Research Article

Microsponge Drug Delivery of Terbinafine Hydrochloride for Topical Application

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ABSTRACT

Microsponges are porous, polymeric microspheres that are used for prolonged topical administration. The purpose of present study was to prepare terbinafine hydrochloride microsponges to avoid the side effects and further incorporate the same into gel. Terbinafine hydrochloride microsponges were prepared by emulsion solvent diffusion technique using Eudragit RS 100 and Ethyl cellulose polymers in different drug:polymer ratios. The formulations were then evaluated for particle size, percentage yield, percentage loading efficiency and *in vitro* drug release study. The SEM image showed microsponges with porous and spherical nature. The optimized formulation of each polymer was incorporated into gel bases of carbopol 940P and HPMC K100M. The prepared gels were further characterized for appearance, pH, viscosity, spreadability, drug content, *in vitro* diffusion and *in vitro* antifungal activity. The gels were homogenous and consistent with sufficient viscosity and spreadability. The drug was uniformly distributed and was released upto 80 % at the end of 10th h. HPMC K100M gels released the drug at a faster rate than carbopol 940P gels. Korsmeyer – Peppas model was observed as the best fitting model for all the gel formulations. The antifungal activity of microsponge gels was comparable with marketed formulation. The stability studies indicated that the gels were stable over a wide range of temperature. Thus if the process of microsponge technology is scaled to manufacturing level, it has the potential to provide terbinafine hydrochloride microsponge gel with better patient compliance.

Keywords: Microsponges, Terbinafine Hydrochloride, Solvent diffusion technique, Antifungal.

INTRODUCTION

Several predictable and reliable systems are developed for systemic drugs as transdermal delivery system (TDS) using the skin as portal of entry. It has improved the efficacy and safety of many drugs that may be better administered through skin. But TDS is not practical for delivery of materials whose final target is skin itself. Controlled release of drugs onto the epidermis gives an assurance that the drug remains primarily localized and does not enter the systemic circulation in significant amounts.

Some vehicles such as ointments require high concentrations of active agents for effective therapy because of their low efficiency of delivery system, resulting into irritation and allergic reactions in significant users. Thus the need exists to maximize amount of time that an active ingredient is present either on skin surface or within the epidermis, while minimizing its transdermal penetration into the body. The microsponge delivery system fulfills these requirements.[1]

Microsponge delivery system is a unique technology for the controlled release of topical agents and consists of microporous beads, typically 10-100 μm in diameter, loaded with an active agent.

When this is applied to the skin, the release of drug can be controlled through diffusion or other variety of triggers, including rubbing, moisture, pH, friction, or ambient skin temperature. Microsponges offers enhanced product performance, extended release, reduced irritation, improved product elegancy, oil control, improved formulation flexibility, improved thermal, physical and chemical stability, flexibility to develop novel product forms.[2]

Superficial fungal infections are among the most common skin diseases and occur in both healthy and immune compromised persons. They are caused by dermatophytes, yeasts and non dermatophyte molds. Terbinafine hydrochloride is a synthetic allylamine antifungal. It is highly lipophilic in nature. Like other allylamines, terbinafine inhibits ergosterol synthesis by inhibiting the fungal squalene monooxygenase (squalene 2, 3-epoxidase), an enzyme that is part of the fungal cell wall synthesis pathway.

It is mainly indicated for the treatment of toenail and fingernail infections, cutaneous candidiasis, ringworms and jock itch.[3]

Hence there is a need for the development of suitable topical formulation of terbinafine hydrochloride. Microsponge delivery system is an alternative to the existing system. In the present research work an attempt is made to develop microsponge drug delivery using different polymers. These microsponges are further incorporated into a suitable gel and characterized.

MATERIALS AND METHODS

Materials

Terbinafine hydrochloride was obtained as a gift sample from Aurabindo pharma, Hyderabad. Eudragit RS 100 and HPMC K100M were obtained from Yarrow Chem Products, Mumbai. Ethyl cellulose, Polyvinylalcohol and

Carbopol 940P were obtained from Loba Chemie, Mumbai. All other reagents and chemicals used were of analytical grade.

