

Formulation and Evaluation of Ketoconazole Shampoo

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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 seborrhoeic dermatitis. So we have made 1 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 metabisulfite, Sodium lauryl sulphate, Stearic acid, Methyl cellulose, EDTA, sodium hydroxide, amaranth color and water. more specifically the product we formulated is sulphate free.

Index Terms: ketoconazole, antidandruff, conditioner, seborrhoeic dermatitis, malassezia yeast.

1.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 should be rinsed out after sometime. It is in the form of a viscous liquid ^[1].

2.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 ^[2-4]

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 seborrhoeic dermatitis ^[5]

3.FACTORS THAT CAUSES DANDRUFF

- 1.Skin oil, commonly referred to as sebum or sebaceous secretions
- 2.The metabolic by-products of skin micro-organisms (most specifically *Malassezia* yeasts)
3. Individual susceptibility and allergy sensitivity

1. Scalp conditions
- 2.Yeast overgrowth
3. Less shampooing
- 4.Underlying medical conditions
5. Allergy ^[6].

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 cryptococcal meningitis, and others.

Ketoconazole is antifungal of azole group , it is a imidazole derivative of antifungal agent ^[7]

Materials used: *Digital balance [Wensar weighing scales Ltd] , Humidity chamber[Humidity chamber], Brookfield viscometer [Brookfield] . ^[8]*

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.

INGREDIENTS	F1	M1
Ketoconazole	1gm	COMOPARISIO N WITH THE MARKETED FORMULATION DANFREE SHAMPOO MARKETED BY CIPLA
PVP	5g	
Sodiummetabisulfite	0.1g	
Sodium lauryl sulphate	40g	
Stearic acid	1.25g	
Methyl cellulose	0.9g	
EDTA	0.1g	
Sodium hydroxide	0.5g	
Rose water	1ml	
Amaranth colour	0.3ml	
Water	Qs	

Table1: Formulation composition of respective ketoconazole shampoo

4.EVALUATION OF KETONAZOLE SHAMPOO

1.ORGANOLEPTIC PROPERTIES:

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

2.P^H 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^[9]

3.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^[9]

4. 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^[9]

5. 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^[9]

5. VISCOSITY MEASUREMENT:

Viscosity was measured by using Brookfield visometer^[9]

6. 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^[9]

$$R2 = \frac{(W3 - W1) n1}{(W2 - W1) n2} \times R1$$

Where,

- 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 tention of shampoo solution

7.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 stop watch started. The time required for the disc to begin to sink was noted as wetting time^[9]

8. 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°C/60±5%Rh, at room temperature 25±2°C/75±5%Rh. the sample kept for stability was evaluated for their appearance, physical stability for a period of 1 month.⁽¹⁰⁾

RESULT AND DISCUSSION

VALUES OF FORMULATED PRODUCT

1 Organoleptic properties

Colour	Odour	Appearance
Pink	Sweet	No aggregates

VALUES OF MARKETED PRODUCT

1 Organoleptic properties

S.no	Parameter	Drug
1	Colour	White
2	Odour	Sweet
3	Clarity	No greedy particles were present

2. Ph Determination

F1	M1
6.5 ± 0.2	5.5 ± 0.2

Table 3: pH of Ketoconazole shampoo

3. DETERMINATION OF PERCENT OF SOLIDS

F1	M1
22 %	21 %

Table 4: determination of percent of solids

4. 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.

In formulated and marketed product none of them shows dirt.

5 Viscosity measurement:

The viscosity evaluated for the prepared formulation was found to be 30,750cps

6. FOAM ABILITY & FOAM STABILITY:

It is determined by using cylinder shake method

F1	M1
70ml after 1mins	108ml after 1mins

Table 5: Foam ability and stability

7. SURFACE TENSION MEASUREMENT

F1	M1
5.01dynes/cm	4.273dynes/cm

Table 6: surface tension measurement

8. WETTING TIME DETERMINATION

F1	M1
30 Secs	45secs

Table 7: WETTING TIME DETERMINATION

9. Solubility studies of ketoconazole :

Solvent	Solubility
Water	Slightly soluble
Ethanol	Soluble
Dimethyl formamide(DMF).	Soluble

Table no.8 solubility of ketoconazole drug

10. STABILITY STUDIES:

The selected formulation was stored at 25±2°C/65±5%RH, 40±2°C/75±5%RH,for a period of 1 month. The sample kept for stability was evaluated for P^H, visual appearance, foam ability & stability, wetting time. All the parameters were found to be within limits after 1 month.

S.no	Duration	PH		Visual appearance		Wetting time(secs)		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%RH	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

Table 9 : stability studies

Discussion- The topical ketoconazole shampoo and conditioner was formulated using different ingredients such as Sodium metabisulfite, 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

5.CONCLUSION

Ketoconazole is azole 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 shamp formulation was found to be 6.5

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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