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Research Article

Formulation and Evaluation of Cefuroxime Axetil

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ABSTRACT

Emulgels, a hybrid system combining emulsions and gels, offer an innovative approach to topical delivery, especially for hydrophobic drugs. The present work aimed to investigate the potential of Emulgel in enhancing the topical drug delivery of Cefuroxime Axetil using different gelling agents. The solubility studies were performed to for the suitable oils, surfactants, through which caproyl 90 was taken as oil, Labrasol ALF as oil phase surfactant and tween 80 as aqueous phase surfactant and Carbopol 940, HPMC and methylcellulose as gelling agents were selected. The influence type of gelling agent and the concentration of both the oil and emulsifying agent on the drug release from the formulated Emulgel was studied showing a 8hrs drug release. The prepared formulation was evaluated for their physical appearance, pH determination and in-vitro release study. The prepared emulgel was showed acceptable physical properties concerning color, homogeneity, consistency and pH value and it also showed desirable drug release during invitro diffusion studies and the microbiology studies were also performed showing inhibitory zone. The formulation has been subjected to accelerated stability condition, where there is no declined release of drug.

INTRODUCTION

Emulsion gels had been gained popularity in pharmaceutical topical circumfluous cure forms since the middle of the 1980s. They were created as a result of the extensive operation of emulsion systems as a system of medicine dosing, especially for dermatological phrasings.(3) Due to its double release control medium (emulsion and gel), emulsion in gel has come one of the most attractive topical medicine delivery technologies. In actuality, an emulsion converts into an emulgel when a gelling agent is present in the water phase. Various specifics are applied to the skin using water- in- oil and oil- in- water composites. composites are elegant to a certain extent and may be removed with ease at any time. They are also fairly good at piercing the skin. thixotropic, greaseless, easily spreadable, readily removable-staining, water-answerable, having a longer shelf

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life, being bio-friendly, clear, and having a nice look are just a numerous of the profitable rates that make emulgel ideal for dermatological operation. (1,2)

In recent years, this kind of innovative formulation has been created for dermatological application and has shown promise in transporting hydrophobic medications. Additionally, it is proved that emulgel will emerge as a crucial method for incorporating hydrophobic therapeutic substances into gel formulations. Emulgel functions as a dual-control medication release method because it combines the properties of gel and emulsion. Numerous pharmaceutical companies have entered the commercial emulgel manufacturing market as a result of these advantages. These include CLINAGEL® (Clindamycin phosphate), Pernox® (Benzoyl peroxide), Miconazole nitrate (Miconaz-H), and Voltaren® Emulgel® (Diclofenac sodium). (4)

Topical drug delivery systems are pharmacological formulations that are administered topically to the skin or mucous membranes with the goal of limiting the medication's impact to the area of application. They are used to treat skin disorders or associated symptoms.

Three primary pathways exist for drugs to enter the skin: transcellular (through cells), paracellular (between cells), or appendages (hair follicles, sweat glands).Localized therapy, increased patient compliance, simplicity of administration, rapid drug cessation, and prevention of gastrointestinal upset are all benefits of topical distribution. Disease-specific delivery methods and customized dosage are being developed to improve treatment results while reducing side effects. Different dose forms, including creams, ointments, lotions, sprays, powders, gels and patches, are included in topical formulations. (1,2)

Mechanism of Action of Emulgel:

Three main skin penetration pathways are used by emulgel to promote medication absorption:

(i) The transcellular route, which passes straight through cells,
(ii) The intercellular route, which passes between cells, and
(iii) Follicular pathway (via sweat glands and hair follicles)

Diffusion and dissolution are the limited in rate processes for absorption, and passive diffusion is the main way that the medication enters the stratum corneum, the outermost layer of skin. While the emulsion phase increases medication solubility and penetration, the gel foundation offers an appropriate carrier that promotes spreadability, stability, and patient compliance. The size of the emulsion droplets (smaller droplets improve release and penetration), the kind of emulsifier, and the gelling agents that regulate viscosity and release rate are some of the variables that affect drug release from emulgel. Emulgel formulations including penetration enhancers (such as oleic acid, menthol, and clove oil) increase medication penetration into the skin by momentarily disrupting the skin barrier or fluidizing lipid channels.