Formulation of Microsponges of Terbinafine Hydrochloride

Microsponges were prepared by quasi emulsion solvent diffusion method. Before formulating the microsponges of terbinafine hydrochloride by the above method, various formulation parameters such as internal and external phases, concentration of stabilizer and binding agent, volume of internal and external phases, stirring speed and time were optimized without addition of drug to achieve uniform microsponges.

The microsponges were then prepared with optimized parameters using different drug: polymer ratios as presented in Table 1. In this method 100 ml of distilled water containing 0.75% polyvinyl alcohol (PVA) was used as an external phase. The external phase was prepared by adding PVA in water at 60 °C and cooled to room temperature. The internal phase consisted of terbinafine hydrochloride, polymer and tri-ethyl citrate (TEC) (added at an amount of 50% of the polymer weight in order to facilitate plasticity) in dichloromethane with continuous stirring.

The internal phase was added to external phase drop wise with the help of syringe. After emulsification the mixture was stirred for 6 h at 800 rpm using propeller mixer. The formed microsponges were filtered and dried for 24 h at 40 °C. After drying, the microsponges were wrapped in aluminium foil and stored in desiccator for further studies.[4]

Table 1: Formulation of terbinafine hydrochloride microsponges

Ingredients	Formulation Code							
	THC MS1	THC MS2	THC MS3	THC MS4	THC MS5	THC MS6	THC MS7	THC MS8
Terbinafine Hydrochloride (mg)	250	250	250	250	250	250	250	250
Eudragit RS 100 (mg)	125	250	500	1000	-----	-----	-----	-----
Ethyl Cellulose (mg)	-----	-----	-----	-----	125	250	500	1000
Triethyl citrate (mg)	75	125	250	500	75	125	250	500
Polyvinyl alcohol (mg)	750	750	750	750	750	750	750	750
Distilled water upto (ml)	100	100	100	100	100	100	100	100

Table 2: Composition of carbopol 940P and HPMC K100M microsponge gel formulations.

S. No	Ingredients	F1	F2	F3	F4	F5	F6
1	Terbinafine hydrochloride (%)	1	---	---	1	---	---
2	Microsponges (%)	---	Equivalent to 1% of drug (THC MS2)	Equivalent to 1% of drug (THC MS6)	---	Equivalent to 1% of drug (THC MS2)	Equivalent to 1% of drug (THC MS6)
3	Carbopol 940P (%)	1	1	1	---	---	---
4	HPMC K100M	---	---	---	1	1	1
5	Propylene glycol (%)	10	10	10	10	10	10
6	Menthol (%)	0.04	0.04	0.04	0.04	0.04	0.04
7	Triethanolamine (ml)	q.s.	q.s.	q.s.	---	---	---
8	Purified water q.s (g)	20	20	20	20	20	20

Table 3: Mean Particle size, production yield and entrapment efficiency of terbinafine hydrochloride microsponges.

S. No	Microsponge Formulation	Mean Particle Size (µm)	Production Yield (%)	Entrapment Efficiency (%)
1	THC MS1	65.23 ± 0.03	80.27 ± 0.45	74.24 ± 0.007
2	THC MS2	67.93 ± 0.04	85.50 ± 0.34	75.93 ± 0.008
3	THC MS3	69.93 ± 0.03	86.21 ± 0.11	80.53 ± 0.005
4	THC MS4	70.91 ± 0.02	88.81± 0.23	83.83 ± 0.012
5	THC MS5	59.24 ± 0.04	77.25 ± 0.33	70.04 ± 0.012
6	THC MS6	60.43 ± 0.04	81.01± 0.10	74.04 ± 0.009
7	THC MS7	75.25 ± 0.02	81.90 ± 0.27	78.40 ± 0.013
8	THC MS8	80.27 ± 0.03	82.89 ± 0.43	80.94 ± 0.013

Table 4: Data of pH, viscosity, spreadability and drug content of terbinafine hydrochloride microsponge formulations in comparison with marketed formulation.

