FORMULATION AND EVALUATION OF ANTIFUNGAL MEDICATED SOAP BARS FOR TREATING MALASSEZIA FURFUR ASSOCIATED SKIN DISEASES.

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Abstract:

Malassezia furfur is a lipid-dependent yeast that lives in the human skin microbiome and is linked to a number of painful dermatomycoses, including seborrheic dermatitis and dandruff as well as pityriasis versicolor and Malassezia folliculitis. Malassezia infections are treated mostly with topical antifungals[1], and Terbinafine is one of these powerful medications.There were several stages to the preparation and research of medicated soap[2] bars. Phase-I: Cold-process soap bars with a 1% terbinafine[3] concentration and dimensions of 5.0 x 3.0 cm and a 0.5 cm thickness were created.Phase II: Characterization of ready medicated soap bars in terms of criteria including thickness, weight, foam test, stability tests, homogeneity of medication content, pH, and FTIR. In the phase-III investigation, antifungal activity was assessed.Phase-IV: For 30 minutes, in-vitro drug release was conducted in phase IV, and the results were acceptable.

KeyWords: Terbinafine,MedicatedSoapBars,Malassezia.

1.Introduction

As early as 1846, researchers identified a yeast that was associated with specific skin conditions; in 1853, this yeast was given the name Malassezia furfur.Several prevalent dermatologic conditions, such as seborrheic dermatitis (SD), pityriasis versicolor (PV), and Malassezia folliculitis, have been linked to Malassezia spp.M. furfur relies on the oils produced in regions of the skin with a high concentration of sebaceous glands, particularly the trunk, face, and scalp, because it is unable to synthesise fatty acids on its own.Head and neck dermatitis is frequently referred to as a sweat allergy.medicated soap bars aid in maintaining personal cleanliness as well as treating the affected area of skin. Therefore, the current study was started in order to create and assess medicatedsoap bars containing 1% Terbinafine for the treatment of Malassezia furfur and related skin conditions.

2.Materials and methods:

2.1 Materials[4]:

olive oil[5],Palm oil[6],coconutoil, sodiumhydroxide[7], Terbinafine.

2.2 METHODS:

Phase-IStudies:

Preparation of Medicated Soap Bars[8,9]

Cold Process Method:

1.In a 250 ml beaker of distilled water, sodium hydroxide (NaOH) pellets were dissolved before being set away to cool (27-380C).

2.After the NaOH solution (lye) had cooled down enough, a hot plate was used to heat the oil and water mixture in a 500 ml beaker to 820C. Until the next stage, the oil globules that develop stay suspended in the water.

3. The heating process was stopped, and the oil and water mixture were then given a gentle swirl while the lye solution was dripped in.

4.Resetting the hot plate to medium heat, the beaker was heated there until the mixture's temperature began to climb back up towards 820C. The mixture was then gently and consistently mixed to achieve consistency. The combination initially resemblesshimmering water with unsaponifiable oil, but after 10 to 15 minutes it progressively thickens and becomes homogeneous. The beaker was periodically withdrawn from the heat and put back on the hot plate as needed after being watched to ensure that the temperature did not rise over 820C or fall below 710C.

5.Pour the mixture into a mould that will work, then cover it. It was set aside for saponification for 18 to 24 hours.

6.After saponification, the cover was taken off and it was left unattended for a further 10 to 12 hours. The soap was then cut into bars of various shapes while being handled with latex gloves.

Phase-IIStudies:

1.Foamtest:[10,11,12]

The "modified vibratory flask shaker" was employed for this purpose. 500 ml measuring cylinders were fastened to the device's arms. Medicated soap bars were hydrated for onehour in 20 ml of distilled water. The remaining soap bar was then taken out after some

mild stirring had been done to prepare the soap solution. The 20 ml of soap solution was then transferred to the 500 ml measuring cylinder and agitated for 10 minutes at a speed of 1000 rpm to measure the initial height of foam from the solution's surface to its height. The apparatus was left open for five minutes, after which a second measurement was taken, and the main reading was determined by the difference in the height of the foam .

2. DrugContentEstimation:[13,14]

Pure Terbinafine medication equivalent to 25 mg is contained in each 1%

Terbinafine Soap Bar (1 gram).

