoo solution was placed into 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.



Figure No. 06.

4. Iscosity Measurement



FIGURE NO: 07.

Viscosity was measured using Brookfield viscometer.

5. DIRT DISPERSION

It is determined by taking 2 drops of shampoo plus conditioner in 10ml of distilled water to which 1 drop of Indian ink was added. Amount of ink in the foam was noted as none.

6. SURFACE TENSION MEASUREMENT

It is measured using a stalagmometer. Data was calculated by the following equation $n1 \times R1$
(W2-W1) n2

Were,

W1=Weight of empty beaker

W2=Weight of beaker with distilled water W3=Weight of beaker with shampoo solution n1= number of drops of distilled water

n2= number of drops of shampoo solution R1= surface tension of distilled water R2= surface tension of shampoo solution

7. WETTING TIME DETERMINATION

It is determined using canvas paper (1 inch in diameter & avg weight of 0.44g). The time required for the disc to begin to sink was noted as wetting time 45secs.

8. STABILITY STUDIES

The selected formulation was stored at 25 \pm 2°C/65 \pm 5% RH, 40 \pm 2°C/75 \pm 5% RH, for a period of

1 month. The sample kept for stability was evaluated for PH, visual appearance, foam ability & stability, wetting

time. All the parameters were found to be within limits after 1 month.

Table No. 02.

S.no	Duration	Wetting time(secs)		Visual appearance		Wetting time		Foam ability	
		25±2°C/ 65±5% RH	40±2°C/ 75%±5 %RH	25±2°C/ 65±5% RH	40± 2°C/75% ±5%RH	25±2°C/ 65±5% RH	40±2°C/75 %±5%R H	25±2°C /65±5% RH	40± 2°C/75%±5 %RH
1	1days	6.5	6.4	No visual changes	No visual changes	32secs	30secs	68ml after 1min	65ml after 1min
2	30days	6.3	6.3	No visual changes	No visual changes	28secs	31secs	72ml after 1min	70ml after 1min

CONCLUSION

Ketoconazole is azole group of drugs used for treating fungal drug and treat dandruff caused by fungus. 1 formulation was prepared, and characterization of formulation were carried out and compared with marketed (dan free) shampoo and shows similar results. The PH values for ketoconazole shampoo formulation was found to be 8.5The 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.

CONFLICT OF INTERESTS

Declared none.

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