Formulations	pH	Viscosity (cps)	Spreadability (g.cm/s)	Drug Content (%)
F1	6.78 ± 0.07	678.23 ± 0.41	12.96 ± 0.07	90.36 ± 0.07
F2	6.75 ± 0.06	721.29 ± 0.99	12.02 ± 0.08	89.55 ± 0.18
F3	6.86 ± 0.08	693.58 ± 0.60	12.57 ± 0.13	90.09 ± 0.07
F4	6.85 ± 0.08	210.50 ± 0.66	17.56 ± 0.14	91.50 ± 0.07
F5	6.91 ± 0.08	248.29 ± 0.64	16.22 ± 0.18	90.41 ± 0.12
F6	6.84 ± 0.06	233.80 ± 0.27	16.50 ± 0.16	90.19 ± 0.13
Marketed sample	6.26 ± 0.08	820.65 ± 0.32	10.29 ± 0.11	99.29 ± 0.15

Table 5: Zone of inhibitions of terbinafine hydrochloride microsponge gels along with pure drug gels and marketed formulation

Zone of Inhibitions (mm)						
F1	F2	F3	F4	F5	F6	Marketed
13	9	12	18	14	15	15

Characterization of Terbinafine Hydrochloride Microsponges

Physical Evaluation

The prepared terbinafine hydrochloride microsponge formulations were inspected visually for their color, odor, nature etc.[5]

Particle Size Analysis

The particle size was determined using an optical microscope. The microscope was fitted with a stage micrometer to calibrate the eyepiece micrometer.

$$\text{One division of stage micrometer} = 0.01 \text{ mm}$$
$$= 10 \,\mu m. \quad C = \frac{SM \times 10}{EM}$$

Where, C = correction factor, SM = reading of stage micrometer which coincides with reading of eyepiece micrometer. The particle diameter of around 100 particles was measured in a field.

The average particle size was determined using the following formula:[5]

$$D_{mean} = \sum nd / \sum n$$

Where, n = number of microsponges observed and d = mean size range. Each formulation was observed six times and average of six trials was calculated.

Scanning Electron Microscopy

For evaluation of surface morphology of microsponges, the sample was analyzed in SEM JSM 5400 after they were being gold platted with 25 nm gold film and placed on the sample specimen. The image was obtained within a fraction of seconds. From the resulting image, average particle size was determined.[6]

Production Yield

For calculating production yield, theoretical mass was calculated initially by taking the mass of solid ingredients. All the prepared microsponge formulations were accurately weighed and the weight was recorded. The production yield of the microsponges was then determined using the following equation:[7]

$$\text{Production yield} = \frac{\text{Practical mass of microsponges}}{\text{Theoretical mass}} \times 100$$

Entrapment Efficiency

Microsponges equivalent to 10 mg of the drug were taken in a beaker and the drug was extracted using 50 ml of ethanol as a solvent. The extraction was carried out for 1 h. The solution was filtered. Filtered solution of 1 ml was placed into a 10 ml volumetric flask and diluted upto 10 ml with filtered phosphate buffer pH 5.8 containing 0.1% sodium lauryl sulphate. From the resulting solution 1 ml was taken and diluted upto 10 ml with phosphate buffer pH 5.8.[7] The entrapment efficiency was measured at 281 nm using UV Spectrophotometer. Six trials of each formulation were carried out. The entrapment efficiency was calculated by using the following formula:

$$\text{Entrapment Ef iciency} = \frac{W_{act}}{W_{the}} \times 100$$

Where; W_{act} is the actual terbinafine hydrochloride content in the weighed quantity of the microsponge and W_{the} is the theoretical amount of terbinafine hydrochloride in microsponges calculated from the quantity added during preparation.

In vitro Drug Release Study

The release of terbinafine hydrochloride from microsponges was investigated in filtered phosphate buffer pH 5.8 containing 0.1% sodium lauryl sulphate(900 ml) using USP (type I) apparatus. A sample of microsponges equivalent to 25 mg of terbinafine hydrochloride was taken in the basket. A speed of 50 rpm and temperature of 37 ± 0.5 °C was maintained throughout the experiment. At fixed intervals, aliquots (5 ml) were withdrawn and replaced with fresh dissolution

media. The samples were then determined by measuring the absorbance using UV spectrophotometer at 281 nm against blank. The release studies were carried out for 7 h. The release profile of microsponges was compared with the pure drug. Each batch was run six times.[8] Based on the evaluation characteristics, the optimized formulation of each polymer was incorporated into suitable gel bases of carbopol 940P and HPMC K100M and evaluated further.

