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Antibiotic Emulgel: Design and Characterization for Topical Drug Delivery

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Abstract

Objectives: The benefits of topical drug delivery systems, which have been used for centuries, include the ability to deliver medications both quickly to the affected area where they are most effective and over an extended period of time. These systems lengthen the drug's mean resident time and contact time. The design and characterization of an antibiotic emulgel for topical medication administration is a goal of the current investigation. ***Methods*:** Cefpodoxime Proxetil emulgel were prepared using different concentration of Carbopol 934, HPMC K4M and xanthan gum as gelling agents and evaluated the relevant parameters such as physical examinations, pH, extrudability, spreadability, viscosity, swelling index, drug content, *in-vitro* diffusion studies and microbiology activities. ***Results*:** All formulations are neutral and viscosity of emulgel was found in the acceptable limits. On physical evaluations were found to be optimum in terms spreadability, swelling index and extrudability. Drug content of all formulations were found in the ranges 69.73% to 97.58% and CEF4 emulgel exhibiting the highest drug concentration and the lowest percentage drug release due to its controlled release pattern and proven non-fickian diffusion mechanism release. The results found that, the selected formulations proven better bacterial activities against both gram positive and gram negative organisms. ***Conclusions*:** Type and concentration of polymers can have an impact on the drug permeability studies and physical-chemical characteristics of the developed antibiotic emulgel, which had excellent results and was suitable for possible therapeutic purposes.

Keywords: Cefpodoxime Proxetil, Emulgel, Gelling agents, Topical drug delivery.

INTRODUCTION

Topical medicines are utilized for the localized effect at the specific site due to medication penetration into the underlying layer of skin or mucous membrane. The application of a drug-containing formulation to the skin's surface in order to directly treat cutaneous problems with hope of having a pharmacological effect on skin. The direct accessibility of the skin as a target organ for diagnostic and treatment is a distinctive feature of dermatological pharmacology. Topical preparations are medications that are applied externally, have effects exclusively in that location, and are created in a way that the systemic absorption of the medicament is minimized. It has the potential for both sustained and controlled drug release and avoids first pass metabolism. Furthermore, there is no trauma or infection risk because it is a noninvasive mode of drug delivery. Solutions, suspensions, emulsions, semisolids, and sprays are some of the most typical examples of topical dosage forms [1].

Gels are a relatively newer class of dosage form and despite the various benefits it's can provide, but hydrophobic medication delivery is a significant drawback. The combination of emulsion and gel, known as Emulgel, has thus been appreciated as a novel modified strategy to solve this issue and used for dermatological purposes. They have several advantageous properties, including being thixotropic,

greaseless, easily spreadable, easily removable, emollient, non-staining, long shelf-life, transparent, pleasing appearance, compatible with various excipients, and water-soluble/miscible [2, 3]. Most lipophilic medications cannot be directly produced as gels due to solubility issues. However, such hydrophobic moieties can be easily integrated into gels utilizing emulsions. Oily globules in an aqueous phase produce an o/w type emulsion, which can then be mixed with a gel base. Emulgels allow hydrophobic drugs to be blended into an oil phase. Compared to merely mixing moiety into a gel base, this demonstrates improved drug stability and release. Because emulgel offers superior lipophilic drug stability and release than a simple gel base [4] and also increase patient acceptability due to high skin penetration rate and contribution to the enhancement of spreadability, adhesion, viscosity and extrusion. It can incorporate herbal compositions and is utilized in pharmaceutical and cosmetic applications.

Several antimicrobial agents are available for topical skin application and soft tissue infections (SSTIs) should be considered an important alternative using the stratum cornea as target organ and have several benefits and an appreciation of the factors that influence percutaneous absorption and much lower undetectable systemic levels. Additionally, it can avoid an unnecessary exposure of gut flora that may exert selection for resistance [5].

Cefpodoxime Proxetil (CP) is a third generation semi-synthetic cephalosporin and a beta-lactam antibiotic (Hydrophobic) with bactericidal action. CP inhibits cell wall/ muco-peptide synthesis by inhibiting final trans-peptidation step of peptidoglycan synthesis in cell walls and active against Gram-positive and Gram-negative microorganisms. It's indicated uncomplicated skin and skin structure infections in which the patients suffering from acne vulgaris and other acne form dermal disorders [6].

To our knowledge, there aren't any commercially accessible Cephalosporin antibiotic gel formulations. However, CP is sold in the pharmaceutical industry in oral and parenteral dosage forms. This information has sparked interest in using CP as a topical gel preparation to better effectively treat bacterial skin infections and soft tissue infections. Designing a unique Emulgel of CP antibiotic employing varying concentration of a gelling agent and a penetration enhancer for a topical drug delivery was one of the goals and objectives of this present study.

