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PHARMACEUTICAL, ANALYTICAL AND ANTIFUNGAL EVALUATION OF *AKALA PALITYAHARA LEPA* AND ITS MODIFIED GEL FOR ENHANCED TOPICAL DRUG DELIVERY

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ABSTRACT

Background: *Akala Palitya* (premature greying of hair) is a common condition described in Ayurveda. *Akala Palityahara Lepa* is a traditional topical formulation used to manage this condition. However, it has some limitations, such as the need for fresh preparation, short shelf life, and difficulty in application. **Aim:** To prepare a modified gel from *Akala Palityahara Lepa* and compare both formulations based on their pharmaceutical properties, physicochemical characteristics, microbial quality, phytochemical profile, and antifungal activity. **Materials and Methods:** *Akala Palityahara Lepa* and its modified gel were prepared using the same ingredients. Both formulations were evaluated for organoleptic characters, physicochemical parameters, microbial contamination, thin-layer chromatography (TLC), and antifungal activity against Candida albicans by the agar well diffusion method. **Results:** Both formulations showed acceptable physicochemical and microbiological quality. The gel had better spreadability, homogeneity, and water-soluble extractive value, while the *Lepa* showed higher viscosity and stronger antifungal activity. TLC confirmed the presence of gallic acid (Rf = 0.69) in both formulations. **Conclusion:** The modified gel showed good quality, was easy to apply, and demonstrated antifungal activity. It may serve as a convenient alternative to the traditional *Lepa*. Further experimental and clinical studies are required to confirm its effectiveness in the management of *Akala Palitya*.

KEYWORDS: *Lepa,* Herbal gel, Topical drug delivery, Ayurveda, Semisolid formulations.

1. INTRODUCTION

Nowadays Premature greying of hair is an upcoming common cosmetic problem. In Ayurveda, this is refered as *Akala Palitya*[1], which refers to the greying of hair before the normal age. *Kesha* is considered the *Mala* of *Asthi Dhatu*[2], and healthy hair depends on the nourishment of *Dhatus*[3] and the balanced state of *Doshas. Akala Palitya* is mainly caused by the aggravation of *Pitta Dosha*[4], along with the involvement of *Vata*, due to factors such as stress, improper diet, unhealthy lifestyle, and excessive physical or mental exertion.

Modern science explains premature greying[5] as a result of reduced melanin production or abnormal function of melanocytes. Genetic factors, oxidative stress, nutritional deficiencies, hormonal imbalance, and psychological stress are considered important contributing factors. Although chemical hair dyes are widely used to mask grey hair, their prolonged use may cause adverse effects such as scalp irritation, allergic reactions, hair damage, and disturbance of the normal scalp microflora.[6]

Ayurveda recommends several external therapies for hair disorders, among which *Lepa* is an important topical formulation. *Akala Palityahara Lepa*, described in *Sharangadhara Samhita*.[7] contains *Haritaki, Bibhitaki, Amalaki, Amra Phala Majja, and Loha*, which possess *Palityahara, Keshya, Rasayana*[8], *and Krimighna* properties. However, the traditiona*l Lepa* requires fresh preparation, has a short shelf life, and may be inconvenient for routine use.

To overcome these limitations, conversion of the classical *Lepa* into a gel[9] formulation may improve stability, spreadability, ease of application, and patient compliance while retaining its therapeutic potential. Therefore, the present study was undertaken to prepare a modified gel of *Akala Palityahara Lepa* and evaluate its pharmaceutical properties, physicochemical characteristics, microbial quality, phytochemical profile, and antifungal activity against Candida albicans.

2. PHARMACEUTICAL ASPECTS OF *LEPA*

Lepa[10] is prepared in a simple way. Suitable herbal drugs are selected and properly dried before being powdered. This powder is then mixed with an appropriate liquid medium such as water, herbal decoction, or oil to form a smooth and uniform paste. The prepared *Lepa* is

then applied over the affected area.

The action of *Lepa* is mainly local. After application, the active components of the herbs are absorbed through the skin. It helps in improving local blood circulation, reducing inflammation, and providing relief from symptoms. Because of this direct action, the effect of *Lepa* can be seen relatively quickly in many conditions.

