Innovative Roll-On Gel Formulation of Miconazole for Enhanced Patient Compliance

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1. Introduction –

Fungal infections, caused by dermatophytes and yeasts, are a widespread global health concern, particularly in warm, humid environments that favour fungal growth. These infections, commonly affecting the skin, hair, and nails, include conditions like Tinea Pedis (Athlete's Foot), Tinea Corporis (Ringworm), and Onychomycosis (nail infections). [1,2] While not life-threatening in most cases, these infections can cause significant discomfort, itching, and social embarrassment, impacting the quality of life. Superficial fungal infections are highly contagious and thrive in communal environments like swimming pools, gyms, and locker rooms, making prevention and effective treatment essential. [3,4]

Among antifungal treatments, azole drugs such as clotrimazole**,** miconazole, and ketoconazol**e** are widely used for their efficacy and safety. These drugs inhibit ergosterol synthesis, a vital component of fungal cell membranes, leading to the disruption of fungal growth. Miconazole**,** in particular, is known for its broad-spectrum activity against dermatophytes and yeasts. Its availability in various formulations, including creams, powders, and gels, makes it versatile for treating different fungal infections. [5,6] The development of a roll-on gel formulation for miconazole further enhances its utility, offering easy application, targeted delivery, and hygienic use, especially for areas like the feet and groin.

A common broad-spectrum antifungal medication used to treat a variety of mucosal and superficial fungal infections is miconazole. Miconazole, a member of the azole antifungal class, works by preventing the production of ergosterol, which is essential for the formation of fungal cell membranes. Miconazole is a successful treatment for a variety of dermatophyte and yeast infections because it causes fungal cell death through a breakdown in the integrity of the cell membrane. [7,8]

The medication is available in creams, powders, sprays, vaginal suppositories, and oral gels, and its effectiveness is extended to both topical and systemic formulations. Miconazole is a well-liked option for

treating mild to moderate fungal infections in outpatient settings due to its accessibility and adaptability. [9,10]

Apart from its well-established medicinal use, miconazole is renowned for having a comparatively low frequency of adverse effects, however skin irritation and, in rare cases, systemic reactions are possible. Due to its safety profile, the medication is now widely used for both clinical treatment of fungal infections and self-care. Despite its wide range of applications, further consideration of its efficacy and use is necessary due to the development of drug resistance in certain fungal strains and the possibility of medication interactions, especially with oral anticoagulants[11,12].

2. Material & Methods –

2.1 Material use:-

- **Miconazole Powder** :- Manufactured for :Coloplast A/S DK -3050 Humlebaek ,Denmark Distributed by: Coloplast Corp. Minneapolis, MN 55411 U.S.A.

- **Glycerine :-** Loba Chemise Pvt. Ltd., Jehangir Vill, 107,Wodehouse Road ., Colaba ,Mumbai Maharashtra , India -400005.

- **Sodium benzoate: -** HO: Loba Chemie Pvt. Nd.. Jehangir Villa, 107, Wodehouse Rd., Colaba, Mumbai (India) Mfg At: Plot No, D-22, Tarapur MIDC, Boisar, Palghar, Maharashtra (India).

- **Carbomer :-** HO: Loba Chemie Pvt. Nd.. Jehangir Villa, 107, Wodehouse Rd., Colaba, Mumbai (India) Mfg At: Plot No, D-22, Tarapur MIDC, Boisar, Palghar, Maharashtra (India).

- **Distilled water:-** HO: Loba Chemie Pvt. Nd.. Jehangir Villa, 107, Wodehouse Rd., Colaba, Mumbai (India) Mfg At: Plot No, D-22, Tarapur MIDC, Boisar, Palghar, Maharashtra (India).

2.2 Phytochemical Test: - Standard procedures were followed for conducting phytochemical screening. Tannins, flavonoids, alkaloids, saponins, .The existence of secondary metabolites such as alkaloids, saponins, tannins, and flavonoids has been established by thin layer chromatography of different C.

Table no.01: - Phytochemical Constituents of Miconazole .

S.NO.	Phytochemical	Positive or Negative
01.	Flavonoids	+
02.	Saponins	+
03.	Alkaloids	+
04.	Tannins	+

2.3 Anti-microbial activity test: - Agar Diffusion Method (Disk Diffusion)

Procedure:-

Get a Sabouraud agar plate or nutrition agar plate ready (for fungus testing).Depending on the target microbe, inoculate the plate with a bacterial or fungal culture.Put Miconazole-impregnated filter paper disks on the infected agar plate's surface.The plate should be incubated at the proper temperature, which is usually 30°C for fungi or 37°C for bacteria.To assess Miconazole's efficacy, measure the zone of inhibition surrounding the disk after incubation.

3. Formulation of Roll on gel -

Table no. 02: - Formula design**.**

S NO.	Ingredients	Quantity (%)
1.	Carbomer	2%
2.	Glycerin	3%
3.	Sodium benzoate	0.8%
4.	Distiled Water	Q.S.
5.	Miconazole	2%

4. Prepration of Miconazole roll on gel -

- Prepration of the Gel Base :-Stirring, dissolve the gelling agent (such as carbomer) in water. You can gently apply heat to dissolve it.

Add humectants such as glycerin once the gel base has developed.

