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Research Article

Formulation Design and characterization of Antifungal Emulgel for Topical Delivery

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ABSTRACT

Emulgel is the latest generation in novel drug transport device used for manage launch of emulsion and gel for the reason of topical use. The steadiness of emulsion is increased, while it is integrated into gel. Miconazole is an antifungal drug has been used inside the remedy of dermatophytic infection. The aim of the existing look at was to formula design and characterization of antifungal emulgel to incorporate hydrophobic or poorly water-soluble drug in formulation and brought via gels and in an effort to increase skin penetration of drug. The gelling component Carbopol 934 is utilized in extraordinary attention in the system of Miconazole emulgel. Further, for oil phase instruction liquid paraffin as oil, span 20 as emulsifier is used and for aqueous section propylene glycol as co-surfactant, tween 20 as emulsifier, methyl paraben & propyl paraben as preservative is used. The pH of emulgel become adjusted to 6- 6.4 the use of triethanolamine (TEA). Miconazole acts by inhibiting the fungus from producing ergosterol, the fungal equivalent of LDL cholesterol, which will increase membrane fluidity and inhibits fungus increase. The organized emulgel were evaluated for his or her bodily appearance, pH determination, viscosity, spreadability. The in-vitro diffusion and drug content material research have been executed for all formulations. Physical characteristics of all the prepared emulgel have been desirable. When compared to all different formulations, the method batch F6 suggests higher drug release.

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INTRODUCTION

Topical drug delivery refers to localized software of formula in the frame through ophthalmic, rectal, nasal, vaginal and skin with the technique to growth its bioavailability and reduction in facet outcomes.[1,2] This shipping is favored while other machine fails or has some predicament and typically used for the skin fungal contamination. Essentially, there may be kind of topical merchandise one is external topical this is unfold to the tissue to cover the diseased place and other is inner topical which can be applied for topical impact to mucous membrane in oral hollow space, vagina, or rectal tissues.[3] It can easily reach to the organ of human body for giving therapeutic outcomes and to therapy problems. TDDS is frequent as most relaxed, crucial, favorable and dependable replacement to the oral and parenteral drug transport gadget because skin act as suitable medium device for drug. Examples consist of the topical remedy of dermatological conditions inclusive of eczema or psoriasis. Corticosteroids, antifungals, antivirals, antibiotics, antiseptics, neighborhood anesthetics, and antineoplastic are examples of medications given topically.

Gels being more modern class of dosage form are created by using entrapment of massive quantities of aqueous or hydro alcoholic liquid in a network of colloidal solid debris, which may additionally achieve from natural or artificial starting place. The higher charter of aqueous thing suggests more dissolution of medicine, and permits easy migration of the drug via a liquid car compared with the ointment or cream base. In spite to tremendous gels show a major problem within the delivery of hydrophobic pills. So, avoid this challenge, emulgel is ready. In reality, the presence of a gelling agent inside the water segment converts a classical emulsion into an emulgel. To deliver the diverse capsules to the skin, each oil-in-water and water in-oil sort of emulsions are used as vehicles. For dermatological

use Emulgel show numerous favorable houses which include being thixotropic, greaseless, without problems spreadable, easily removable, emollient, non-staining, long shelf lifestyles, biofriendly, obvious & alluring look. Molecules can basically penetrate into skin through intact stratum corneum, sweat ducts and sebaceous follicle. The floor of the uppermost layer of skin that is stratum corneum offers more than 99% of the overall pores and skin surface and this is available for percutaneous drug absorption. Passage through this outer maximum layer is the rate restricting for percutaneous absorption. step The percutaneous absorption consists of the concentration gradient, it presents the driving force for drug motion throughout the pores and skin, release of drug from the vehicle this is partition coefficient, and drug diffusion across the layers of the skin that is diffusion coefficient. Emulgel having advantages many like Incorporation of hydrophobic drugs, Better loading capacity, Production feasibility and low preparation cost, Better stability, Controlled release etc.[4]

ADVANTAGES OF EMULGEL:

- 1. Reliable platform for transport of hydrophobic drugs: Emulgel avoid the problem of solubility, when maximum of water insoluble drug (hydrophobic drug) can not dissolve in gel base, where gel base is water. To conquer this challenge emulsified gel (emulgel) provide hydrophobic drug to be blended into an oil segment which bring about o/w emulsion, in which oil globule are dispersed in aqueous section. After that emulgel can be without difficulty prepared by means of blending emulsion in gel base. This will be replacement for oral therapy when oral course consist incompatibility.
- 2. Emulgel has better loading potential: emulgel shows better loading potential than liposomes and niosomes due to the fact



niosomes & liposomes have nano length due to small arrangement of mobile (small or vesicular systems) probably will result in leakage of consequences or performance.