One of the main advantages of *Lepa* is that it acts directly at the site of application, which reduces the need for systemic medication. However, it also has some limitations. It usually needs to be freshly prepared before use, which may not always be convenient. It has a short shelf life and may get contaminated if not handled properly. The application process can also be messy, and the consistency may vary depending on preparation, which can affect its use.

3. NEED FOR TRANSFORMATION INTO MODERN DOSAGE FORMS

In today's time, patients prefer treatments that are simple, clean, and easy to use. There is also a need for formulations that remain stable for a longer time and maintain consistent quality. Traditional *Lepa*, although effective, does not always meet these requirements. Because of its short shelf life, inconvenience in use, and lack of uniformity, its wider use becomes limited.

To overcome these issues, there is a need to convert traditional *Lepa* into more suitable and modern dosage forms Such modifications can help in improving stability, convenience, and overall acceptability of the treatment.

4. HERBAL GEL AS A MODERN TOPICAL SYSTEM

Herbal gels[11] are one of the modern semisolid dosage forms that can be used for topical application. In this form, the active herbal ingredients are incorporated into a gel base, which makes the formulation smooth and easy to apply.

Herbal gels have several advantages compared to traditional preparations. They are non-greasy and more comfortable to use on the skin. They spread{12} easily and can be removed without difficulty. They also allow better penetration of the drug into the skin and have a longer shelf life.

A typical herbal gel contains the herbal extract as the active ingredient, along with a gelling agent that gives it proper consistency.[13] Preservatives are added to prevent microbial growth,

and a suitable base like water is used to prepare the formulation.

5. MATERIAL AND METHOD[14]

Raw drug collection & weighing

(Haritaki 12 g + Bibhitaki 3 g + Amalaki 10 g + Amra Majja 20 g + Loha Bhasma 1 tola)

↓

Cleaning, drying & removal of impurities

↓

Powdering of each ingredient separately

↓

Sieving & uniform mixing of all *churna*

↓

Trituration with sufficient water

→ formation of smooth homogeneous paste *(Lepa)*

↓

Transfer into *Loha Patra* & keep overnight

↓

Observation (color, consistency, uniformity)

↓

Storage in airtight container

GEL[15]

Weighing of drugs (*Haritaki 8 g + Bibhitaki 2 g + Amalaki 6.67 g + Amra Majja 13.3 g + Loha Bhasma* 7.73 g)

↓

Kwath[16] preparation (30 g *churna* + 480 mL water → reduced to 60 mL → 40 mL used)

↓

Cooling of *kwath*

↓

Carbopol 940 dispersion (1.5 g in water, hydrated 20–30 min)

↓

Filtration of *kwath* (40 mL obtained)

↓

Mixing of *kwath* into Carbopol base

↓

Neutralization with TEA

↓

Addition of *Loha Bhasma* & homogenization

↓

Final gel

↓

Packaging in sterile containers

6. ROLE OF MICROBIAL FACTORS IN SKIN AND SCALP HEALTH[17]

Different types of microorganisms normally reside on scalp and skin. When this natural balance is disturbed, it can lead to infections and other problems. Fungal organisms such as *Candida albicans* are known to affect skin and scalp health in certain conditions.

Herbal drugs like *Haritaki, Amalki* etc often have natural antimicrobial properties, which help in controlling such infections. Using formulations that can manage microbial growth is important for maintaining healthy skin and improving treatment results.

7. EVALUATION PARAMETERS OF HERBAL GEL[18]

To make herbal gel safe and effective, it is tested using different evaluation parameters. The pH[19] of the gel should be suitable for skin application so that it does not cause side effect. Viscosity[20] is checked to understand the thickness of the gel for application. Spreadability is also important, as it shows how easily the gel can be applied over the skin.

To make lump free gel, homogeneity is tested. Stability studies are carried out to determine how long the gel remains effective and unchanged. Microbial testing is also important to ensure that the formulation is safe and free from contamination.

8. OBSERVATION AND RESULTS

1.1 Pharmaceutical study

***Lepa*- Table 1.1.**

SR. NO.	*Panchbhautik Pariksha*	Observation
1.	*Sparsha*	Rough paste
2.	*Roopa*	Blackish brown
3.	*Rasa*	*Tikta kashaya*
4.	*Gandha*	Herbaceous, Earthy

GEL- Table 1.2.