MATERIALS AND METHODS

MATERIALS

Cefpodoxime Proxetil was obtained as a Gift sample from Orchid Pharma Limited, Chennai, India. Carbopol 934, Propyl Paraben, Methyl Paraben and Xanthan Gum were obtained as Gift samples from Qualikems Fine Chem. Pvt Ltd, Vadodara, Gujarat and HPMC KM4 were also obtained from Balaji Drugs Pvt Ltd, Gujarat. All other chemicals and solvents used were of analytical grade.

METHODS

Identification of Pure Drug

Cefpodoxime Proxetil (CP) stock solution was made using 0.1N methanolic hydrochloride. 100mg of pure drug was precisely weighed, dissolved in 100mL of methanolic Hcl, and UV spectrum was recorded using a Schimadzu (UV 1700) double beam spectrophotometer. For a working standard of 100µg/ml, the stock solution was further diluted using NaH_2PO_4 buffer (pH 6.8). The solution was scanned in the range of 200-400nm [7].

Construction of Calibration Curve

To make the standard stock solution, 10mg of CP was dissolved in 20ml of methanol in a 100ml volumetric flask. The volume was then filled using pH 6.8 buffer to achieve concentrations of 100µg/ml. To dissolve any remaining undissolved particles, the flask was shaken mechanically. The standard curve was produced after a series of dilutions from the stock solution were generated using buffer at various concentrations of 2, 4, 6, 8 & 10µg/ml. The absorbance was measured at 260.8 nm using a UV visible spectrophotometer with pH 6.8 as the blank [8].

Pre formulation Studies

The first step in the logical development of drug substance is the pre-formulation testing. In addition to providing a framework for the drug combination with pharmaceutical excipients in the dosage form, it provides the information necessary to define the nature of the selected drug substance. Therefore, pre formulation studies for identification and compatibility studies were carried out for the optimum sample of drug [1].

Preparation of Emulgel

Emulgel preparations were involved in two processes. In step I, the gel phase was prepared and in step II, prepared gel phase was combined with an oily phase in order to give the final Emulgel (Table-1).

Gel Phase: In order to create a homogeneous gel base, carbopol934 or xanthan gum was individually dispersed in 30ml distilled water using a magnetic stirrer. After adjusting pH with a 5% m/m triethanolamine solution, further air bubbles were eliminated using ultrasonic water bath for 1h.

Emulgel: Using a thermostatic water bath, the oil and water phases were heated independently to 65°c before being combined using a magnetic stirrer. After an emulsion was formed, the prepared gel phase was introduced gradually while being continuously stirred [9].

EVALUATION OF EMULGEL

Physical Examination

Prepared emulgel formulations were assessed visually for their color, homogeneity, consistency, grittleness and phase separation [10].

pH Measurements

The pH of the emulgel was carried out using a digital pH meter. 100ml of distilled water were used to dissolve 1gm of emulgel, which was then kept for 2hrs. The pH of all formulations was measured in triplicate, and the average results being computed [11]

Viscosity

The Brookfield viscometer (spindle type model LVDV-E) was used to measure the emulgel's viscosity at 10rpm. The spindle was dipped in adequate quantities of formulation emulgel for 5 min before the reading was recorded [12].

Spreadability

It is made up of a wooden block with a pulley attached to one end. Based on the Emulgel's "Slip" and "Drag" properties, spreadability was measured. On the wooden block was fastened a ground glass slide. An excess of Emulgel (Approx.2gm) under study was placed on this ground slide.

Emulgel preparation was then sandwiched between this slide and second glass slide having same dimension as that of the fixed ground slide. There is a hook included with the second glass slide. Weight 1gm was placed on top of the two slides for 5 min to expel air and to provide a uniform film of Emulgel between the two slides. A specified amount of weight was placed to the pan, which was hooked to the pulley. It was noted how long (in sec) it took for the top slide to separate from the ground slide. Better spreadability is indicated by a shorter interval. The following formula is used to compute spreadability:

$S = M. L / T$

Where, M = weight tied to upper slide, L = length of glass slides, T = time taken to separate the slides [1].