- 3. Emulgel has higher stability: Similarly, transdermal preparations which include emulsion, powders, and lotions are much less solid then emulgel. For instance, emulsions are thermodynamically risky because of inappropriate preference of emulsifying agent can occur into segment inversion and on occasion beside the point formation or association might also bring about cracking. So that's why emulgel is approached for avoiding this hassle due to the fact they're extra strong than different topical and transdermal arrangements.
- 4. Low practice price and manufacturing partibility: manufacturing of emulgel is faster developing in both pharmaceutical and cosmetic semisolid topical dosage shape due to the fact formation of emulgel encompass of easy and clean steps. In further instances there is no want of high-priced materials or instruments. which result in decrease production value.[5]

MATERIALS AND METHODS MATERIALS:

Products, Mumbai, Liquid paraffin, Propyl

paraben, Triethaloamine, Span 20, Tween 20, glycol procured from Chemex Propylene Chemicals, Mumbai. Carbopol 934 purchased from Oryn health care, Ahmedabad.

Methods:

Method of Preparation of Miconazole loaded Emulgel:

1. Preparation of Carbopol gel base:

0.5 g Carbopol 934 weighed and dispersed in water with moderate stirring and allowed to swell for twenty-four hours to acquire 0.5% gel. Later triethanolamine was introduced to maintain pH of gel base.

2. Preparation of Miconazole emulgel:

Prepared oil phase by way of mixing Span 20 in liquid paraffin to make the emulsion, while Tween 20 changed into dissolved in distilled water to make the aqueous section. Both methyl and propyl paraben had been dissolved in propylene glycol, at the same time as miconazole become dissolved in methanol and each answer were combined with the aqueous segment. Both the oily and aqueous phases have been heated to 70-80°C separately, and then the oily section became added to the aqueous phase, stirred for 15-20 mins before being cooled to room temperature.[6]

MICONAZOLE COMPOSITION OF **EMULGEL**

-	1 1 /	1.						
Sr. No.	Ingredients (% w/w)	B1	B2	B3	B4	B5	B 6	B 7
1.	Miconazole nitrate	1.0	1.0	1.0	1.0	1.0	1.0	1.0
2.	Carbopol 934 gel	0.5	1.0	1.5	2.0	2.5	3.0	3.5
3.	Liquid paraffin	2.5	3.0	2.5	3.0	2.5	3.0	2.5
4.	Span 20	0.5	0.5	0.5	0.5	0.5	0.5	0.5
5.	Tween 20	0.5	0.5	0.5	0.5	0.5	0.5	0.5
6.	Propylene glycol	2.0	2.5	2.0	2.5	2.0	2.5	2.0
7.	Methyl paraben	0.01	0.01	0.01	0.01	0.01	0.01	0.01
8.	Methanol	1.5	1.5	1.5	1.5	1.5	1.5	1.5
9.	Propyl paraben	0.02	0.02	0.02	0.02	0.02	0.02	0.02
10.	Triethanolamine	q.s.	q.s.	q.s.	q.s	q.s.	q.s.	q.s.
11.	Distilled water (q.s.)	50	50	50	50	50	50	50

Miconazole nitrate purchased from Yarrow Chem

Table.1: Composition of Miconazole emulgel



Characterization of Miconazole Emulgel:

A. Preformulation Study:

1. Physical Appearance:

The organized Emulgel formula of Miconazole was inspected for their Physical Appearance which include color, consistency, homogeneity.

2. Solubility:

Aqueous solubility is a vital physicochemical assets of drug substance, which determines its systemic absorption and in turns its therapeutic efficacy. Solubility of Miconazole Nitrate turned into determined in water and methanol, ethanol, chloroform and acetone and different solvents.

3. Melting point determination:

Melting point of Miconazole Nitrate was determined by Open capillary method.

