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Formulation and Evaluation of Fluconazole Topical Gel

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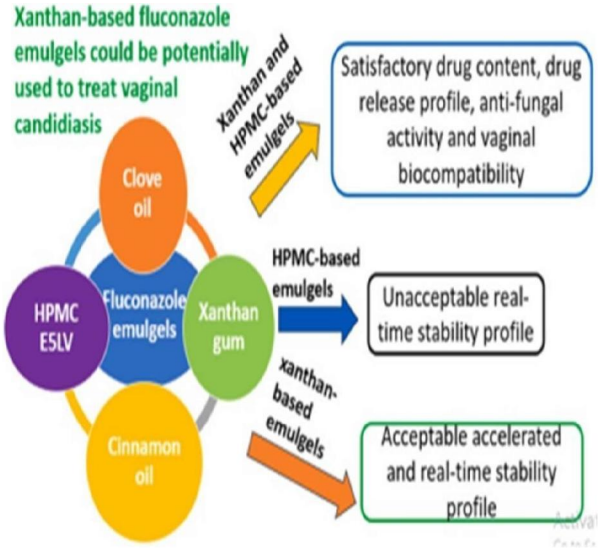
Abstract: *Fluconazole is an imidazole derivative and used for the treatment of local and systemic fungal infection. The oral use of fluconazole is not much recommended as it has many side effects. Commercially fluconazole topical gel preparation are not available in the market, thus this formulation is made for better patient compliance and to reduce the dose of drug and to avoid the side effects like liver damage and kidney damage.. The gel was formulated by changing the polymer ratio. FT-IR study confirmed the purity of drug and revealed no interaction between the drug and excipients. Gel formulations were characterized for drug content, pH determination, viscosity measurement, in vitro diffusion, antifungal activity and skin irritation. Among the five formulations,F1 was selected as the best formulation as its %CDR after 4½ h was 97.846% and release rate of drug from F1 formulation is best fitted to Higuchi model. The viscosity of the F1 formulation was within the limits and F1 formulation did not show any skin irritation. Gel formulation F1 was found to be stable at 30 ±2°C and 65 ± 5 RH. It was found that at 40 ± 2°C and 75 ± 5 RH the gel formulation was not stable and %CDR was decreased. Efficient delivery of drug to skin application was found to be highly beneficial in localizing the drug to desired site in the skin and reduced side effects associated with conventional treatment.*



Keywords: formulation & evaluation of fluconazole topical gel.

I. INTRODUCTION

Nowadays dermatological infections are treated with antimicrobials formulated in broad range of semisolid dosage forms comprising of ointments, creams, gels, pastes, aerosols, solutions

[1] The skin has become a significant site of drug delivery due to easy access, greater surface area and non-invasive, pain free nature of therapy where bioavailability is systemic or local

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[2]. The therapy can be stopped without any complications if any adverse effects occur
[3].Ointments are homogenous, semisolid dosage form applied to the skin or mucous membrane
[4].Few authors have postulated diverse formulations of azole antimycotic ointments [5-7]. Hydrocarbon, absorption bases and water-soluble bases are various types of ointment base that facilitates the manufacture of optimum formulation.

Polyethylene glycols (PEGs) are being employed in topical pharmaceutical preparations due to their chemical stability, hydrophilicity, safety and washable property. Current research work is underway for optimal release of antimicrobial drugs from water soluble PEG base maintaining bioavailability, efficacy and safety for improved treatment [8]. The primary goal of this research study was to prepare Fluconazole ointment containing water soluble base PEG 4000 and 400 in combination and to evaluate its drug content and antifungal activity.

Fluconazole is an antifungal drug; fluconazole fights opportunistic infections in people with HIV, severe fungal infection.

- Fluconazole is antifungal agent of triazole class.
- It is new existing drug.
- It overcomes all the side effects of the other fungal drugs like, Ketoconazole, Amphotericin B, Clotrimazole, and Miconazole.
- Even though it has some of the side-effects in the oral and I.V dosage forms.

Fluconazole remains one of the most frequent prescribed triazoles because of its excellent bioavailability, tolerability, and side-effect profile. More than 80 % of ingested drug is found in the circulation, and 60 to 70% is excreted in the urine. Only 10% of fluconazole is protein bound(12).

