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Formulation and In-Vitro Evaluation of Poly-Herbal Anti-Fungal Eco-Friendly Soap Strips

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ABSTRACT:
This project focuses on the formulation and in-vitro evaluation of poly-herbal anti-fungal eco-friendly soap strips. The soap strips are developed using natural extracts from plants such as Lantana camara, Moringa Oleifera, and Corn silk, known for their anti-fungal properties. The formulation process involves creating a transparent soap base infused with these herbal extracts. The evaluation includes assessing the soap strips' physical properties, pH levels, foaming ability, foam stability, and anti-fungal efficacy. The results indicate that the poly-herbal soap strips exhibit superior physicochemical properties and significant anti-fungal activity, making them a promising eco-friendly alternative to conventional anti-fungal soaps.

KEYWORDS: Poly-Herbal, Anti-Fungal, Eco-Friendly, Soap Strips, Natural Extracts, In-Vitro Evaluation, Transparent Soap Base, Physicochemical Properties , Ph Levels, Foaming Ability, Foam Stability, Anti-Fungal Efficacy.

INTRODUCTION:

Skin:

The largest organ in the body, the skin is composed of water, protein, lipids, and minerals. Skin controls body temperature and guards against infections. Skin nerves enable you to experience emotions like heat and cold. The epidermis, dermis, and hypo-dermis are its three constituent layers; each has a distinctive anatomy and function. The complicated network that makes up the skin's structure acts as the body's first line of defense against viruses, UV rays, chemicals, and mechanical harm.

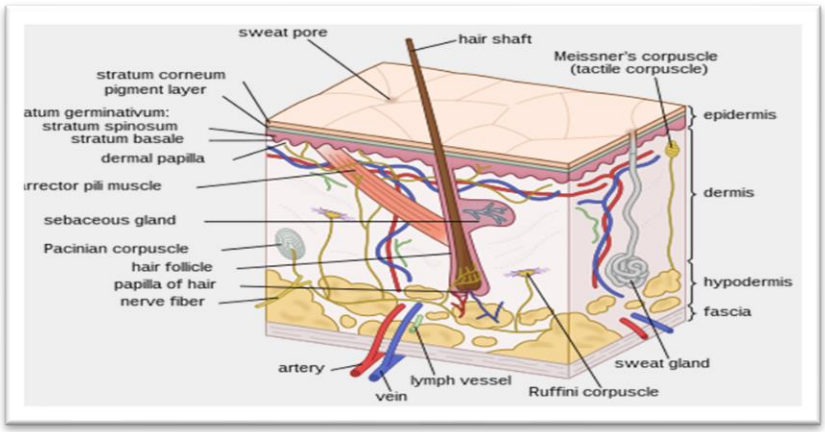


Fig.no.1.1 Structure of Skin

Skin types and their Care:

- Normal
- Dry
- Greasy
- Combination skin, which includes both dry and oily skin.

Skin-care instructions:

- One of the most crucial skin care tips is to understand your skin type.
- Sip plenty of water.
- Constantly keep your skin hydrated.
- Make use of products devoid of synthetic materials. Introduction to

Fungal Disease Mycosis, often known as a fungal infection, is a condition brought on by different topical formulations, such as soaps, lotions, serums, ointments, gels, liquids, and creams, can be used to treat fungus infections. But in daily life, soaps are more practical and environmentally friendly both in terms of cost and time efficiency.

Fungal infection and Symptoms:

- Skin that is scaly and itchy.
- Redness & Itching.
- Swelling & Blisters.

Fig.no. 1.2 Fungal infection on skin

Type of Fungal Infection:

- On the body fungus can cause skin infections.
- Athlete's foot, jock itch, ringworm, and yeast infections are a few of the most prevalent.[1]

The skin or cutaneous membrane covers the external surface of the body. It is the largest organ of the body in surface area and weight. The function of the skin is body temperature regulation, a reservoir for blood, protection from the external environment, cutaneous sensations, excretion and absorption, and vitamin D synthesis.

Skin is the most exposed part of the body to the sunlight, environmental pollution and also to some protection against the pathogens. The most common skin disorders are eczema, warts, acne, rashes, psoriasis, allergy, etc. Staphylococcus aureus (S. aureus) is a Gram-positive bacterium that can live as a commensal organism on the skin and in the nose and throat. Approximately 30% of healthy people are

asymptomatically colonized by S. aureus. S. Aureus causes a range of infections, from minor skin infections to abscesses, endocarditis, and sepsis. aureus is also a major cause of food poising induced by heat resistant enterotoxin A and is a leading cause of nosocomial infections.[2]

Skin from infectious microorganisms and their spreading the skin hygiene Plays an important role to avoid the contagious diseases. This polyherbal soap help reduce healthcare-associated transmission of contagious Disease more effectively. Plants having the Medicinal properties are being used as a traditional medicine from times immemorial. The various extract from the stem, roots and leaves, of various medicinal plants have been employed as a natural remedy in curing various ailments and diseases. Even many of the plant based products have been replaced use of synthetic chemicals, the efficacy and safety of ayurvedic Products could not find their match. The many plant-based medicines have been supplanted by Synthetic chemicals, ayurvedic goods' safety and usefulness have not been proven. In comparison to chemical products treatment, herbal treatments have the benefit of being, readily available, Having less adverse effects and inexpensive The advantage of using herbal drugs is that they are Cheap, easily available and has fewer side effects in comparison to chemical products. As a result, research has accelerated in the direction of developing natural products for various disease treatment, that are higher in quality, less costly, and have no adverse side effects when compared to chemical products.

Types of Soap Preparation:

Melt and Pour Soap: Technically, all handmade soap is "Glycerin Soap." In much Commercial soap, all the extra glycerin is harvested out. Thus, all handmade soap is glycerin rich. Generally, the clear soap has extra Glycerin added to it to produce a very nourishing, Moisturizing bar. Glycerin is a "humectant." It provide moisture to skin; the theory is that if you wash with Glycerin soap, a thin layer of glycerin will remain, drawing Moisture to your skin. Clear soap base can be purchased in large blocks to be Melted down, colored and fragranced, and placed into molds. Because of its ease of use Melt and Pour soap making is Gaining in popularity. This method involves all the Aspects of cold process soap making, but takes it a few steps such as adding alcohol for clarity and a glycerin and Sugar to suspend and enhance the clarity of the soap.

Cold Process Soap: Cold process soap is made by combining fatty acids and sodium hydroxide (lye) together the Fatty acids used can be almost any oil. In the cold process soap making there some portion of sodium hydroxide and water that forms a chemical reaction. It is hard, long lasting quality technique.

Hot Process Soaps: There are variations on the cold process method. In Hot Process soap take all your Ingredients, and add them to a pot (that is then placed over a Heat source, such as a stove) and stir frequently until the Soap goes through various stages in this process the excess water is Evaporated off.

Rebatching Soaps: Rebatching, also called French milled, or triple milled soap is another form of cold process Soap making. Making cold process soap from scratch, grate it up, place it over a heat source, in a kettle, with a little liquid, and the mixture melts down into a mushy Mess you can add fragrance and colorant to it. This method Is often used to preserve the scent or the healing properties of some essential oils.[3]

Properties of good soap:

- A good soap gets dissolved easily and remove stains from body.
- Skin or any material being cleaned.
- It gets dissolved in water and produces enough suds.