Preparation of Microsponge Gels of Terbinafine Hydrochloride

Carbopol 940P (1%) and HPMC K100M (1%) was dispersed in 14 ml of water with continuous stirring for 2 h and allowed to swell overnight. Optimized microsponges equivalent to 1% of terbinafine hydrochloride were then uniformly dispersed. Menthol was dissolved in propylene glycol and added to the dispersion with careful stirring and the volume was made upto 20 g with water. The solution was then neutralized by adding triethanolamine (if necessary) slowly with constant stirring until the gel was formed.

The gel was allowed to stand overnight to remove entrapped air. The formulation was transferred to a suitable container and stored for further studies.[9] Carbopol 940P and HPMCK100M gels of pure drug were also prepared by adding the drug solubilized in methanol as per the procedure mentioned above. The composition of microsponge gels is represented in Table 2.

Evaluation of Terbinafine Hydrochloride Microsponge Gels

The prepared gels were evaluated for different parameters such as pH, viscosity, spreadability, drug content and drug release, *in vitro* antifungal activity and stability studies in order to check efficacy of the formulations.

Physical Examination

Gels should have a pleasant appearance with respect to color, consistency etc. The prepared gels were inspected visually for their color, homogenity and consistency.[9]

pH

Formulation of 1 g was dissolved in 100 ml water and the pH was determined with the help of pen pH meter (Eutech Instruments). All the gels were tested for pH six times and average of six determinations was calculated.[10]

Viscosity

Viscosity of all the gels and marketed formulation was determined by Brookfield viscometer (DV II + pro) with spindle No 96 at 20 rpm. The spindle was lowered perpendicular in the center taking care that the spindle does not touch the bottom of the jar. The factors like temperature and pressure which affect the viscosity were maintained during the process. Each formulation was tested six times and the average value was calculated.[9]

Spreadability Studies

Apparatus was designed in the laboratory as per the literature surveyed for spreadability studies. Two glass slides of standard dimension were selected. The formulation whose spreadability had to be determined was placed over one of the slide. The other slide was placed on top of the formulation and 100g weight was placed on top of the two slides so that the formulation was uniformly spread. The weight was removed and excess formulation was scraped out. One of the slides was fixed on which the formulation was placed. The movable slide was placed over it, with one end tied to a string to which load could be applied by the help of a simple pulley and a pan.

A 30 g weight was put on the pan and the time taken for the upper slide to travel the distance of 7.5 cm and separate away from the lower slide was noted. The experiment was repeated and the mean time taken for six such determinations were calculated:[11]

$$S = \frac{m.l}{t}$$

Where,

m = weight tied to the upper slide (30 g)

l = length of glass slide (7.5 cm)

t = time taken in seconds.

Drug Content

One gram of gel formulation containing drug equivalent to 10 mg of terbinafine hydrochloride was extracted with 30 ml of ethanol and the volume was made upto 50 ml with ethanol. The resulting solution was filtered. Suitable dilutions of the filtrate were prepared with filtered phosphate buffer pH 5.8 containing 0.1% sodium lauryl sulphate and absorbance was measured at 281 nm using Jasco V-630 spectrophotometer. Experiment was repeated six times and average was calculated [60].