Fluconazole also exhibits excellent tissue penetration. CSF levels are 70% of matched serum levels, and levels reported in saliva, sputum, and other sites are well within therapeutic ranges. The half-life is 27 to 34 h in the presence of normal renal function allowing once-daily dosing. In patients who have a reduced creatinine clearance the normal dose should be reduced by 50%. Fluconazole serum levels are rarely necessary. Currently 50, 100, 150, and 200 mg tablets are available and IV formulation exits in 200 or 400 mg doses(13, 14).

MATERIALS

Fluconazole was procured from Chandra Labs, Hyderabad. PEG 4000 from Chemical Crunch, Mumbai and PEG 400 from Bangalore Fine Chem (BFCLAB). All other excipients of analytical grade were utilised for this study.

METHOD:

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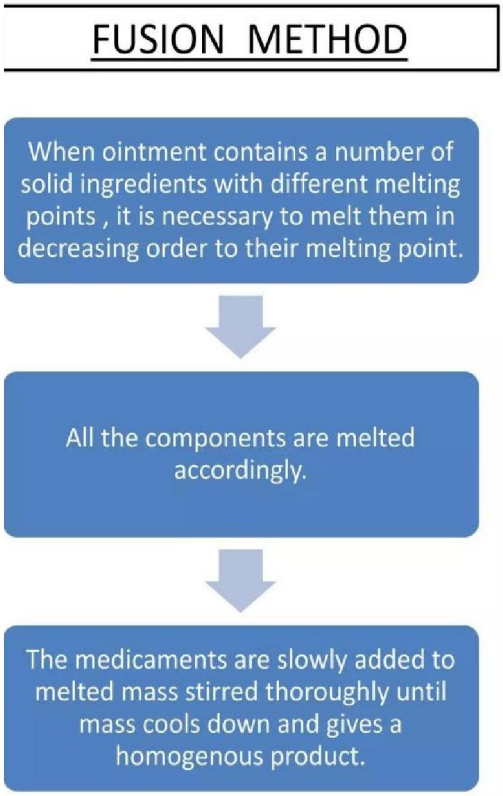

The topical ointment of fluconazole comprising of water-soluble base was developed by the process of fusion. Water soluble bases selected are Polyethylene glycol 4000 and PEG 400 and are heated in descending order of their weights and mixed thoroughly. The drug Fluconazole 0.5%w/w was added and dissolved in propylene glycol and then incorporated into the PEG ointment base.

II. AIM AND OBJECTIVE

AIM :

To formulate & evaluate the fluconazole ointment.

Objective :

- To prouide local antifungal action.
- To reduce systemic side effects.
- To enhance patient compliance
- To ensure a suitable ointment base.

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Plan of work :

Preformulation studies

Selection of ointment base

Formulation deuelopment

Preparation of Fluconazole ointment

Evaluation tests

Physical test, Physicochemical test, performance test

Drug content & in vitro release study

Stability studies

Result & discussion

Conclusion

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Standard Ingredients for Fluconazole Ointment

A typical 0.5% w/w fluconazole topical formulation relies on the following components

- **Active Ingredient:** Fluconazole (typically 0.5% to 1% text w/w).
- **Base/Gelling Agents:** Carbopol 934, Carbopol 940, or Hydroxypropyl methylcellulose (HPMC) to provide thickness and spreadability.
- **Penetration Enhancers:** Propylene glycol or methanol to help the drug absorb into the skin.
- **Moistening Agent:** Glycerine to keep the skin hydrated.
- **Neutralizing Agent:** Triethanolamine to adjust the pH and thicken the gelling agent.
- **Preservatives:** Methyl paraben sodium and propyl paraben sodium to prevent microbial growth.
- **Solvent:** Distilled water.

Standard Preparation Process (Cold & Fusion Method)

Topical fluconazole can be formulated through either a polymer gel method or a water-soluble ointment base process:

1. Preparing the Gel or Ointment Base

• **For Gels:** The gelling polymer (e.g., Carbopol) is slowly dispersed in a portion of distilled water and allowed to hydrate for several hours.

• **For PEG Ointments:** Polyethylene glycol (PEG 4000 and PEG 400) is heated in descending order of weight until fully melted and mixed to form a water-soluble base.