Procedure:

A tiny amount of distilled water was used to dissolve the medication, which was ingested and equated to 25 mg of the formulation. The formulation is then heated in a water bath until the drug contained has completely dissolved. The solution was then filtered through Whatman filter paper in a 25 ml volumetric flask, and the volume was then brought up to the required level by distilled water to give Terbinafine a concentration of 1000 g/ml.

Phase-IIIStudies:

MicrobiologicalStudies:[15]

By taking skin scrapings from the ill patient using the traditional cup-and-plate method, antifungal activity of prepared formulations was tested against lipophilic yeast Malassezia furfur (i.e., pityrosporumorbiculare and pityrosporumovale) as the organism is involved with superficial infections. Under the close observation of a dermatologist and with previous notification of the reason the sample was collected, live samples of Malassezia furfur were collected. Beforeinoculating the samples into the appropriate media, the samples were kept in peptone water. The patient's skin scraping was right away inoculated with peptone water to broth medium. For 5-7 days, the medium used to isolate the yeast was cultured at 30°C. Colonies with various morphologies were chosen from the plates and sub cultured on corresponding agar slopes.

Phase-IVStudies:

***In-vitro*DrugRelease**:[16]

For a total of 30 minutes, these tests are carried out using a modified USPXII dissolution apparatus. The drug samples will be taken out at 5-minute intervals and tested for drug release. Shimadzu UV-visible spectrophotometer at 283 nm will be used to analyse the samples.

TABLE-1:FORMULATIONOF 1%TERBINAFINE SOAP BARS(F1)

Sr No.	Ingredient	QuantityGiven	QuantityTaken
1.	Terbinafine	1 gm	0.5 gm
2.	Coconut Oil	44 gm	22 gm
3.	DistilledWater	20ml	10ml
4.	SodiumHydroxide	13 gm	6.50 gm
5.	DistilledWater	22ml	11ml
	Total	**100 gms**	**50 gms**

.**Table-2:Formulationof 1%Terbinafine Soap Bars(F2)**

Sr No.	Ingredient	QuantityGiven	QuantityTaken
1.	Terbinafine	1 gm	0.5 gm
2.	PalmOil	59 gm	29.5 gm
3.	Lye	10 gm	5 gm
4.	DistilledWater	30ml	15ml
	Total	**100 gms**	**50 gms**

Table-3:Formulationof 1%Terbinafine Soap Bars(F3)

SrNo.	Ingredient	QuantityGiven	QuantityTaken
1.	Terbinafine	1 gm	0.5 gm
2.	Coconut Oil	46.66 gm	23.33 gm
3.	PalmOil	20 gm	10 gm
4.	Lye	12.34 gm	6.17 gm
5.	DistilledWater	20ml	10ml
	Total	**100 gms**	**50 gms**

Table-4:Formulationof 1%Terbinafine Soap **Bars(F4)**

Sr No.	**Ingredient**	**QuantityGiven**	**QuantityTaken**
1.	Terbinafine	1 gm	0.5 gm
2.	Coconut Oil	44 gm	22 gm
3.	PalmOil	15 gm	7 .5gm
4.	Olive Oil	8 gm	4 gm
5.	Lye	12 gm	6 gm
6.	DistilledWater	20ml	10ml
	Total	**100 gms**	**50 gms**

3.RESULTS AND DISCUSSION

The goal of the current effort was to create medicated soap bars that had the right size, shape, weight, and capacity to produce foam. Foam on the affected area of the body significantly reduces fungal infection by facilitating medication release from and penetration through the stratum corneum.

According to in-vitro drug release experiments, the 1% Terbinafine Soap Bars released 37.22, 47.55, 51.52, and 45.45% of the drug, respectively, over the course of 30 minutes.

Under the guidance of expert dermatologists, the organisms were extracted from the skin scrapings of the patient who had a fungal infection during the microbiological study. A good zone of inhibition was visible in the 1% Terbinafine Soap Bars.

4.SUMMARY AND CONCLUSION:

The results of the current study showed that the prepared 1% Terbinafine Soap Bars with foam formulation stayed in contact with the affected body part for a considerable amount of time and prevented moistening the area, which in turn inhibited further fungal growth and effectively managed the initial symptoms.

This is a really novel idea for a uniform dosage of medication in medicated soap bars for those with fungal infections on the skin, particularly on the hands and legs.current development, medicated soap bars, is industry-focused because it is simple to use, portable, and affordable to produce.