Swelling Index

1gm of prepared emulgel is placed on porous aluminium foil to assess its swelling index before being placed separately in a 50ml beaker with 10 ml of 0.1 N NaOH. The samples were then taken out of the beakers at various intervals, and then placed on a dry surface for a short period of time, and after reweighed. These steps are used to compute swelling index:

$Swelling\ Index\ (SW)\ \% = [(Wt - Wo) / Wo] \times 100.$

Extrudability

Standard collapsible aluminium tubes with caps were filled with the emulgel formulation and crimped shut at the end and then the weight of tubes was recorded. The tubes were placed and clamped in between two glass slides. After placed 500gm over the slides, the cap was removed. A percentage amount of the extruded emulgel was collected and weighed [13]. The extrudability is then calculated by using the following formula.

Extrudability = weight applied to extrude emulgel from tube (in gm) / Area (in cm2)

Drug Content

A 50ml volumetric flask containing 1gm of prepared emulgel was filled with it before being diluted with 100% methanol. 5ml of this solution was further diluted to 25ml with 100% methanol in the flask and drug content was determined at 260.8 nm using UV-Visible spectrophotometer.

In-vitro Drug Release Study

An *in-vitro* drug release studies of Emulgel were carried out in double side open ends cylinder using cellophane membrane which was soaked in phosphate buffer (pH 6.8) for 9-12 hrs previously and it was clamped carefully to one end of the hollow glass tube before proceeding the work. Then the Emulgel was spread uniformly on the cellophane membrane. A beaker was employed as the receptor compartment, and 50ml of phosphate buffer (pH 6.8) was added to it. The donor compartment was kept in contact with receptor compartment.

This whole assembly was kept on a magnetic stirrer and the solution on the receptor side was continually swirled using a magnetic bead and temperature was maintained at 37°C. As a control, a comparable blank set was run concurrently. At appropriate times, the sample (5ml) was removed and equal parts of new dissolving medium were substituted. The cumulative percent of drug release was estimated after the samples underwent spectrophotometric analysis at 260.8nm. The actual reading in each case was the difference between the readings for drug release and control [1].

Kinetics Analysis of *in-vitro* Drug Release Studies

To examine the drug release kinetics and mechanism, the results obtained from an *in-vitro* release studies were plotted in four kinetic models of data treatment as follows: Cumulative percentage drug release Vs Time (Zero order rate kinetics), Cumulative % drug retained Vs Time (First order rate kinetics), Cumulative percentage drug released Vs Square root of Time (Higuchi's classical diffusion), Log cumulative percentage drug release Vs log Time (Korsmeyer-Peppa's exponential equation). Generally, on the basis of the diffusion exponent, an "n" value of 0.5 or less than 0.5 indicates the drug release mechanism approaches to a Fickian diffusion controlled release; whereas "n" value from 0.5 to 1 indicates the drug release mechanism is Non Fickian diffusion [14].

Microbiological Assay

Microorganism

Four bacterial species, comprising two gram positive bacteria (*Bacillus Subtilis* & *Staphylococcus Aureus*) and two gram negative bacteria (*Escherichia Coli* & *Pseudomonas Aeruginosa*), were used to test an antibacterial activity of emulgel formulations (*Culture Media***:** Nutrient agar medium).

Determination of the Zone of Inhibition

Using the agar well diffusion method, the antibacterial effectiveness of emulgel is determined and it was compared against a standard. In this method, transferred 15-20 ml of a previously liquefied medium into sterile test tubes and cool all the test tubes at 42°C-45°C temperature. One loopful of the culture was transferred in each agar medium containing test tube and mix. The entire inoculated liquid agar medium was then placed into a different, sterile petri plate and allowed to solidify agar medium. Agar plates were filled with the necessary amount of emulgel for imitation after the medium had solidified, and the plates were then incubated at 37°C±1°C for 24hrs [15].

RESULTS

An antibiotic emulgel was created to enhance the delivery of hydrophobic drug, which is intended to lessen/reduce bacterial infections. Six formulations were designed using varying concentration of Carbopol 934, $HPMCK_4M$ and xanthan Gum and formulations were also evaluated in terms of physical examination, pH, Extrudability, Spreadability, Viscosity, swelling index, Drug content, *in-vitro* diffusion studies and microbiological assay.

Identification of Pure Drug

An absorption maximum of CP identified by UV spectrum (Range: 200-400 nm) were found be 260.8 nm using 0.1 N Methanolic Hcl and Sodium Dihydrogen Phosphate buffer (pH 6.8). Graph shown in Figure 1.

Calibration Curve of Pure Drug

Using 0.1N Methanolic Hydrochloric acid, the standard calibration curve of pure drug was plotted, and it was found to be linear as shown in Figure 2. The calibration curves produce a straight line, demonstrating the selected drug compliance with Beer's law in the concentration range of 2–12 mcg/ml with R^2value of 0.997 for CP (ƛmax of 260.8nm), respectively. Using drug standard solutions, the slope value (S) and intercept (I) were also found to be 0.066 and 0.008, respectively.