- It gives a clear and sparkling kind of cleanliness.
- It gives a pleasant smell.
- A good soap does not leave sticky traces on the clothes or on the skin.
- It has a good color that is even and does not streak.
- It disinfects and kills germs.[4]

Herbal cosmetics are prepared by the association of bioactive ingredients and pharmaceutical products. The presence of number of photochemical and botanicals in the herbal products have dual significance, one that they are used as cosmetics for body care and another that photochemical improve the biological functions of human body naturally results in healthy skin. As the realization said that the chemical medicines are not always work as magic bullets and they may have side effects. The current trend moves toward the herbalism and use of natural products. Indian herbs are the richest source to be used in cosmetic industries. Herbal cosmetics were gaining tremendous demand in the world market. There is a wide range of herbal cosmetic products used as beauty regime to satisfy the purpose of beautification.[5]

Health hygiene is very essential due to increasing number of diseases caused by microorganisms. Since ancient time, soap is a fundamental part of human health hygiene. In the modern era bath soap that is available in the market are mainly of two types: solid soap and liquid soap.

Selection of soap by people depends on various factors one of which is ease of carrying. Paper soap itself is an innovation to the soap formulation which is printed and moulded as slender as paper. To keep us the essential cleanliness while traveling, it is very imperative to have soaps handy. This is the place where travel soaps populated as paper soaps become an integral factor. When comes in contact with water it easily gets wet and produce foam similar to ordinary soap and gels. The paper soap is made from variety of materials, such as methyl paraben, propyl paraben, glycerin, carbomer. Until now there are very a smaller number of paper soap preparations available from natural ingredients/agents such as eucalyptus oil, neem oil, coconut oil which are safe and healthy for topical use. [6]

Superficial and deep cutaneous fungal infections are common worldwide and constitute one-fourth of common skin infections caused by dermatophytes. The dermatophytes tend to invade the keratinized tissue of stratum corneum (SC) and cause dermal seborrheic dermatitis followed by severe psychological, social, and financial consequences for patients. Most fungal infections survive in the lower epidermal (stratum basales layer), superficial region, and the vellus hairs. Most fungal cells have specialized efflux system resulting in frequent drug resistance. Sub-optimal concentration at the site of infection, poor compliance to therapy, and poor delivery modalities, and active efflux system result in frequent recurrence, chronic infections, and serious drug resistance development. Dermatophyte-mediated intracellular infections are critical to treat due to long-term therapy and patient noncompliance using conventional dosage form. These sites are poorly accessible to the conventional formulations resulting in challenged therapeutic efficacy. Ketoconazole (KTZ) is a broad-spectrum, anti fungal agent clinically recommended to control cutaneous fungal infections (candidiasis, tinea, and related skin fungal infections). The drug has a potential to control cutaneous superficial (Candida and Malassezia), localized, and secondary infections such as androgenic alopecia, leishmaniasis, and yeast-induced blepharitis. Pharmaceutically, KTZ is a lipophilic drug (log P=4.74), with poor aqueous solubility (0.04 mg/mL) and light sensitivity, and it is challenging to formulate it into an efficient topical product with promising therapeutic efficacy across the SC barrier. KTZ is associated with several undesirable effects (nausea, vomiting, gastrointestinal disturbance, and hepatotoxicity) after oral administration. Likewise, conventional creams are associated with limited drug access to the target site, side effects (swelling, irritation/redness, itching, and contact dermatitis), and poor

therapeutic efficacy to control deeper skin infections. Improved permeability/availability at sites of infection including villus hair and viable epidermis and dermis coupled with a slow-controlled release which can manage side effects is thus desired for KTZ. All of this can be addressed using nano carrier systems for delivering KTZ. [7]

Cleanliness is a very important thing due to the increasing number of diseases caused by bacteria as and germs. Soap is a substance used with water for washing and cleaning, made of a compound of natural oils or fats with sodium hydroxide or another strong alkali, and typically having perfume and coloring added. Even today, soap is not just used for cleaning to maintain the health of the skins; there are also some soap that also serves as softening soap and whitening soap. In making soap often used various kinds of fats or oils as raw material. For being used in soap manufacture the type of oil needs to be selected in accordance with the use of soap itself. Soap is an important surface-active agent and it is chemically the alkaline metal salt of long-chain fatty acids. The most common used fat or oils for production of soap through saponification reactions.[8]

Infections are caused by fungus ranges from superficial conditions of the skin (e. g., athletes foot and ringworm) and nails (e. g., onychomycoses) to the deadly contagious disease. Ketoconazole is widely used recent synthetic imidazole ring containing powerful antifungal agent active against most of the species of fungi and yeast. A topical preparation of ketoconazole is used for the treatment of infections caused by a wide variety of fungi like candida and tinea. In biopharmaceutics classification system (BCS), ketoconazole is classified as a class-II drug, based on its absorption and dissolution property, since it has a high permeability but its solubility in aqueous media is insufficient for the whole dose to be dissolved in the gastrointestinal (GIT) fluids under normal condition. It is very lipophilic, practically it is insoluble in mineral oil.[9]

AIM:

To Formulate and conduct *In-Vitro* evaluation of Poly-herbal Anti-fungal Eco-friendly Soap Strips.

OBJECTIVE:

1. To carry out the formulation of poly-herbal Anti-fungal Eco-friendly soap strips.
2. To design the formulation with different vegetable oils and concentration.
3. To carry out the characterization of prepared poly-herbal Anti-fungal Eco-friendly soap strips.

a. Skin Irritation
b. pH
c. Foam Height
d. Foam Retention
e. Moisture Content
f. Percentage Drug Content
g. IR Spectral Analysis
h. Microbial Study.

PLAN OF WORK:

7 Soap strips were prepared – out of which 3 formulations were with different vegetable oils concentration and 3 formulations with combination oils.

↓

One Formulation was prepared with combination of all the 3 vegetable oils.

↓

The prepared soap strips were then subjected to evaluation.

PARAMETERS:

1. Organoleptic
2. Skin Irritation
3. pH
4. Foam Height
5. Foam Retention
6. Moisture Content
7. Weight Variation
8. Basicity
9. Percentage Drug Content
10. IR Spectral Analysis
11. Microbial Study

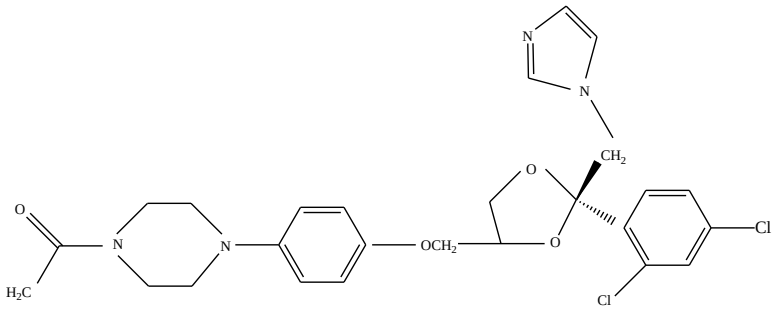
DRUG PROFILE:

Ketoconazole

Chemical Formula: $C_{26}H_{28}Cl_2N_4O_4$

IUPAC name: 1-[4-[4-[[2-(2,4-dichlorophenyl)-2-(imidazole-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone.

