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# Formulation and Evaluation of Topical Fluconazole Gel for Antifungal Activity

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**ABSTRACT**

Fluconazole, a widely used antifungal agent from the triazole class, is effective against both superficial and systemic fungal infections. However, its oral administration is often limited due to adverse effects such as liver and kidney toxicity. To enhance patient safety and compliance, this study focuses on the development of a topical gel formulation incorporating fluconazole. The gels were prepared using varying concentrations of Carbopol 940 and Sodium Carboxymethyl Cellulose (NaCMC) as gelling agents, with methanol serving as a penetration enhancer. The prepared formulations were evaluated for key parameters including appearance, pH, spreadability, homogeneity, and drug content. Results showed that all formulations had acceptable physical characteristics. Notably, formulations F4 and F5 demonstrated higher drug content, correlating with increased polymer concentration. Formulation F6 yielded the highest output at 94.19%. A decrease in spreadability was observed with higher polymer concentrations. All formulations maintained a skin-compatible pH, suggesting their potential safety for dermal use. Overall, the study indicates that fluconazole-loaded topical gels offer a viable alternative to oral therapy by reducing systemic side effects while ensuring effective localized treatment.

Keywords: Fluconazole; bis-triazole; Carbopol-940; Na CMC (Sodium Carboxy Methyl Cellulose); topical drug delivery system etc

## Introduction

The use of topical medication delivery has become a major alternative to conventional methods like oral and parenteral administration. One of the key benefits of this method is that it can deliver high concentrations of the medicine right to the site of action, which lowers systemic exposure and lessens the adverse effects. Depending on the preparation and drug characteristics, this method of delivery, which is often used via the skin, eyes, rectum, and vagina, provides both localized and systemic therapeutic advantages. The skin is a good location for topical treatment among these routes because of its accessibility and vast surface area. The purpose of topical compositions is either to improve the skin's normal function or to administer therapeutic substances to the underlying tissues for localized treatment. These preparations, which are commonly known as dermatological products, are frequently employed in the treatment of skin-related illnesses. The goal of topical dosage forms is to enhance drug penetration into or through the skin layers while preserving a localized action. This not only improves the therapeutic result but also prevents the hepatic first-pass metabolism and gastrointestinal irritation, both of which increase the drug's bioavailability. Topical formulations enable the drug to work directly at the site of infection, resulting in quicker, more effective treatment with less systemic participation.

Fluconazole is a polar bis-triazole antifungal drug that works by blocking fungal cytochrome P-450 enzymes involved in the production of ergosterol, a critical component of the fungal cell membrane. Because of its broad-spectrum antifungal activity and favourable pharmacokinetic profile, fluconazole is frequently used to treat infections like candidiasis and other fungal conditions, including those occurring in immunocompromised people, particularly HIV patients. The oral and intravenous forms of fluconazole, despite their efficacy, are linked to side effects such nausea, vomiting, liver damage, and gastrointestinal problems. In addition, oral treatment requires higher dosages to achieve systemic efficacy, which can be expensive and result in low patient compliance.

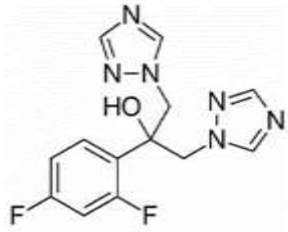


**Fig 01: Chemical Structure of Fluconazole drug**

According to pharmacokinetic studies, over 80% of fluconazole ingested orally enters the systemic circulation, with just a little amount bound to proteins and most of it eliminated in the urine. Due to hepatic metabolism, there is a significant chance of liver toxicity. Topical fluconazole gels can be a safer therapeutic option in this situation, especially for superficial fungal infections. Gel-based preparations are semi-solid systems with improved drug penetration properties, which provide distinct advantages in terms of ease of application, non-greasy texture, and patient comfort. Hydrophilic polymers such as Carbopol 940, Sodium Carboxymethyl Cellulose (NaCMC), or Hydroxypropyl Methylcellulose (HPMC) are often included in their composition. These gelling agents are commonly employed at concentrations between 0.5% and 2% to achieve the desired viscosity and drug release profile. Because of their aesthetic attractiveness and superior absorption capabilities, transparent gels are particularly popular in dermatology. They adapt well to skin motions and aid in the continuous release of medication. Overall, gel formulations appear to be a good method for administering antifungal medications like fluconazole, with increased local effectiveness and a lower chance of systemic adverse effects [1].

