

DEVELOPMENT AND EVALUATION OF ANTIFUNGAL SOAP WITH HERBAL ANTIBACTERIAL PROPERTIES

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ABSTRACT

Herbal products have become increasingly important worldwide in medical and economic terms. Antifungal herbal antibacterial soap of Luliconazole were prepared & evaluated for dermal infection along with the addition of the oils and the extract of *Azadirachta indica*, *Ocimum tenuiflorum*, *Aloe barbadensis miller*, *Santalum album*. The API used for the preparation of antifungal herbal antibacterial soap belongs to the antifungal class of azoles, inhibits the enzyme lanosterol demethylase, which is required for the production of ergosterol, which is a major component of the fungal cell membrane. It is mainly used in the treatment of skin infections such as athlete's foot, jock itch, and ringworm. The physicochemical parameters of formulations (Physical evaluation, pH, Foaming ability and foam stability) were determined. The results showed that the formulation have pH level nearly equal to skin pH, foaming index was excellent. The % drug release, % drug content, % solid content and microbial study was performed for API.

Keywords: Luliconazole, Herbal soap, Aloe Vera, Dermal infections

INTRODUCTION:

Luliconazole is an azole antifungal that works by preventing the growth of the fungus.^[1]

The skin diseases are common among all age groups and can be due to exposure towards microbes, chemical agents, biological toxin present in the environment, and also to some extent due to malnutrition^[2]. Fungal infections are contagious and spread easily just close contact or sharing a comb or hairbrush with the infected person. They can be controlled in their initial stage by proper medications^[1]. In this research the herbal medicated soap containing API, aloe vera gel, sandalwood oil, Neem oil, and Tulsi oil has shown the antibacterial and antifungal activity.

Sandalwood (*Santalum album*)

Sandalwood essential oil has many traditional uses. For centuries, East Indian sandalwood oil has been a popular ingredient in Ayurvedic medicine, the folk medicine of India. It's also

been used in Traditional Chinese Medicine (TCM). Sandalwood essential oil is found in many perfumes and air fresheners. ^[3]

Tulsi (*Ocimum tenuiflorum*)

Tulsi has a great medicinal value mainly for diabetes and severe acute respiratory syndrome. Also, Tulsi plays key role in reducing stress, enhance stamina, relief inflammation, and also shows anti-fungal activity. ^[4]

Neem (*Azadirachta Indica*)

“Sarva Roga Nivarini - the curer of all ailments” Role of *Azadirachta Indica* is as a wonder drug is stressed as far back as 4500 years ago. Some of its health restoring benefits Effective in skin infection, rashes & pimples, Immunity booster, Anti-obesity, Blood purifier for beautiful & healthy skin, Anti diabetic, Anti-viral, Dispels intestinal worms and parasites, Malaria, Piles, Hair disorder & Oral disorders. ^[5]

Ghiu Kumari (*Aloe Vera*)

Aloe Vera is a most ingenious mixture of an antibiotic, an astringent coagulating agent, a pain inhibitor and a growth stimulator (also called a “wound hormone”), whose function is to accelerate the healing of injured surfaces. It is used for pain relief and healing of haemorrhoids, applied externally and internally it is also used for sunburn, scratch and a cleansing purge for the body or skin. It is an aid to growing new tissue and alleviating the advance of skin cancer caused by the sun. ^[6]

MATERIALS AND METHODS:

Plant Materials

All the plant materials were collected from local herbal retail shops of Chinchwad (Pune).

Chemicals

The drug Luliconazole used was gift sample from Emcure Pharmaceuticals, Hinjewadi, Pune. Sodium carboxy methyl cellulose, Carbopol 934, Methyl Paraben, Propyl Paraben, Propylene glycol, Triethanolamine, Glycerine, Ethanol, Sodium lauryl sulphate (SLS), Stearic Acid, NaOH etc. All the above chemicals are of laboratory grade chemicals from college laboratory SJVPM's Rasiklal M. Dhariwal Institute of Pharmaceutical Education and Research, Chinchwad Pune.

Preparation of aloe vera gel:

The leaves of Aloe Vera were collected washed with water, the thick epidermis was selectively removed and the inner gel-like pulp in the centre of the leaf was separated with a spoon, minced, and homogenized in a mixer. ^[6,7]



Fig No. 02- Prepared Aloe- Vera gel.