Structural Formula:



Molecular Weight: 531.431g/mol.

Melting Point: Between 148 – 152°C.

Description: A white to off – white crystalline powder.

Solubility: Freely soluble in dichloromethane, soluble in chloroform and methanol, sparingly soluble in ethanol (95%), practically insoluble in water and ether.

Indication: Ketoconazole is a Anti-fungal medication used to treat various fungal infection. It's commonly indicated for conditions like athletes foot, ringworm, and certain types of dandruff.

Ketoconazole is classified in the BCS as a class II drug, hence it helps in treating fungal infections.[10]

Mechanism of Action:

Ketoconazole works by inhibiting the synthesis of ergosterol, a crucial component of fungal cell membranes. It specially targets the enzyme lanosterol 14 α – demethylase, which is involved in the conversion of lanosterol to ergosterol. By inhibiting this enzyme, ketoconazole disrupt the synthesis of ergosterol, leading to alter fungal cell membrane structure and function. This interference with membrane integrity ultimatrlyimpares the growth and replication of the fungal cells, helping to control or eliminate the infection.

Pharmacodynamics:

The pharmacodynamics of ketoconazole involve its interaction with the fungal cell membrane. Ketoconazole is an antifungal agent that belongs to the azole class. It's primary target is the inhibition of lanosterol 14α – demethylase, a key enzyme in the ergosterol biosynthesis pathway. Ergosterol is a vital component of fungal cell membranes, playing a role similar to cholesterol in human cells. By inhibiting lanosterol 14α – demethylase, ketoconazole disrupts the conversion of lanosterol to ergosterol, leading to a decrease in ergosterol levels within the fungal cell membrane. The disruption compromises the integrity and function of the fungal cell membranes, resulting in increased permeability and structural abnormalities. As a consequence, essential cellular process are impaired, inhibiting the growth and viability of the fungus.

Half-Life:

The half-life of ketoconazole can vary among individuals, but it typically ranges from 2 to 8 hours. This means that it takes this amount of time for half of the administered dose to be eliminated from the body.

Toxicity:

Ketoconazole can be associated with adverse effect, and its use should be closely monitored. Some potential toxicities and side effects include liver toxicity, adrenal insufficiency, and interactions with other medications. Liver toxicity is a concerned with ketoconazole, and severe liver damage can occur in rare cases. Regular monitoring of liver function through blood test is often recommended during prolonged therapy. Ketoconazole can also affect adrenal functions, leading to adrenal in sufficiency, especially at higher doses or with prolonged use. Interactions with other medication or another consideration. Ketoconazole can inhibit various liver enzymes involved in drug metabolism, potentially leading to increased levels of certain medications in the blood. This may increase the risk of side effects from those drugs.

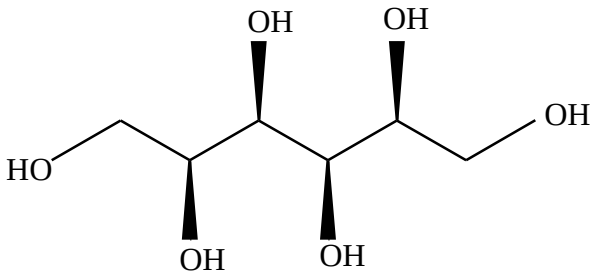
EXCIPIENTS PROFILE:

1. Sorbitol

Synonym: Glucitol, Sorbilax

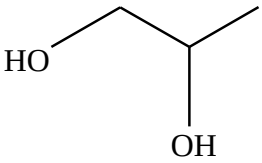
Molecular Formula: $C_6H_{14}O_6$

Structural Formula:



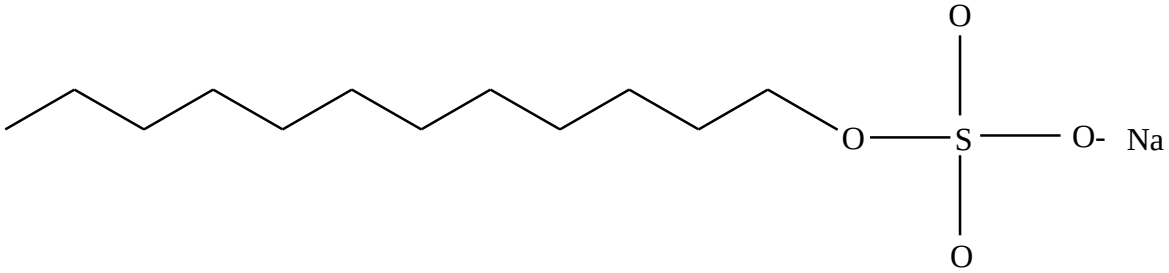
Molecular Weight: 182.17 g/mol.
Melting Point: 96.8°C
Boiling Point: 296°C
Description: These are the excipients that belongs to the category of Co solvents and Humectant. Co solvents works by reducing the interfacial tension between predominantly aqueous solutions and hydrophobic solutes. Humectant retard evaporation of aqueous vehicles from dosage forms.[11]

2. <u>Propylene Glycol</u>
Synonym: 1,2-dihydroxypropane, 1,2-propanediol
Molecular Formula: $C_3H_8O_2$
Structural Formula:



Molecular Weight: 76.09 g/mol.
Melting Point: -59°C
Boiling Point: 188.2°C
Description: These are the excipients that belongs to the category of Co solvents and Humectant. Co solvents works by reducing the interfacial tension between predominantly aqueous solutions and hydrophobic solutes. Humectant retard evaporation of aqueous vehicles from dosage forms.[12]

3. <u>Sodium Lauryl Sulfate</u>
Synonym: Sulfuric acid monododecyl ester sodium salt, dodecyl alcohol
Molecular Formula: $C_{12}H_{25}NaO_4S$
Structural formula:



Molecular Weight: 288.38 g/mol.
Melting Point: 204°C
Boiling Point: 288.4°C
Description: Sodium lauryl sulfate is a harsh synthetic detergent and foaming agent that corrodes in order

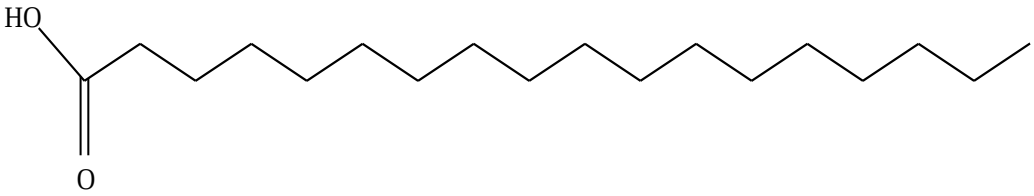
to clean. Companies use SLS to create a rich lather, and for its intense cleaning action.

