

FORMULATION AND EVALUATION OF TOPICAL PATCHES OF MICONAZOLE NITRATE

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ABSTRACT

Miconazole nitrate, an antifungal agent, is widely used for the treatment of various fungal infections. The development of topical patches as a delivery system for miconazole nitrate aims to enhance localized drug delivery, minimize systemic absorption, and improve patient compliance. This study focuses on the formulation and evaluation of miconazole nitrate topical patches using a solvent casting technique. Patches were prepared using biocompatible polymers such as hydroxypropyl methylcellulose grades including HPMC K100M, HPMC K4M, HPMC E50, along with plasticizers to optimize flexibility and adhesion. The patches were evaluated for physical properties, including thickness, tensile strength, and moisture content. In vitro drug release studies were conducted using diffusion cells, revealing a sustained release profile conducive to effective fungal treatment. Permeability studies demonstrated that the

patches can achieve therapeutic concentrations in the skin layers. Overall, the developed miconazole nitrate topical patches show promising potential as an effective and patient-friendly alternative management of localized fungal infections.

KEYWORDS: Miconazole nitrate, Antifungal agent, Hydroxypropyl methylcellulose.

INTRODUCTION

A topical drug delivery system involves applying a drug formulation to the skin or mucous membranes to treat localized conditions. The method leverages the skin's large surface area and its ability to absorb certain substances. Topical drug delivery systems provide a versatile

and effective means of administering medications for both local and systemic effects. Topical drug delivery (TDD) is a route of drug administration that allows the topical formulation to be delivered across the skin upon application, hence producing a localized effect to treat skin disorders like eczema. The mechanism of topical delivery includes the diffusion the metabolism of drugs in the skin. The delivery of topical drugs needs to pass through multiple skin layers and undergo pharmacokinetics, hence factor like dermal diseases minimize the bioavailability of the topical drugs.



Fig. 1: Topical Patch.

Miconazole is an azole antifungal with a broad spectrum of activity that also exhibits some activity against *gram-positive* bacteria. The principal mode of action is the suppression of CYP450 14 α -lanosterol demethylase enzyme, leading to modified ergosterol production and compromised permeability and composition of cell membranes. Furthermore, Miconazole increases the generation of reactive oxygen species (ROS) by blocking the activities of catalase and fungal peroxidase, but not NADH oxidase activity. Elevated reactive oxygen species within cells cause pleiotropic consequences later on and ultimately apoptosis.

This research focuses on the formulation and evaluation of miconazole nitrate topical patches aimed at optimizing the delivery mechanism for improved efficacy against dermatological infections. We aim to explore various polymer matrices, penetration enhancers and fabrication techniques that can influence the release profile and permeation of miconazole nitrate through skin barrier. The ultimate goal of this study is to select a range of polymers with diverse physicochemical properties suitable for topical patch formulation, evaluate the physical characteristics of each formulated patch, including thickness, flexibility and surface morphology and determine the percent drug content and drug release of each patch formulation using *in vitro* diffusion studies and to develop safe effective and patient friendly patch.

LITERATURE REVIEW

The exploration of topical delivery systems for antifungal agents has led to significant advancements in the treatment of dermatological fungal infections. Recent developments in the formulation of Miconazole into topical patches aim to enhance drug delivery while reducing systemic side effects and improving patient adherence to treatment regimens.

Miconazole is extensively utilized for the treatment of various fungal infections, which encompass a wide range of dermatophytic and candidal infections. The following are the key conditions for which Miconazole is indicated.

1. **Tinea Pedis (Athletes Foot):** a prevalent fungal infection affecting the skin of the feet, particularly between the toes.
2. **Tinea Cruris (Jock Itch):** a fungal infection localized in the groin area, commonly seen both men and women.
3. **Tinea Corporis (Ringworm):** a dermatophyte infection and manifests on various skin sites, presenting as circular, red patches.
4. **Vulvovaginal Candidiasis (Vaginal Yeast):** a widespread yeast infection leading to discomfort and irritation in vaginal area.
5. **Oropharyngeal Candidiasis (Oral Thrush):** a fungal infection characterized by white patches in the mouth and throat.
6. **Tinea Versicolor:** a condition causing small discolored patches on the skin due to fungal overgrowth.