Fungal infections are generally categorized as either superficial or systemic. Superficial infections affect the skin, hair, and nails and are primarily caused by dermatophytes such as *Trichophyton*, *Microsporum*, and *Epidermophyton* species. These organisms are responsible for conditions like ringworm (*Tinea corporis*) and athlete's foot (*Tinea pedis*). Another common superficial infection is candidiasis, caused by *Candida* species, which typically affects mucosal surfaces such as the mouth, vagina, and skin. In contrast, systemic fungal infections involve internal organs and can affect the entire body. These infections may arise from inhalation, ingestion, or direct inoculation of fungal spores from the environment, or they may occur opportunistically in individuals with weakened immune systems due to underlying diseases or immunosuppressive treatments. The pharmacological management of fungal infections includes agents such as fluconazole, itraconazole, miconazole, clotrimazole, ketoconazole, and griseofulvin. Among these, fluconazole—a synthetic antifungal belonging to the imidazole class—is frequently used due to its broad-spectrum activity and favourable safety profile. While fungal infections can be treated through various routes—topical, oral, or parenteral—the topical route is preferred for localized infections. This is because oral and systemic antifungal therapies, although effective, are associated with potential systemic side effects, making topical application a safer and more targeted treatment option for superficial fungal conditions [2].

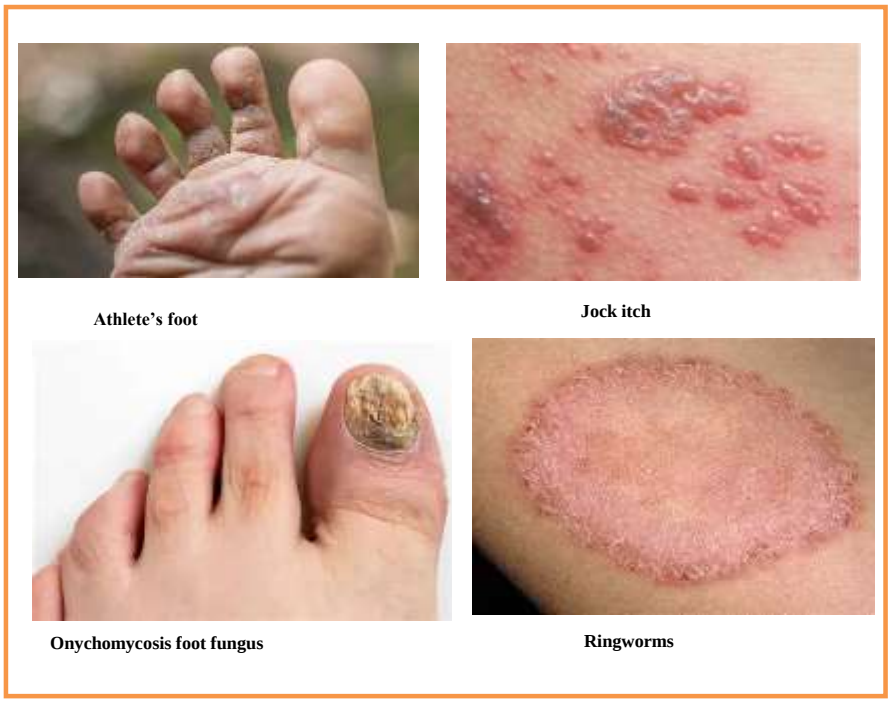


**Fig 02: Different types of fungal infections**

***Mechanism of Action of Fluconazole****:* Fluconazole is a very selective inhibitor of fungal cytochrome P-450 dependent enzyme lanosterol 14-αdemethylase.

