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# FORMULATION AND EVALUATION OF AN ANTIFUNGAL DRUG FLUCONAZOLE AS EMULGEL USING EUCALYPTUS OIL

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## ABSTRACT

Emulgel is a mixture of two independently mixed solutions, followed by the incorporation of hydrogel and emulsion. But when it comes to wet pharmaceuticals, gels have a structural restriction, yet the medicinal constituent can take advantage first of the gel's special characteristics. The active ingredient known as emulgel was created while gel and emulsion were being used together. Since 2000's, many innovative techniques in polymeric materials would be used for the creation of aesthetic products with immediate links to the epidermis like an infection site for assessment and therapy. Both anionic and cationic molecules are blocked by the arrangement of polar keratinized cells in the non-polar tight junction layer. The use of such nanosolids in cosmetic and pharmaceutical remedies has surged because of semisolid preparation. Hydrogel has the ability to dissolve and transform the potential of those kinds of molecules. It reduces the risk of cross-contamination, permitting the production of solid lipids and cosmetics. Simultaneously, the water-soluble phase's viscosity was boosted. The addition of a rheological thickener in liquid media thus transforms a conventional emulsion into an emulgel. Compounds exhibited in various configurations will enhance the occurrence of exceptional orthodox and growing of new blood vessels network in complex ways. Emulgels

are now widely regarded as a more effective cutaneous medication delivery technique than the current dose form model. Emulgels can be used in pain relievers and fungal medications.

**KEYWORDS:** Emulgel, Aesthatic products, Pain relievers, Fungal medications, Fluconazole, Polymeric materials.

## INTRODUCTION

When the hydrogel and a dispersant are combined in a recipe or blended together, emulgel is the name given to this obtained substance. In modern drug delivery system of drugs, for the distribution of soluble medicines, emulgels have been the most prescribed drug transportation technology.[1-2] Emulgels are a fresh type of active component produced by injecting large amounts of moist or aqueous extracts solvent into a network of aqueous solids that could hold various chemicals.[3-4] e.g. aluminium salts or semi-synthetic polymeric compounds. Due to strong gel forming capabilities, optimal polymeric materials are now applied as non-ionic surfactants and foaming agents to generate stable emulsion products by minimize the oil/water interfacial resistance and boosting the permeability of the liquid medium. Emulgels also have higher watery content, leading to greater drug absorption and faster molecular migration across a water-based medium.[5] Consequently, the water phase's gelling ingredients turns a traditional emulsification into emulgel. Because it's the bioadhesive material in the liquid medium that transforms an emulsion into an emulgel. It has a delivery system, is easily fluffy and upgradable consistency, is silicone coated, lipid-soluble, velvety has a better texture, microbially, and seems to have a crystalline and elegant appearance.[6-8] For that reason, a large number of vehicles applied to administer numerous medications to the skin. As a vehicle, both water/oil and oil/water emulsions are enormously utilised for their therapeutic properties. Emulgel is also known as creamed gel, gelled emulsion, or quassi emulsion.[9-12] Local medications are directly addressed to the outer layer of the skin distributed throughout the surface, spraying, or assembling and rubbing. The local transport of distribution has been used to generate either a regional impact to diagnose a skin condition or systemic medication effects.[13]

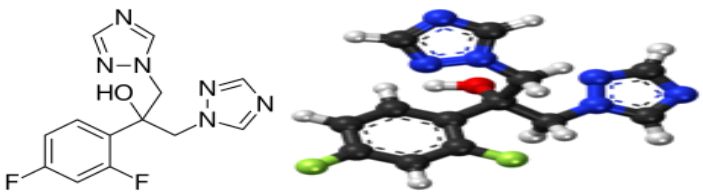


**Figure 1: Fluconazole's Chemical Structure.**

The concept of this research is to examine the progress made in the development of a fluconazole emulgel formulation and analyzing changes of physical, chemical features of the medication and stability of the drug product.

**Emulgel's Explanation as a Topical Medication Delivery System**

To create a topical formulation that incorporates a hydrophobic medication, which is not conceivable with a simple hydrogel and can only be done with emulgel formulations, many commonly used topical treatments like creams, lotions, and ointments, have a number of drawbacks when it comes to improving patient compliance. When administered, they are sticky and cause dizziness in the sufferer. Additionally, they have a lower surface tension and interfacial tension, and require applying to obliterate, as well as a stability issue. Treatments for soft tissue infections, such as acne, avoid first-pass metabolism, enhancing the drug's bioavailability.

## MATERIALS AND METHODS

All the material used was a pharmaceutical or analytical grade. Details of the materials used during the course of the project are shown in Table1.

**Table 1: List of Resources Consulted During the Research.**

| Id. Number | Name | Manufacturer |
|---|---|---|
| 1 | Fluconazole | Yarrow Chem Products |
| 2 | Unopol 934 or Carbopol 934 | Loba Chem Pvt. Ltd. Mumbai |
| 3 | Triethanolamine | s d Fine-Chem Limited, Mumbai |
| 4 | Tween 20 | Central Drug House Pvt. Ltd., Mumbai |
| 5 | Span 20 | Central Drug House Pvt. Ltd., Mumbai |
| 6 | Methyl paraben & Propyl paraben | Central Drug House Pvt. Ltd., Mumbai |
| 7 | Potassium dihydrogen orthophosphate | Loba Chem Pvt. Ltd. Mumbai |
| 8 | Sodium hydroxide pellets | Loba Chem Pvt. Ltd., Mumbai |
| 9 | Methanol | Finar Limited, Ahmedabad |
| 10 | Ethanol | Finar Limited, Ahmedabad |
| 11 | Distilled water | In-house distillation |
| 12 | Propylene glycol | Merck chemical Sco. Ltd, Mumbai |