SR. NO.	*Panchbhautik Pariksha*	Observation
1.	*Sparsha*	Smooth
2.	*Roopa*	Smooth brown
3.	*Rasa*	*Tikta Kashaya*
4.	*Gandha*	Herbaceous

Table 1.3.

SR. NO.	OBSERVATION	*AKALAPLAITYA HARA LEPA*	MODIFIED GEL
1.	Weight of ingredients taken	56.7gm	43.2gm
2.	Water added	q.s	480ml *kwath* + 60ml dm water
3.	Time required for preparation	1hr	1 hr 30min
4.	Appearance	Smooth homogenous paste	Smooth homogenous brown gel
5.	Loss of water	-	440ml
6,	Final yield obtained	63gm	110gm
7.	Total duration of process	19hrs	1hr 30mins

1.2] Analytical Study

A) Observations and results of analytical study of *Akalapalityahara lepa* and modified gel.

Table 1.4.

Sr.No.	Parameter	*Akala Palityahara Lepa*	Modified Gel
1	Density / Weight per ml (g/ml)	1.011	0.98
2	pH	6.1	6.5

3	Moisture Content (%)	5.25	—
4	Loss on Drying (LOD) (%)	—	2.3
5	Ash Value (% w/w)	9.45	7.25
6	Acid Insoluble Ash (% w/w)	1.22	0.82
7	Alcohol Soluble Extractive (% w/w)	8.45	—
8	Water Soluble Extractive (% w/w)	21.04	34.06
9	Total Solid Content (%)	—	21.05
10	Solubility	—	Soluble
11	Refractive Index	—	1.315
12	Viscosity (cP)	24000	2000
13	Spreadability	—	0.760
14	Homogeneity	Uniform, smooth homogeneous paste with slight grittiness	Uniform, smooth homogeneous gel with slight lumps and grittiness

The *lepa* had a higher density because it contained more solid material. Both the *lepa* and gel had a pH close to neutral, making them suitable for skin application. Their low moisture content indicates good stability. The *lepa* showed higher ash values due to the presence of more herbs, while the gel had a higher water-soluble extractive value because of its water-based gel base. The *lepa* was thicker, whereas the gel spread more easily and was simpler to apply. Both formulations were fairly uniform, with slight grittiness caused by the herbal ingredients.

B) MICROBIAL CONTAMINATION[21]

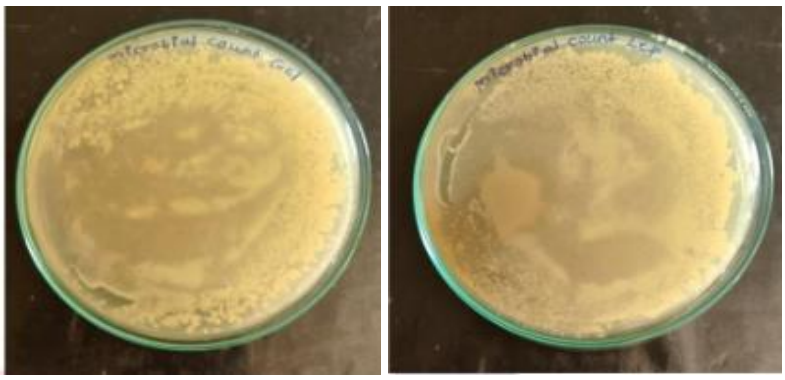


Table 1.5.

Sr. No.	Sample	No of Colonies	CFU/ml	Permissible Limit (API/WHO)	Result
1.	*LEPA*	1125	11250	Not more than 10^5 CFU/g or mL	Within Limit
2.	GEL	1256	12560	Not more than 10^5 CFU/g or mL	Within Limit

Both the *Lepa* and Gel showed microbial counts much lower than the maximum limit suggested by API/WHO (10^5 CFU/ml). This indicates that both formulations were prepared under proper hygienic conditions and are microbiologically safe for use. The slightly higher count observed in the gel may be due to its moisture-rich nature

C) TLC[22]

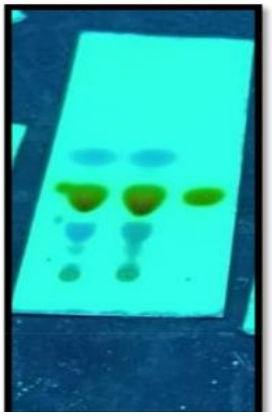


Table 1.6.