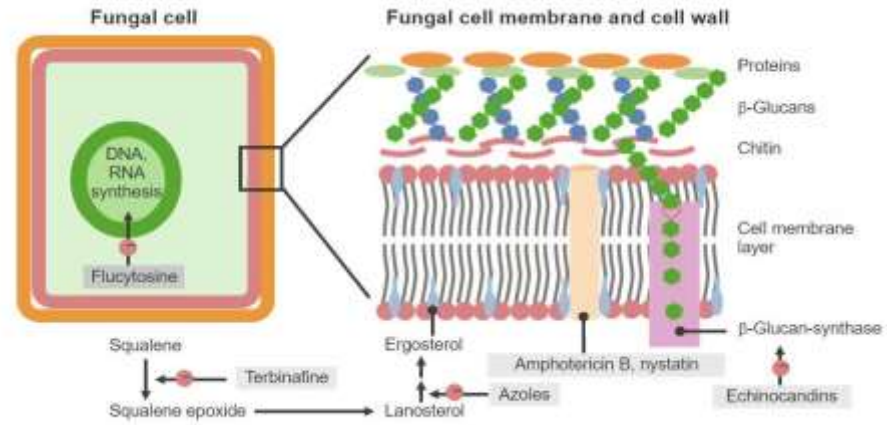


***Fig 03: Mechanism of fluconazole***

***Characteristics of gels***

- *Swelling*: Swelling refers to the process in which a gelling agent absorbs a significant quantity of solvent upon contact, leading to an increase in volume. This occurs as the solvent permeates the polymer matrix, disrupting the original gel–gel interactions and replacing them with gel–solvent interactions. The extent of swelling is influenced by both the number and strength of the intermolecular bonds within the gelling agent network.
- *Ageing*: Colloidal systems, including gels, often undergo a slow and spontaneous aggregation over time—a process known as ageing. In gels, ageing leads to the progressive formation of a more compact and structured network. This densification may affect the texture, viscosity, and performance of the gel over its shelf life.
- *Structure*: The structural integrity and rigidity of a gel are due to the three-dimensional network formed by the interconnected molecules or particles of the gelling agent. The configuration and strength of this network govern the gel's mechanical stability and its resistance to deformation under applied stress.
- *Rheology:* Gels typically exhibit pseudoplastic or non-Newtonian flow behaviour, characterized by a decrease in viscosity with increasing shear rate. In such systems, the weak internal structure is disrupted under applied stress, reducing intermolecular associations and facilitating flow. Inorganic gels respond to shear by breaking the interparticle linkages, while organic gels composed of macromolecules experience alignment of polymer chains in the direction of flow, thereby reducing viscosity [3].

***Route of Penetration for Topical Drug Delivery***

When a drug is applied to the skin, it initially encounters various surface barriers including cellular debris, microbial flora, and other environmental contaminants that can impact its ability to permeate the skin layers. There are three primary routes by which a drug can penetrate into the viable tissues of the skin:

i Through hair follicles

ii Via sweat ducts

iii Across the intact stratum corneum, the continuous outermost layer of the epidermis located between skin appendages such as hair follicles, sebaceous glands, eccrine and apocrine glands, and nails.