## FORMULATION AND EVALUATION

### Formation and Assessment of Every Topical Emulgel Batches:

**Table 2: Layout Summary of Events.**

| Variable | Title | Grade Codes | | | Absolute grade | | |
|---|---|---|---|---|---|---|---|
| | | Lower Limit | Medium Limit | Higher Limit | Lower Limit | Medium Limit | Higher Limit |
| A | Unopol 934 | -1 | 0 | +1 | 0.75 | 1.0 | 1.25 |
| B | Eucalyptus oil | -1 | 0 | +1 | 4.0 | 5.0 | 6.0 |

**Table 3: Formulation composition of Fluconazole as Topical Emulgel.**

| Components(%W/W) | S1 | S2 | S3 | S4 | S5 | S6 | S7 | S8 | S9 |
|---|---|---|---|---|---|---|---|---|---|
| Fluconazole | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 |
| Unopol 934 | 1.25 | 0.75 | 1.0 | 1.0 | 0.75 | 1.25 | 1.25 | 0.75 | 1.0 |
| Eucalyptus oil | 4.0 | 5.0 | 6.0 | 4.0 | 6.0 | 5.0 | 6.0 | 4.0 | 5.0 |
| Span 20 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 |
| Tween 20 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 | 0.6 |
| Ethanol | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 |
| Trimethyl glycol | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Methyl hydroxyl benzoate | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 |
| Propyl parahydroxy benzoate | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Triethanolamine | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. |
| Purified water | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. | Ltd. Qty. |

### Preparation of Emulsion

The greasy stage of the immiscible liquids was manufactured by splitting up Sorbitan monolaurate in Eucalyptus oil using warm water. Tween 20 was diffused in filtered water to make the liquid transition of the emulsion (q. s.). Preservatives such as methyl hydroxyl benzoate and Propyl para-hydroxy benzoate are dissolved in Trimethyl glycol. Fluconazole was solubilized in Methanol and combined with the water process in both cases. The aqueous and oil phases were both warmed up to 70 to 80 degrees Celsius. The oil was then dissolved in distilled water solution and stirred constantly until it was cool. It was possible to obtain the emulsion.[14-15]

### Preparation of Hydrogels

The gel was made by dissolving a determined amount of Unopol 934 in warm water and spirited continuously at a reasonable momentum with a magnetic stirrer. Triethanolamine 5.0-6.5 was used to alter the pH.[16]

**Establishing the Emulgel**

The emulsion was mixed into the hydrogel in a 1:1 ratio using a magnetic stirrer at 900–1000rpm for 15–20 minutes, yielding an emulgel.

**Pre-formulation Investigation**

**Description**

**Table 4: Interpretation of Physical Properties of Fluconazole.**

| S. No. | Organoleptic properties | Result obtained |
|---|---|---|
| 1 | Color | Yellowish to white |
| 2 | Taste | Bitter |
| 3 | Texture | Smooth homogeneous |
| 4 | Odour | Odorless |

**Drug's Descriptive Assessment**

**Drug Fusion Point:** The heating limit of fluconazole was identifying using the capillary fusion method and the Perfit India melting point device. The drug was placed in the capillary tube, one end was sealed, and the capillary was placed in the apparatus with the sealed end facing the apparatus. With the thermometer provided, the temperature at which the solid medication transforms into liquid was recorded. The heating point of the medication was determined to be 139.0–141.0° C, which is quite similar to the literature value. This verifies the sample's purity and identity.

**Solubility: Qualitative Solubility of Fluconazole in Different Solvents**

Purified water, methanol, ethanol and phosphate buffer (7.4pH) was all used to determine solubility. Separate test tubes holding 10 ml of each solvent were filled with 10 mg of medication. For 5–10 minutes, the complete test tube was taken. The solubility was then determined visually, and the following findings were obtained:

**Table 5: Qualitative Solubility Data of Fluconazole.**

| Solvents | Solubility |
|---|---|
| Purified Water | Sparingly soluble |
| Methanol | Easily dissolvable |
| Ethanol | Easily dissolvable |
| Phosphate buffer pH 7.4 | Sparingly soluble |

**FTIR spectroscopy**

The major uses of FTIR Spectrophotometry are to identify compounds by comparing their spectra to those of genuine samples and to confirm the existence of binding sites in

unexplored entities. A fluconazole sample was put in an FTIR chamber and digitally scanned from the range between 4000/cm to 400/cm. Pure drug IR spectra were performed for investigation, and no significant variations in the absorption coefficient patter were found.

**UV spectroscopy**

When we examined the drug in the range of 200nm to 400nm by making 0.025 percent w/v solution in methanol shows absorption maxima at about 266nm and 261nm.

**Procedure:** Take 25mg weight of fluconazole and delivered into 100ml of analytical volumetric flask. After that add 90ml of methanol and shake it well. Then make up the volume up to 100ml.

The prepared solution was checked in the UV range 200-400nm. It shows two peaks one at 266nm and another was at 261nm.