The gel's pH should be adjusted to a skin-friendly range, usually between 4.5 and 6.

Figure no.01 Gel Base

- Miconazole Incorporation:-Miconazole nitrate should be dissolved in an appropriate solvent, such as propylene glycol or ethanol, to aid in the solvation of the active component. To guarantee that the active ingredient is distributed evenly, add the Miconazole solution to the gel base an

Figure no. 02 Mix soluation

- Final Modifications and Preservatives:-To guarantee that the product doesn't develop microorganisms while being used, add preservatives. To make sure all the ingredients are incorporated evenly, give the mixture a good stir.

Figure no. 03 Slowly Stir

- Use Sonicator ;- The gel may be in the bath to break up particles, extract certain components, or mix with other substances. Make sure the sonicator bath is appropriate for your particular application and that the gel is designed for such usage.

Gel can be added to the bath to break up particles, combine with other substances, or extract specific components.
Make sure the sonicator bath is appropriate for your particular application and that the gel is designed for such usage.

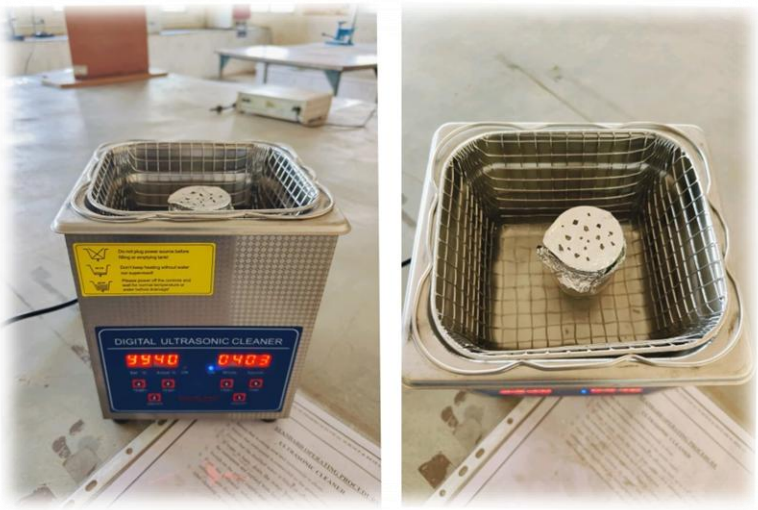

Figure no. 04 Use Ultrasonic Bath

- Packaging:-The gel can be loaded into roll-on applicators for easy, accurate application after it has been completely prepared and allowed to cool to room temperature.

Figure no. 05 Gel in container

5. Evaluation of Miconazole roll on gel -

5.1 Physical Appearance:- The physical appearance test of Miconazole roll on gel is done by observing it through sensory organ and following observation is made.

Table no. 03: - Organoleptic Properties of model drug .

S.no	Properties	Observation
1	Colour	Colourless
2	Odour	Slightly alcoholic
3	Appearance	Slightly cloudy
4	Texture	Smooth and non-greasy

5.2 PH Test:- The ideal pH range for a topical preparation is between 4.5 to 6.5, which is the same range as the pH of the skin. A pH that is excessively acidic could irritate the skin.

Figure no.06 PH Test

Table no. 04: - PH of various formulation

S.no	Sample	pH
1	F1	3.86
2	F2	4.43
3	F3	4.89
4	F4	4.98

5.3 Angle of repose: -The angle of repose is the greatest angle that can be established between the base line or horizontal surface and the powder pile's surface.

Tan0h/r

r is the pile's base radius, while h is the pile's height.

Table no. 05: - Angle of repose of various formulation.

Flow Character	Angle of repose
Very good	<20
Good	20-30
Poor	30-34
Very poor	>40

5.4 Spreadability:- The following values were recorded for spreadability of formulated gels and it has been found that the formulations have good spreadability shown in.

Table no. 06; - Spreadability of various formulation.

Formulation Code	Quantity (mg)	Diameter (cm)
F1	3	2
F2	3	1.8
F3	3	1.8
F4	3	1.5
F5	3	1.3

5.5 Skin irritation:- After the test period, carefully check the area for signs of irritation ,is does not cause Redness, Itching or discomfort, Swelling, Rash or hives, Blisters or peeling skin, Burning sensation.

Figure no.07 Skin irritation

5.6 Rheological Study:-

Table no. 06; - Viscosity of various formulation.

Formulation code	Viscosity(g/cm2)
F1	15.3
F2	24.3
F3	20.3
F4	19.8
F5	16.8

The viscosities of various formulations were measured using a Brookfield viscometer at 37°C and 100 rpm with spindle no. 64. The viscosity ranges from 15.3 to 24.3g/cm2

6. **Conclusion** - The formulation of a Miconazole roll-on gel presents a convenient and effective topical solution for treating fungal infections. The study successfully developed and evaluated a gel-based formulation that ensures easy application, targeted drug delivery, and enhanced user hygiene. Through various tests, including pH, spreadability, viscosity, and antimicrobial activity, the formulation demonstrated stability, effectiveness, and good skin compatibility. The roll-on gel provides an improved alternative to conventional antifungal treatments, offering a non-greasy, smooth texture with optimal pH balance. Overall, this research highlights the potential of Miconazole roll-on gel as a practical and efficient solution for fungal infections.

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