4. Stearic acid

Synonym: Octadecanoic acid, stearophanic acid

Molecular Formula: $C_{18}H_{36}O_2$

Structural Formula:



Molecular: Weight: 284.48 g/mol.

Melting Point: 69.3°C

Boiling Point: 361°C

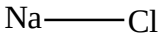
Description: Stearic acid traditionally used as a thickening agent in lotion, this vegetable derived waxy substance is also used as hardening agent in soaps(at a. 5% of your oils as a usage rate).

5. Sodium chloride (NaCl)

Synonym: common salt, Table salt

Molecular Formula: NaCl

Structural Formula:



Molecular Weight: 58.44 g/mol.

Melting Point: 801°C

Boiling Point: 1,413°C

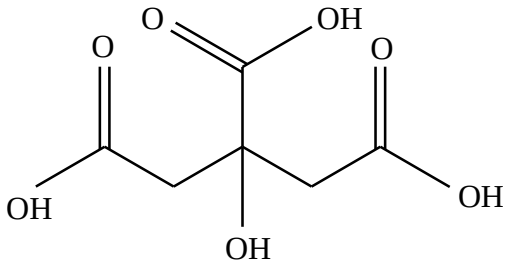
Description: Sodium chloride in soap making can alter the pH. Nacl is used to create the desired texture of soap, hence creating soapy molecules adhere to one another.

6. Citric acid

Synonym: Anhydrous citric acid, citrate

Molecular Formula: $C_6H_8O_7$

Structural Formula:



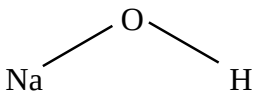
Molecular Weight: 192.12 mol^{-1}

Melting Point: 153°C

Boiling Point:175°C

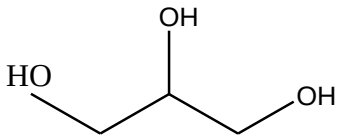
Description: Citric acid helps to reduce soap scum and reduces spoilage and DOS (dreaded orange spots) in finished soap products.

7. Sodium Hydroxide
Synonym: Lye, Caustic soda
Molecular Formula: NaOH
Structural Formula:



Molecular Weight: 39.997 g/mol.
Melting Point: 318.4°C
Boiling Point: 1,390°C
Description: Sodium Hydroxide can saponify oils. That means it helps the oils and fats lather and foam into a soap. It's also used in small amounts to establish and maintain the pH of a product.

8. Glycerin
Synonym: Glycerol, Glycerine
Molecular Formula: $C_3H_8O_3$
Structural Formula:



Molecular Weight: 92.0938 g/mol.
Melting Point: 17.8°C
Boiling Point: 290°C
Description: Glycerin is reported to function in cosmetics as a denaturant, fragrance ingredients, hair conditioning agent, humectant, oral care agent drug, skin protection, skin conditioning agent- humectant and viscosity - decreasing agent.[13]

MATERIALS AND METHODS:

Materials

Table 1: List of Instruments

SL.NO	INSTRUMENTS	SOURCE
1	Weighing balance	Contech
2	pH meter	Labon instruments
3	Incubator	Redundant power
4	FTIR Spectrophotometer	Alpha II
5	Automatic Water bath	

Table 2: List of Chemicals and Reagents

SL.NO	MATERIALS	SOURCE
1	Ketoconazole	Danopharm chemicals
2	Glycerin	Nice chemicals
3	Sorbitol	Simson chemicals
4	Propylene glycol	Thomas baker
5	Citric acid	Thomas baker
6	Stearic acid	Nice chemicals
7	Nacl	Merck chemicals
8	NaOH	Loba chemicals
9	Sodium lauryl Sulfate	Thomas baker

MATERIALS:

Ketoconazole was obtained from Danopharm Chemical Pvt.Ltd as a gift sample. Sodium Hydroxide (NaOH), coconut oil, peanut oil, soyabean oil, Neem oil, lavender oil, almond oil, shikakai powder these were purchased from local market in pure form. Propylene glycol, glycerine, sorbitol, stearic acid, sodium chloride (Nacl), citric acid, sodium lauryl sulfate (SLS) were obtained from college (East Point College Of Pharmacy). Dissolvable paper and butter paper were purchased from online store.

Fig.no. 4.1 Dissolvable papers

Fig.no.4.2 Ketoconazole pure drug.

Oils used in preparation:

1. Coconut Oil:

A traditional and trusted moisturizing and protective oil from the topics. One of the most respected oils found in the British Pharmacopoeia.

2. Peanut Oil:

A traditional oil for use in sunscreen preparations and after-sun oils. It is substantive and protective of the harshest of the external conditions.

3. Soybean Oil:

This plant has been known and used by the Chinese for more than 4,000 years, through today most of the oils comes from the USA. This oils is cost-effective base on which to prepare hair and body products where good honest moisturisation is required at a budget price.

4. Neem Oil:

Fig.no.4.3 pure neem oil

A very aromatic oil, neem is one of Indo-Pakistan's most respected treatment for problem skin.

5. Almond Oil:

Fig.no.4.4 Pure almond oil

Much loved for generations; listed in the British Pharmacopoeia and an excellent choice for even the most simple of the moisturizers or massage oils. Almond oil should be very formulator's palette[14] .

6. Lavender Oil:

Fig.no.4.5 Pure lavender oil

Lavender is a small, aromatic shrub used in the fragrance, specially food, and alternative medicine industries. Although family farmers may find large-scale extraction of lavender's valuable oil too expensive and laborious, small scale lavender production is feasible for some farmers using alternative marketing strategies.[15]

7. Shikakai Powder:

Fig.no.4.6 Pure shikakai powder

Shikakai is used for hair care, Ayurvedic shampoo, cleansing, Anti dandruff purpose and shikakai belongs to Leguminosae family.[16]

METHODS

A. PHASE-I

Preparation of Basic Soap Base

To make Crystal clear Melt and Pour soap Base; Create lye solution by mixing NaOH and distilled water in 250ml labeled beaker. Measure propylene glycol solution, glycerin, 70% sorbitol solution, sodium lauryl sulphatein 250 ml beaker on water bath with stir bar and heat mixture with 60°C. Once this

heat is attained add Stearic acid, Citric acid and Nacl heat mixture to 68°C. When at temperature slowly add 50:50 lye solution and mix for 20 minutes while continuously stopping and starting stirring until mixture becomes transparent. Let solution sit for cool and harden at 62-64° C and pour into soap base.

Fig.no. 4.7 Soap base

Table 3: Ingredients of basic soap base.

Sr.no	Ingredients	Quantity
1	NaOH	4 gm
2	Distilled water	4 ml
3	Propylene glycol	10 ml
4	Glycerin	15 ml
5	Sorbitol	10 ml
6	Stearic acid	5 gm
7	Nacl	1 gm
8	Citric acid	2 gm
9	Sodium lauryl Sulfate	5 gm

Table 4: Formulation of soap base with different oils (coconut oil, peanut oil, soyabean oil).