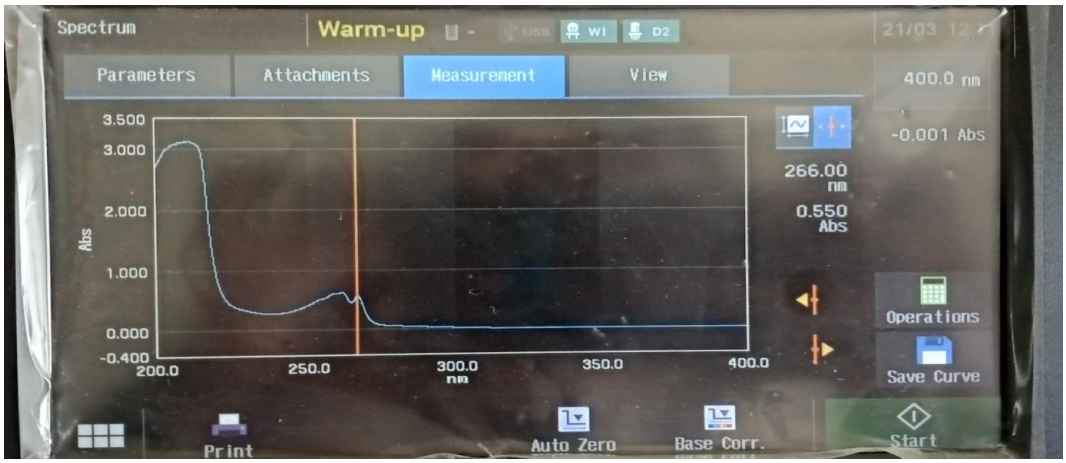


**Figure 2: Calibration Curve of Fluconazole at 266nm.**

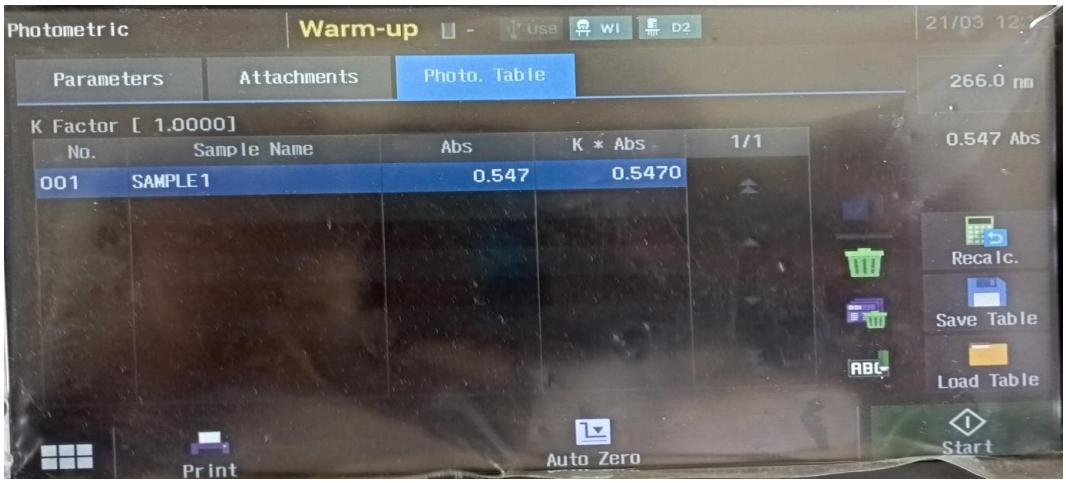


**Figure 3: Absorbance of Fluconazole at 266nm.**

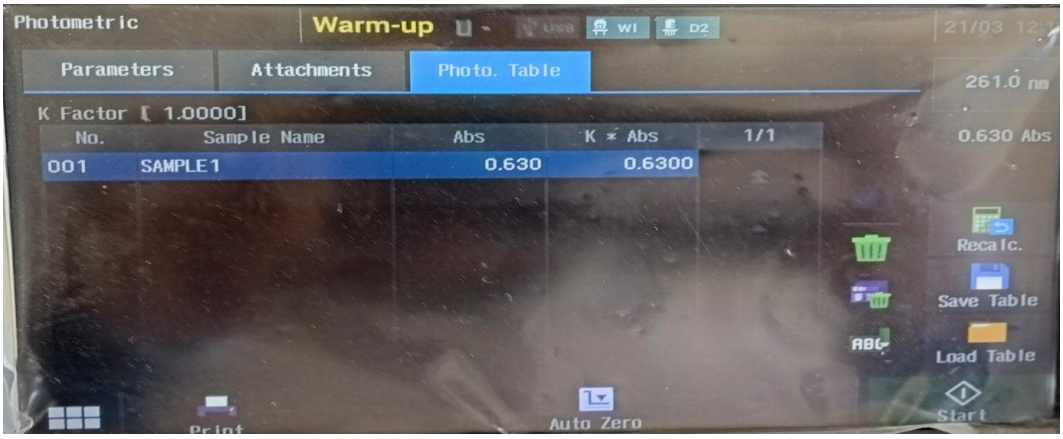


**Figure 4: Absorbance of Fluconazole at 261nm.**

**Calibration curve of Fluconazole in Phosphate buffer pH 7.4**

100mg of drug was taken and liquefied in 5ml of methanol (as co-solvent) and made volume 100ml with phosphate buffer 7.4pH. After that, in 10ml of volumetric flasks prepare the 0.5ml, 1ml, 1.5ml, 2ml, 2.5ml, 3ml, 3.5ml and 4ml of dilution and make up with phosphate buffer 7.4pH.The absorbance was measured at 261nm using phosphate buffer 7.4 pH as blank.

**Table 6: Calibration data of Phosphate buffer 7.4pH.**

| Concentration(µg/ml) | Absorbance At 261nm |
|---|---|
| 50 | 0.135±0.016 |
| 100 | 0.282±0.02 |
| 150 | 0.381±0.015 |
| 200 | 0.481±0.011 |
| 250 | 0.605±0.022 |
| 300 | 0.729±0.03 |
| 350 | 0.868±0.023 |
| 400 | 1.003±0.027 |

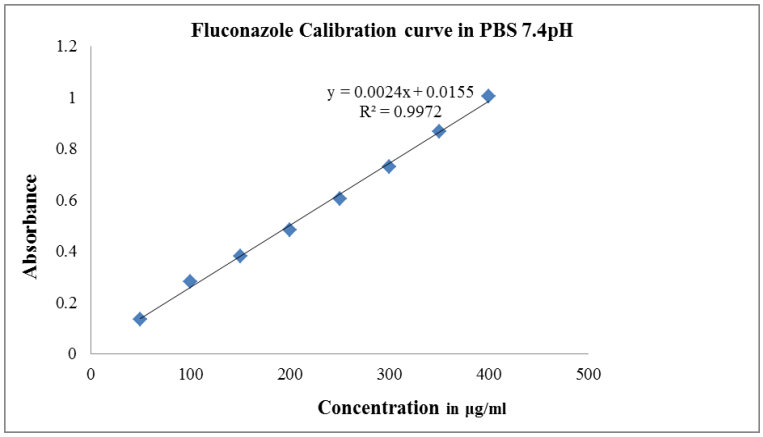


**Figure 5: Calibration curve in Phosphate buffer 7.4 pH.**

## RESULTS

### Evaluation of Fluconazole-containing Emulgel (S1- S9)

### Physical examination

In comparision to a white and black surface, the formulation's colour was examined. Emulgel's consistency was evaluated by sniffing and mixing it with water.