ADVANTAGES OF MICONAZOLE TOPICAL PATCHES

1. **Enhanced Permeability:** penetration enhancers such as propylene glycol, which significantly improve the permeability of the active ingredient through stratum corneum.
2. **Controlled Release:** design of topical patches allows for controlled and sustained release of Miconazole which is advantageous for addressing deeply rooted fungal infections.
3. **Reduced Side Effects:** by providing a localized treatment approach, these patches minimize the potential systemic side effects associated with oral or intravenous antifungal administration. Furthermore, avoiding first-pass metabolism in the liver significantly enhances bioavailability.

FORMULATION AND COMPONENTS

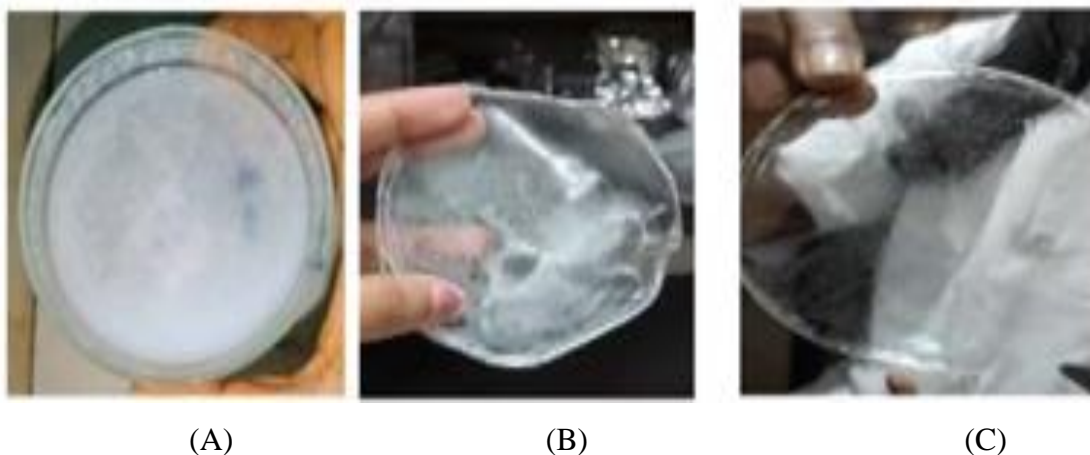
- 1. Drug Reservoir:** The patches typically contain a drug reservoir made of polymers that control the release rate of Miconazole. These polymers must be compatible with the drug and should not alter its pharmacological properties.
- 2. Backing Laminates:** To prevent drug loss and maintain moisture control, patches use backing laminates. These materials support the patch and ensure that the drug is only released in the desired direction towards the skin.
- 3. Plasticizers:** Added to enhance the flexibility and durability of the patch, plasticizers like glycerol and propylene glycol help maintain the structural integrity of the patch without affecting the drug's efficacy.
- 4. Permeation Enhancers:** To facilitate the drug's penetration through the skin, permeation enhancers are incorporated.
- 5. Surfactants:** Surfactants like tween is used to increase the solubility and enhance the permeation rate of the drug.
- 6. Drug Loading:** Miconazole is typically dissolved or dispersed in a suitable solvent like methanol and then in polymer solution ensuring uniform distribution within the patch matrix. The polymer controls the release rate of the drug. These polymers must be compatible with the drug and should not alter its pharmacological properties.

PRELIMINARY TESTS

Based on literature review a number of film-forming polymers, like Eudragit RS 100, Eudragit RL 100, PVP, Hydroxypropyl methylcellulose (HPMC), HPMC E50, HPMC K100M, HPMC K4M, were screened for their ability to create films.