Sr.no	Ingredients	Single oil			Two oils			Three oils
		F_1	F_2	F_3	F_4	F_5	F_6	F_7
1	NaOH	4 gm	4 gm	4 gm	4 gm	4 gm	4 gm	4 gm
2	Distilled water	4 ml	4 ml	4 ml	4 ml	4 ml	4 ml	4 ml
3	Coconut oil	44 ml	---	---	34 ml	22 ml	---	24 ml
4	Peanut oil	---	37 ml	---	10 ml	---	20 ml	10 ml
5	Soyabean oil	---	---	29 ml	---	15 ml	9 ml	10 ml
6	Propylene glycol	10 ml	12 ml	15 ml	10 ml	12 ml	15 ml	10 ml
7	Glycerin	15 ml	20 ml	25 ml	15 ml	20 ml	25 ml	15 ml
8	Sorbitol	10 ml	10 ml	10 ml	10 ml	10 ml	10 ml	10 ml
9	Stearic acid	5 gm	5 gm	5 gm	5 gm	5 gm	5 gm	5 gm

10	Nacl	1 gm	1 gm	1 gm	1 gm	1 gm	1 gm	1 gm
11	Citric acid	2 gm	2 gm	2 gm	2 gm	2 gm	2 gm	2 gm
12	Sodium lauryl sulfate	5 gm	5 gm	5 gm	5 gm	5 gm	5 gm	5 gm

Procedure Of Polyherbal Anti-fungal Paper Soap Strips Formulation

To make polyherbal medicated paper soap: Take the already prepared soap base to a beaker and keep it for heating on water bath at 60°C for melting. Weigh the Neemoil , almond oil , lavender oil and shikakai powder all together to a soap base melted beaker. Add the Ketoconazole drug to the melted solution and stir it until drug gets dissolved with solution. The liquid was poured on to the dissolvable paper and spread the solution clearly on the dissolvable paper. Dry the dissolvable paper at room temperature and keep it away from the moisture content.

Fig.no.4.8 Paper soap

Table 5: Formulation Ingredients of Polyherbal Anti-fungal Paper Soap Strips.

Sr.no	Ingredients	Quantity	Uses
1	Soap Base	45 gm	
2	Neem oil	1 ml	Antibacterial
3	Almond oil	1 ml	Anti-inflammatory
4	Lavender oil	2 ml	Fragrance
5	Shikakai powder	0.5 gm	Cleanser
6	Ketoconazole	0.5 gm	Anti-fungal

B. PHASE-II

Evaluation Parameters of polyherbal soap

Evaluation of Herbal Paper Soap

1. Organoleptic evaluation

Colour

Odour

Apperance

2. **Skin irritation test:** For this atleast three volunteers was selected and prepared soap strips was given an applying in hand the amount of irritation was been checked.
3. **pH:** The pH was determined before and after the preparation of paper soap. At first the liquid soap was prepared and the pH was detected by using litmus paper the result was red litmus paper turned

blue in colour and blue litmus remained unchanged. Then after the production of paper soaps the piece of paper soap was taken an added into water a then shaked fully then the pH meter was used for testing of pH.

4. **Foam Height:** The sample was dispersed in 20 ml of distilled water and then transferred into the measuring cylinder and then it was shaked for a min and immediately its foam height was calculated as F1 and then after 10-15 min measure the foam height and the foam height were measured and noted as F2 it should be 2 cm. Foam height calculation - F1-F2.
5. **Foam retention:** It is tested by patch test. Apply product on 1 cm patch of skin, if no any inflammation or rashes then it considered as free from sensitivity.[17]
6. **Moisture content:** The moisture content was estimated by measuring the weight of water content in soap and the difference in the weight after the paper soap is fully dried in 100 to 115 c or by using dryer . the formulae used to find the moisture content is:% Moisture content = initial weight - final weight/ final weight × 100.[18]
7. **Percentage (%) drug content:** The (%) percentage drug content is measured by using UV spectroscopy at λmax 278nm.[19]
8. **Weight variation test:** Each paper soap was weighed and noted down.
9. **IR Spectral analysis for drug :** The studies were carried out using IR method with the help of IR spectrophotometer.
10. **Basicity:** Dissolve a small piece of your paper soap in 5 ml of ethanol and then add 2 drops of phenolphthalein indicator.[20]
11. **Microbial study:** Microbial study has been done using microorganism S. aureusspecies. For measuring the effectiveness of an antimicrobial agent against fungi/bacteria grown in culture, the microorganism was swabbed uniformly across a culture plate.[21]

After swabbing microorganism across culture plate then a soap strips of 4×4 mm was compared with the marketed product of Ketoconazole Anti-fungal soap by placing it on the surface of the agar culture plate by making holes with borer. Then the plates were placed in incubator for 24hrs at 30°C. The drug diffuses out from the paper soap strip into agar culture media. The concentration of the compound will be higher next to the strip, and will decreases gradually as distance from the strip increases. Comparing both the marketed and anti-fungal polyherbal paper soap strips of 4×4 mm of it's drug activity. This microbial test shows that there is no bacterial growth surrounding it. When commercial ketoconazole soap and ketoconazole paper soap were compared, it was found that there was no bacterial growth surrounding the sample that was put in culture media. Both comparison shows the same action of controlling bacteria growth.

Fig.no. 4.9 Borer

Fig.no. 4.10 Marketed Ketoconazole soap

Table 6: Ingredients of Agar culture media

Sr.No	Ingredients	Quantity
1	Beef extract	1 gm
2	Peptone	1 gm
3	Sodium chloride	0.5 gm
4	Agar	2 gm
5	Water	q.s to 100 ml