**pH:** Utilizing electronic pH tester, the acidity and alkalinity of the sample formulation was determined. The pH of every created formula as appeared in table were span in 5.7-6.5 which is considered acceptable to avoid the danger of allergic reaction during exposure to the body surface due adult human beings' skin pH is 5.5. The reading was taken in triplicate.

### Drug –Excipients study

FTIR spectroscopy of fluconazole and several excipient such as Unopol 934 were correlated to the spectrums of created samples of emulgel formulation.

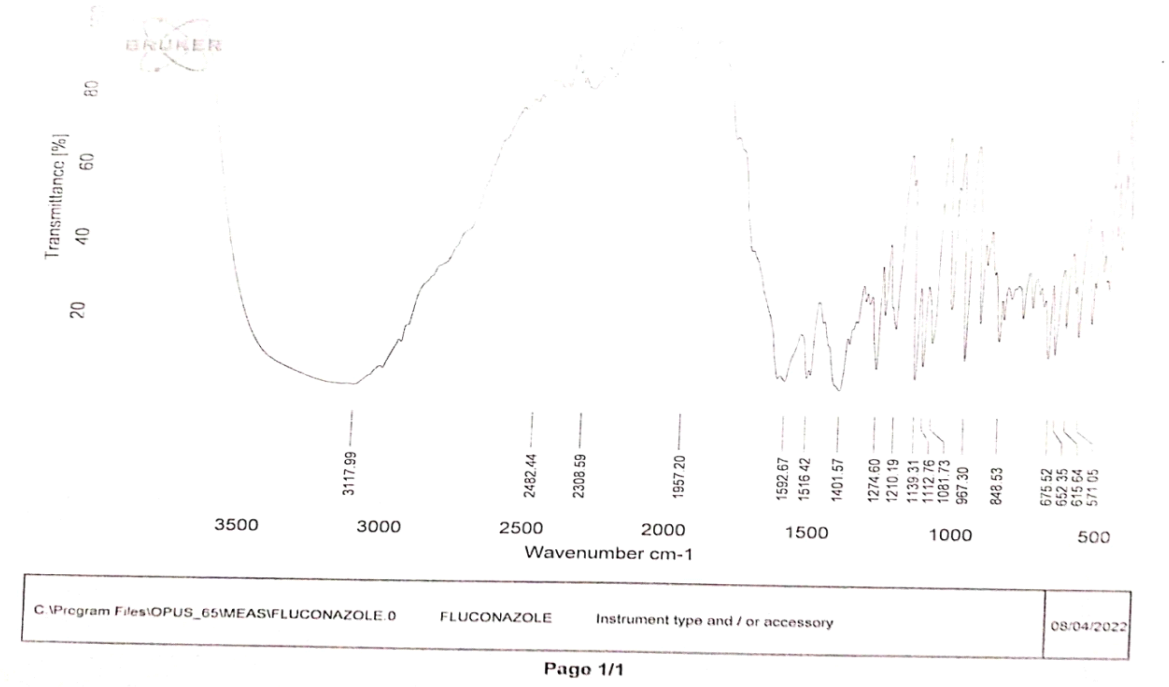


**Figure 6: FTIR Spectra of Fluconazole.**

**Table 7: FTIR spectrum of Fluconazole**

| Sample | IR range | Functional group present |
|---|---|---|
| **Fluconazole** | 3117.99 | O-H stretching |
| | 1592.67 | C-N stretch |
| | 848.53 | C-F stretch |

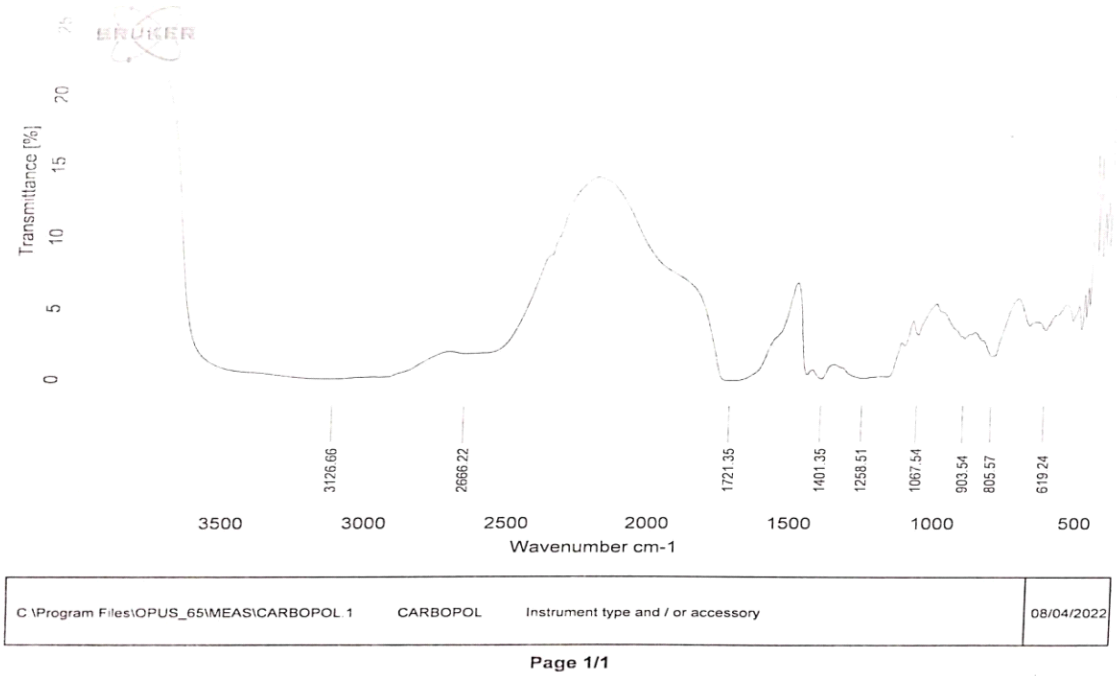


**Figure 7: FTIR Spectra of Carbopol or Unopol 934.**

**Viscosity:** The prepared emulgel's formulation viscidiness was measured using Brookfield Viscometer with arbour no. 64 and the shear rate was 3rpm.