2. Dissolving the Active Ingredient

• Fluconazole powder is dissolved in a solvent or penetration enhancer, such as propylene glycol or methanol.

3. Blending and Neutralization

• The dissolved fluconazole mixture is gently added into the base (gel or PEG) under continuous mechanical stirring to ensure uniform distribution.

• If using a polymer like Carbopol, a neutralizing agent like Triethanolamine is added drop-by-drop while stirring until the formulation reaches the proper pH (typically 5.0 to 7.5) and thickens into a homogenous gel .

4. Adding Preservatives

• Preservatives (methyl and propyl paraben) are dissolved in a small amount of warm water or solvent and stirred into the final mixture to ensure shelf stability .

PREFORMULATION STUDIES

Any formulation development work has to be proceeded by Preformulation studies. This Preformulation study includes drug-excipients compatibility study.

FT-IR study showed that there was no major change in the position of peak obtained in the drug alone and in a mixture of drug with excipients, which shows that there was no interaction between drug and excipients.

Estimation of fluconazole was carried out by SHIMADZU-1700 UV spectrophotometer at λmax 260 nm in alcohol. The linear coefficient was found to be r2= 0.997 which shows that Beer's law obeyed. By using the regression coefficient the %CDR were calculated.

UV Spectrum Analysis of Fluconazole The method for the estimation for the drug fluconazole showed maximum absorption at wavelength 260 nm in alcohol. Standard curve obeyed Beer's law at given concentration range of 10 µg/ml to 50 µg/ml and when subjected to regression analysis, the value of regression coefficient was found to be 0.997, which showed linear relationship.

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III. FORMULATION STUDIES

FORMULATION DEVELOPMENT

Various formulation of fluconazole gel was developed using carbopol 934p, alcohol, methyl paraben, propyl paraben, glycerine, Triethanolamine and water. Carbopol 934p was used as polymer; alcohol was used as penetration enhancer; methyl paraben and propyl paraben were used as preservatives; glycerine used as moisturising agent; Triethanol amine used as pH balancer and water used as vehicle.

Formulation Table

Sr.no	Ingridients	Quantity
1.	Fluconazole base	1 gm
2.	Carbapol	0.5 gm
3.	Triethanolamine	2ml
4.	Methyl paraben	0.2 gm
5.	Ethanol	2ml
6.	Glycerin	5 drops
7.	Dil Water	q.s

1. General Information

Drug Name: Fluconazole
Category: Antifungal agent
Class: Triazole antifungal
Dosage Form: Ointment (topical)
Route of Administration: Topical (skin application)

2. Chemical Information

Chemical Name: 2-(2,4-difluorophenyl)-1,3-bis(1H-1,2,4-triazol-1-yl)propan-2-ol Molecular Formula: $C_{13}H_{12}F_2N_6O$
Molecular Weight: 306.27 g/mol

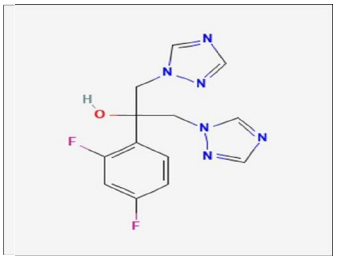

Fig. Structure of Fluconazole

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1. Mechanism of Action

Fluconazole works by:

Inhibiting fungal cytochrome P450 enzyme (14- α -demethylase)

Blocking conversion of lanosterol → ergosterol

Disrupting fungal cell membrane formation

➞ Leads to fungal cell death

2. Spectrum of Activity

Effective against:

Candida albicans Cryptococcus neoformans

Dermatophytes (limited activity in topical form)

3. Indications (Topical Use)

Fluconazole ointment is used for:

Cutaneous candidiasis

Fungal skin infections

Ringworm (Tinea infections)

Athlete's foot

Skin irritation caused by fungi

4. Dosage and Administration

Apply a thin layer on affected area

Usually 1–2 times daily

Duration depends on infection severity

5. Pharmacokinetics (Topical)

Minimal systemic absorption

Acts locally at site of application

Reduced systemic side effects compared to oral form

6. Advantages of Ointment Form

Provides localized action

Reduced systemic toxicity

Suitable for skin infections

Moisturizing effect on dry lesions

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7. Adverse Effects Common:
Skin irritation
Burning sensation
Redness
Rare:
Allergic reaction