Although appendageal pathways account for only about 0.1% of the skin surface area, they play a crucial role in the transport of ions and large polar molecules. However, the stratum corneum remains the most significant barrier to transdermal drug delivery. Consequently, various enhancement strategies have been developed to either disrupt or bypass this layer to facilitate drug absorption. Once the drug passes the stratum corneum, it may undergo metabolism or activation within the viable epidermis. Prodrugs, for example, can be activated enzymatically in these layers. The deeper dermal tissues generally have minimal influence on the extent of drug absorption but may serve as reservoirs or sites for systemic uptake in some cases. Over the past two decades, extensive research has focused on utilizing the skin as a non-invasive route for drug administration to overcome limitations associated with oral delivery, such as gastrointestinal irritation, first-pass metabolism, and enzymatic degradation. Topical drug delivery is particularly beneficial for localized treatment of dermatological conditions. Its primary goal is to deliver the active agent directly to the affected site on the skin, minimizing systemic exposure. However, due to the protective function of the skin barrier, especially the stratum corneum, only a small fraction of the applied dose often reaches the target site, which can limit therapeutic efficacy. Fungal infections, which may be superficial or systemic, are commonly

managed through both topical and oral therapies. However, for localized infections, topical antifungal treatment is generally preferred due to its reduced risk of systemic side effects and direct action at the site of infection [4].

## Methodology

***Materials:*** Active drug Fluconazole was purchased from Sisco Research Laboratories Pvt. Ltd (SRL), Mumbai supplied by Srikrishna Chemicals and suppliers, Bangalore and the other chemicals such as Carbopol-940, glycerine, methanol, sodium carboxy methyl cellulose, triethanolamine, methyl paraben sodium, propyl paraben sodium was purchased from Karnataka fine chem., Bangalore. The equipment like electron balance, double beam UV-spectrophotometer, magnetic stirrer and pH meter were used.

***Method of preparation of gel*:** Five formulations of fluconazole topical gel (F1-F5) were prepared using different concentrations of polymers. Carbopol-940 and NaCMC of different concentrations and purified water were taken in a beaker and allowed to soak for 24 hr. To this required amount of drug was dispersed in water and then Carbopol-940 was then neutralized with a sufficient quantity of Triethanolamine. Glycerine is a moistening agent and alcohol (methanol) as a penetration enhancer was used. Methyl paraben Sodium and Propyl paraben sodium as preservatives were added slowly with continuous gently stirring until the homogenous gel was formed [6].