Fig.no. 4.11 Agar solution preparation

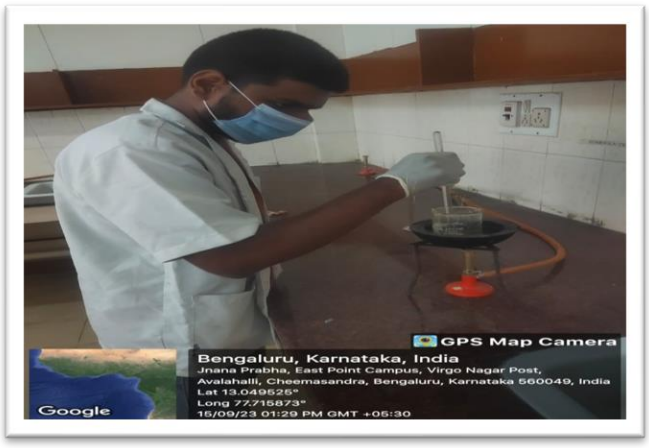
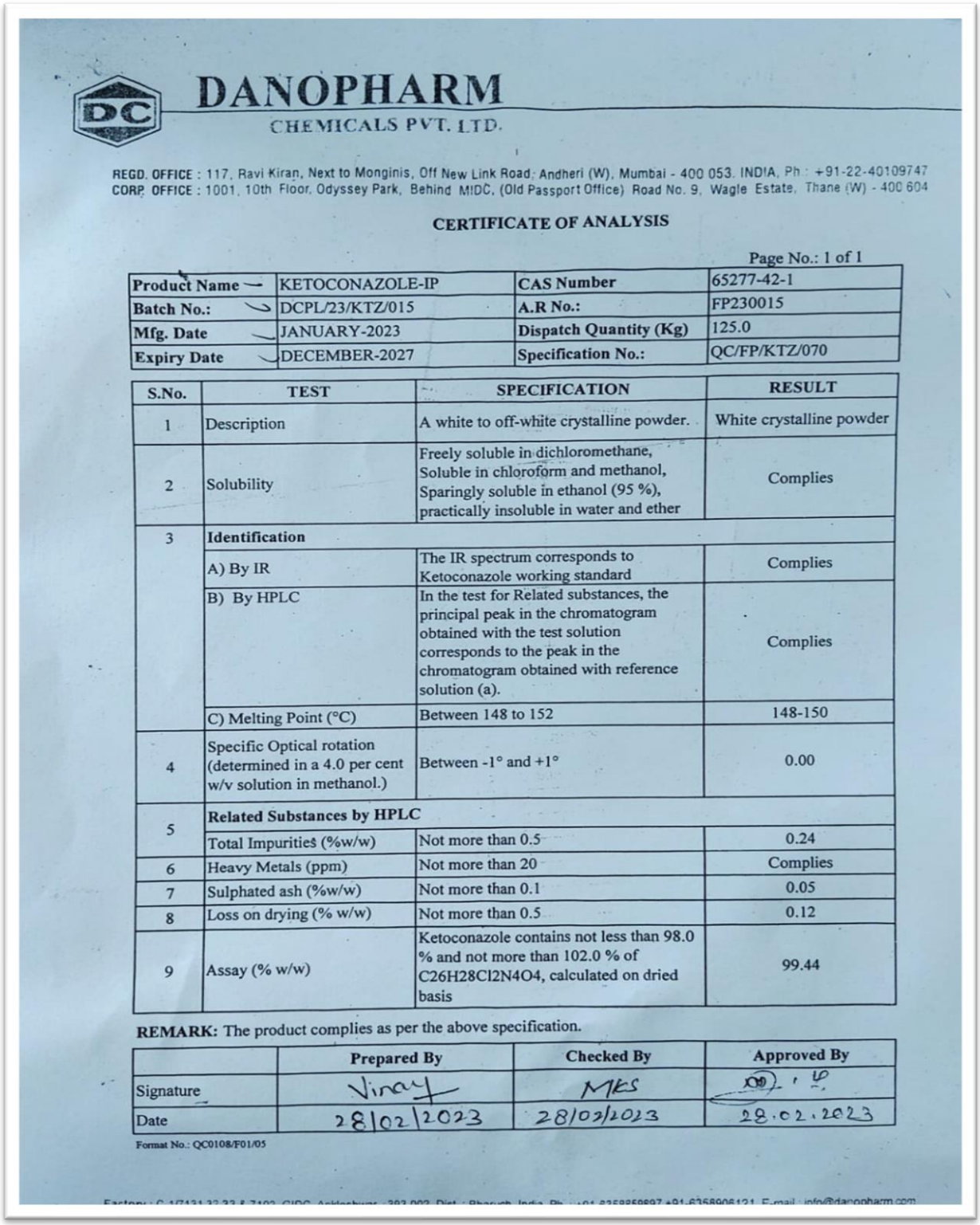


Fig.no. 4.12 Soap base preparation process.

RESULTS:

1. IR Spectrophotometer:



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CERTIFICATE OF ANALYSIS

Page No.: 1 of 1

Product Name	KETOCONAZOLE-IP	**CAS Number**	65277-42-1
Batch No.:	DCPL/23/KTZ/015	**A.R No.:**	FP230015
Mfg. Date	JANUARY-2023	**Dispatch Quantity (Kg)**	125.0
Expiry Date	DECEMBER-2027	**Specification No.:**	QC/FP/KTZ/070

S.No.	TEST	SPECIFICATION	RESULT
1	Description	A white to off-white crystalline powder.	White crystalline powder
2	Solubility	Freely soluble in dichloromethane, Soluble in chloroform and methanol, Sparingly soluble in ethanol (95 %), practically insoluble in water and ether	Complies
3	**Identification**		
	A) By IR	The IR spectrum corresponds to Ketoconazole working standard	Complies
	B) By HPLC	In the test for Related substances, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	Complies
	C) Melting Point (°C)	Between 148 to 152	148-150
4	Specific Optical rotation (determined in a 4.0 per cent w/v solution in methanol.)	Between -1° and +1°	0.00
5	**Related Substances by HPLC**		
	Total Impurities (%w/w)	Not more than 0.5	0.24
6	Heavy Metals (ppm)	Not more than 20	Complies
7	Sulphated ash (%w/w)	Not more than 0.1	0.05
8	Loss on drying (% w/w)	Not more than 0.5	0.12
9	Assay (% w/w)	Ketoconazole contains not less than 98.0 % and not more than 102.0 % of C26H28Cl2N4O4, calculated on dried basis	99.44

REMARK: The product complies as per the above specification.

	Prepared By	Checked By	Approved By
Signature	Vinay	MKS	
Date	28/02/2023	28/02/2023	28.02.2023

Format No.: QC0108/F01/05

Fig.no.5.1 IR spectrophotometer test.

2. Foam Height

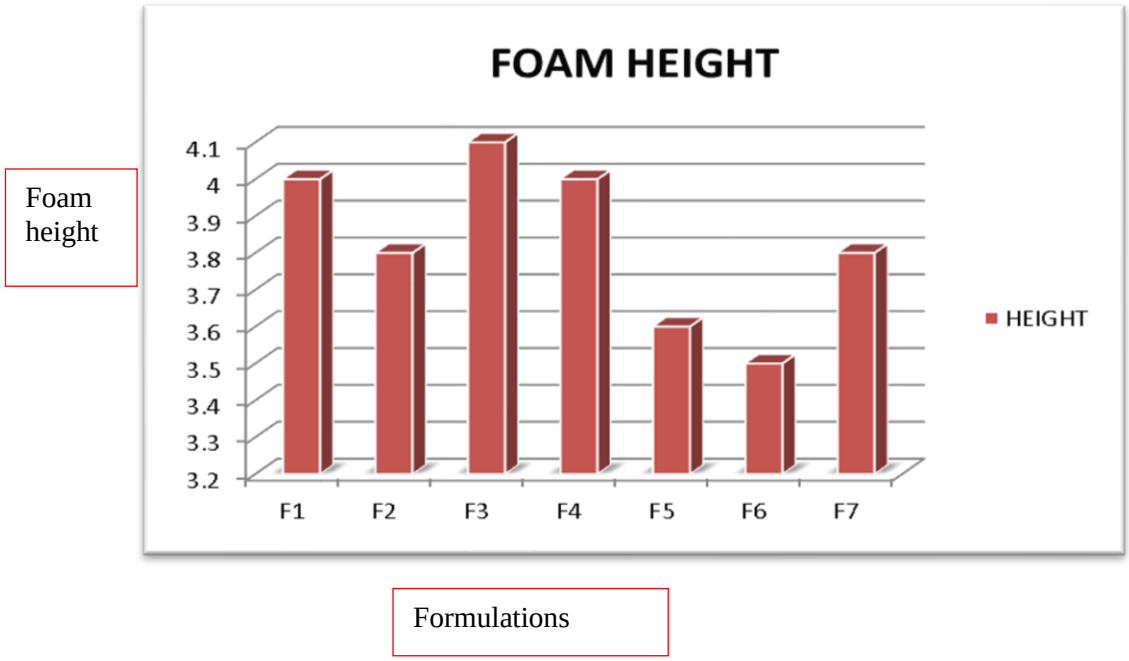


Fig.no. 5.2 Foam height test for different paper soap strips formulations.