Sr. no.	Sample	Distance Travelled by Spot (cm)	Solvent Front (cm)	Rf Value
1.	Sample –Gallic Acid[23]	3.2	4.6	0.69
2.	Sample- *Lepa*	3.2	4.6	0.69
3.	Sample- Gel	3.2	4.6	0.69

Sr. no.	Sample	Concentration	Zone of Inhibition (mm) Candida Albicans
1.	Control		
2.	Standard Fluconazole	1 mg/mL	29
3.	Sample- *lepa*	5 mg/mL	03
		10 mg/mL	20
4.	Sample- Gel	5 mg/mL	02
		10mg/mL	04

The TLC profile indicates that both *Lep* and Gel samples exhibit a prominent spot with Rf ≈ 0.69, matching the Gallic Acid standard, suggesting the presence of Gallic Acid or a closely

related phenolic compound in both samples.

1.3) Experimental Study

ANTI- MICROBIAL STUDY[24]

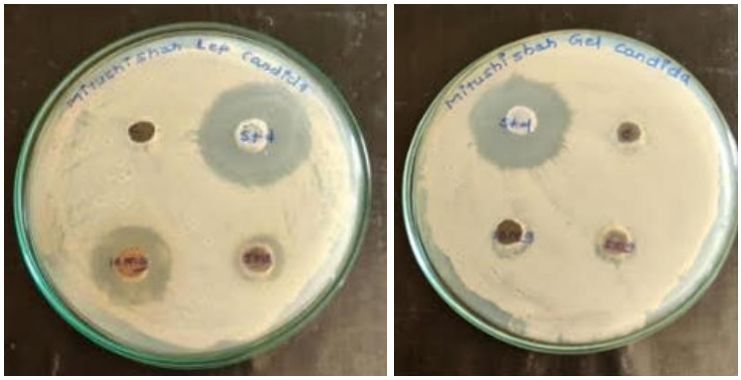


Table 1.7

The antifungal study against Candida albicans[25] showed that the standard drug Fluconazole (1 mg/mL) produced the highest zone of inhibition (29 mm), confirming the test was valid. The *lepa* formulation showed better antifungal activity than the gel, with inhibition increasing as the concentration increased. The gel showed lower activity, which may be due to the slower release of active compounds from the gel base. Overall, both formulations demonstrated concentration dependent antifungal activity.

9. RESULTS

Analytical Evaluation

Both formulations showed physicochemical properties within acceptable range for local use. The *Lepa* had higher density, viscosity, and ash values because it contained more solid herbal material. The modified gel showed better spreadability, homogeneity, and a higher water-soluble extractive value. The pH of both formulations was close to neutral, making them suitable for skin application. Low moisture content suggested good stability.

Microbial Quality

The microbial counts of both formulations were well within the API/WHO permissible limits, indicating that they were prepared under hygienic conditions and were microbiologically safe.

Thin Layer Chromatography

The TLC study showed an Rf value of 0.69 for both the *Lepa* and gel, which matched the

gallic acid standard. This confirmed the presence of gallic acid or related phenolic compounds in both formulations.

Antifungal Activity

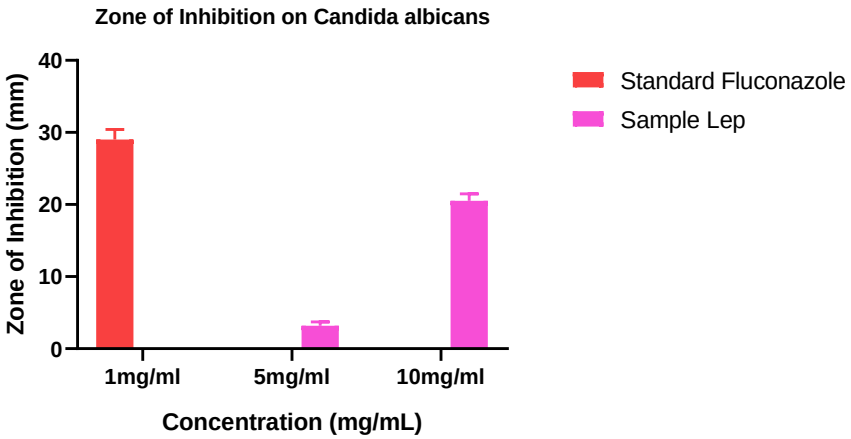
Both formulations showed concentration-dependent antifungal activity against Candida albicans. The Lepa produced a larger zone of inhibition than the modified gel, while the standard Fluconazole showed the highest antifungal activity.