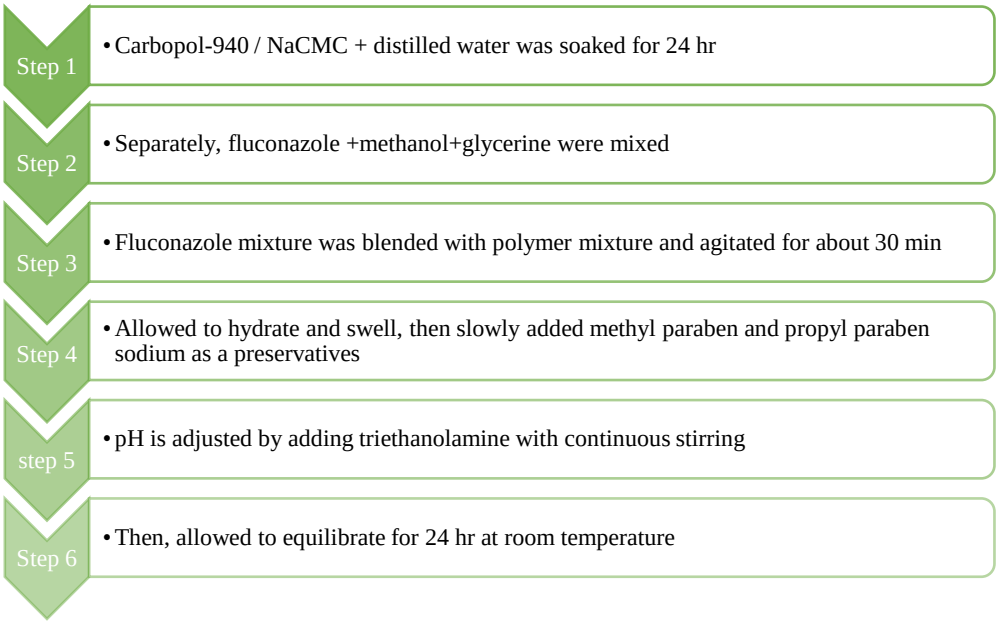


**Fig 04:** Method development of Fluconazole gel

***Physicochemical evaluation of fluconazole gel formulation***

- *Visual examination:* The prepared gel formulations were inspected visually for their colour and syneresis. The developed preparations were much clear and transparent. All developed gel formulations showed good homogeneity with absence of lumps and syneresis. Results are shown in table [7].
- *Clarity:* Clarity of various formulation was determined by visual inspection under black and white back ground and it was graded as follows: turbid +; clear ++; very clear (glassy) +++ [8].
- *Homogeneity and grittiness*: All developed gels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates. Similarly, it was applied on the skin and observed for the presence of grittiness and all the gel formulations is checked microscopically for the presence of any particulate matter [9].
- *Percentage yield:* The empty container was weighed in which the gel formulation was stored then again, the container was weighed with gel formulation. Then subtracted the empty container weighed with the container with gel formulation then it gives the practical yield. Then the percentage yield was calculated by the formula.

$$Percentage\ yield = \frac{practical\ yield}{\Delta xtheoretical\ yield} \times 100$$

- *Drug content:* Weighed 10gm of each gel formulation were transferred in 250ml of volumetric flask containing20ml of alcohol and stirred for 30min. The volume was made up to 100ml and filtered. 1ml of above solution was further diluted to 10ml with alcohol and again 1ml of the above solution was further diluted to 10ml with alcohol. The absorbance of the solution was measured spectrophotometrically at wavelength 260nm. Drug content was calculated by the following formula.

$$Drug\ content = \frac{Absorbance}{Slope} \times Dilution\ factor \times \frac{1}{1000}$$

- *Determination of pH*: Weighed 50gm of each gel formulation were transferred in 10ml of beaker and measured it by using the digital pH meter. The ideal pH of the topical gel formulation should be between 3 – 9 to treat the skin infections.
- *Spreadability:* The spreadability of the gel formulation was determined by measuring diameter of 1gm gel between horizontal plates (20×20 $cm^2$). Above the plates, the standardised weight of 125gm was placed and left for 1min. Then the diameter was measured by using scale.
- *UV Spectrum analysis:* The solution was scanned in the range of 200 to 400 nm to fix the maximum wavelength and UV spectrum was obtained.
- *Standard stock solution of fluconazole:* Accurately weighed 100mg of fluconazole and was dissolved in 100ml of methanol, from this stock solution 10ml was withdrawn and transferred into 100ml volumetric flask. Volume was made with methanol in order to get standard stock solution containing 100µg/ml.
- *Standard Graph of Fluconazole:* From this standard stock solution, a series of dilution (10, 20, 30, 40, 50µg/ml) were prepared using methanol. The absorbance of these solutions was measured spectrophotometrically against blank of methanol at 260nm for fluconazole [10].

## Results & Discussion

Different formulations (F1–F6) were prepared and evaluated for their physicochemical properties including percentage yield, drug content, pH, spreadability, homogeneity, and appearance. The evaluation data indicated that all formulations met acceptable criteria, suggesting excellent formulation efficiency. The gels were formulated using Carbopol 940 and Sodium Carboxymethyl Cellulose (NaCMC) as gelling agents, along with excipients such as methanol (as a penetration enhancer), triethanolamine (as a pH adjuster), glycerine, and preservatives including methyl and propyl paraben sodium. Gels offer advantages such as non-greasy texture, enhanced drug release, ease of application, and removability compared to conventional creams and ointments. The results of various parameters are represented below;