Formulation of Antifungal Herbal Antibacterial Soap:

All the ingredients were weighed accurately as mentioned in formulation table. Firstly, Lye solution was prepared by mixing NaOH with deionised water in a beaker. Then other ingredients like Propylene glycol, Vegetable glycerine, 95% ethanol, SLS, were mixed with stirring rod at melted in a beaker using a digital hot plate with the maximum temperature to 60°C until homogenous mixture is attained. After attainment of the temperature stearic acid was added and temperature was raised up to 68°C then slowly and with constant stirring 1:1 lye solution was added to the above mixture with stopping and starting stirring unless and until the solution gets clear appearance. Additionally, required quantity of *Azadirachta indica* oil, *Ocimum tenuiflorum* oil, *Aloe barbadensis miller* gel, *Santalum album* oil and the API was incorporated in it and then were mixed vigorously in the above mixture and the desired volume was taken up. Post the complete solution was kept to settle at the maximum temperature of 68°C for 1 hour. Then slowly triethanolamine was added and was poured into soap moulds just before pouring glycerine was applied over the mould with cotton and the moulds were kept in ice bath aside for about an hour in cool and dry place indirect to sunlight till it hardens and was used after 48 hours after keeping at room temperature for stability and analytical testing.^[8]

Sr. No.	Ingredient	Quantity (%)
01.	Drug	1%
02.	Propylene Glycol	18.80%
03.	Glycerine	6.27%
04.	Ethanol	20%
05.	Sodium Lauryl Sulphate	30.23%
06.	Steric Acid	12.99%
07.	Sodium Hydroxide	1.6%
08.	Triethanolamine	2.49%
09	DMSO	1%
10.	Aloevera Gel Extract	2%
11.	Tulsi Oil	1%
12.	Neem Oil	1%
13.	Sandalwood Oil	1%
14.	Water	q.s.

Table no. 01- Composition of Antifungal Herbal Soap



Fig No. 02- Formulate Anti-Fungal herbal Anti-Bacterial Soap.

Evaluation of Antifungal Herbal Antibacterial soap:

The prepared medicated herbal soap was evaluated for weight gain, Foam test, pH, in vitro drug release; Microbial studies have been done by using microorganism like *c. albicans*. The % Drug content is measured by using UV spectroscopy at λ_{\max} 296 nm.

Physical Evaluation:

Size and shape:

Rectangular shaped soap- The size and shape were randomly selected as it was convenient and it was also similar to that of commercially available soap.

Physical parameters such as colour and appearance were checked.^[9]

Measurement of pH: The pH of 10% formulated product solution in distilled water was determined at room temperature 25°C.^[10]

Determination of percent of solids contents:

A clean dry evaporating dish was weighed and added with a small piece of formulated herbal soap to the evaporating dish. The dish and formulated product were weighed. The exact weight of the formulated medicated herbal soap was calculated only and put the evaporating dish with formulated products were placed on the hot plate until the liquid portion was evaporated. The weight of the formulated product only (solids) after drying was calculated.^[2]

Foaming ability and foam stability:

Cylinder shake method was used to test for the foaming ability. 50 ml of the 1% formulated soap solution was placed into a 250 ml graduated cylinder, covered with one hand and shaken for 10 times. After 1 min of shaking, the total volume of the foam content was recorded. Foam stability was valued by recording the foam volume after 1 min and 4 min of shake test.^[1]

% Drug release:

In vitro drug release of the drug from prepared soap was studied by using Franz diffusion cell. Prehydrated Cellophane paper was used as a membrane in this study. The study was done by using phosphate buffer Ph 7.4 media. The samples were collected at the interval of 3 min for a period of 30 min. The drug content was estimated by measuring the absorbance at 296 nm.^[12]

Percentage Drug content: The small piece of soap is dissolved in 100 ml of phosphate buffer Ph 7.4 by stirring it with magnetic bead and estimated spectrometrically at 296 nm.^[11]

Microbial study:

Microbial study has been done using microorganisms such as *c. albicans*. For measuring the effectiveness of an antimicrobial agent against fungi/bacteria grown in culture, the microorganism of interest was swabbed uniformly across a culture plate. Then a soap solution was poured on the surface of the agar. Then the plates were placed in incubator for 24 hrs at 30 °C. The drug diffuses out from the soap into the agar. The concentration of the compound will be higher near the solution.^[13]

Results and Discussion**Evaluation of Herbal Soap:**

Physical Appearance/Visual Inspection: The results of visual inspection of series of formulations are listed below. As can be seen, herbal medicated soap had the good characteristics with respect to foaming.

pH: The pH of Herbal Soap has been shown to be important for minimizing irritation to the eyes and stabilizing the ecological balance of the skin Soap was acid balanced and were ranged around 7.2, which is near to the skin pH.