Pre formulation Studies

Compatibility Studies - Fourier transforms infrared spectroscopy (FTIR)

Compatibility studies of pure drug with the polymer mixtures (intactness of CP in the physical admixtures) were determined by IR spectroscopy using Shimadzu FT-IR by KBr method. FT-IR spectra of prepared sample were taken in the wavelength region was 600-3800cm-1at ambient temperature and the resolution was 4cm-1 and compared the position and relative intensity of absorption band of physical admixtures and drug. The IR spectra of all individual samples and CP physical admixtures were subject to the study and results were found in Figure 3 to 5.

Therefore, it is established that physical admixtures show that the main peaks in the functional group region and finger print region are identical, indicating that the chosen medication and polymers did not undergo any change / chemical interaction. Additionally, there was no discernible difference between the IR spectra of pure drug and physical admixtures, which produced the same kinds of peaks, demonstrating the drug's intactness in the physical admixtures, and with no shifts in the peak shape. There were no significant interactions between the drug and polymers in the physical admixtures, which supports the conclusion that the drug was compatible with the polymers and was predicted to be stable.

Characterizations of Emulgel

Physical Examination

Prepared various emulgel formulations were examined visually for nature, consistency, homogeneity, phase separation and results were tabulated in Table - 2 and Figure - 6. The physical parameters were checked by visually and all formulations shown cream colour smooth in nature and translucent depending on the proportion of polymer concentration.

pH Measurements

pH measurements of emulgel were carried out using a digital pH meter and the results were found in Figure - 7. All formulations pH were found to be neutral (pH 6.4 to 7.0). So it was conclude that the enclosed drug is thereby effectively expected to deliver through the skin.

Viscosity

Viscosity of emulgel formulations was determined by Brookfield viscometer spindle type, (LVDV- E) at 10 rpm and the results was shown in Figure - 8. Results showed that the concentration of selected polymer in the formed gel improved its viscosity. Overall, it was discovered that all gel viscosities were within acceptable limits.

Spreadability

Spreadability denotes the extent of area to which the gel readily spreads on application to skin or the affected part. The bioavailability efficiency of an emulgel depends on its spreading value. Overall CEF3 was found to have the highest spreading value from Figure 9.

Swelling Index

With regard to all formulations, CEF4 emulgel using $HPMCK_4M$ (2%) demonstrated the highest swelling index. Additionally, the polymer's chain strength of the polymer and water uptake characteristics may affect the swelling index value. Result of swelling index shown in Table-3.

Extrudability

It is calculated by the force required to extrude the emulgel from the tube and the results of extrudability are shown in Table-4. The majority of formulations exhibit excellent and good extrudability.

Drug content

Drug content of emulgel formulations was determined by UV spectroscopy and the absorbance was measured at 260.8nm against methanol as blank. Percentage drug content was shown in Figure 10. From results, the range of drug content of all formulations was found to be 69.73% to 97.58%. CEF4 formulation had the highest drug concentration than other emulgel. The outcomes showed that the medication dispersed evenly throughout the Emulgel.

***In-vitro* Drug Release Study**

In-vitro release profile of all batches of CP Emulgel was conducted using 0.1N methanolic HCl (pH 6.8). The results of comparative drug release curves as shown in Figure 11 to 13. Overall, CEF4 emulgel demonstrated 72.57±0.42% drug release at the end of 8 hrs compared to other formulations that demonstrated maximum percentage drug release, owing to the highest drug concentration ranges.

Kinetic Analysis of *in-vitro* Drug Release Studies

When the data was subjected to zero order and first order kinetic model, a linear relationship was observed with high R2 values for zero order model as compared to first order suggested that the formulations were zero order-controlled release. Higuchi's model was applied to *in-vitro* drug release data and linearity was obtained with high r 2 values 0.95 to 0.99 were obtained, suggested that the drug release from Emulgel followed diffusion mechanism. For the purpose of determining the n values that characterize the drug release mechanism, the collected release data were also substituted in the Korsmeyer-Peppas model. An "n" value of 0.5 or less generally indicates that the drug release mechanism is approaching a Fickian diffusion controlled release, whereas a "n" value of 0.5 to 1 indicates that the drug release mechanism is non-Fickian diffusion, and the models with the highest correlation coefficient (r) are used to describe the mechanism of drug release. Overall results, the data showed that the n values of the emulgels ranged from 0.57 to 1.0, and the correlation coefficients ranged from 0.91 to 0.99, indicating a non-Fickian diffusion mechanism. As a result of the observation from Table-5, it was demonstrated that CP emulgels had a controlled release pattern for a sufficient number of hours.