4. Determination of partition Coefficient:

25 mg of Miconazole Nitrate with aqueous phase and n octanol was taken in 3 separating funnels. The separating funnels were shaken for 2 hrs in a wrist motion shaker for equilibration. Two phases were separated and the amount of the drug in aqueous phase become analyzed spectrophotometrically. The partition coefficient of the drug in phases was calculated.[7,8]

5. Determination of λ max:

A solution of Miconazole Nitrate containing the concentration 1000 μ g/ml was prepared in PBS pH 6.8 and UV spectrum was taken using double beam spectrophotometer (Systronic, 2200). The solution was scanned in the range of 200–400 nm.

6. Calibration curve of Miconazole Nitrate in Methanol:

In this method weighed accurate 10 mg of Miconazole Nitrate and transferred to 100 ml volumetric flask. The drug was dissolved in methanol and made up the volume and sonicated for 5 min. This was used as the standard stock solution for further dilutions. Appropriate quantities of aliquots (1 ml) of the standard stock solution were taken in 10 ml volumetric flask. These were then diluted and made volume with methanol to made 2-12µg/ml concentrations. The above solution was analyzed by UV spectrometer at λ max 271.72 nm methanol was used as a blank during spectrophotometric analysis.[9]

7. Drug – Excipient Interaction Studies:

FTIR Infra-red spectroscopic approach was used for the detection of any possible chemical reaction between the drug and the excipients. A physical mixture (1:1) of drug and excipients was prepared and mixed with suitable quantity of potassium bromide. About 100 mg of this mixture was compressed to form a transparent pellet using a hydraulic press at 10 tones pressure. It was scanned from 4000 to 150 cm^{-1} in a Bruker FTIR spectrophotometer. The FTIR spectrum of the physical mixture was compared with those of pure drug and excipients and matching was detect appearance done to any or disappearance of peaks.[10]

B. Evaluation of Miconazole Emulgel

1. Physical examination:

Prepared topical miconazole emulgel formulations were observed for their colour, odour, wash ability, appearance, presence of any aggregate or lumps by visual inspection.

2. pH Determination:

The pH of emulgel formulations was determined by means of the use of a digital pH meter. 1 gram of emulgel dissolved in 100 mL of distilled water and stored for two hours. The measurement of pH of all formulation was done in triplicate, and average values were calculated.

3. Viscosity Determination:

The measurement of viscosity of the prepared emulgel turned into finished by way of the



usage of Brookfield Viscometer. The emulgel became rotated at 20 and 30 rpm the use of spindle no. Five (LV) at each velocity; the corresponding dial analyzing changed into noted.

4. Drug Content:

Drug content was studied by an accurately weighing 100 mg of emulgel and was dissolved in 100 ml of phosphate buffer (pH 6.8) and methanol (7:3 ratio). Then the solution was stirred continuously for 24 hours on a magnetic stirrer. Then the whole solution After sonicated. sonication was and subsequent filtration, the drug in solution was spectrophotometrically estimated by appropriate dilution.

5. Spreadability Study:

Two glass slides of standard dimensions were taken for this study. The emulgel was placed over one slide and the other slide was placed over the top of the emulgel such that the emulgel sandwiched between the two slides was pressed uniformly to form a thin layer. The pressure was removed, and the excess of the emulgel adhering to the slides was scrapped off. The two slides were fixed to a stand without disturbance in such a way that only the lower slide was held firmly by the opposite fangs of the clamp allowing the upper slide to slip off freely by the force of weight tied to it. 20 gm weight was tied to the upper slide carefully. The time taken for an upper slide to travel the distance of 6 cm and separate away from the lower slide under the direction of weight was noted.[11] The spreadability of the emulgel formulation was calculated by using a formula,

S = ML/T

Where, S - Spreadability M –Weight tied to upper slide L-Length of slides T-Time taken

6. Extrudability Study:

It is a usual empirical test to measure the force required to extrude the material from the tube. It consists of a wooden block inclined at an angle of 450 fitted with a thin metal strip at one end. While the other end was free. The aluminium collapsible tube containing 10 gm of emulgel was positioned on an inclined surface of the wooden block; 30 gm weight was placed on a free end of the aluminium strip and was just touched for 10 seconds. The quantity of gel extruded from each tube was noted. More quantity extruded better was extrudability. The measurement of extrudability of each formulation was measured.[12]