Percent of Solids Contents: If the Soap have too many solid contents it will be very hard to work too hard to wash out. The result of percent of solids contents is tabulated was found around 25.05%. Hence, they were easy to wash out.

Sr. No.	Parameters	Observation
01.	Colour	White
02.	Transparency	Transparent
03.	Odour	Good
04.	pH (10% solution)	7.2
05.	Percentage of solid contents	25.05%
06.	Foam Producing ability	Yes
07.	Foam Volume(ml)	7 ml
08.	Foam Type	Small, compact, Thick& uniform
09.	Foam Stability	Good
10.	Percent Drug content	55.320%
11.	Drug release	81.113%

Table no. 02- Evaluation of Antifungal Herbal Antibacterial Soap

Solubility Study of the Drug:

According to USP 2009, Luliconazole is slightly soluble in ethanol and very slightly soluble in water, in dil. acids and most organic solvents. Solubility study of drug sample was studied

in different types of solvent and data shows that drug was very sparingly soluble in methanol, soluble in phosphate buffer (pH-7.4) and freely soluble in rest of another solvent and insoluble in water.

Sr. No.	Solvent	Solubility(mg/ml)
01.	Methanol	10
02.	DMSO	20
03.	Phosphate Buffer (pH- 7.4)	30
04.	Ethanol	10

Table no. 03- Solubility of Luliconazole in various solvents.

Melting Point:

According to Indian Pharmacopoeia, a substance's melting range/time is defined as those points at which the substance coalesces and is fully melted except as otherwise defined for such substances. The melting range is defined. The drug's melting point meets the literature values published. The melting point of the drug was observed to be in the range of 150 °C-155 °C.

Fourier Transform Infrared Spectroscopy of Drug:

The infrared spectroscopy mostly used for the identification of organic compound whose spectra are complex and provides numerous maxima and minima that are useful for comparison purpose. A sampler registered the powdered medication-KBr-Mixture and the spectrum by scanning with the FTIR spectrophotometer in the 4000-400 cm^{-1} wavelength region. The FTIR spectra of luliconazole were taken which is shown in Figure. The principal peak for IR of drug sample matched with the standard spectrum for luliconazole which is shown in Table. IR interpretation data of Luliconazole:

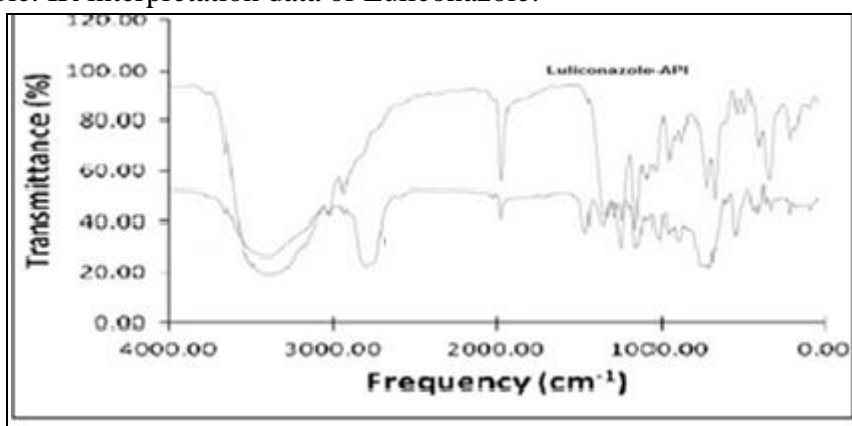


Fig No. 03- FTIR spectra of Luliconazole

Calibration curve of Luliconazole was determined by using (ethanol) with the help of instrument UV spectrophotometer (Lab India UV3000) at 296 nm. The Regression coefficient was found to be 0.9777 and slope 0.0744. The result indicated that there was a linear relationship between concentration and absorbance.