**Table 01:** Absorbance of different formulations at different concentration

| Sl.no. | Concentration (µg/mL) | Absorbance (260 nm) |
|---|---|---|
| **1** | 0 | 0 |
| **2** | 10 | 0.175 |
| **3** | 20 | 0.192 |
| **4** | 30 | 0.205 |
| **5** | 40 | 0.207 |
| **6** | 50 | 0.218 |

Calibration Curve: UV spectrophotometric analysis confirmed that fluconazole exhibits maximum absorbance at 260 nm in methanol. A standard calibration curve prepared using a concentration range starting from 10 µg/mL demonstrated adherence to Beer's law. The regression analysis yielded a correlation coefficient ($R^2$) of 0.94, indicating a strong linear relationship between drug concentration and absorbance. Thus, the regression equation of y=0.001x+0.1691.

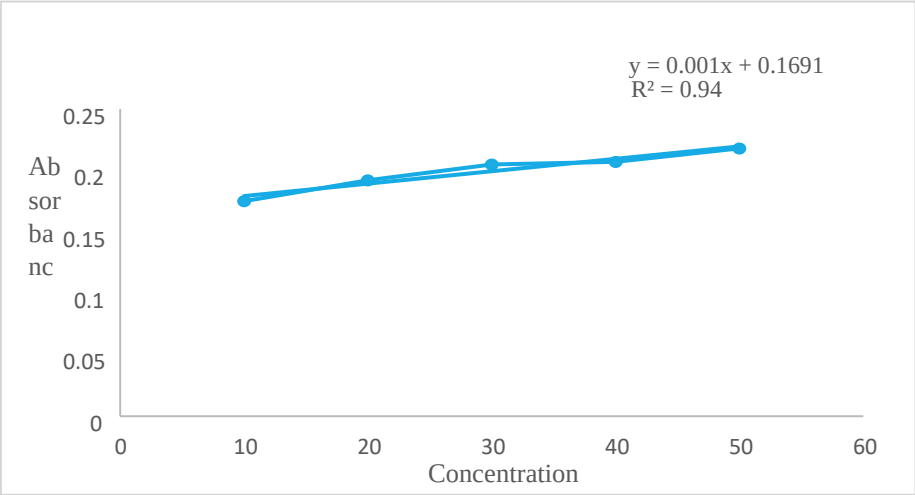


**Fig 05**: Standard Calibration curve of Fluconazole gel in methanol

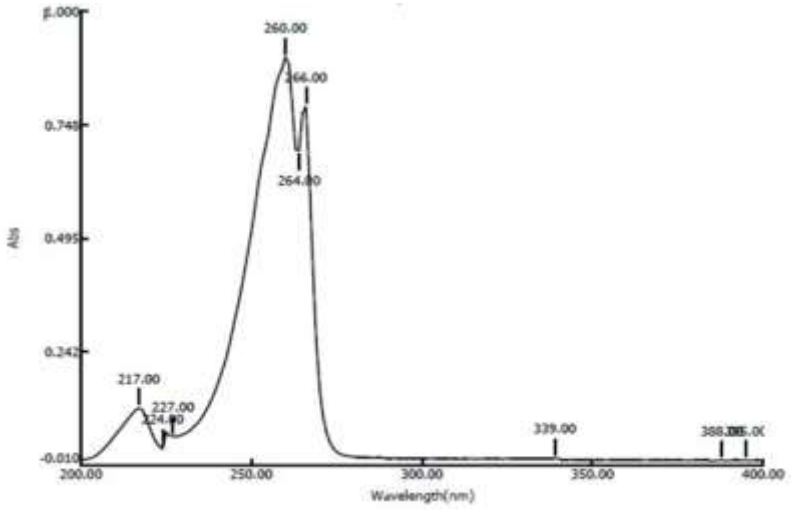


**Fig 06: UV spectrum of Fluconazole gel**

**Table 02:** Physicochemical properties of Fluconazole

| Sl.no. | Parameter | Properties |
|---|---|---|
| **01** | IUPAC name | 2-(2,4-Difluorophenyl)-1,3-bis(1H-1,2,4-triazol-1-yl) propan-2-ol |
| **02** | Chemical formula | $C_{13}H_{12}F_2N_6O$ |
| **03** | Molar mass | 306.277 $gmol^{-1}$ |