7. In vitro diffusion study:

The drug release test was conducted using a Franz diffusion cell (effective diffusion area 3.14 cm² and cell volume 110ml). 1 gm emulgel was placed to the cellophane membranes surface. Between the donor and receptor chambers of the diffusion cell, a cellophane membrane was clamped. To solubilized the drug, the receptor chamber was filled with 25ml solution of freshly prepared phosphate buffer (pH 5.5) and methanol (80:20) solution. A magnetic stirrer was used to agitated the receptor chamber. After proper dilution the samples were collected at appropriate time intervals. And tested for drug content using a UV Visible spectrophotometer at λ max.[13]

8. Drug Release kinetics:

To study the release kinetics, data obtained from in vitro drug release studies was fixed in various kinetic models: zero-order as a cumulative percent of drug release v/s time, first-order as cumulative log percentage of drug remaining v/s time, Higuchi's model as a cumulative percent of drug release v/s square root of time. To determine the mechanism of



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drug release, the data was fixed into Korsmeyer Peppas equation as log cumulative percentage of drug released v/s log time, and calculated the exponent 'n' from the slope of the straight line. The value of n characterizes the release mechanism of the drug; if the exponent is 0.5, then diffusion mechanism is Fickian; if $0.5 < n \ 1$ to super case II transport.[14]

9. In-vitro Antifungal Study:

In a 500ml of conical flask required amount of saboured dextrose agar was taken and 250ml of purified distilled water was added. Heat is applied to dissolve the saboured dextrose agar completely. Sterilized for 15 minutes at 121°C at 15 lb pressure in autoclave for about 20 minutes. Then cooled at room temperature and the fungal strain Candida albicans was dispersed in the medium. The medium was poured into the required Petri dish and allowed it cool it until it got solidified at room temperature. The cups are then bored in agar plate by using a cork borer with 6mm diameter and calculated concentration of the emulgel formulations were placed in the bores and incubated the Petri plates for 72 hours at 28°C in incubators. Then the zone of inhibition was measured and calculated the radius of the zone of inhibition.[15]

RESULTS AND DISCUSSION

A. Preformulation study

1. Physical appearance:

The supplied powder of miconazole nitrate was white in colour and odourless.

2. Melting point:

Melting point of miconazole was determined by open capillary method and found to be 178^{0} C.

3. Solubility study:

Sr.no.	Solvent	Solubility
1.	Water	Very slightly soluble
2.	Ethanol	Slightly soluble

Solvents				
	Table 2: Solubili	ty Determination in		
5.	Acetone	Slightly soluble		
4.	Chloroform	Slightly soluble		
5.	memaner	5014010		

Methanol

4. Determination of partition coefficient:

Partition coefficient value of miconazole nitrate was found to be 5.47 in n-octanol and water system.

Soluble

5. Determination of λ max:

A solution of miconazole nitrate containing 10μ l/ml was prepared in methanol. This solution was scanned in the range of 200-400nm using UV-Visible spectrophotometer and the λ max of miconazole was found to be 271nm.

6. Calibration curve of miconazole nitrate in methanol:

A calibration curve of miconazole nitrate in methanol was constructed at a λ max of 271nm using UV-Visible spectrophotometer. Beers law obeyed to construct the calibration curve in the concentration range of 5.0-25 µl/ml. The calculation of the drug release rate studies is based on the standard curve.

Sr. No.	Concentration (µl/ml)	Absorbance
1.	05	0.053
2.	10	0.099
3.	15	0.155
4.	20	0.205
5.	25	0.26





Fig.1: Calibration curve of miconazole nitrate



7. Drug excipient interaction:

The IR spectra of the drug-polymer combinations and optimal formulation were compared to the standard spectrum of the pure medication Miconazole Nitrate, and the distinctive peaks associated with particular functional groups and the bonds of the molecules were recorded in table. The peak ranges from C=N 2105.9 cm-1, C-H aliphatic 2937.1 cm-1, C-H aromatic 3037.8 to 3071.3 cm-1, C=O 1699.7 cm-1. The ranges of peak values were found to be same, suggesting that Miconazole Nitrate did not interact with various polymers, indicating the drug's stability in the formulation. Therefore, it can be concluded that the drug and polymer are compatible as shown in table.4.