In vitro Drug Diffusion Studies

The *in vitro* drug diffusion study was carried out by beaker method. The apparatus consists of a cylindrical tube to the base of which a dialysis membrane was attached. The tube was placed in a beaker containing the dissolution medium such that the base of the tube just touches the dissolution medium. One g of gel formulation was placed in the tube. The study was carried out using 200ml of filtered phosphate buffer pH 5.8 containing 0.1% sodium lauryl sulphate at 100 rpm on a magnetic stirrer. The temperature was maintained at 37 ± 0.5 °C. At fixed intervals aliquots (5ml) were withdrawn and replaced with fresh buffer media. Suitable dilutions were made and concentration of drug released at different time intervals was determined by measuring the absorbance using UV Spectrophotometer at 281 nm against the blank. The release studies were carried out for 10 h and the release profile of the microsponge gels along

with gel containing pure drug was compared with marketed formulation of terbinafine hydrochloride. Each batch was run six times and average of six trials was calculated[12].

Release Kinetics

Data obtained from release studies of gels was subjected to kinetic treatment such as zero order drug release, first order drug release, Higuchi's square root plot and Korsmeyer-Peppas model to obtain the order of release and release mechanism.[13]

In vitro Antifungal Study

Composition of sabouraud's dextrose agar was taken in a 250 ml conical flask and was dissolved in 100 ml of distilled water. The pH was adjusted to 5.8. The medium was sterilized in an autoclave at 15 lbs for 20 min. After sterilization, the medium was kept aside at room temperature. The medium was poured into sterilized petridishes to give a depth of 3-4 mm inside a laminar airflow unit and was assured that the layer of medium was uniform in thickness.

After solidification, a loop of diluted suspension culture (*Candida albicans*) in nutrient broth was added on to the surface of solidified agar and was spread uniformly with the help of L shape rod.

After stabilization of culture, with the help of a sterile cork borer, cups of each 6 mm diameter were punched and scooped out from the petridish. Gels of known concentration along with marketed preparation were fed into the cup. The petridishes were then incubated for 24 h at 37 °C. After incubation the zone of inhibition was measured.[14]

Stability Studies

According to the modified ICH guidelines, the stability studies were performed for all the formulations of microsponge gels on storing them at 25 ± 2 °C (60 ± 5%) and 45 ± 2 °C (70 ± 5%) for 3 months. Microsponge gel formulations were stored in stability chamber (Lab top instruments). Sampling was done at the end of each month for three months and parameters such as appearance, pH, drug content and drug release were estimated.[15]

RESULTS AND DISCUSSION

The emulsion solvent diffusion method used for preparation of microsponges was selected based on the flexibility of method to form microsponges. Since microsponges are meant for controlled release of the drug release retardant polymers such as Eudragit RS 100 and Ethyl cellulose were used.

Characterization of Terbinafine Hydrochloride Microsponges

Physical Appearance

All the prepared microsponges were white in color,

odorless, free flowing and rigid in nature.[8]

Particle Size Analysis

The average particle size of terbinafine hydrochloride loaded eudragit RS 100 andethyl cellulose microsponges ranged from 59.24 μm-80.27μm as shown in Table 3. It was found that with increase in concentration of the polymer the mean particle size increased. This may be attributed to the higher viscosity of the internal phase, thus increasing the chances of formation of bigger particles and faster diffusion of the solvent.

Production Yield

The production yield of terbinafine hydrochloride loaded eudragit RS 100 and ethyl cellulose microsponges was found to be in the range of 77.25 - 88.81 % as presented in Table 3. With increase in polymer concentration, production yield increased. This may probably be due to the higher amount of polymer present thus resulting in increase in total mass.

Entrapment Efficiency

The entrapment efficiency of terbinafine hydrochloride loaded eudragit RS 100 and ethyl celluloseranged from 70.04 - 83.83% as shown in Table 3. The results of entrapment efficiency showed that with increase in polymer concentration of both the polymers, the entrapment efficiency increased. The increase in entrapment efficiency with increase in polymer concentration may be attributed to sufficient amount of polymer available for the drug to be entrapped.