10. STATISTICAL ANALYSIS

Table 1.8: Zone inhibition on Candida Albicans of Flucanazole and *lepa.*

Concentration	Standard Fluconazole	Sample – *Lepa*
1mg/ml	29±3.46*	0
5mg/ml	0	3.17±1.17*
10mg/ml	0	20.5±2.66*

Data are expressed as mean ± standard deviation. Significance was determined using two-way ANOVA followed by Sidak's multiple comparisons test; * indicates $p < 0.0001$

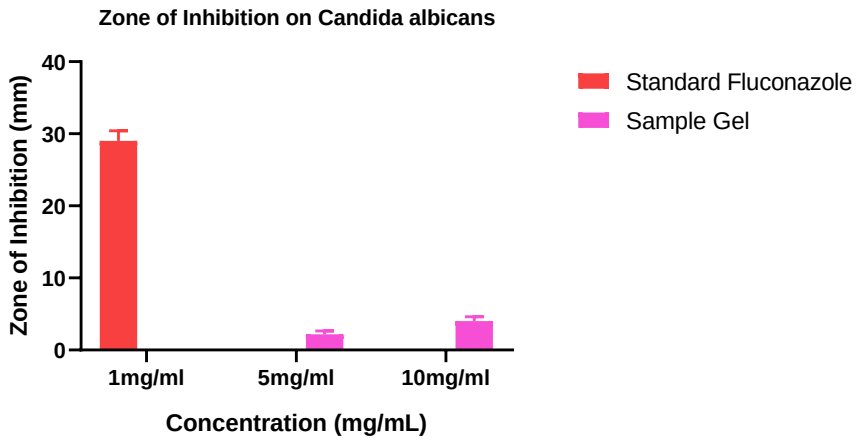


Bar chart 1.1 - Zone of inhibition of Candida Albicans on Flucanazole and *lepa*

- The Standard Fluconazole at 1 mg/ml showed the highest mean zone of inhibition (29.00 ± 3.46 mm), indicating the strongest antifungal activity.
- *Lepa* showed no inhibition at 1 mg/ml but exhibited increasing zones of inhibition at 5 mg/ml (3.17 ± 1.17 mm) and 10 mg/ml (20.50 ± 2.66 mm), indicating concentration-dependent antifungal activity.
- Two-way ANOVA followed by Sidak's multiple comparisons test demonstrated a highly significant difference between the Standard Fluconazole and *Lepa* groups ($p < 0.0001$).

Table 1.9: Zone inhibition on Candida Albicans of Flucanazole and Gel.

Concentration	Sample – *Lepa*	Sample - Gel
1mg/ml	0	0
5mg/ml	3.17±1.17	2.17±1.17
10mg/ml	20.5±2.66*	3.67±1.51

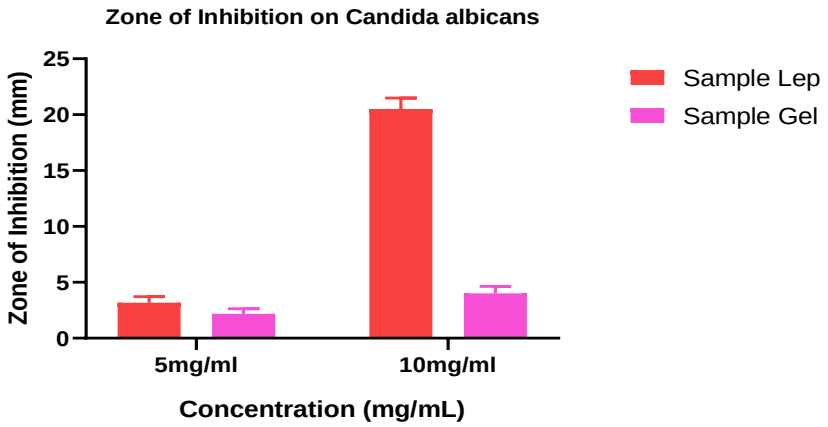


Bar chart 1.2 - Zone of inhibition of Candida Albicans on Flucanazole and Gel

- The Standard Fluconazole at 1 mg/ml showed the highest mean zone of inhibition (29.00 ± 3.46 mm), indicating the strongest antifungal activity.
- The Gel exhibited no inhibition at 1 mg/ml but demonstrated measurable antifungal activity at 5 mg/ml (2.17 ± 1.17 mm) and 10 mg/ml (3.67 ± 1.51 mm), suggesting a concentration-dependent response.
- Two-way ANOVA followed by Sidak's multiple comparisons test revealed a highly significant difference between the Standard Fluconazole and Sample Gel groups ($p < 0.0001$).