Microbiological Assay

Gram positive and gram negative microorganisms were used to test an antibacterial activity of best CP emulgel. The activities were also determined using agar well diffusion technique and the data of zone of inhibition were shown in the Table-6. An anti-bacterial activity of selected formulations is active against micro-organisms and these findings show that the chosen emulgel have a much higher level of activity against *Pseudomonas Aeroginosa* and *Staphylococcus Aureus* pathogens. In contrast to standard, formulations with a significant zone of inhibition showed maximum inhibition ranging from 20 to 25 mm.

Table 1: Compositions of Emulgel Formulations

Ingredients	Formulations Code					
	CEF 1	CEF 2	CEF 3	CEF 4	CEF 5	CEF 6
Cefpodoxime Proxetil (gm)	1	1	1	1	1	1
Oleic Acid (ml)	2	2	2	2	2	2
Light Liquid Paraffin (ml)	4	4	4	4	4	4
Acetone (ml)	2	2	2	2	2	2
Span 80 (ml)	0.5	0.5	0.5	0.5	0.5	0.5
Propylene Glycol (ml)	5	5	5	5	5	5
Tween 80 (ml)	1	1	1	1	1	1
Methyl Paraben (gm)	0.03	0.03	0.03	0.03	0.03	0.03
Propyl Paraben (gm)	0.03	0.03	0.03	0.03	0.03	0.03
Carbopol 934 (gm)	1	2	-	-	-	-
HPMCK4M (gm)	-	-	1	2	-	-
Xanthan Gum (gm)	-	-	-	-	1	2
Triethanolamine (ml)	0.2l	0.2l	0.2l	0.2l	0.2l	0.2l
Water	q.s	q.s	q.s	q.s	q.s	q.s

Table-2: Physicochemical Characteristics of Emulgel

Formulations Code	Appearances	Phase Separation	Consistency & Homogeneity
CEF1	Cream	None	Good
CEF2	Cream	None	Good
CEF3	Cream	None	Good
CEF4	Cream	None	Good
CEF5	Cream	None	Good
CEF6	Cream	None	Good

Table-3: Determination of Swelling Index of Emulgel

Formulations Code	At end of 2 Hours	At end of 4 Hours	At end of 8 Hours	At end of 12 Hours
CEF1	32±0.1	36±0.2	38±0.11	47±0.1
CEF2	24±0.1	26±0.3	28±0.1	39±0.2
CEF3	52±0.2	58±1.2	58±0.2	69±0.2
CEF4	58±0.1	62±0.3	69±0.3	76±0.4
CEF5	48±0.2	51±0.4	46±0.1	58±0.2
CEF6	18±0.03	22±0.1	24±0.2	28±0.6

Results are mean±SD of three trials (n=3)

Table-4: Determination of Extrudability of Emulgel

Formulations Code	Net weight of emulgel (g)	Weight of emulgel extruded (g)	Extrudability* (%)	Observations
CEF1	12.36±0.014	10.31±0.015	82.14±0.003	Good
CEF2	12.35±0.013	10.39±0.016	84.12±0.007	Good
CEF3	12.37±0.012	11.43±0.013	92.40±0.006	Excellent
CEF4	12.38±0.011	11.98±0.115	96.76±0.007	Excellent
CEF5	13.35±0.013	11.57±0.016	86.66±0.007	Good
CEF6	13.25±0.015	11.29±0.016	85.20±0.004	Good

Results are mean±SD of three trials (n=3)

* (>90%: Excellent), (>80%: Good), (>70%: Fair)

Table-5: Kinetics Analysis of *in-vitro* Drug release Data of Emulgel

Formulations Code	Release model							
	Zero order		First order		Higuchi's		Korsmeyer and Peppa's	
	R	S	R	S	R	S	R	S
CEF1	0.99	7.98	0.95	-0.11	0.98	31.30	0.98	0.57
CEF2	0.98	8.38	0.95	-0.15	0.99	33.10	0.98	0.66
CEF3	0.97	9.40	0.91	-0.10	0.97	36.85	0.99	0.70
CEF4	0.93	9.50	0.90	-0.07	0.98	38.44	0.91	1.0
CEF5	0.95	7.20	0.93	-0.20	0.99	28.77	0.98	0.72
CEF6	0.90	7.91	0.89	-0.91	0.95	32.12	0.93	0.64