Fig.2: FTIR Spectra of Miconazole nitrate



Fig.3: FTIR Spectra of Drug and Polymer

Sr.	Functional	Reported	Observed frequency		
no.	group	(cm ⁻¹)	Drug	Drug+ Polymer	
1.	C=N	1640	2105.9	2105.9	
2.	C-H (aliphatic)	2960	2937.1	2937.1	
3.	C-H (aromatic)	3048	3037.8	3071.3	
4.	C=O	1635	1699.7	1699.7	

Table 4: Interpretation of IR spectrum of Drug +Polymer

B. EVALUATION OF MICONAZOLE EMULGEL:

1.	Physical	examination	of emulgel
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Formulations	Colour	Odour	Washability	Consistency	Presence of any aggregate
B1	White	No	Washable	Good	No
B2	White	No	Washable	Good	No
B3	White	No	Washable	Good	No
B4	White	No	Washable	Good	No
B5	White	No	Washable	Good	No
B6	White	No	Washable	Excellent	No
В7	White	No	Washable	Good	No

Table 5: Physical examination of emulgel



2. pH determination:

All formulations had pH value ranging from 5.8 to 6.2, which are deemed suitable for avoiding skin irritation when applied to the skin. Table 6 shows the pH of all of the formulations.

Sr. No.	Formulation	рН
1.	B1	5.8
2.	B2	6.0
3.	B3	5.9
4.	B4	5.8
5.	B5	6.1
6.	B6	6.2
7.	B7	6.1



Table 6: pH determination of Miconazole emulgel

Fig.4: pH of Miconazole emulgel 3. Viscosity determination:

The viscosity of all formulations where measured using a Brookfield viscometer at 20 to 30 rpm with spindle no. 5. Table no. shows the viscosity of all formulations.

Sr.No.	Formulation	Viscosity
1.	B1	28.110
2.	B2	48.561
3.	B3	34. 520
4.	B4	52.534
5.	B5	40.321
6.	B6	37.500
7.	B7	44.814

Table 7: Viscosity of Miconazole emulgel 4. Drug content determination:

The drug content of emulgels was determined by UV-Spectrophotometer at 272 nm. With drug concentration ranging from 79.81 to 94.24 %. B6 had highest drug content (94.24%).

Sr.No.	Formulation	Drug content (%)	
1.	B1	86.73	
2.	B2	79.81	
3.	B3	80.55	
4.	B4	88.43	
5.	B5	90.48	
6.	B6	94.24	
7.	B7	85.94	
Table 8: Drug content of Miconazole emulgel			

Drug content of miconazole emulgel (%)



Fig.5: Drug content of Miconazole emulgel 5. Spreadability:

Table no. displays all the formulations spreadability values. The highest spreadability achieved by B6 formulation (32.22 g cm/sec).

Sr.No.	Formulation	Spreadability (gcm/sec)	
1.	B1	22.30	
2.	B2	27.44	
3.	B3	25.58	
4.	B4	29.90	
5.	B5	30.00	
6.	B6	32.22	
7.	B7	24.85	
Table 9: Spreadability of Missonazola amulgal			





Fig.6: Spreadability of Miconazole emulgel



6. Extrudability:

Table no. 10 shows the extrudability values of all formulations. Extrudability of formulations ranging from 4.87 to 8.31. the highest extrudability achieved by B6 formulation.

r.No.	Formulation	Extrudability (gm/cm ²)	
1.	B1	4.87	
2.	B2	7.50	
3.	B3	3.82	
4.	B4	5.20	
5.	B5	7.87	
6.	B6	8.31	
7.	B7	6.80	
Table 10: Extrudability of Miconazole emulgel			



Fig.7: Extrudability of Miconazole emulgel 7. In-Vitro diffusion study:

Time (Hr)	B 1	B2	B3	B4	B5	B6	B7
1	32.78	37.89	43.90	34.24	41.90	27.10	40.23
2	40.47	49.06	53.29	45.84	48.72	30.52	50.45
3	55.87	53.13	61.78	54.89	60.23	45.76	69.34
4	69.13	69.78	70.65	68.34	76.43	60.63	75.12
5	73.67	71.56	81.64	73.21	82.10	76.46	82.67
6	80.12	85.45	87.45	77.34	87.23	86.98	90.65
7	82.76	87.67	90.75	79.97	91.54	97.45	93.70
Table 10. In Vitra difference of the set of the second sec							