**Spreadability:** When no more spreading was anticipated, a sampling of 0.5g per each composition was squashed between two slides (which were divided into squares with 5mm slides) as well as left for around five minutes. Spreaded circle diameters were measured in centimetres and used as benchmarks for spreadability. Three determinations were obtained on average for the result.

**Drug Information:** A 1 gram sample of emulgel was withrawal and liquefied in 100ml of volumetric flask with 40-60ml of Phosphate buffer pH 7.4. The analytical volumetric flask were placed on magnetic stirrer for 2 hours or till the drug is completely dissolved into the phosphate buffer solution. Then, the solution was made upto the mark and this solution was filtered using filter paper. Use 1ml of this mixture in 10ml of volumetric flask and makeup with phosphate buffer pH 7.4. Then, using a matching emulgel concentration as a blank, this solution was analysed using spectrophotometry at 261nm.

**Table 8: Observations of colour, phase separation, spreadability, pH, drug content and viscosity.**

| Topical Emulgels | Color | Phase Difference | Spreadability (cm) | pH | Drug content (%age) | Viscosity |
|---|---|---|---|---|---|---|
| S1 | Viscous-white | Zero Phase Difference | 5.16 | 6.2 | 93.5 | 45400 |
| S2 | Milky-white | | 4.88 | 5.8 | 96.5 | 20600 |
| S3 | Viscous -white | | 5.57 | 6.1 | 89.5 | 28800 |
| S4 | Milky-white | | 5.71 | 6.0 | 93.5 | 29660 |
| S5 | Viscous-white | | 6.17 | 5.9 | 96.5 | 22360 |
| S6 | Viscous-white | | 5.64 | 6.3 | 89.5 | 43800 |
| S7 | Viscous-white | | 6.06 | 5.7 | 90.5 | 44660 |
| S8 | Milky-white | | 5.49 | 6.2 | 93.5 | 27780 |
| S9 | Viscous-White | | 5.93 | 6.0 | 91.5 | 21460 |

**In-vitro drug diffusion study**

The produced gel was tested for in-vitro diffusion using a Keshary-Chein diffusion cell. Fluconazole 10 mg/gram emulgel 500 mg was used for the diffusion research. The cellophane membrane was covered with emulgel in a homogeneous layer. In a Keshary-Chein diffusion cell, 6 ml of Phosphate buffer with a pH of 7.4 was employed as the receptor section. The heating condition was held at 37°C±0.5°C and he receptor site and the donor compartment were continuously in contact. Using a tiny bead, an externally driven Teflon-coated magnetic stirrer was used to mix the fluid on the receptor side. At various intervals, 2mL samples were taken out and replaced with 2mL of brand-new buffer. Spectrophotometer measurements were made against a blank to estimate the amount of the drug in the responder fluid.

For each formulation, the cumulative percent of fluconazole emulgel penetrated was plotted. Following 6 hours, the total amount of medication that had infiltrated the cellophane membrane was compared Fluconazole's in-vitro release from different topical emulgel preparations was examined kinetically using four different kinetic models. Statistical indicators like $R^2$ are used to determine the equation's applicability based on the best fit equation.

**Table 9: Percentage of Drug Released S1-S3.**

| Time(Hrs) | S1 | S2 | S3 |
|---|---|---|---|
| 0.5 | **7.4** | 6.1 | 8.3 |
| 1 | **20.5** | 24.8 | 26.7 |
| 2 | **34.4** | 33.9 | 36.5 |
| 3 | **44.3** | 39.9 | 42.6 |
| 4 | **60.4** | 57.1 | 61.5 |
| 5 | **79.3** | 75.8 | 77.7 |
| 6 | **93.5** | 88.3 | 92.5 |