Table-6: Measurement of Zone of Inhibition of Emulgel

Microorganisms	Zone of inhibition (mm)		
	CEF1	CEF4	Standard
Bacillus Subtilis	20	23	47
Escherichia Coli	23	20	41
Staphylococcus Aureus	25	25	47
Pseudomonas Aeruginosa	25	25	52

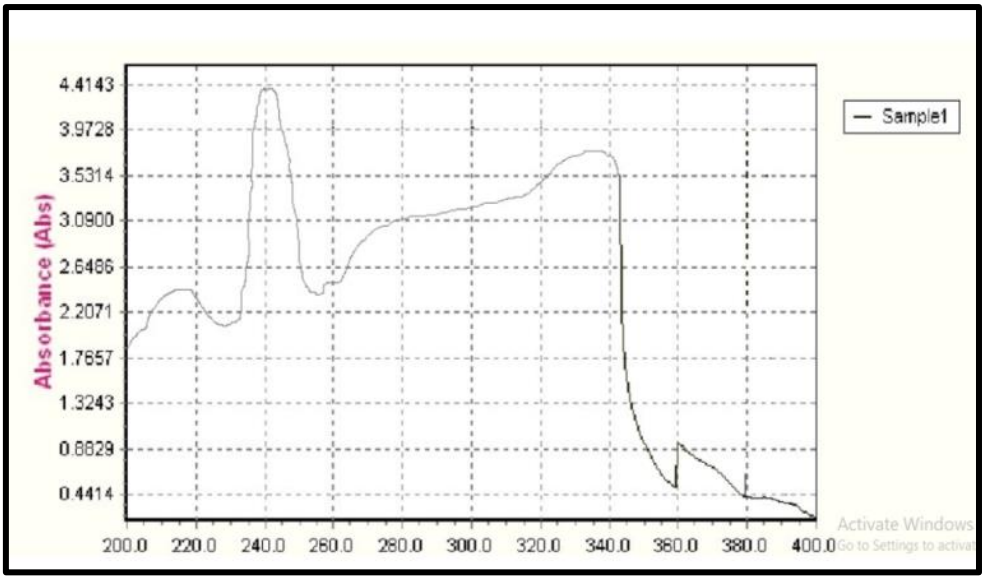

Figure 1: UV Spectrum of Pure Cefpodoxime Proxetil