Scanning Electron Microscopy

The morphology of one of the optimized microsponge formulation (THC MS6) was investigated by SEM. The SEM report is shown in Figure 1. The report showed that the microsponges were spherical in shape and uniform in size. No intact crystal of drug was seen visually and the inner structure consisted of porous void spaces. Based on SEM studies. The mean particle size of microsponges was found to be 50 μm.
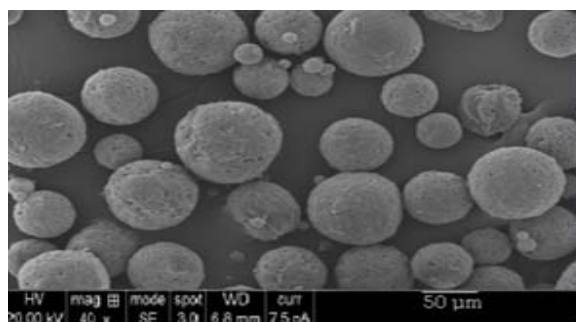

Figure 1: SEM image of ethyl cellulose loaded terbinafine hydrochloride Microsponges.

In vitro Drug Release

The prepared microsponge formulations of terbinafine hydrochloride were subjected to *in vitro* drug release studies. The comparative dissolution profiles of

microsponge formulations are shown in Figure 2. The microsponge formulations prepared using Eudragit RS 100 and ethyl cellulose released the drug upto 80% at the end of 7th h. The initial burst release could be due to the drug near or on the surface of microsponges and the porous nature of microsponges. The studies showed that, an increase in polymer concentration resulted in a decrease in drug release from microsponges. This may be due to the decrease in porosity of microsponges with increase in polymer concentration.[9] The microsponge formulations were compared with pure terbinafine hydrochloride.
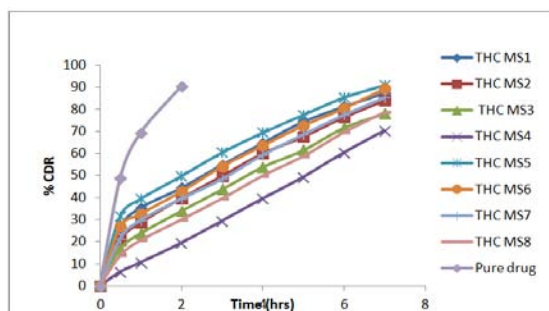
Figure 2: Drug release profile of terbinafine hydrochloride from eudragit RS 100 and ethyl cellulose microsponge

Evaluation of Terbinafine Hydrochloride Microsponge gels

Physical Appearance

The prepared gel formulations were white in color, consistent, viscous with a smooth and homogenous appearance.

pH

The pH of all the gel formulations was found to be in the range of skin pH as shown in Table 4. The marketed formulation showed pH of 6.26.

Viscosity

The viscosity of gel formulations was found to be ranging from 210.50 - 693.58 cps, as shown in Table 4. The marketed sample exhibited viscosity of 820 cps. The results of viscosity studies showed that pure drug gels of both the polymers (carbopol 940P and HPMC K100M) (F1 and F4) were less viscous when compared to microsponge enriched gels. Within both the polymers, HPMC K100M gels were less viscous when compared to carbopol 940P gels owing to the high viscosity of carbopol 940P when compared to HPMC K100M. The marketed formulation showed a higher viscosity than all the formulations.

Spreadability

The spreadability of gel formulations ranged from 12.96-17.56 g.cm/sec as shown in Table 4. The marketed sample exhibited spreadability of 10.29 ± 0.15 g.cm/sec. From the spreadability studies, it was observed that formulation F4, F5 and F6 (HPMC K100M gels) were more spreadable when compared to formulation F1, F2 and F3

(Carbopol 940P gels) because of their lower viscosities than carbopol gels. The marketed formulation was less spreadable in comparison to rest of the formulations.

Drug Content

The drug content of carbopol 940P gels, pure as well as microsponge enriched gels was found to be in the range of 89.55 - 91.50 % as shown in Table 4. The marketed formulation drug content was found to be 99.29. From this it can be inferred that drug remains in entrapped form in microsponges and is uniformly distributed into the gels.

