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Formulation, Development and Evaluation of Anti-Dandruff Shampoo using Piroctone Olamine

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ABSTRACT

The aim of this study was to formulate and develop anti dandruff shampoo by determining the antifungal activity of Piroctone olamine as well by agar diffusion method based on zone of inhibition. Piroctone olamine, also known as Octopirox and piroctone ethanolamine, is a compound reported to be used in the treatment of fungal infections. Piroctone olamine is the ethanolamine salt of the hydroxamic acid derivative piroctone. In this study, shampoo was formulated using various concentrations of Piroctone olamine. Piroctone olamine and shampoo formulations containing Piroctone olamine were evaluated for antifungal activity against Malassezia furfur (1374) and Candida albicans. The results showed that Piroctone olamine and shampoo formulation containing Piroctone olamine is effective against the microorganisms responsible for dandruff.

Keywords*: Dandruff, Piroctone olamine*

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INTRODUCTION

Dandruff

Dandruff represents a common scalp disorder affecting half of the world's population regardless of gender or ethnicity [1]. In recent days, many people are facing problems due to dandruff. Dandruff causes lots of problems such as itching, scaling, irritation etc. Due to dandruff, hair fall occurs giving a dull and diminish look to the hair. Microorganisms such as *Malassezia furfur* 1374 and *Candida albicans* are mainly responsible for the formation of dandruff [2].

Piroctone Olamine

Piroctone olamine, also known as Octopirox and piroctone ethanolamine, are compounds reported to be used in the treatment of fungal infections [3]. Piroctone olamine is the ethanolamine salt of the hydroxamic acid derivative of piroctone [4].

Piroctone olamine is a white crystalline powder, having the empirical formula, $C_{14}H_{23}NO_2 \cdot C_2H_7NO$ and molecular weight of 317.7 g/mol. Its chemical name is 1-Hydroxy-4-methyl-6- (2, 4, 4-trimethylpentyl) 2-(1H) pyridinone, 2-aminoethanol salt. Its pH ranges from 8.5-10.0 (for a 1% suspension in water, at 20°C) and the temperature range for melting is 130-135°C. It is freely soluble in 10% ethanol in water; soluble in solution containing surfactant in water or in 1%- 10% ethanol; slightly soluble in water and in oil. It can be used up to 1.0% in various cosmetic preparations [5]. With reference to literature survey, in this study,

an attempt has been made to evaluate the anti-fungal property of Piroctone olamine against *Candida albicans* and *Malassezia furfur 1374.*

MATERIALS AND METHODS

Physical and Chemical Analysis of Piroctone Olamine

Piroctone olamine was procured from Yasham Bio-Science Pvt. Ltd., 401, Satya Dev, Veera Industrial Estate, Off. Veera Desai Road, Andheri (W.) Mumbai-400053 (India), along with a certificate of analysis; it was analyzed by the methods recommended by IP.

The procured sample was validated by performing the following tests, such as colour, odour, pH, melting point, solubility, residue on ignition %, and % purity. The results were compared with values mentioned in Certificate of Analysis of Piroctone olamine. The results are summarized in (Table 1).

Antimicrobial Analysis of Piroctone Olamine

Piroctone olamine was subjected to *in-vitro* testing by using well agar-diffusion method to evaluate its anti-fungal activity against *Candida albicans* and *Malassezia furfur 1374.* This method is based on zones of inhibition and gives the efficacy of antifungal agents [6]. The cultures of *Candida albicans*and *Malassezia furfur 1374* were subcultured and grown in a suitable growth medium.

For screening, 1 gm % sample solution of Piroctone olamine was prepared by using sterile distilled water, and was poured in the wells made by using sterile cork borer of diameter 8mm, at the centre of petriplates, seeded with *Candida albicans* and *Malassezia furfur 1374.* The plates were then incubated. For *Candida albicans* incubation was done at 37^0c for 48 hours and for *Malassezia furfur 1374* incubation was done at room temperature for 7 days. For each species one plate was kept as blank, in which only distilled water was poured.The zone of inhibition of Piroctone olamine against *Candida albicans,* and *Malassezia furfur 1374* were measured and are given in (Table 2).

Formulation and Development of Anti Dandruff Shampoo with Varying Concentrations of Piroctone Olamine

Synthetic detergent based shampoo was formulated using different concentrations of Piroctone olamine as 0.1%, 0.2%, 0.3%, 0.4% and 0.5% in formulation 1, 2, 3, 4 and 5 respectively as shown in (Table 3).

Analysis of the Finished Product as per Indian Standards [7]

All the shampoos containing 0.1%, 0.2%, 0.3%, 0.4%, and 0.5% of Piroctone olamine were subjected to analysis as per the specifications given in Indian Standards (BIS 7884: 1992).The results are summarized in (Table 4).

Antimicrobial Analysis of Shampoo

For screening, 1 gm % sample solution of each shampoo was prepared by using sterile distilled water, and was poured in the wells made by using sterile cork borer of diameter 8 mm, at the centre of petriplates containing *Candida albicans* and *Malassezia furfur 1374.*, The plates were then incubated (for *Candida albicans* at 37^0c for 48 hours and for *Malassezia furfur* at room temperature for 7 days). For each species one plate was kept as blank, in which only distilled water was poured.The zone of inhibition of shampoo formulations against *Candida albicans* and *Malassezia furfur 1374* were measured and are given in the (Table 5).