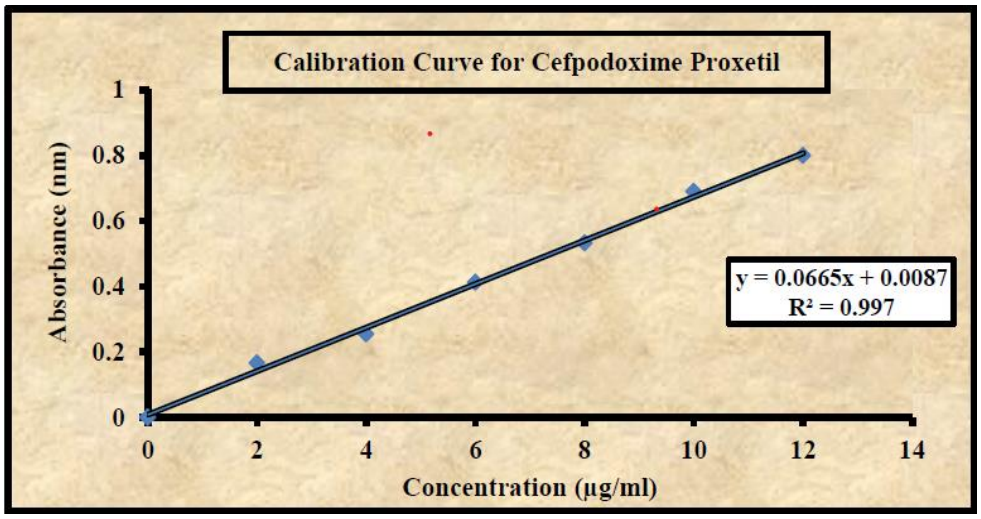

Figure 2: Calibration Curve for Cefpodoxime Proxetil

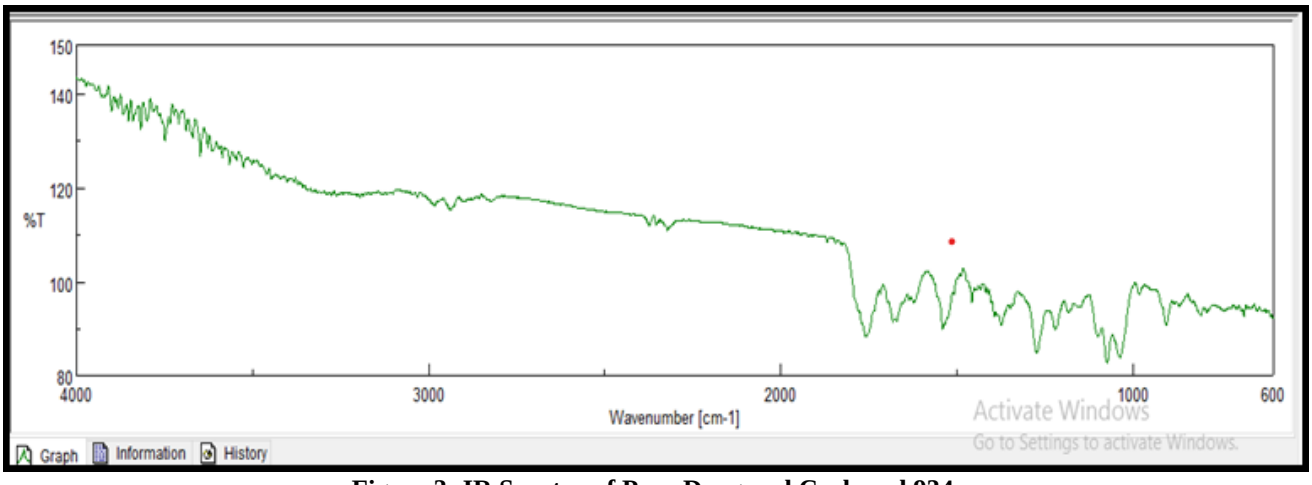

Figure 3: IR Spectra of Pure Drug and Carbopol 934

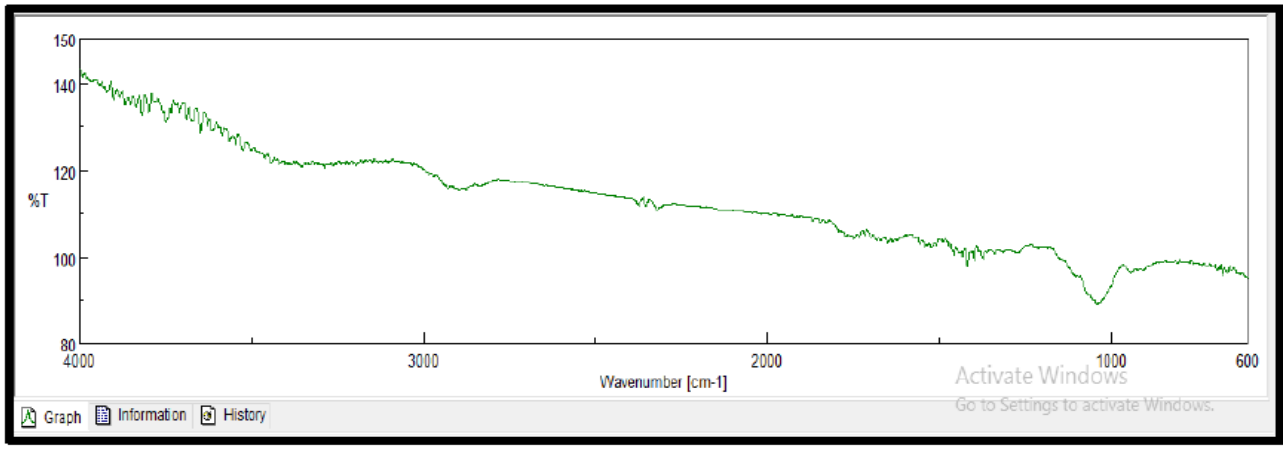

Figure 4: IR Spectra of Pure Drug and HPMC K4M