Components of Emulgel

a. Aqueous Material/ Vehicles

In the emulgel medication, oleaginous and waterless vehicles are used, and both hydrophobic and hydrophilic medicines are used.

e.g.: alcohol, water, and other aqueous materials are used in aqueous phase emulsions

b. Oils

Used to prepare an emulsion and to dissolve lipophilic drugs.

e.g.: castor and mineral oils.

c. Emulsifiers

Emulsifying composites are used to manage stability throughout a shelf life that can range from days for spontaneously generated phrasings to numerous times or months for marketable medications, as well as to promote emulsification during manufacturing and also reduces face pressure.

e.g.: Tween 80, Span80, Tween 20, stearic acid, etc

d. Penetration enhancers

These substances create a flash and reversible increase in skin permeability by partitioning into and interacting with the factors of the skin. alter the hedge's characteristics to make it easier for medicines to pass through the skin.

e.g. Menthol, oleic acid, clove oil, and cinnamon oil

e. Gelling agent

These substances can be employed as thickening agents or to ameliorate the thickness of any lozenge form. Give the expression the gel's texture, thickness, and structure.

e.g. Carbopol 940, Carbopol 934, HPMC-2910, and others are gelling agents.

f. Preservatives

Prevent microbial contamination and extend shelf life.

e.g. Methylparaben, propylparaben, phenoxyethanol, benzalkonium chloride.

g. pH adjusting agent

Maintain the formulation pH within the skin-compatible range (usually 5–6.5).

e.g. triethylamine, NaOH, etc.

METHODOLOGY

The serial dilutions of range 2.5-20µg/ml has been prepared from the working standard of 100µg/ml then the absorbance was taken with the diluent acetonitrile.

Solubility studies of API in various oils and surfactants

Accurately weighed 500mg of excipients was taken in to vials and 10mg of drug is added till saturation and cyclomixed. The vial placed in the beaker if the drug is not dissolved kept on a water bath for dissolving of the drug. After the saturation is attained in the respective excipients kept in the shaking incubator for 72 hrs. The above solution is centrifuged at 3000rpm for 10mins and 0.1ml supernatant is collected. The supernatant of 0.1ml is diluted to 10ml with respective solvents. The concentrations of drug in various excipients have been observed in the UV.

Preparation of gelling agent

The gel phase has been prepared by dispersing the gel quantity in purified water with constant stirring at a moderate speed and then the pH is adjusted to 6.5 using Triethanolamine (TEA).

Preparation of oil phase

The drug was weighed and dissolved in the caproyl 90 and labrosol ALF was added in measured quantity.

Preparation Of aqueous phase

The aqueous phase was prepared by dissolving Tween 80 in purified water.

- The both oil and aqueous phases were heated separately heated to 70℃ to 80℃.
- Then the aqueous phase was added to the oil phase with continuous stirring until cooled to room temperature.
- Then the mixture was homogenized by homogenizer which forms an emulsion.
- The above emulsion is added to the gel which forms a gellified emulsion and the preservative is added and mixed thoroughly.
- Few drops of glycerin were added.

Formulation for Emulsion:

Ingredient	FE1(g)	FE2(g)	FE3(g)
Cefuroxime Axetil	0.250	0.250	0.250
Oil Phase			
Caproyl 90	0.5	1	1.5
Labrasol ALF	1	1.5	0.5
Aqueous phase			
Water	3	3	3
Tween 80	1.5	0.5	1
Preservative			
Methyl Paraben	0.030	0.030	0.030

Table: Formulation table for emulgel

Ingredient	FG1 (g)	FG2 (g)	FG3 (g)	FG4 (g)	FG5 (g)	FG6 (g)	FG7 (g)	FG8 (g)	FG9 (g)
Cefuroxime Axetil	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250
Caproyl 90	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Labrasol ALF	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Water	1	1	1	1	1	1	1	1	1
Tween 80	3	3	3	3	3	3	3	3	3
Methyl paraben	0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.030
Carbopol 940	-	--	0.250	0.300	0.500	-	-	-	-
Methyl cellulose (300-560cps)	0.250	-	-	-	-	0.500	-	0.750	-
Hydroxy Propyl Methyl cellulose 15cps+Ethyl cellulose)	-	1+0.250	-	-	-	-	0.750+0.250	-	0.500+0.250
Water	15ml	15ml	15ml	15ml	15ml	15ml	15ml	15ml	15ml
Triethanolamine	0.500	0.500	0.250	0.250	0.250	0.500	0.500	0.500	0.500
Glycerin	qs	qs	qs	qs	qs	qs	qs	qs	qs

Evaluation studies:

Physical Characteristics of Emulsion:

The prepared emulsion was evaluated visually for its appearance, color, phase separation, consistency, homogeneity, grittiness and stability of the emulsion.