5.Acknowledgement:

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Table-1:Determination of Foam Height (ml) of 1% Terbinafine SoapBars

Formulation Code	Soap Bar No.	Foam height (ml.)		Mean± SD
		Initial	After5 mins.	
F1	1	51	49	48.66±0.5773
	2	50	48	
	3	50	49	
F2	1	54	53	52.3±0.5773
	2	54	52	
	3	53	52	
F3	1	56	54	53.66 ±0.5773
	2	55	54	
	3	55	53	
F4	1	53	52	52.66 ±0.5773
	2	54	53	
	3	54	53	

Table-2:Physio-chemicalEvaluationofTerbinafine SoapBar

SI.No	Formulationcode	Appearance	pH	DrugContent
1.	F1	White	7.6	96.50 %
2.	F2	White	7.9	97.00 %
3.	F3	White	7.2	98.83 %
4.	F4	White	8.2	98.16 %

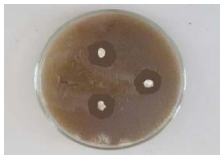
- Each reading is a mean of three replicates.All above formulation contain 1% Terbinafine
- **Table-3:MicrobiologicalStudiesof1% terbinafine SoapBars**

Sl. No.	Formulation Code	ZoneofInhibition(mm)		
		After24 hrs	After48 hrs	After72 hrs
1.	PureDrug	1.4	1.5	1.5
2.	F_1	1.1	1.1	1.1
3.	F_2	1	1.2	1.2
4.	F_3	1.3	1.3	1.4
5.	F_4	1.2	1.2	1.3

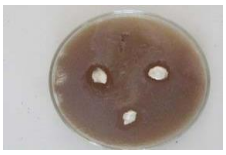
*Each reading is a mean of three replicates.

F_1,F_2,F_3,F_4=1% terbinafine SoapBarformulations.

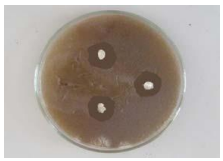
Comparative Zone of Inhibition Studies of Drug in the Formulations With Pure Drug



PUREDRUG

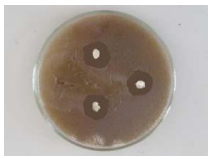


FORMULATION F1

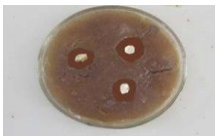


PURE DRUG

FORMULATION F2



PURE DRUG



FORMULATION F3

PURE DRUG

FORMULATION F4

Table 4-:Comparative*In-vitro*DrugReleaseProfileofTerbinafine 1% SoapBar(F1)WithMarketedFormulation(MF)

SI. No	Time (min)	Log of time	Square root oftime	Cumulative % DrugReleased		Log Cumulative % DrugReleased		Cumulative % DrugRemaining		Log Cumulative % DrugRemaining	
				F1	MF	F1	MF	F1	MF	F1	MF
1	0	0	0	0	0	0	0	100	100	2	2
2	5	0.6989	2.2360	10.82 ± 0.25	14.02 ± 0.37	1.0342	1.1467	89.18	85.98	1.9502	1.9343
3	10	1.0000	3.1622	13.89 ± 0.41	19.11 ± 0.16	1.1427	1.2812	86.11	80.89	1.9350	1.9078
4	15	1.1760	3.8729	20.29 ± 0.20	25.88 ± 0.28	1.3072	1.1429	79.71	74.12	1.9015	1.8699
5	20	1.3010	4.4721	27.36 ± 0.12	31.34 ± 0.40	1.4371	1.4960	72.64	68.66	1.8611	1.8367
6	25	1.3979	5.0000	33.38 ± 0.28	37.57 ± 0.21	1.5234	1.5748	66.62	62.43	1.8236	1.7953
7	30	1.4771	5.4772	37.22 ± 0.28	40.42 ± 0.24	1.5707	1.6065	62.78	59.58	1.7978	1.7751

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- Eachsample of1 gm. SoapBar contain25 mg ofdrug.