8. Contraindications
Hypersensitivity to fluconazole
Avoid use on open wounds (unless prescribed)

9. Drug Interactions
Minimal in topical form Systemic interactions negligible

10. Storage Conditions
Store below 25°C
Keep in a cool, dry place Protect from light

11. Excipients Used in Ointment
Base: White soft paraffin / polyethylene glycol
Preservatives, Stabilizers, Emulsifying agents

IV. IN VITRO DRUG RELEASE STUDY

Method Used:
Franz Diffusion Cell Method (most common) Procedure:
Take a cellophane membrane / dialysis membrane Mount it between:
Donor compartment (contains ointment) Receptor compartment (contains buffer)
Fill receptor with:
Phosphate buffer pH 7.4 (simulates skin conditions) Maintain temperature at 37 ± 0.5°C
Apply ointment on membrane
Withdraw samples at regular intervals (e.g., 15, 30, 45, 60 min) Replace with fresh buffer
Measure absorbance using UV spectrophotometer (λ max $\approx$ 260 nm for fluconazole)

3. Drug Release Kinetics
Drug release data is fitted into models: Zero-order kinetics
Constant drug release over time First-order kinetics
Release depends on concentration
Higuchi model (most common for ointments)
Drug release is proportional to square root of time: Q = k\sqrt{t}
Where:
Q = amount of drug released k = release constant t = time

4. Factors Affecting Drug Release
Type of base:
Oleaginous → slow release
Water-soluble → faster release

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Drug concentration Particle
size
pH of medium Temperature
Presence of penetration enhancers

5. Typical Drug Release Profile
Initially slow release (lag phase)
Followed by steady diffusion
Often shows Higuchi diffusion-controlled pattern

V. EVALUATION OF PHYSICOCHEMICAL PARAMETERS DRUG CONTENT

After various formulation of fluconazole gel the drug content of the formulated gel was estimated by SHIMADZU-1700 UV spectrophotometer at λmax 260 nm in alcohol. The results were in the official limits.

VI. SPREADABILITY

Spreadability test which were carried out for all the formulations, spreadability was of the gel formulation was decreases with the increases in the concentration of the polymer. The spreadability is very much important as show the behaviour of gel comes out from the tube.

VII. IN VITRO DRUG DIFFUSION STUDIES

The release of fluconazole from the gel was varied according to concentration of polymer. The progressive increase in the amount of drug diffusion through a rat skin from formulation F1 attributed to gradual decrease in the concentration of polymer. It has been concluded that, if we increase the concentration of polymer, the diffusion of drug through the skin also decreases. The amount of drug diffused from formulation F1 was 97.846 ± 0.966 in 4½ h which was higher among all the gel formulation.

The order of drug diffused from various formulations was found to decrease in the following order.
F1 > F2 > F3 > F4 > F5

PHARMACOKINETIC PROFILE

The release rate of drug from F1 formulation is best fitted to Higuchi matrix model.

VIII. SKIN IRRITATION STUDY

In the skin irritation study no group was used as standard group only two groups was used one for control and another for formulation. The results of skin irritation study revealed no irritation from gel formulation of F1 as it produce a score of 0.5, which was less than 2.

FUNGAL STUDIES

In the anti fungal studies the fungi used was Candida albicans. The studies were carried for the best formulation and zone of inhibition observed at F1 (6.6 mm2), placebo gel (0 mm2) and pure form of the fluconazole (7.6 mm2). The results were satisfactory.

EVALUATION OF FLUCONAZOLE OINTMENTS:

1. PHYSICAL EXAMINATION:

Physical appearance of six formulations was observed visually and Spreadability by spreading 1g of prepared ointment on a clean glass surface[10].

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2. pH DETERMINATION:
The ointment formulations were evaluated for their pH using pH meter[9].