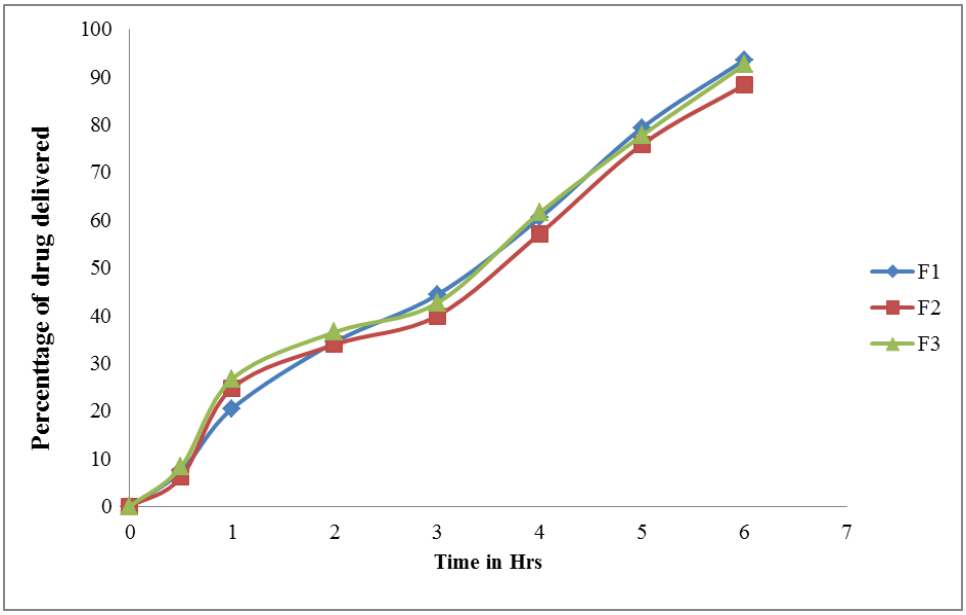


**Figure 8: Graphical Representation of %age of Drug Released S1-S3.**

**Table 10: Percentage of Drug Release S4-S6.**

| Time(Hrs) | S4 | S5 | S6 |
|---|---|---|---|
| 0.5 | 7.7 | 6.6 | 7.2 |
| 1 | 23 | 24.8 | 24.2 |
| 2 | 35.1 | 33.1 | 32.4 |
| 3 | 44.8 | 42.2 | 41.3 |
| 4 | 59.2 | 59.9 | 61.5 |
| 5 | 78.3 | 75.4 | 76 |
| 6 | 91.9 | 89.7 | 88.1 |

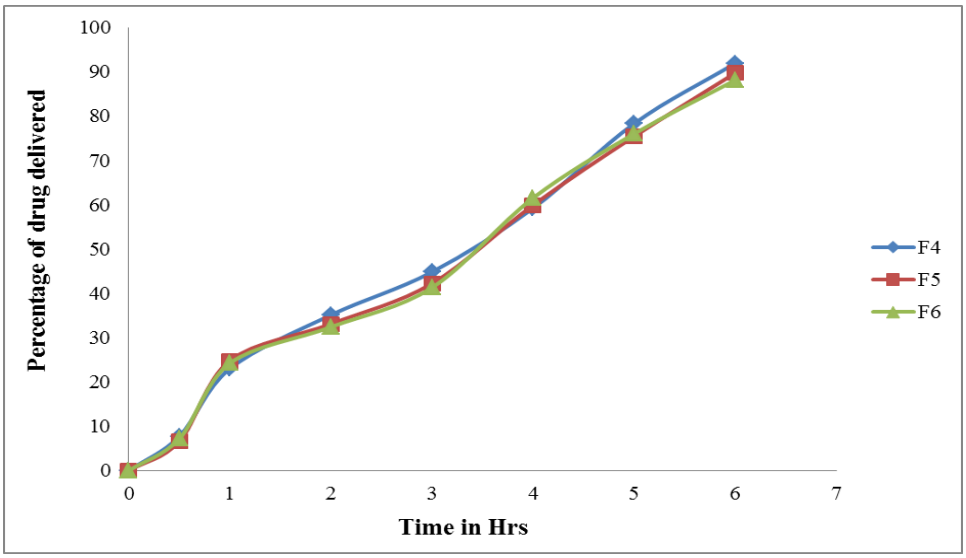


**Figure 9: Graphical Representation of %age of Drug Released S4-S6.**

**Table 11: Percentage of Drug Released S7-S9.**

| Time(Hrs) | S7 | S8 | S9 |
|---|---|---|---|
| 0.5 | 7 | 6.6 | 7.2 |
| 1 | 21.4 | 23.8 | 23.3 |
| 2 | 33.4 | 32.4 | 33.1 |
| 3 | 44.8 | 42.2 | 41.7 |
| 4 | 59.2 | 59.9 | 57.6 |
| 5 | 73.9 | 75.6 | 75 |
| 6 | 86.4 | 88.7 | 90.3 |

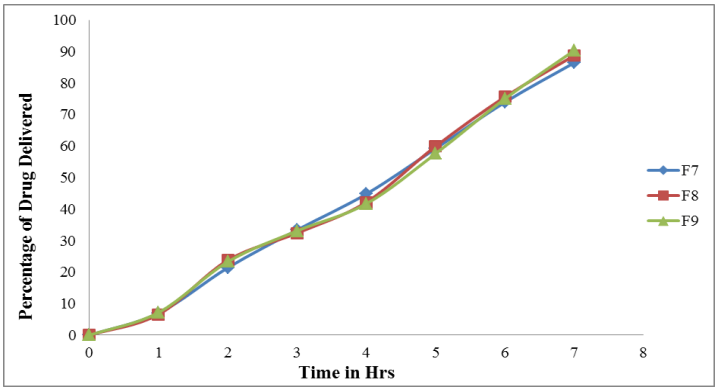


**Figure 10: Graphical Representation of %age of Drug Released S7-S9.**

## Data analysis of formulations

Two components were assessed at three levels in a three-square factorial design. Drug release and viscosity were chosen as the dependent factors, whereas the amount of Unopol 934 and eucalyptus oil were chosen as the independent variables. Stat-ease Design Expert software was used to process the data that was obtained. The statistics unequivocally demonstrate that viscosity and drug release were highly dependent on the chosen independent variables.