Fig.no.5.3 Foam height test.

3. Skin Irritation:

Fig.no.5.4 Skin Irritation test.

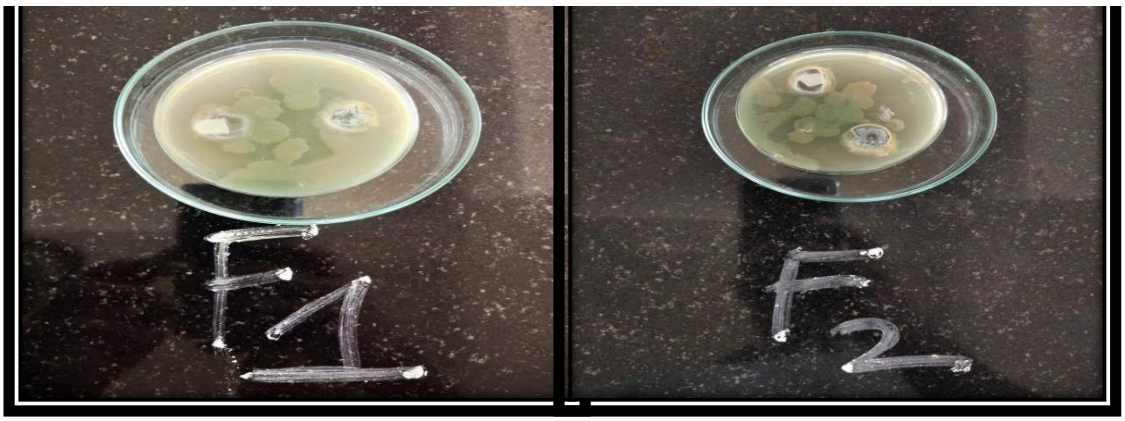
4. pH

Fig.no.5.5 pH test.

5. Basicity:

Fig.no.5.6 Basicity test.

6. Microbial test:



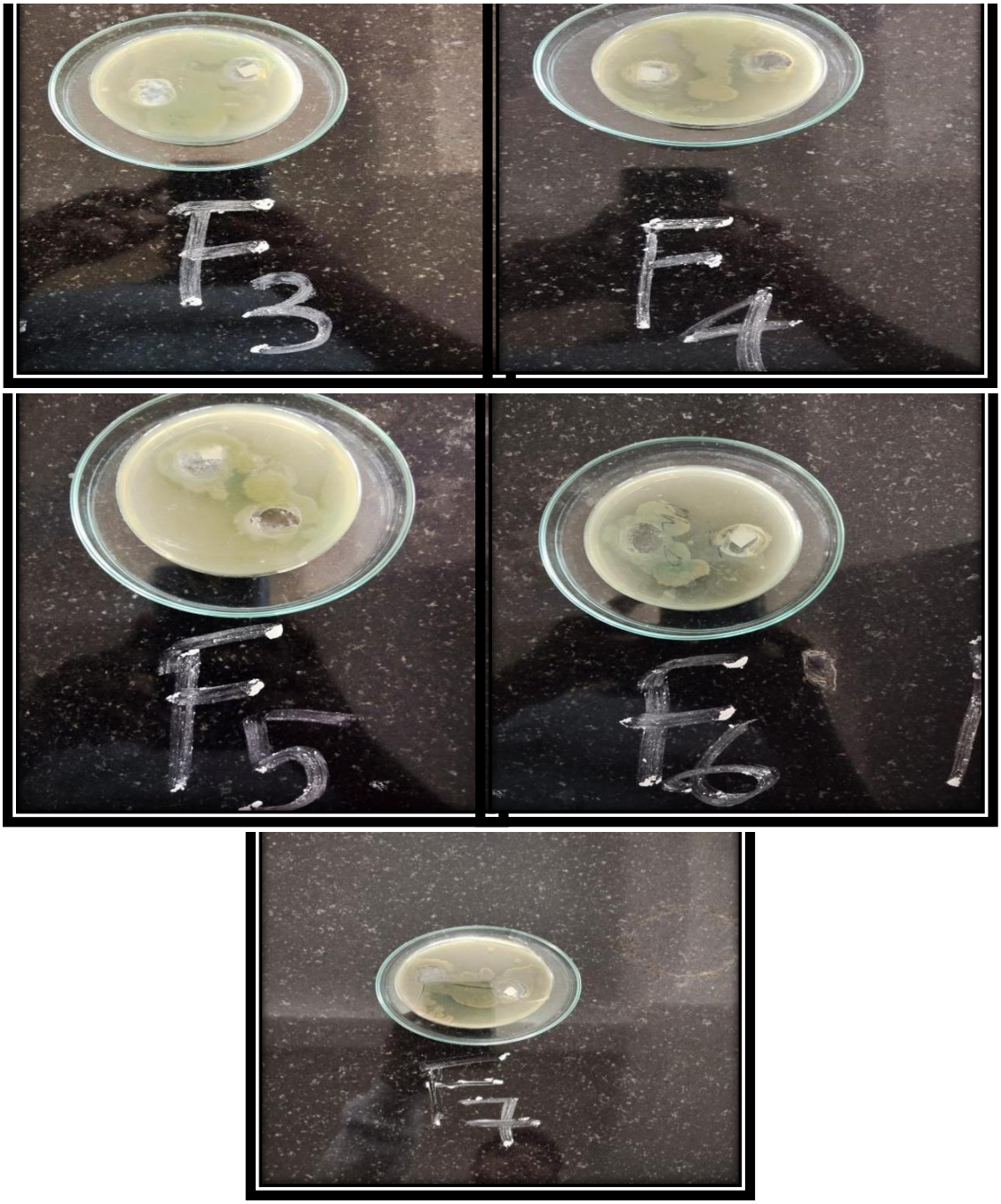


Fig.no.5.7 Microbial evaluation of medicated polyherbal paper soap.