Trial patches of Eudragit RL, EUDRAGIT RS and Polyvinyl pyrrolidone and three different HPMC grades were prepared. Patches made out of Eudragit RL and Eudragit RS were difficult to remove from the petri dish. In case of PVP, patches did not have the desired characteristics. Hence HPMC grades were selected for further studies as they produced desirable patches.

Ethanol in small amounts was used for dispersing the polymer and water was used for dissolving the polymer. Different concentration of polymer and solvents were taken to find out the best suiting concentration to get patches having desired characteristics.



(A) (B) (C)
FIG. 2: (A) EUDRAGIT RS, (B) PVP, (C) HPMC K100M.

Miconazole nitrate is insoluble with water. Ethanol was used to dissolve the drug. This drug solution when added to the polymeric solution exhibited crystallization of the drug. Hence **Solid Dispersion method** was selected for improving drug stability and then it was added to the polymeric solution.

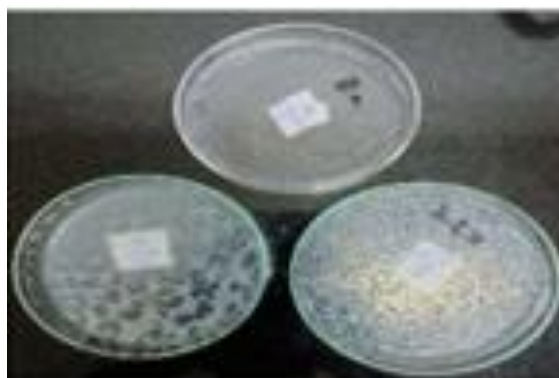


Fig. 3: Crystallisation.



Fig. 4: Patch After Solid Dispersion Method.

PLASTICIZERS AND PERMEATION ENHANCER

Polyethylene glycol 400, Polyethylene glycol 6000, Propylene glycol and glycerine were explored as plasticizers and permeation enhancers. However, PEG's gave turbid patches. Hence Glycerine and Propylene glycol were selected since they produced clear patches. Surfactant viz Tween 20 was added to improve overall solubility of the mixture. The patches were prepared by Solvent Casting method.

METHODOLOGY

1) SOLID DISPERSION METHOD

FORMULATION CONSIDERATION

To compensate the losses 2% excess quantity of drug and urea was taken.

TABLE 1: INGREDIENTS

Ingredients	Quantity taken
Miconazole nitrate	25mg
Urea	25mg
Methanol	5ml + 10ml

PROCEDURE

- Weigh Miconazole nitrate (25mg) and Urea (25mg used as carrier)
- Triturate them and put this mixture in evaporating dish and then add sufficient quantity of methanol till Miconazole nitrate and Urea dissolves completely
- Evaporate the methanol and keep this mixture in desiccator for 24 hrs
- Scrap the powder
- Weigh 50mg of solid dispersed powder (25mg drug + 25 mg urea)
- Dissolve it in 10ml of methanol and then add it to polymeric mixture of known concentration.

POLYMERS

- HPMC E50 is used for controlled delivery of medicament, transparent patches and good elasticity.
- HPMC – type E (E50) has higher level of hydrophobic groups hence contributes more to crystallization inhibition as compared to HPMC – type K (K100)
- HPMC K4 is typically used in formulations that require low to medium viscosity and good solubility.

- HPMC K100 is used in formulations that require high viscosity and a strong thickening effect.

1) PROCEDURE FOR POLYMERIC MIXTURE

Table 2: Formulation Consideration

INGREDIENTS	QUANTITY TAKEN
Polymer [HPMCMC K100, HPMC K4, or HPMC E50]	500mg
Ethanol	10ml
Water	14ml
Methanol	10ml
Propylene glycol	0.5ml
Glycerine	0.8ml
Tween 20	0.3ml

- Keep this mixture for overnight soaking
- Dissolve 50mg of the solid dispersion in 10ml methanol (keeping on magnetic stirrer)
- Slowly add this mixture to the polymeric solution by continuously stirring it.
- Then add Propylene glycol, Glycerine and Tween 20 to this solution.
- Sonicate this mixture for 10 mins
- Pour it in clean petri dish
- Keep it in an oven (60°C) after few minutes of air drying for 48 hours.
- Clear patches of Miconazole nitrate were obtained after 48 hours.