5.5.2 Physical Characteristics of Emulgel:

The prepared emulsion was evaluated visually for its appearance, color, phase separation, consistency, homogeneity, grittiness and stability of the emulsion.

1. **Homogeneity**

The gels were examined for their physical properties like color, clarity and phase separation by visual examination. They are tested for the presence of any aggregates.

2. Grittiness

Presence of any particulate matter in the formulations was observed visually.

5.5.3 pH Determination

pH evaluation is an important-criteria for topical formulation. Ideal pH value for topical formulations is 5-7.5. If the pH is either acidic or basic, it causes skin irritation. A digital pH meter was used to determine the pH of gels.

Procedure

- Calibrate the pH meter using the distilled water taken in beaker.
- Then place the formulation against the electrode of pH meter and note the pH of each formulation.

Spreadability:

- Take the fixed amount of emulgel i.e, 1-2g of each formulation.
- And place the emulgel between the two glass slides.
- Place a weight on top of the upper slide for about 5 minutes to expel air and form a uniform thin layer of emulgel between the slides.
- Remove the weight on top and apply a pulling force to the upper slide.
- Measure the time (in seconds) taken for the upper slide to slide a fixed distance (e.g., 6 to 7.5 cm) over the lower slide.

$$S = M. L / T$$

Where:

S = Spreadability (g·cm/s)
M = Weight tied to the upper slide (g)
L = Length of the glass slide (cm)
T = Time taken for the slide to move the set distance (s)

Viscosity

- Take the appropriate amount of emulgel which is free of air bubbles and ensure it is well mixed before performing the viscosity.
- Use a rotational viscometer such as a Brookfield viscometer or a cone and plate viscometer.
- Attach the appropriate spindle (e.g., spindle 7 or spindle 52 depending on viscosity range).
- Set the temperature control to 25°C (room temperature or as specified). Maintaining temperature is important as viscosity is temperature-dependent.
- Place the emulgel sample in a suitable container
- Immerse the spindle into the emulgel sample without trapping air bubbles.
- Rotate the spindle at a low speed (commonly 1 rpm to 100 rpm depending on the formulation).
- Allow the spindle to rotate freely and stabilize, then record the dial reading or viscosity value displayed.
- The viscosity is usually measured in centipoise (cP) or milliPascal seconds (mPas).

Invitro Diffusion studies

- Invitro diffusion study was carried out in Franz diffusion cell using pretreated egg membrane.
- The egg membrane was placed on the Franz diffusion cell.

- Formulation was applied through the donor compartment on the dialysis membrane.
- Reservoir compartment was filled with 20ml phosphate buffer of pH 7.4.
- The study was carried out 37±1℃ and at speed of 540rpm.
- Samples were withdrawn from reservoir compartment at intervals of 15,30,60,120,360,480,720,1440 mins and absorbance was measured spectrophotometrically at 277 nm by diluting the sample with acetonitrile to 100ml.
- Each time the reservoir compartment was replaced with the same quantity of 7.4 pH phosphate buffer.

Microbiology studies

Preparation of Nutrient Media

2.8 grams of Agar-Agar is dissolved in 100ml distilled water and kept for autoclave at 121℃ for 15mins in conical flask.

Preparation of plates

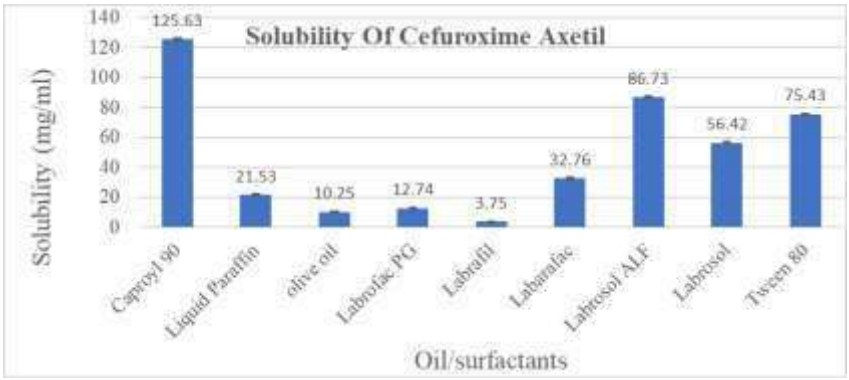
- After the Nutrient media is cooled down then along with the media, petri plates, spatula, cotton swab, are subjected for the surface sterilization in the laminar air flow at UV region.
- Then the cultures were taken and sample of emulgel is also kept in the laminar air flow area.
- The whole procedure is carried out laminar air flow region.
- The petri plates are cleaned with alcohol/spirit and nutrient agar media is poured on to the petri plates and allowed the media to get solidify.
- Then the bacteria cultures like E-coli, Bacillus and JC 82 are streaked with cotton swab in multi-direction.
- Then one side of petri plate is kept with control and other side with the emulgel with the spatula for each bacteria culture containing petri plate.
- Close the petri plate with its cap.
- Then place the petri plates in the incubator for 24hrs for the microbial growth and the inhibitory growth of the sample against the bacterium.