## Quadratic model ANOVA

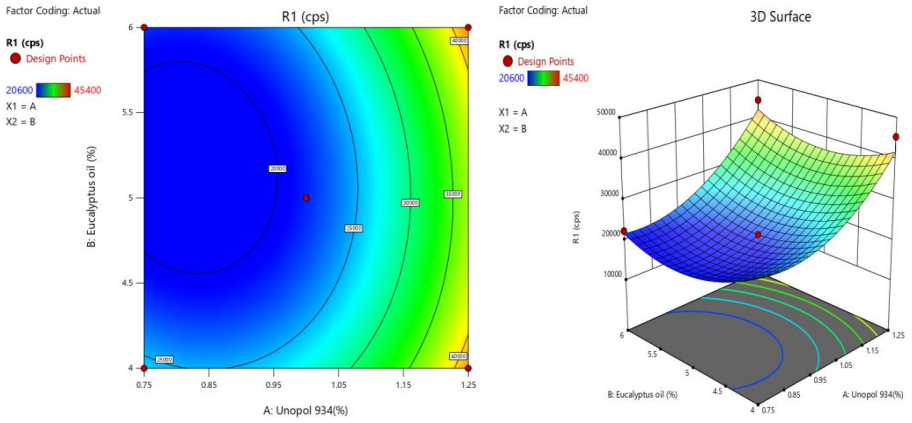


**Figure 11: Unopol 934 and Eucalyptus oil for viscosity (cps) contour plot and response 3D surface plot.**

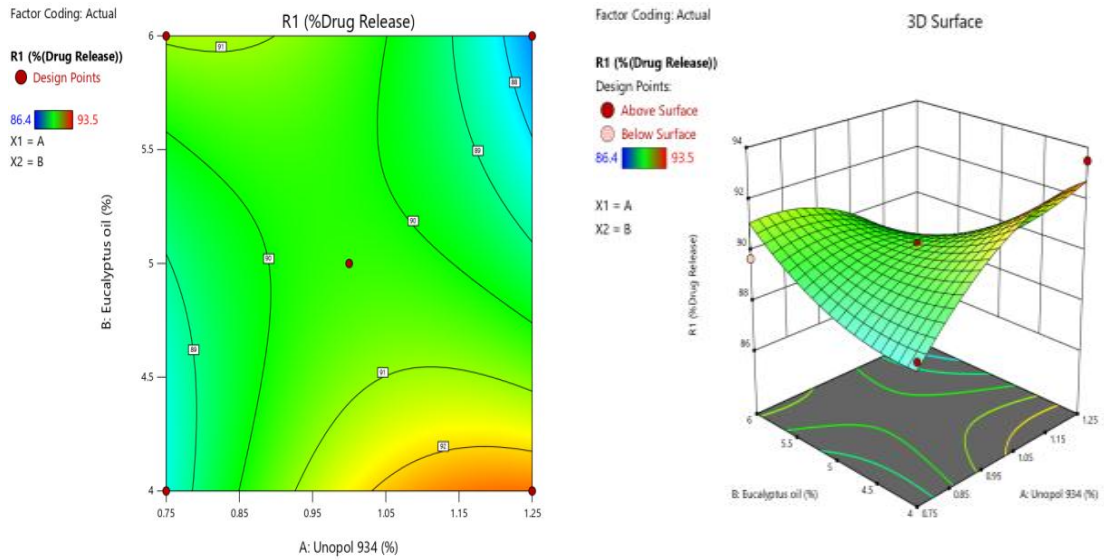


**Figure 12: Unopol 934 and Eucalyptus oil for %Drug Release Contour plot and 3D Surface plot.**

The amount of percentage of drug released from (S1-S9) emulgel batches ranged in rate from 86.4 to 93.5%. Based on the p-value of 0.05, we can furthermore say that Unopol 934 and eucalyptus oil have a significant impact ($p<0.05$) on the percentage of drug discharge. The amount of viscosity from the (S1-S9) batches of samples varies from 20600 to 45400cps. From the p-value of 0.05, we might therefore say that Unopol 934 and Eucalyptus oil have a dominant influence ($P <0.05$) on viscosity.

## DRUG-EXCIPIENTS INTERACTION STUDIES

FTIR Spectra of fluconazole and excipients such as Unopol 934 were contrasted with the resulting emulgel formulation spectra. Drug excipient study showed that there was no discoloration, liquefaction and clump formation between drug and polymer physical mixtures. This suggested that all was no physical correlation between a therapeutic and a polymer.

Nothing notable shift in the curve was observed which revealed that both the drug and polymer are suitable together.

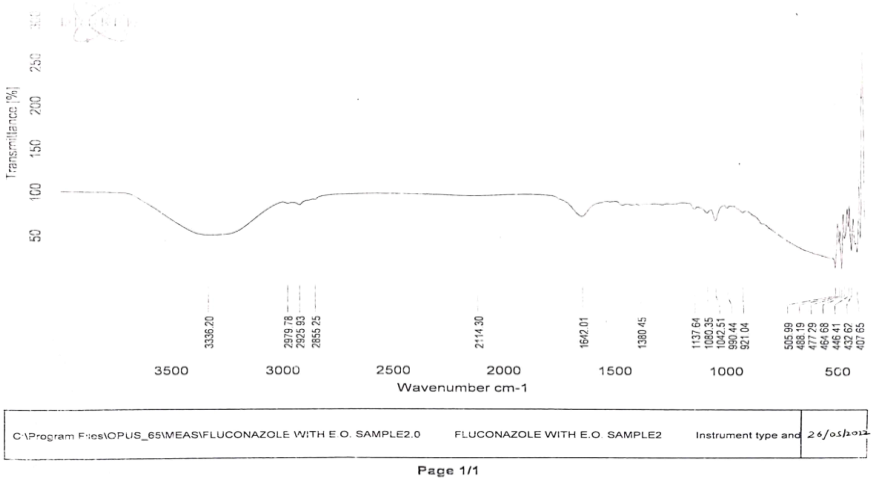


**Figure 13: FTIR Spectra of Emulgel Sample.**

**Table 12: Comparision between peaks Obtained in Drug and in a Mixture.**

| Peak achieved with drug(frequency/cm) | Identification | Peak received using a mixture(frequency/cm) |
|---|---|---|
| 3117.99 | O-H stretching | 3336.20 |
| 1592.67 | C-N stretch | 1642.01 |
| 848.53 | C-F stretch | 921.04 |

**Table 13: % CADD of Emulgel Sample before Storage and After Storage.**

| TIME(Hr) | S1(Emulgel) | F1(Emulgel After Storage) |
|---|---|---|
| 0.5 | 7.4 | 6.8 |
| 1 | 20.5 | 24.2 |
| 2 | 34.4 | 33.1 |
| 3 | 44.3 | 38.3 |
| 4 | 60.4 | 57.4 |
| 5 | 79.3 | 75.8 |
| 6 | 93.5 | 88.9 |