Fig. 5: Poured In Petri Dish.



Fig. 6: Clear Patch.

Table 3: Formulation Of Topical Patches.

Sr. No.	Ingredients	F1	F2	F3
1	Drug	25mg	25mg	25mg
2	Polymer	HPMC K100M (500mg)	HPMC K4M (500mg)	HPMC E50 (500mg)
3	Propylene glycol	0.5ml	0.5ml	0.5ml
4	Glycerine	0.8ml	0.8ml	0.8ml
5	Methanol	10ml	10ml	10ml
6	Ethanol	10ml	10ml	10ml
7	Water	14ml	14ml	14ml
8	Tween 20	0.3ml	0.3ml	0.3ml
9	Urea	25mg	25mg	25mg

**Fig. 7: Polymeric And Drug Mixture On Magnetic Stirrer.****Fig. 8: Polymeric And Drug Mixture.**

RESULTS AND DISCUSSION

EVALUATION OF DRUG LOADED PATCHES OF HPMC K4M, HPMC K100M AND HPMC E50

F1 = formulation containing HPMC K100M as polymer

F2 = formulation containing HPMC K4M as polymer

F3 = formulation containing HPMC E50 as polymer

1) Physical Appearance

- Shape and size: each of the film were square shaped and of 1x1 dimension (area = 1 cm²)
- Texture: smooth texture
- Transparency: all the films obtained were transparent
- Odour: odourless
- Recognizable marking: no entrapment of any air bubble or precipitation of drug was observed.

2) Folding Endurance

- Folding endurance was found to be above 300 times. This range of folding endurance showed that all the formulations have good film properties which doesn't break easily.

3) Thickness

- The average thickness of individual film is mentioned in the table given below. The thickness of all the five films of each of the 3 patches were in the range 0.15 to 0.47 mm, therefore thickness of the films within the limit of 0.20-0.80 mm.

Table 4: Thickness of The Patch.

Sr. No.	F1 (mm)	F2 (mm)	F3 (mm)
1	0.21	0.36	0.24
2	0.25	0.47	0.20
3	0.29	0.23	0.33
4	0.19	0.26	0.15
5	0.20	0.21	0.16
Avg.	0.22 ± 0.04	0.30 ± 0.10	0.21 ± 0.07

4) Weight and Weight Variation of Patches

- The average weight of individual patch is mentioned in the table given below

Table 5: Weight And Weight Variation Of Patches.

Sr. No.	F1 (mg)	F2 (mg)	F3 (mg)
1	24.80	15.40	26.11
2	32.00	18.41	27.60
3	8.70	14.33	25.66
4	20.60	15.12	13.90
5	30.90	18.80	8.90

6	21.81	15.90	17.00
7	31.30	19.64	25.40
8	25.12	14.80	14.64
9	19.00	19.40	21.66
10	31.32	18.81	22.21
Avg.	24.55	16.05	20.29

The weight of the patches was in the range 8.7 to 31.3 mg.

Weight variation among different formulations was obtained which may be related to different type and amount of polymer used.

5) Percent Elongation

Table 6: Percent Elongation Of Patches.

F1	F2	F3
$\% \text{ Elongation} = \frac{FW - IW}{IW} \times 100$	$\% \text{ Elongation} = \frac{FW - IW}{IW} \times 100$	$\% \text{ Elongation} = \frac{FW - IW}{IW} \times 100$
$= \frac{2.3 - 2}{2} \times 100$	$= \frac{2.4 - 2}{2} \times 100$	$= \frac{2.2 - 2}{2} \times 100$
= 15%	= 20%	=10%

Percent elongation values range from 10 to 20%

It can be associated to the type and amount of polymers used which indicates good flexibility and strength of the patch

6) Percent moisture content.