3. VISCOSITY MEASUREMENT:
The drug release from six fluconazole PEG ointment formulations depends on the viscosity that is evaluated using Brookfield viscometer[9]

4. DRUG CONTENT:
An accurately weighed amount of each formulation was dissolved in 5ml 0.1 N NaOH, filtered using a nylon membrane filter disk (0.45µm). Then they were suitably diluted and assayed spectrophotometrically for drug content λmax at 303nm against blank.[11]

5. In VITRO DRUG RELEASE STUDY:
The 6 formulations for in-vitro release were examined using dialysis method.1 gram sample of each formulation positioned on a cellophane membrane submerged in 25ml of phosphate buffer 7.4(receptor medium) for 24 hours and spread on the glass tubes lower end sealed using a rubber band and, in a beaker maintained for 3 hours at 37 ± 0.5ºC in a thermostatic shaking water bath (50 rpm). 5 ml sample of each prepared formulation was removed at intermissions of 1, 2, 3, 4, 5, and 6 hours and substituted byequivalent volume of buffer solution.[9].

6. ANTI-FUNGAL ACTIVITY:
The anti-fungal potency of the prepared fluconazole PEG ointment base was evaluated using Agar cup plate method. Strains of Trichophyton rubrum, one of the most common dermatophyte fungi was selected for the study. Spores of the selected strain were mixed with Sabourad Agar media and allowed to solidify. Wells of 1cm depth were created and 0.5gm of each formulation was added and incubated for 7 days and the zone of inhibition was calculated.[9].

7. DRUG RELEASE KINETICS:
Fluconazole release kinetics expressed by Zero order, First order, Higuchi model and Peppas model[9].

IX. RESULT

1. Physical Examination: The 6 prepared fluconazole ointments are white coloured viscous in nature with suitable consistency and Spreadability.
2. pH Determination: The following pH values (6-7) indicate that on application each formulation will not lead to any skin irritation.

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S. No	Formulation	pH
1.	F1	6.21±0.1
2.	F2	6.68±0.29
3.	F3	7.17±0.4
4.	F4	6.70±1.2
5.	F5	6.51±0.6

Table 1: pH of Fluconazole ointments

3. Viscosity Determination: The table 2 represents the viscosity evaluated for the prepared formulations.

S. No	**Formulation**	**Viscosity(cps) at rpm**
1.	F1	30890±14.2
2.	F2	31218±10.8
3.	F3	32600±15.1
4.	F4	33129±20.4
5.	F5	34254±15.8

Table 2: Viscosity of Fluconazole ointment

4. Drug Content: The results indicate that the range of drug content of prepared formulation was 97-99% which infers uniform distribution of drug.

S. no	Formulation	Drug content
1.	F1	97.1±0.58
2.	F2	98.3±0.61
3.	F3	98.5±0.43
4.	F4	98.7±0.32
5.	F5	99.8±0.51

Table 3: Drug content of Fluconazole Ointments

5. In-vitro Drug release study: Key evaluation of API release from the formulation essential during drug development process.

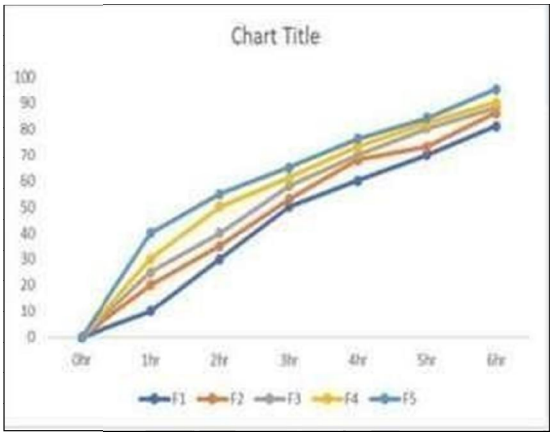

Fig 1-In Vitro release of Fluconazole from PEG ointment base

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S. No	Formulation	%CDR (6hr)
1.	F1	85.089±1.01
2.	F2	87.021±1.67
3.	F3	89.181±0.72
4.	F4	90.038±0.96
5.	F5	92.016±0.52

Table 4: In-vitro drug release of fluconazole ointments

6. In Vitro Antifungal Study: The average value of zone of inhibition of three plates for each formulation was determined.