In vitro Drug Diffusion Studies

The in vitro diffusion studies showed a minimum of 70% release at the end of 10th h for all the formulations. The studies revealed that carbopol 940P as a gelling agent released the drug slower when compared to HPMCK100M. From the results it is also evident that terbinafine hydrochloride loaded microsponge gels controlled the release of drug when compared to pure drug gels. The drug release of microsponge enriched gels showed a slower release when compared to microsponge formulations. This may be due to the longer diffusion path the drug has to follow. First the drug has to diffuse from microsponges into the vehicle and from there on to the skin. When compared with microsponge enriched gels of eudragit RS 100 and ethylcellulose loaded microsponges of terbinafine hydrochloride, ethyl cellulose loaded microsponge enriched gels showed a higher release. The marketed formulation showed a lower drug release in comparison to pure drug gels of terbinafine hydrochloride using Carbopol 940P and HPMC K100M. The comparison release profile of drug from microsponge gels, pure drug gels and marketed formulation is shown in Figure 3.

Release Kinetics

The best fit model for all the formulations was found to be Korsmeyer – Peppas with regression coefficient in the range of 0.987- 0.998 except for F1 and F4 which followed Higuchi matrix model as shown in Table 6. The n value for all the formulations was found to greater than 0.5. This suggested that the drug release followed non – fickian diffusion mechanism i.e., the drug was initially released by erosion followed by controlled diffusion.
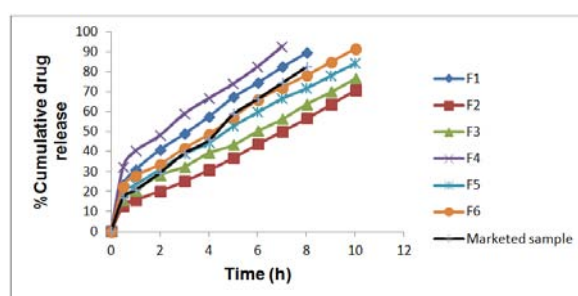
Figure 3: Drug release profile of terbinafine hydrochloride from microsponge enriched carbopol 940P and HPMC K100M gels in comparison with marketed sample.

In vitro Antifungal Studies

Among all the formulations, formulation F4 (pure drug HPMC K100M gels) showed a maximum zone of inhibition of 18 mm which indicates that HPMC releases the drug at a faster rate than carbopol 940P. From amongst the microsponge enriched gels of both the polymers, the one with eudragit RS 100 microsponges of terbinafine hydrochloride showed a lesser inhibition than ethyl cellulose loaded microsponges of terbinafine hydrochloride thus proving that eudragit RS 100 is more retardant than ethyl cellulose. When compared to marketed formulation, it was observed that carbopol 940P gels showed less inhibition in comparison to HPMC K100M gels. The results are represented in Table 5.

Stability Studies

The formulations were evaluated for pH, drug content and drug release studies. All the parameters were observed for three months by taking the samples monthly. There was no variation in the initial and final values at the end of three months of pH, drug content and drug release. From the stability studies it was inferred that there was no significant changes observed both at 25 ± 2 °C (60% ± 5%) humidity and 45 °C ± 2°C (70% ± 5%) relative humidity as far as appearance, pH, drug content and drug release was concerned. The other parameters such as viscosity and drug content were also found to be stable. This proves that microsponge enriched gels were stable over wide range of temperature and microsponges incorporated into gels does not lose their properties.

CONCLUSION

In the present study, terbinafine hydrochloride loaded microsponges of eudragit RS 100 and ethyl cellulose were successfully developed using quasi emulsion solvent diffusion method. It was concluded that in order to obtain microsponges with uniform particle size and rigidity, various parameters such as selection of internal and external phase, volume of internal and external phase, concentration of stabilizer, concentration of binding agent, stirring speed, stirring time etc. needs to be optimized. The gel formulations possessed a desirable viscosity and spreadability for topical applications. The microsponge gels showed a controlled release of the drug in comparison to pure drug gels and the efficacy of microsponge gel formulations was comparable with marketed formulation. The stability studies concluded that microsponge gel formulations are stable over wide range of temperature for three months. Further it is concluded that if the process of microsponge technology is scaled to manufacturing level, it has the potential to provide terbinafine hydrochloride microsponge gel with better patient compliance since the frequency of dosing is reduced. On the basis of significant results achieved, the developed gels will have a significant role in topical treatment of fungal infections.

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