Interpretation of results

- After 24hrs take the petri plates from the incubator and observe if zone of inhibition has been formed.
- Then measure the area of zone of inhibition with help of scale or vernier calliper.
- Then check if the area of zone of inhibition is between the resistance and susceptible range according to the standards mentioned.

RESULTS AND DISCUSSIONS

Solubility studies:



Evaluation Studies for Emulsion

Firstly, the emulsion should be stable to prepare a stable Emulgel. So, the Emulsion has been prepared at different concentrations, and physical parameters were evaluated to check the stability of the emulsion.

Table: Physical Characteristics of Emulsion

Property	FE1	FE2	FE3
Color	Off white	Milky white	Milky white
Phase separation	Yes	No	No
Stabe	Not stable	Moderate	stable
Consistency	Thick	Moderate	Good
Grittiness	No	No	No
Homogenity	Not good	Moderate	Good

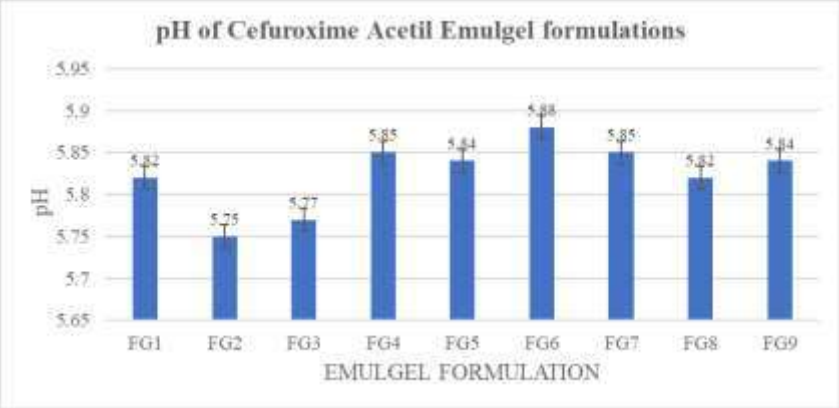
Physical Characteristics of formulated Emulgel

The prepared emulgel formulations were inspected visually for their color, odor, homogeneity and grittiness, and phase separation.

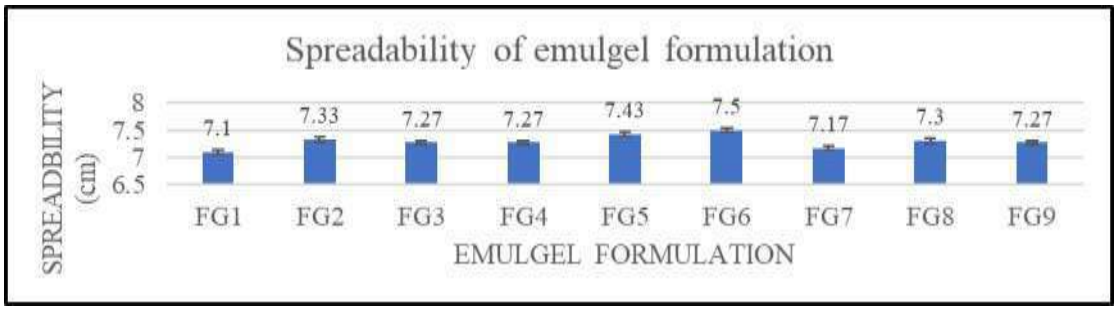
Table: Physical Evaluation of Emulgel

Formulation	Color	Odor	Phase separation	Homogeneity	Consistency	Grittiness
FG1	White	No	No	Good	Thick	No
FG2	White	No	No	Good	Thick	No
FG3	White	No	No	Good	Thick	No
FG4	White	No	No	Good	Thick	No
FG5	White	No	No	Good	Thick	No
FG6	White	No	No	Good	Thick	No
FG7	White	No	No	Good	Thick	No
FG8	White	No	No	Good	Thick	No
FG9	White	No	No	Good	Thick	No