S. No	Formulation	Zone of inhibition diameter(mm) Trichophyton rubrum
1.	F1	25
2.	F2	29
3.	F3	34
4.	F4	37
5.	F5	39

Table 5: Zone of inhibition of prepared Fluconazole ointments

7. Drug Release Kinetics of Optimized Formulation (F5): Optimized formulation (F5) was subjected to Zero, first order, Korsmeyer peppas model and Higuchi model. From the following results it can be inferred that Higuchi model best expressed the formulation (F5)

Fig. Fluconazole Topical Gel

X. STABILITY STUDIES

Stability studies were carried for the most satisfactory formulation-F1, at 30 ± 2°C and 40 ± 2°C at 65 ± 5 and 75 ± 5 RH for 2 months. At the end of 2 months, samples were evaluated.

Drug content study showed that, there was no major change in the content drug of F1 (from 97 ± 0.027 to 96%) at 30 ± 2°C at 65 ± 5 RH and decrease at 40 ± 2°C at 75 ± 5 RH (from 97 ± 0.027 to 6%). There was no significant change in the in vitro drug diffusion study F1 (from 97.846 ± 0.966 to 97.19%) at 30 ± 2°C at 65 ± 5 RH. However, after stability at 40 ± 2°C at 75 ± 5 RH showed decrease in the in vitro diffusion study of F1 (from 97 ± 0.027 to 2.54%). This may

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be due to the effect of temperature on gel-to-liquid transition of lipid bilayers together with possible chemical degradation of the drug. There was no major in the parameters evaluated like drug content and in vitro drug diffusion study of F1 at 30 ± 2°C at 65 ± 5 RH. Thus it can be concluded that, F1 is stable at 30 ± 2°C at 65 ± 5 RH for a period of 2 month

XI. DISCUSSION

Topical and transdermal drug delivery systems offer several advantages over oral delivery systems. These delivery systems include patch, gel, cream, ointment and lotion. However it has been found so many side-effects were proved by the oral delivery system of fluconazole and here to over the side-effects of oral dosage form. The dosage form has been changed by formulation and evaluation of fluconazole gel.

Fluconazole is an imidazole derivative, used in the treatment of topical as well as systemic fungal infection. The bioavailability of fluconazole is 90%. In the present study, an attempt was made to formulate fluconazole gel for efficient delivery of drug to the skin. In the present study, fluconazole gel was prepared by using carbopol 934p, alcohol, methyl paraben, propyl paraben, Triethanol amine and distilled water. A total number of five formulations were prepared. The preformulation study of drug-excipients interaction was carried out by FT-IR, which showed no interactions. The data obtained from viscosity studies, drug content, spreadability test, in vitro drug diffusion, skin irritation and anti fungal studies gave satisfactory results.

XII. CONCLUSION

- Fluconazole is an imidazole derivative, used for the topical as well as systemic fungal infections. The bioavailability of fluconazole is 90%. In the present study, an attempt was made to formulate topical gel of fluconazole for efficient delivery of drug across the skin.
- A suitable method of analysis of drug by UV spectrophotometry. Fluconazole showed maximum absorption at a wavelength of 260 nm in alcohol. The value of correlation co-efficient was found to be r2 = 0.997, which showed linear relationship between concentration and absorbance. Thus, it can be concluded that, it can be concluded that, beer's law was obeyed.
- Preformulation study for drug-excipients compatibility by FT-IR showed no interaction between drug and selected excipients.
- Various formulation (F1, F2, F3, F4, F5) were developed by using suitable polymer (carbopol 934p) and penetration enhancer.
- Developed formulations of fluconazole were evaluated for the physiochemical parameters such as drug content, viscosity, spreadability, in vitro diffusion.
- Viscosity studies of various formulations revealed that formulation F1 was better compare to others.
- Skin irritation study indicated that no irritation have been produced by gel formulation F1.
- Anti fungal studies also showed the good results of formulation F1.
- Viscosity studies of various formulations revealed that formulation F1 was better compare to others.
- From among all the developed formulation, F1 shows better drug diffusion for a period of 4½ h, did not produced skin irritation, good Rheological properties and good results of antifungal studies. Therefore, it was selected as the best formulation.
- The release rate of drug from F1 formulation is best fitted to Higuchi matrix model.
- The most satisfactory formulation-F1 did show any significant change in drug content, In vitro drug diffusion studies pattern after stability studies at 30 ± 2°C and at 65 ± 5 RH for 2 months. Thus, the objective of the present work of formulation and evaluating of fluconazole topical gel has been achieved with success.

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