Table 2.0: Zone inhibition on Candida Albicans of Flucanazole, *Lepa* and Gel.

Concentration	Sample – Lep	Sample - Gel
1mg/ml	0	0
5mg/ml	3.17±1.17	2.17±1.17
10mg/ml	20.5±2.66*	3.67±1.51



Bar chart 1.3-Zone of inhibition of Candida Albicans on Flucanazole, *lepa* and gel

- Both the *Lepa* and Gel formulations showed no zone of inhibition at 1 mg/ml but demonstrated antifungal activity at higher concentrations.
- The highest mean zone of inhibition was observed for the *Lepa* at 10 mg/ml (20.50 ± 2.66 mm), whereas the Gel showed 3.67 ± 1.51 mm at the same concentration.
- Two-way ANOVA followed by Sidak's multiple comparisons test showed no significant difference between the formulations at 5 mg/ml but a highly significant difference at 10 mg/ml ($p < 0.0001$).

Overall, the statistical findings support that both the *Lepa* and Gel formulations possess antifungal activity against Candida albicans. The concentration-dependent increase in the zone of inhibition observed in both formulations indicates their potential as topical antimicrobial formulations and supports further pharmacological and clinical evaluation.

11. DISCUSSION

The present study successfully prepared a modified gel from the *Akala Palityahara Lepa*. The results showed that both formulations had acceptable pharmaceutical quality and were suitable for local application.

The *Lepa* showed higher density, viscosity, and ash values because it contained more solid herbal ingredients. The modified gel showed better spreadability and homogeneity due to the gel base, making it easier to apply. The near-neutral pH of both formulations indicates that they are suitable for skin application, while the low moisture content suggests good stability.

The microbial load of both formulations was within the acceptable API/WHO limits, indicating that they were microbiologically safe. The TLC profile showed the same Rf value

as the gallic acid standard, confirming the presence of gallic acid or similar phenolic compounds in both formulations.

In the antifungal study, both formulations inhibited the growth of Candida albicans, and the effect increased with concentration. The *Lepa* showed greater antifungal activity than the modified gel.

The lower activity of the gel may be due to the slower release of active compounds from the gel base during the test. Statistical analysis using Two-way ANOVA revealed that both formulations show concentration dependent antimicrobial activity between the samples and the standard drug ($p < 0.05$).

Two-way ANOVA followed by Sidak's multiple comparisons test confirmed that both the Lepa and Gel formulations exhibited significant antimicrobial activity against *Candida albicans* in a concentration-dependent manner.

However, the gel provided better spreadability, ease of application. These findings suggest that the modified gel can be considered a suitable alternative to the traditional Lepa. Further experimental and clinical studies are needed to confirm its therapeutic efficacy.

12. CONCLUSION

The present study concludes that *Akalapalityahara Lepa* and its modified gel formulation were successfully prepared and evaluated. The literature review supported the therapeutic importance of *Haritaki, Amalaki, Bibhitaki, Amraphala Majja,* and *Loha Churna* in promoting hair health and managing premature greying of hair. Both formulations matched with the required physicochemical standards and showed satisfactory quality.

The analytical evaluation of both formulations showed satisfactory results. Organoleptic examination, physicochemical parameters and microbial load analysis indicated that the prepared formulations were of acceptable quality and matched with the recommended limits for herbal preparations. The gel formulation exhibited good consistency, homogeneity and spreadability, making it convenient for topical use.

The antifungal study against Candida albicans revealed that both the *Lepa* and Gel formulations were capable of inhibiting fungal growth. The *Lepa* showed a greater zone of inhibition, whereas the Gel also demonstrated noticeable antifungal activity.

The results obtained provide supportive evidence for the development of this *lepa* into a more user-friendly dosage form and create a foundation for further clinical studies in the management of *Akala Palitya.*

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