pH

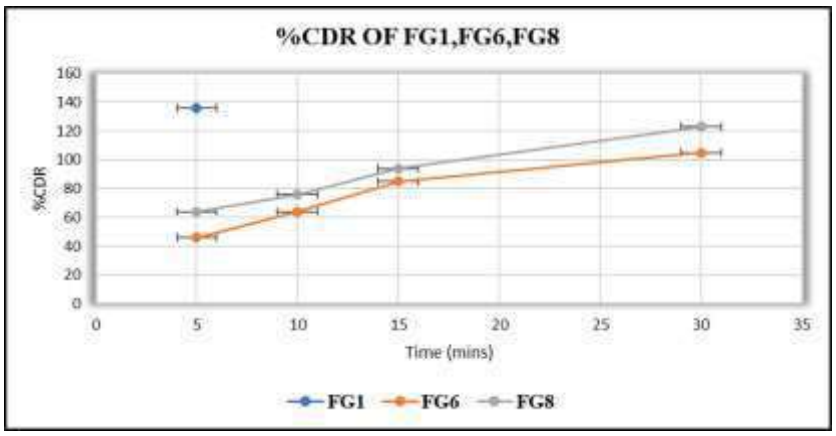


Spreadbility Studies of the formulated Emulgel



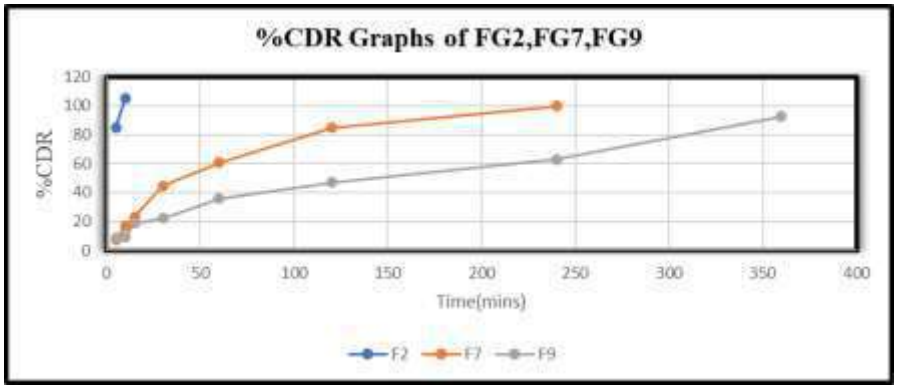
In vitro- Diffusion Studies of Emulgel

%CDR Graphs of Methyl Cellulose (300-560cps)



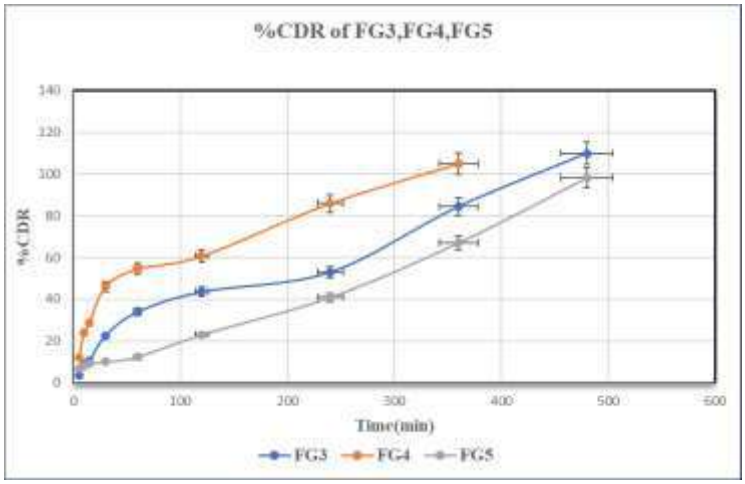
Observation: The formulation with Methylcellulose as a gelling agent was found to be an immediate release.

% CDR Graphs of Hydroxy Propyl Methyl Cellulose 15cps + Ethyl cellulose



Observation: The formulation of HPMC 15cps in combination with the ethyl cellulose was found to be not satisfactory.