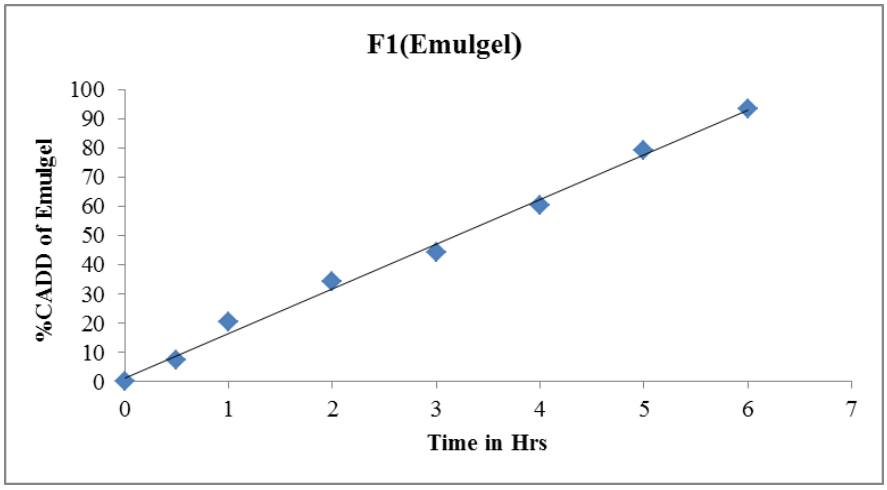


**Figure 14: Emulgel Drug Diffusion In-vitro Experiment.**

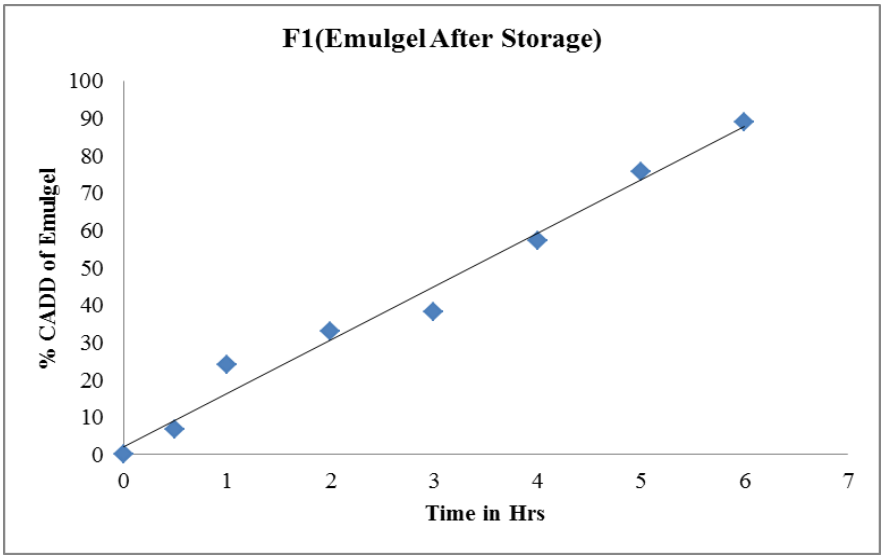


**Figure 15: In-vitro drug diffusion study of emulgel sample after storage.**

**Table 14: Stability Study data of Fluconazole Emulgel Sample (S1).**

| PARAMETERS | Optimized Fluconazole Loaded Emulgel | | | |
|---|---|---|---|---|
| | At Room Temperature/70±5% Relative Humidity | | | |
| | 0 day | 10days | 20days | 30days |
| Visual Inspection | Milk-white | Milk-white | Milk-white | Milky-white |
| Phase Separation | No | No | No | No |
| pH Value | 5.8 | 5.8 | 5.8 | 5.9 |
| Spreadability | 5.16 | 5.14 | 5.11 | 5.09 |
| Viscosity(cps) | 45400 | 45320 | 45180 | 45020 |
| Drug Content | 93.5 | 93.0 | 93.0 | 91.5 |

## DISCUSSION AND CONCLUSION

Topical medication delivery is the administration of a pharmaceutical dosage form directly to the skin in order to treat cutaneous and subcutaneous disorders and to limit the drug's pharmacological and other effect to the skin's surface. In this study, fluconazole as an emulgel for the treatment of candidiasis was developed and evaluated. Fluconazole was formulated as an emulgel with the primary goal of achieving controlled release and optimal fluconazole concentration at the location of the action for the necessary time. Because fluconazole has effective antifungal properties, it was used as a topical formulation to produce the desired effects.

Fluconazole's physiochemical characteristics, such as melting point, solubility studies, FTIR and UV spectrophotometric methods, were used in pre-formulation studies to characterize it. The absorption maxima was discovered at 261 nm. The process for making emulgel involves adding the oil in water or water in oil emulsion to gel to create a gellified emulsion.

Emulsions are controlled release systems that are modified by the application of emulsifying agents. They are made up of two or more immiscible liquids that are both unstable and in which one liquid is distributed into the other. The drug is contained in the under the surface of the emulsion, which serves as a drug stock from which the drug is released into the exterior phase and is then absorbed by the skin and gel.

Emulgels appear to be a better option for BCS class 2 drugs with high permeability and poor solubility. Emulgel has thixotropic, grease-free, spreadable, removable, emollient, non-staining, water soluble, long shelf-life, biocompatible, and aesthetically pleasing properties that increase patient acceptability. All the emulgel formulation samples were milky color in appearance. The pH of all formulation lies between 5.8 to 6.3 which lie normal pH range of the skin. The viscosity of all formulations lies between 20600 to 45400 cps for formulations F1-F9. The drug content 91.5% to 96.5%. In an in vitro drug diffusion assay, the greatest cumulative percentage drug release for formulation samples S1–S9 was 86.4 to 93.5% at 6 hours.

The highest release of the drug found in formulation F1 which is having drug (Fluconazole) and excipients Unopol 934. From the above results, it is clear that the Unopol 934 showed promising results.

On the basis of this finding, "we can conclude that fluconazole was successfully incorporated into the carbopol 934 containing hydrogel and suitable for topical application".

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