Accelerated Stability Study

The objective of accelerated stability studies is to predict the shelf life of a product by accelerating the rate of decomposition, preferably by increasing the temperature [8]. The evaluation employs a combination of tests. This method of evaluation not only indicates

the stability of base formulation, but also indicates the stability of functional ingredient s [9]. For the shampoos containing all concentrations of Piroctone olamine, the accelerated stability studies were carried out for 3 months. The samples were kept at room temperature, refrigerator and oven temperatures, for the observation of changes in colour, odor, pH, viscosity and foam height.

Table. 1. *Analytical test observation for piroctone olamine.*

Sr. No.	Test	Specification	Results	Inference
1	Colour	White to Creamish	Complies	Passes test
2	Odour	To match Std.	Complies	Passes test
3	pH (1% Solution)	8.5 - 10.0	9.48	Passes test
4	Melting Point	130 - 136 ˚C	133.7 ˚C	Passes test
5	Solubility	Freely soluble in 10% ethanol, Slightly soluble in water, completely soluble in surfactant solution	Clear Solution	Passes test
6	Residue on Ignition (%)	Max. 0.1	0.065%	Passes test
7	Purity (%)	98.0 – 101.5%	99.49%	Passes test

Table 2. *Antimicrobial test observation for zone of inhibition (in mm).*

Sr. No.	Microorganism	Concentration of Active	
		0% (Blank)	1%
1	*Candida albicans*	00 mm	12 mm
2	*Malassezia furfur1374*	00 mm	13 mm

Table 3. *Formulation of antidandruff shampoo with varying concentrations of piroctone olamine.*

Sr. No.	Ingredients	Quantity in % (w/w)				
		Base + 0.1% Active	*Base + 0.2% Active*	*Base + 0.3% Active*	*Base + 0.4% Active*	*Base + 0.5% Active*
Phase A						
1	Distilled Water	49.5	49.4	49.3	49.2	49.1
2	Sodium Lauryl Ether Sulfate	25	25	25	25	25
3	Coco amido propyl betaine	3.5	3.5	3.5	3.5	3.5
4	Coco diethanol amide	2.5	2.5	2.5	2.5	2.5
5	Sodium chloride	0.5	0.5	0.5	0.5	0.5
Phase B						
1	Coco monoethanol amide	3.5	3.5	3.5	3.5	3.5
2	Ethylene glycol monostearate	2.3	2.3	2.3	2.3	2.3
3	Sodium lauryl Ether Sulfate	10	10	10	10	10
4	Propylene glycol	2.5	2.5	2.5	2.5	2.5
Phase C						
1	Phynoxyethanol	0.5	0.5	0.5	0.5	0.5
2	Ethylene diamine tetraacetic acid	0.1	0.1	0.1	0.1	0.1
3	Piroctone olamine	0.1	0.2	0.3	0.4	0.5

Table 4. *Common analytical results of antidandruff shampoo (initial at 0 days).*

Sr. No.	Characteristics	Requirement as per BIS	Base + 0.1% Active	Base + 0.2% Active	Base + 0.3% Active	Base + 0.4% Active	Base + 0.5% Active
1	Non-volatile alcohol soluble matter, percent by mass, min.	10	14.82	14.88	14.86	14.96	14.94
2	Active detergent content, as SLES of its equivalent, percent by mass, min.	5	18.93	19.67	19.61	20.57	20.69
3	pH at 27 ± 2 ˚C	5.0 to 9.0	7.45	7.56	7.88	8.27	8.59
4	Foam Height for 1% solution, min.	150 mm	270	270	273	272	273
5	Viscosity at 25 ˚C (in cps)	-	2420	2410	2420	2440	2440

Table 5. *Observation for zone of inhibition (in mm).*

Sr. No.	Microorganism	Concentration of Active in shampoo					
		Blank	0.10%	0.20%	0.30%	0.40%	0.50%
1	*Candida albicans*	0 mm	9mm	9 mm	10 mm	11 mm	11 mm
2	*Malassezia furfur*	0 mm	10mm	10 mm	11mm	12mm	12 mm

Subjective Evaluation

Anti-dandruff shampoo containing 0.4% Piroctone olamine was given to 10 subjects for 8 weeks to carry out the subjective evaluation on the basis of their feedback. These subjects were asked to use the shampoo twice a week for 8 such weeks. The changes they observed on the scalp before and after the use of shampoo were noted. Subjective evaluation was carried out on the basis of the parameters like color, odor, cleansing effect, foaming effect, rinse off, irritation, hair fall, conditioning and antidandruff activity.

RESULTS AND DISCUSSION

From the antimicrobial test of Piroctone olamine, it was observed that Piroctone olamine is effective against *Candida albicans* and *Malassezia furfur 1374.* Shampoo formulations containing 0.4% and 0.5% of Piroctone olamine showed same zones of inhibition against *Candida albicans* and *Malassezia furfur 1374.* Hence, shampoo containing 0.4% concentration of Piroctone olamine was selected for further study of the shampoo. From the results of accelerated stability study and antimicrobial analysis of antidandruff shampoo, it was found that the shampoo containing 0.4% Piroctone olamine was stable and effective with respect to colour, odor, pH, viscosity, foam height and antidandruff activity. Hence, the shampoo containing 0.4% Piroctone olamine was selected for further subjective evaluation. From the results of subjective evaluation, it was observed that shampoo containing 0.4% Piroctone olamine was well appreciated. It showed good antidandruff effects along with excellence in terms of appearance, foaming, rinse off, cleansing and conditioning properties.

CONCLUSION

It can be concluded that the shampoo formulation containing 0.4% Piroctone olamine was acceptable in view of appearance, foaming, rinse off, cleansing, conditioning and antidandruff properties. Piroctone olamine is an effective antidandruff agent, and hence can prove to be beneficial for incorporation in antidandruff preparations.

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