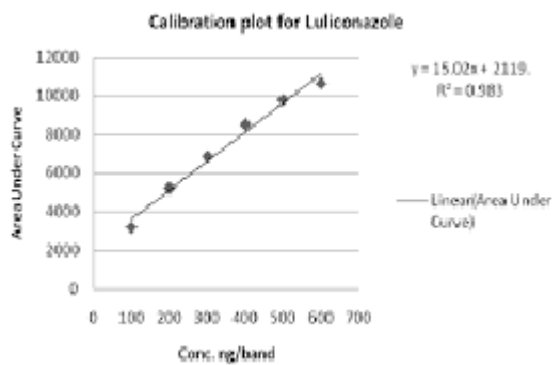


Fig No. 02: Calibration curve of Luliconazole

Microbiological study showed good zone of inhibition i, e, 1.20 cm. of diameter for 1 % Luliconazole soap solution as compared to controlled sample of drug.

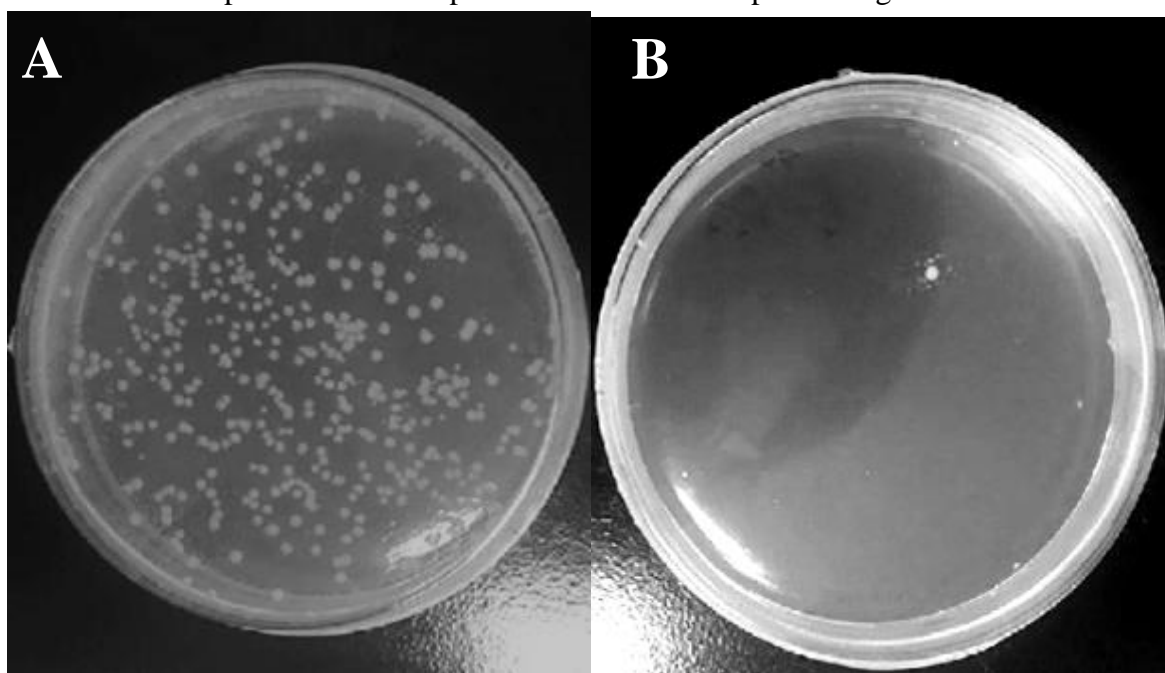


Fig No. 03- Anti-Microbial Examination of Soap Solution

[A]-Control sample[B]-1% Antifungal Herbal Antibacterial Soap Solution.

Conclusion:

The purpose to develop and evaluate a novel drug delivery system in the form of Antifungal Herbal Antibacterial soap was achieved; as the results revealed that the soap produced good foam on affected part, delivered the drug at faster rate, and is economic, convenient and can effectively cure the topical fungal infection. The formulation was designed for the use of patients of all ages and sex. From the above evaluation and tests, it can be concluded that the method and procedure applied in formulating Antifungal Herbal Antibacterial Soap product, was successfully carried out and the method used was valid and reliable.

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