Table-5:Comparative*In-vitro*DrugReleaseProfileofTerbinafine 1% SoapBar(F2)WithMarketedFormulation(MF)

SI.No	Time (min)	Log Oftime	Square root oftime	Cumulative % DrugReleased		Log Cumulative % DrugReleased		Cumulative % DrugRemaining		Log Cumulative % DrugRemaining	
				F2	MF	F2	MF	F2	MF	F2	MF
1	0	0	0	0	0	0	0	100	100	2	2
2	5	0.6989	2.2360	15.53 ± 0.36	14.02 ± 0.37	1.1911	1.1467	84.47	85.98	1.9267	1.9343
3	10	1.0000	3.1622	22.33 ± 0.21	19.11 ± 0.16	1.3488	1.2812	77.67	80.89	1.8902	1.9078
4	15	1.1760	3.8729	28.73 ± 0.24	25.88 ± 0.28	1.4583	1.1429	71.27	74.12	1.8529	1.8699
5	20	1.3010	4.4721	36.69 ± 0.32	31.34 ± 0.40	1.5645	1.4960	63.31	68.66	1.8014	1.8367
6	25	1.3979	5.0000	43.51 ± 0.16	37.57 ± 0.21	1.6385	1.5748	56.49	62.43	1.7514	1.7953
7	30	1.4771	5.4772	47.55 ± 0.32	40.42 ± 0.24	1.6771	1.6065	52.45	59.58	1.7197	1.7751

Eachreadingisameanofthreereplicates.

- Eachsample of1 gm. SoapBar contain25 mg ofdrug.

Table-6:Comparative*In-vitro*DrugReleaseProfileofTerbinafine 1% SoapBar(F3)WithMarketedFormulation(MF)

SI. No	Time (min)	Log	Squareroot oftime	Cumulative% DrugReleased	Log Cumulative %	Cumulative % DrugRemaining	Log Cumulative % DrugRemaining

		oftime				DrugReleased					
				F3	MF	F3	MF	F3	MF	F3	MF
1	0	0	0	0	0	0	0	100	100	2	2
2	5	0.6989	2.2360	14.91 ± 0.37	14.02 ± 0.37	1.1734	1.1467	85.09	85.98	1.9298	1.9343
3	10	1.0000	3.1622	21.31 ± 0.30	19.11 ± 0.16	1.3285	1.2812	78.69	80.89	1.8959	1.9078
4	15	1.1760	3.8729	29.29 ± 0.12	25.88 ± 0.28	1.4667	1.1429	70.71	74.12	1.8494	1.8699
5	20	1.3010	4.4721	36.66 ± 0.33	31.34 ± 0.40	1.5641	1.4960	63.34	68.66	1.8016	1.8367
6	25	1.3979	5.0000	44.08 ± 0.25	37.57 ± 0.21	1.6442	1.5748	55.92	62.43	1.7475	1.7953
7	30	1.4771	5.4772	51.52 ± 0.32	40.42 ± 0.24	1.7119	1.6065	48.48	59.58	1.6855	1.7751

Eachreadingisameanofthreereplicates.

Eachsample of1gm. SoapBarcontain25mgofdrug.

Table-7:Comparative*In-vitro*DrugReleaseProfileofTerbinafine 1% SoapBar(F4)WithMarketedFormulation(MF)

SI. No	Time(min)	Log oftime	Square root oftime	Cumulative % DrugReleased		Log Cumulative % DrugReleased		Cumulative % DrugRemaining		Log Cumulative % DrugRemaining	
				F4	MF	F4	MF	F4	MF	F4	MF
1	0	0	0	0	0	0	0	100	100	2	2
2	5	0.6989	2.2360	13.32 ± 0.30	14.02 ± 0.37	1.1245	1.1467	86.68	85.98	1.9379	1.9343
3	10	1.0000	3.1622	20.61 ± 0.39	19.11 ± 0.16	1.3140	1.2812	79.39	80.89	1.8997	1.9078
4	15	1.1760	3.8729	27.19 ± 0.24	25.88 ± 0.28	1.4344	1.1429	72.81	74.12	1.8621	1.8699
5	20	1.3010	4.4721	35.16 ± 0.21	31.34 ± 0.40	1.5460	1.4960	64.84	68.66	1.8118	1.8367
6	25	1.3979	5.0000	40.56 ± 0.21	37.57 ± 0.21	1.6080	1.5748	59.44	62.43	1.7740	1.7953
7	30	1.4771	5.4772	45.45 ± 0.37	40.42 ± 0.24	1.6575	1.6065	54.55	59.58	1.7367	1.7751

eachreadingisameanofthreereplicates

- Eachsample of1gm. SoapBarcontain25mgofdrug.