Table 10: In-Vitro diffusion study of Miconazole emulgel



Fig.8: In-Vitro diffusion study of Miconazole emulgel

8. Drug release Kinetics:

In-vitro drug release for all formulations of the miconazole emulgel was fixed into different equations and kinetic models to explain the release kinetics of Miconazole nitrate from emulgel. Calculated regression coefficient R2 of formulations for different kinetics models were shown in Table. When the R2 values of the regression coefficient for a first-order and zeroorder were considered. R2 values of zero-order graphs were higher for Formulating B2, B3, B5, B6, and B7 than first-order graphs. Hence it is evident that the drug release from optimized batch B6 proniosomal gel formulation followed zeroorder kinetics. By incorporating release data in Higuchi and Erosion models, the R2 values of all the formulations were found to be greater for Higuchi model. So all the formulations in this study were best expressed by Higuchi's classical diffusion equation. The linearity of plot indicated that the release process was diffusion controlled. To know the further mechanism of drug release, the drug release data was fitted into the Korsmeyer Peppas model and from the value of release exponent 'n' concluded the mechanism of drug release. All the formulations show release exponent 'n' in between 0.5 to 0.89. This showed that the drug released from all the formulations followed non-Fickian diffusion. Hence drug release was controlled by a diffusion mechanism.



Correlation coefficient of model fitting (R ²)								
Formulation code	Zero-order	First-order	Higuchi	Korsmeyer Peppa's				
B1	0.9432	0.9692	0.9614	0.9228				
B2	0.9825	0.9740	0.9708	0.9787				
B3	0.9808	0.9804	0.9644	0.9780				
B4	0.9608	0.9691	0.9744	0.9588				
B5	0.9886	0.9754	0.9675	0.9639				
B6	0.9925	0.9757	0.9843	0.9852				
B7	0.9892	0.9850	0.9846	0.9918				

9. Anti-fungal activity:

Table no.12 shows the antifungal assay values. The antifungal studies revealed that the miconazole emulgel containing Carbopol 934 in different concentration shows the maximum zone of inhibition value ranges from 8 to 17mm respectively upto 72 hrs. All formulations possessed the antifungal activity. The formulation B6 shows maximum zone of inhibition (17 mm).

Formu	Zone of inhibitions (mm)						
lations	1000 µg	750 μg	500 µg	Std			
B1	12	14	11	14			
B2	11	10	09	14			
B3	13	12	11	14			
B4	14	13	10	14			
B5	12	10	09	14			
B6	17	16	14	14			
B7	12	12	11	14			

Table 12: Anti-fungal activity of Miconazole emulgel

CONCLUSION

In the present study, an attempt has been made to formulate the topical drug delivery system of Miconazole Emulgel. Miconazole is widely used antifungal agent mostly used for fungal disease. The Miconazole was firstly characterized for its identification by using physical characterization test like melting point, UV absorption in methanol and FTIR. Emulgel was developed using gelling agent Carbopol 934. Span 20 and tween 20 used as emulsifier. Propylene glycol used as a penetration enhancer. Methyl paraben and propyl paraben used as a preservative and Miconazole as hydrophobic drug. All the formulation designed and evaluated for the post formulation studies like color, pH, viscosity, spreadability, Extrudability, drug content, In-vitro drug diffusion and Antifungal studies etc. All the result observed was within official limit.

No phase separation was observed in F6 optimized formulation. Drug content was found in the range of 94.24%, Spreadability in range of 32.22 g.cm/sec, Extrudability 8.31g/cm2, Viscosity 37.50 Cps, In-vitro drug release is 97.45 %, Antifungal activity for Candida albicans shown 14-17mm zone of inhibition. pH of all the formulation was found in the range of 6 to 6.4 that suits the skin pH indicating skin compatibility. This is the primary requirement for a good topical formulation. From the In – vitro drug diffusion study we have concluded that the Emulgel prepared from Carbopol 934, controls the drug release for longer period of time which will be helpful.

Based on the above studies, it can be concluded that the topical Miconazole Emulgel prepared with Carbopol 934 having good spreadability, homogeneity and soothening effect. In all these aspect formulation F6 satisfied all the pharmaceutical parameter of emulgel and appears to be good topical agent.

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