The moisture content which influences both the mechanical properties and the drug release of patches was found to be within limit i.e. <10%.

The moisture content value for each of the patch is as follows

Table 7: Percent Moisture Content.

F1	F2	F3
$\% \text{ moisture content} = \frac{FW - IW}{IW} \times 100$	$\% \text{ moisture content} = \frac{FW - IW}{IW} \times 100$	$\% \text{ moisture content} = \frac{FW - IW}{IW} \times 100$
$= \frac{31.6 - 31.4}{31.4} \times 100$	$= \frac{16.4 - 16.2}{16.2} \times 100$	$= \frac{21.8 - 21.1}{21.1} \times 100$
= 0.63%	= 1.23%	= 3.31%

7) Percent moisture uptake.

Ability of the patches to uptake moisture can be detrimental to the system by altering the chemical and mechanical properties of materials within the system over time hence it should be within the limits. Following are the results of the same

Table 8: Percent Moisture Uptake.

F1	F2	F3
% moisture uptake	% moisture content	% moisture content
$\frac{FW - IW}{IW} \times 100$	$\frac{FW - IW}{IW} \times 100$	$\frac{FW - IW}{IW} \times 100$
$= \frac{31.3 - 30.9}{30.9} \times 100$	$= \frac{19.3 - 18.8}{18.8} \times 100$	$= \frac{22.3 - 21.9}{21.9} \times 100$
= 1.20%	= 2.65%	= 2.75%

Percent moisture uptake by each patch was found to be within limits i.e. 15% w/w

8) Percent flatness

Percent flatness allows a limit over the waviness or variation in a surface without tightening its dimensional tolerance hence it should be within the limits.

Table 9: Percent Flatness.

F1	F2	F3
% constriction	% constriction	% constriction
$\frac{L1 - L2}{L2} \times 100$	$\frac{L1 - L2}{L2} \times 100$	$\frac{L1 - L2}{L2} \times 100$
$= \frac{3 - 2.8}{3} \times 100$	$= \frac{3 - 2.9}{3} \times 100$	$= \frac{3 - 2.6}{3} \times 100$
= 6.66%	= 3.33%	= 13.33%
% flatness = 93.34%	% flatness 96.67%	% flatness 86.67%

Flatter the patch is better will be the release of the drug

9) Drug Content

Drug content for the full patch was determined by first estimating the drug content in 1cm² with the help of absorbance using the formula

- F1

Amount of the drug added = 25mg

Area of the patch = 65cm²

Table 10: Drug Content Of F1.

Absorbance	Drug in 1cm ²	Drug in full patch (mg)
0.089	0.443	28.84
0.068	0.325	21.17
0.079	0.387	25.15
	Avg.	25.05 ± 15.28%

Percent drug content = $\frac{\text{Amount of drug obtained}}{\text{Amount of drug added}} \times 100$

$$= \frac{25.05}{25} \times 100$$

$$= 100.2\%$$

- **F2**

Amount of the drug added = 25 mg

Area of the patch = 72.34 cm²

Table 11: Drug Content Of F2.

Absorbance	Drug in 1cm ²	Drug in full patch (mg)
0.061	0.286	20.68
0.084	0.422	30.58
0.068	0.325	23.57
	Avg.	24.90 ± 20.32%

Percent drug content = $\frac{\text{Amount of drug obtained}}{\text{Amount of drug added}} \times 100$

$$= \frac{24.90}{25} \times 100$$

$$= 99.6\%$$

- **F3**

Amount of the drug added = 25 mg

Area of the patch = 63.58 cm²

Table 12: Drug Content Of F3.