**Table 03:** Pharmacokinetic properties of Fluconazole

| Sl.no. | Parameter | Pharmacokinetic properties |
|---|---|---|
| **01** | Absorption | >90% oral (GIT) |
| **02** | Distribution | 0.7 L/kg |
| **03** | Metabolism | Liver |
| **04** | Excretion | Kidney (61-81%) |
| **05** | Half-life $t_{1/2}$ | 30 hrs (oral) |
| **06** | Storage condition | Store at room temperature keep away from light |

**Table 04:** Formulation chart of fluconazole gel with different concentrations

| Chemical Ingredients | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|
| **Fluconazole (gm)** | 0.34 | 0.34 | 0.34 | 0.34 | 0.34 | 0.34 |
| **Carbopol-940p (gm)** | 1.29 | 0.45 | - | - | 1.52 | 1.33 |
| **NaCMC (gm)** | - | - | 1.39 | 1.45 | - | - |
| **Methanol (ml)** | 3.45 | 3.45 | 3.45 | 3.45 | 3.45 | 3.45 |
| **Glycerine (ml)** | 8.62 | 8.62 | 8.62 | 8.62 | 8.62 | 8.62 |
| **Triethanolamine(ml)** | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 | 0.25 |
| **Methyl paraben sodium (gm)** | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 | 0.08 |
| **Propyl paraben sodium (gm)** | 0.04 | 0.04 | 0.04 | 0.04 | 0.04 | 0.04 |
| **Distilled water (ml)** | 51.75 | 51.75 | 51.75 | 51.75 | 51.75 | 51.75 |

***Percentage yield****:* The lowest percentage yield was found in F1 formulation (83.10%) and the maximum yield was found in F6 (94.19%). All obtained values were tabulated below;

**Table 05:** Percentage yield of different formulation

| Formulation | Percentage Yield (%) |
|---|---|
| **F1** | 83.10 |
| **F2** | 93.53 |
| **F3** | 92.38 |
| **F4** | 83.60 |
| **F5** | 88.90 |
| **F6** | 94.19 |

***Drug content:*** After the formulations of six different concentrated gels, the drug content was estimated by using double beam UV spectrophotometer at wavelength of 260 nm in methanol. The obtained values are tabulated below:

**Table 06:** Drug content of different formulation

| Formulation | Drug Content (%) |
|---|---|
| **F1** | 86.0% |
| **F2** | 85.2% |
| **F3** | 90.8% |
| **F4** | 92.4% |
| **F5** | 94.0% |
| **F6** | 83.2% |

***Determination of pH:*** *The pH of all the batches was measured and the obtained values were tabulated below:*

**Table 08:** Determination of pH for fluconazole gel formulations

| Formulation | pH |
|---|---|
| **F1** | 7.2 |
| **F2** | 7.6 |
| **F3** | 7.9 |
| **F4** | 7.8 |
| **F5** | 7.6 |
| **F6** | 7.1 |

***Spreadability test:*** *The spreadability of fluconazole gel was measured and the obtained values were tabulated below:*

**Table 09:** Determination of Spreadability for fluconazole gel formulations

| Formulation | Spreadability ($gm.cm^2$) |
|---|---|
| **F1** | 9.61 |
| **F2** | 10.24 |
| **F3** | 12.60 |
| **F4** | 12.96 |
| **F5** | 10.04 |
| **F6** | 10.43 |

***Homogeneity and grittiness***

***Table 10****: Determination of homogeneity and grittiness*

| Parameters | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|
| **Colour** | Colourless | White | Pale yellow | Slight yellow | Colourless | White |
| **Homogeneity** | +++ | ++ | +++ | +++ | +++ | + |
| **Grittiness** | - | - | - | - | - | - |