Table 7: Evaluation parameter test results

Sr.no	Evaluation parameters	F_1	F_2	F_3	F_4	F_5	F_6	F_7
1	Colour	white	white	white	white	white	White	white
2	Odour	Fragr-ant	Fragr-ant	Fragr-ant	Fragr-ant	Fragr-ant	Fragr-ant	Fragr-ant
3	Appearance	Good	Good	Good	Good	Good	Good	Good
4	Texture	Smoo-th	Smoo-th	Smoo-th	Smoo-th	Smoo-th	Smoo-th	Smoo-th

5	pH	7	7	7.5	7	7.5	7.5	7.5
6	Moisture content %	50%	50%	50%	50%	50%	50%	50%
7	Foam height	4 cm	3.8 cm	4.1 cm	4 cm	3.6 cm	3.5 cm	3.8 cm
8	Foam retention (min)	3.8 cm	3.7 cm	3.9 cm	3.9 cm	3.4 cm	3.3 cm	3.7 cm
9	Basicity	Colourl ess	Colourl ess	Colour less	Colour less	Colour less	Colour less	Colour less
10	Skin Irritation	No irritat- ion	No irritati- on	No irritat- ion	No irritat- ion	No irritat- ion	No irritat- ion	No irritat- ion
11	Weight variation	0.2	0.2	0.2	0.2	0.2	0.2	0.2

DISCUSSION:

1. Organoleptic Evaluation:

The assessment of various eco-friendly soap strips made from a combination of herbs, which can act as anti-fungal agents, involves evaluating them based on four different criteria namely, colour, odour, apperance and texture. All seven formulations are characterized by their white colour, pleasant fragrance, good apperance and smooth texture. The Organoleptic evaluation is assured that each formulation of soap strips shows accurate result.

2. Skin Irritation Test :

The skin irritation test for poly herbal antifungal eco-friendly paper soap is crucial to ensure its safety and effectiveness. Conducting patch test on a small group of individuals help asses potential adverse reaction such as redness or itchiness and analyzing the overall skin compatibility.

After conducting the test for all the seven formulation didn't showed any skin irritation such as redness or itchiness. From this test it ensures the consumer safety throughout the testing process.

3. pH:

The pH test of antifungal paper soap is vital to evaluate its acidity or alkalinity which can influence the skin compatibility. Maintaining a balanced pH is crucial to prevent skin irritation or disruption of the skin natural barrier.

The pH test conducted on the paper soap was found that the pH for F1, F2, F4 having pH of 7 whereas, the pH for F3, F5, F6, F7 have pH of 7.5 ensuring no deviations from the pH range.

A pH of 7 is neutral anything above pH 7 is alkaline and anything below pH 7 is acidic which may show some incompatibility for the skin. All prepared formulations showed neutral pH so there was no major changes in the skin feel of formulation.

4. Foam Height Test:

The foam height test for antifungal paper soap assesses its lathering ability, and it's important aspect of user experience adequate foam height indicates effective soap distribution and coverage during use. This test involves creating standardized condition and measuring the height of the soap foam.

Upon measuring the soap foam height for all the seven formulation the foam height of F1, F4 has shown the foam height of 4 cm and F2, F7 has shown the height of 3.8 cm and F3 has shown the height of 4.1 cm and F5 and F6 has show the foam height of 3.5cm indicating a good foaming ability for all the formulation thereby, giving a good user satisfaction.

5.

6. Foam Retention Time:

The foam retention time of poly herbal antifungal eco-friendly paper soap is measure of how long the lather persist during use. This property is significant for user convenience and effectiveness. A soap with good retention time of foam ensures prolonged contact with the skin, potentially enhancing the distribution of poly herbs and antifungal agents.

The foam retention time for all the seven formulation was found to longer foam duration time. The result shown that the reduction of foam height of 0.1cm to 0.6cm from its original foam height in the span of 1 minute ensuring a good foam retention property of the product.

7. Moisture Content:

The moisture content of poly herbal antifungal eco-friendly paper soap is a critical parameter in determining its physical properties and overall quality an optimal moisture level is essential to maintain the soap structural integrity preventing it from becoming too dry or too soft and ensure pleasant texture during use. Excessive moisture can lead to mushy while insufficient moisture may result in dry and brittle.

The moisture content for all the seven formulation was observed to 50% of moisture available after drying the paper soap in a hot air oven at 100 to 115 degree celcius or by using dryer. The 50% moisture available in the paper soap is ensuring the soap's good moisture ability thereby, not giving too dry or mushy soap and preserving the soaps efficacy and user experience.

8. Percentage (%) Drug Content:

The percentage of drug content of paper soap is a crucial parameter indicating the amount of the active antifungal ingredient present in the product. The measurement ensures that the soap provides the intended therapeutic effect.

Accurate and consistent drug content is essential for the product effectiveness and safety. Deviations from the specified percentage may lead to sub optimal antifungal activity or in the case of excess potential irritation or adverse reactions.

9. Weight Variation Test:

The weight variation test for antifungal paper soap is conducted to assess the uniformity of individual soap units within a batch. It involves the measuring the weight of a sample of soaps to ensure they fall within a specified range of acceptable weights.

Consistency in weight could indicate the direct impact of dosage and efficacy. The test conducted on all the seven formulation resulting in equal weight of all the formulation of o.2gm providing user with a consistent and reliable product in terms of both dosage and effectiveness.

10. IR Spectral Analysis For Drug:

IR spectral analysis of the drug in antifungal paper soap involves using infrared spectroscopy to identify and characterize the chemical bonds present in the active pharmaceutical ingredient. The analytical technique provide valuable information about the molecular structure of the drug.

By examining the IR spectrum we can identify the functional group and specific chemical bonds in the drug molecule. This information is critical for confirming the presence of intended active ingredient and ensuring its purity.

11. Basicity:

The basicity of antifungal paper soap to its alkaline nature which is determined by its pH level soap is typically alkaline and has a pH above 7. The basicity is important because it influences the soap's cleaning ability and its interaction with the skin.

The test result show neutral pH of all seven formulation indicating equal number of hydroxide and

hydrogen ions giving less toxic and sensitive effect for the skin giving user friendly and safe to use.

12. Microbial Study:

The microbial study of antifungal paper soap involves assessing its effectiveness in inhibiting or eliminating micro organisms, particularly fungi. This study is for confirming the antifungal properties claimed by the soap. Upon conducting the microbial studies the result shown by the seven formulation of the product was a significant prevention of fungal growth comparing with the marketed product confirming the antifungal property of the product.

CONCLUSION:

The present research work involves the preparation, formulation and in-vitro evaluation of poly herbal anti-fungal eco-friendly soap strips. Under this study, the active active pharmaceutical ingredient ketoconazole and characterization of the formulation were carried out, in this study the effect of varying concentration and combination of vegetable oils in the formulation were studied. The formulation of poly herbal anti-fungal eco-friendly soap strips were prepared by melt and pour method. A total of 7 formulation were prepared and evaluated for different parameters.For the formulation and in-vitro testing of polyherbal anti-fungal eco-friendly soap strips, parameters such as foam height, foam retention time, skin irritation, pH , basicity, IR spectroscopy, weight variation test, percentage (%) drug content and moisture content were assessed. The results for each parameter fell within the ideal range. The promising results have been obtained from the formulation and in-vitro assessment of eco-friendly soap strips with a polyherbal anti-fungal action. The addition of herbal substances to the soap strips has demonstrated potential in augmenting its anti-fungal characteristics, thereby offering an environmentally sustainable substitute for personal hygiene. The formulation's efficacy against fungus strains is demonstrated by the in-vitro assessment, opening the door for future research and possible practical implementation. The study emphasizes the significance of ecologically friendly options in the personal care industry, adding to the expanding field of sustainable and herbal-based hygiene products.

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