Absorbance	Drug in 1cm ²	Drug in full patch (mg)
0.070	0.337	21.42
0.081	0.398	25.35
0.072	0.348	22.12
	Avg.	22.96 ± 9.1%

Percent drug content = $\frac{\text{Amount of drug obtained}}{\text{Amount of drug added}} \times 100$

$$= \frac{22.96}{25} \times 100$$

$$= 91.84\%$$

$$= 91.84\%$$

10) Diffusion studies

Diffusion studies of all three patches were conducted and the following observations were noted. With the help of the following equation the concentration of drug $\mu\text{g/ml}$ was determined.

Table 13: Diffusion Studies Of F1.

Time (mins)	Absorbance	Concentration in $\mu\text{g/ml}$	Conc. in $\text{mg}/50\text{ml}$	Cumulative	%cumulative drug release
0	0	0	0	0	0
30	0.035	1.44	0.072	0.072	2.81%
60	0.057	2.66	0.133	0.205	8.00%
120	0.130	6.72	0.336	0.541	21.11%
180	0.195	10.33	0.516	1.057	41.27%
240	0.192	10.16	0.508	1.566	61.10%
300	0.150	7.83	0.341	1.957	76.38%
360	0.125	6.44	0.322	2.279	88.95%
420	0.111	5.66	0.283	2.562	100.00%

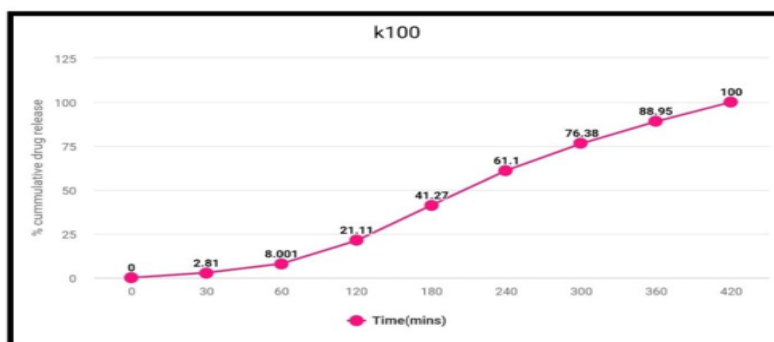


Fig. 9: In Vitro Cumulative Drug Release Profile Of Miconazole Nitrate For Formulation F1.

EVALUATION TABLE**Table 14: Physicochemical Evaluation Of Topical Patches (Thickness, Weight Variation, Moisture Content And Moisture Uptake).**

Formulation	Thickness (mm)	Weight variation (mg)	% Moisture content	%Moisture uptake
F1	0.22	24.55	0.63%	1.20%
F2	0.30	16.05	1.21%	2.65%
F3	0.21	20.27	3.21%	2.75%

Table 15: Mechanical Properties And Drug Content Evaluation Of Topical Patches.

Formulation	% Elongation	% Flatness	Folding Endurance	%Drug Content
F1	15%	93.34%	>300	100.20%
F2	20%	96.67%	>300	99.60%
F3	10%	86.67%	>300	91.84%

CONCLUSION

Topical patches of Miconazole nitrate were successfully formulated using varying grades of hydroxypropyl methylcellulose (HPMC) and systematically evaluated for physicochemical and drug release characteristics. The prepared formulations exhibited satisfactory mechanical integrity, uniformity in drug content, and acceptable folding endurance, indicating robustness of the patch system.

In vitro release studies confirmed that polymer grade plays a critical role in modulating drug release kinetics. Formulation F1 (HPMC K100M) demonstrated a controlled and sustained release profile extending up to seven hours, likely attributable to its higher viscosity and gel-forming capacity. F2 (HPMC K4M) showed comparatively moderate release, while F3 exhibited rapid drug diffusion.

These findings establish F1 as an optimized formulation for sustained topical delivery of Miconazole nitrate. The developed system offers a promising alternative to conventional semisolid formulations by enhancing drug residence time, improving therapeutic outcomes and potentially increasing patient adherence.

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