%CDR Graphs of Carbopol 940



Observation: The formulations of Carbopol 940 induced Emulgel has shown the results satisfactory.

Microbiology studies

The microbiology studies had been conducted in order to determine to which extent the formulation is susceptible against the bacterium according to the standards. Here, below the study had been conducted by the three types of bacterium i.e., E-coli, bacillus and JC-82 (chemotroph).

JC-82 culture sample with zone of inhibition after 24hrs

Stability studies

At 40°C/75%RH for FG5 formulation.

Physical Characteristics evaluation

Duration	Color	Odor	Phase separation	Homogeneity	Consistency	Grittiness	Remarks
1M	White	No	No	Good	Thick	No	-
2M	White	No	No	Good	Thick	No	-
3M	Slightly off-White	No	No	Good	Thick	No	Slightly off-white and back to white colour with minimal mixing

6.4.7.2 Spreadbility, Viscosity and pH studies

Duration	Spreadbility ± SD	Viscosity (cp) ± SD	pH ± SD
1M	7.42±0.05cm	>100	5.84±0.01
2M	7.42±0.05cm	>100	5.84±0.01
3M	7.40±0.05cm	>100	5.84±0.01

6.4.7.3 In vitro-Diffusion studies

The in vitro-diffusion studies were performed at 3 months for the optimum FG5 formulation

Time(min)	% Cumulative drug release ± SD
5	6.75±0.02
10	7.85±0.01
15	9.14±0.02
30	11.46±0.04
60	13.46±0.05
120	25.64±0.02
240	41.33±0.15
360	69.4±0.10
480	99.6±0.10

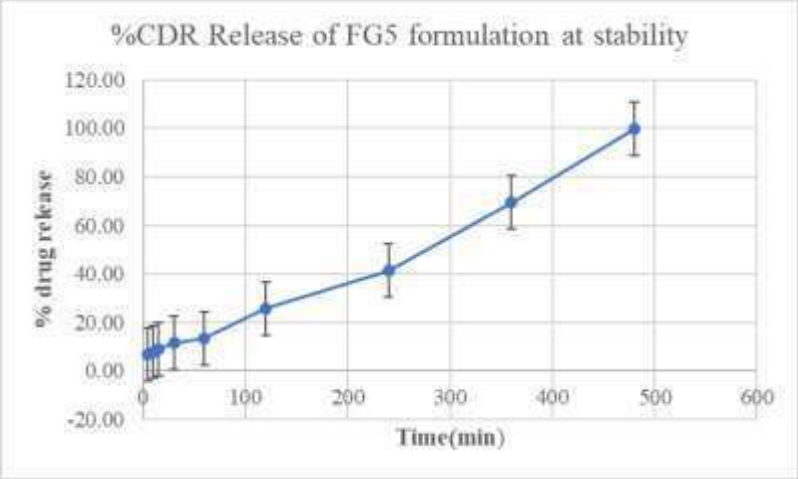


Fig: %CDR release of FG5 stability sample at 3 months

CONCLUSION

Cefuroxime Axetil a second-generation cephalosporin antimicrobial drug formulated as topical emulgel formulation for having better treatment in bacterial infection mainly to the skin belonging to the BCS class II has a special dual controlled release mechanism. The Cefuroxime axetil emulgel was prepared by using caproyl 90 as oil, Labrasol ALF, Tween 80 as surfactants and water as aqueous phase incorporating Carbopol 940 as a gel phase which are confirmed by solubility studies. Solubility has shown the compatible excipients for the formulation of an emulgel. Acetonitrile as solvent the calibration curve was plotted at 277nm having regression coefficient of 0.9964.

The 3 formulations of emulsion were prepared among which the FE3 emulsion was foumd to be stable when compared to other 2 formulations. By keeping the emulsion formulation constant 9 Emulgel formulations were prepared among which FG5 has shown optimum range and found to be stable.

The formulations such as FG1, FG6, FG9 using methylcellulose as a gelling agent has shown a immediate release. FG3, FG4 and FG5 with Carbopol 940 has shown a sustained release of drug giving the optimum formulations.

The physical characteristics were evaluated for both emulsion and emulgel formulations and also pH, spreadability, viscosity, invitro diffusion studies along with the microbiology studies. By the study I can say that the formulations with Carbopol 940 has shown sustained release rather that methylcellulose or HPMC 15cps in combination with ethylcellulose.

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