Excellent (+++), Good (++), Satisfactory (+), No grittiness (-)

***Clarity***

**Table 11:** Clarity of different batch formulations

| Formulation | Clarity |
|---|---|
| **F1** | + |
| **F2** | + |
| **F3** | +++ |
| **F4** | +++ |
| **F5** | + |
| **F6** | + |

Turbid (+); Clear (++); Very clear/ glossy (+++)

**Fig 03: F2 formulation of Fluconazole Gel**

All formulations exhibited pH values within the physiologically acceptable range for topical application (approximately pH 7.1–7.9), ensuring skin compatibility and reduced risk of irritation. Spreadability tests revealed an inverse relationship between polymer concentration and spreadability—formulation F4 (NaCMC-based) had the highest spreadability (12.96 g·cm²), while formulation F1 (Carbopol-based) had the lowest (9.61 g·cm²). In terms of physical appearance, all gels were smooth, homogeneous, and free from grittiness. Carbopol-based gels had a firmer, solid-like texture, while NaCMC-based gels were more fluid-like, indicating variability in viscosity and rheological behaviour depending on the polymer used. Both gel types were clear and visually appealing. By this study confirms that fluconazole gel formulations using Carbopol 940 and NaCMC are pharmaceutically acceptable and show promising attributes for topical antifungal therapy. The variations in polymer type and concentration allow flexibility in tailoring gel properties according to therapeutic needs.

## Conclusion

All formulations exhibited pH values within the physiologically acceptable range for topical application (approximately pH 7.1–7.9), ensuring skin compatibility and reduced risk of irritation. Spreadability tests revealed an inverse relationship between polymer concentration and spreadability—formulation F4 (NaCMC-based) had the highest spreadability (12.96 g·cm²), while formulation F1 (Carbopol-based) had the lowest (9.61 g·cm²). In terms of physical appearance, all gels were smooth, homogeneous, and free from grittiness. Carbopol-based gels had a firmer, solid-like texture, while NaCMC-based gels were more fluid-like, indicating variability in viscosity and rheological behaviour depending on the polymer used. Both gel types were clear and visually appealing. By this study confirms that fluconazole gel formulations using Carbopol 940 and NaCMC are pharmaceutically acceptable and show promising attributes for topical antifungal therapy. The variations in polymer type and concentration allow flexibility in tailoring gel properties according to therapeutic needs.

The results obtained from the physicochemical evaluation were found to be satisfactory. All formulations were physically stable, with acceptable consistency, clarity, and homogeneity. The UV spectrophotometric method used for drug analysis demonstrated that fluconazole exhibits maximum absorbance at 260 nm in alcohol. The standard calibration curve yielded a regression coefficient ($r^2$) of 0.94, indicating a strong linear correlation between concentration and absorbance, thus confirming adherence to Beer's law.

Most of the gels were found to be easily spreadable, washable, and non-irritating, with an appearance ranging from colourless to pale yellow. All formulations were odourless and visually appealing. The pH values of the gels fell within the acceptable range for dermal application, ensuring safety and effectiveness in treating fungal infections.

In terms of gelling characteristics, NaCMC-based formulations exhibited lower viscosity compared to Carbopol-based gels, although both polymers responded predictably to changes in concentration. Drug content across all formulations remained within pharmaceutically acceptable limits, and variations in spreadability were influenced by the type and amount of polymer used.

Hence, the developed fluconazole gel formulations demonstrated promising physicochemical properties suitable for topical antifungal therapy. Their ease of application, local targeting, and reduced potential for systemic side effects suggest that such gel-based drug delivery systems can offer improved patient compliance and therapeutic outcomes in managing superficial fungal infections.

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**Conflicts of interest**

All authors declare there are no conflicts of interest.

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