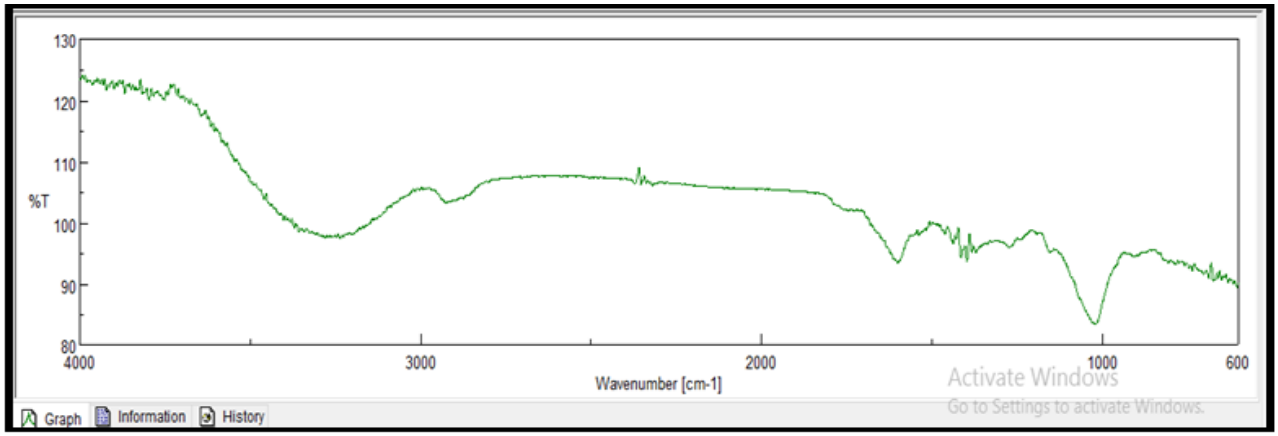

Figure 5: IR Spectra of Pure Drug and Xanthan Gum

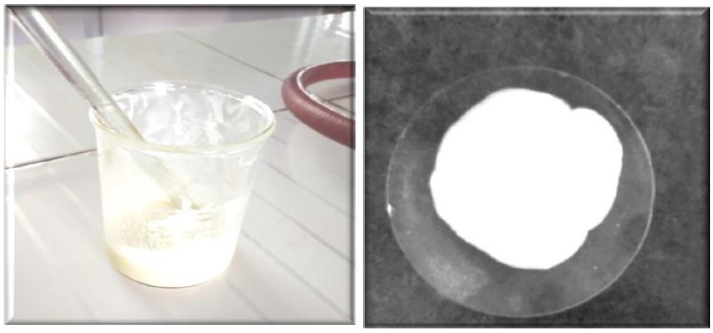

Fig-6: Pictorial image of CP Emulgel

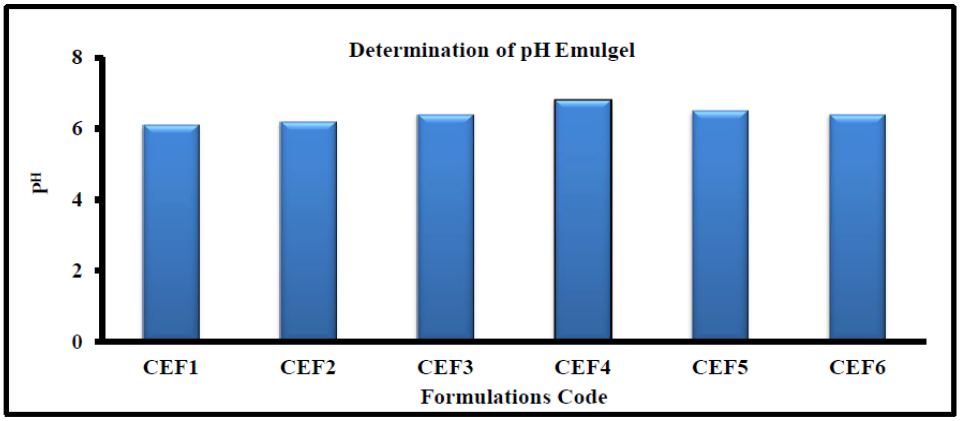

Fig-7: pH of CP Emulgel

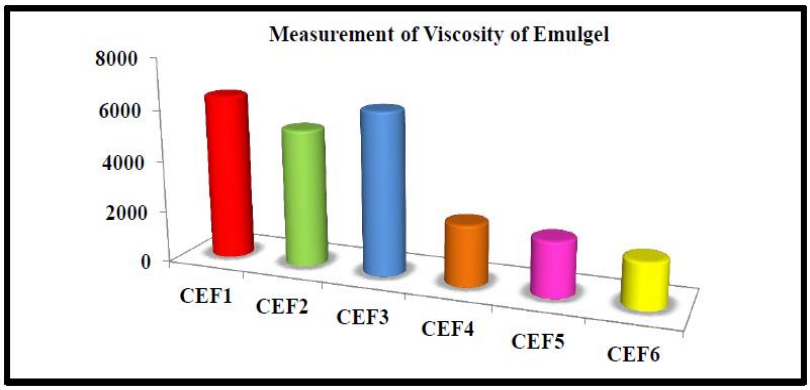

Fig 8: Viscosity of CP Emulgel

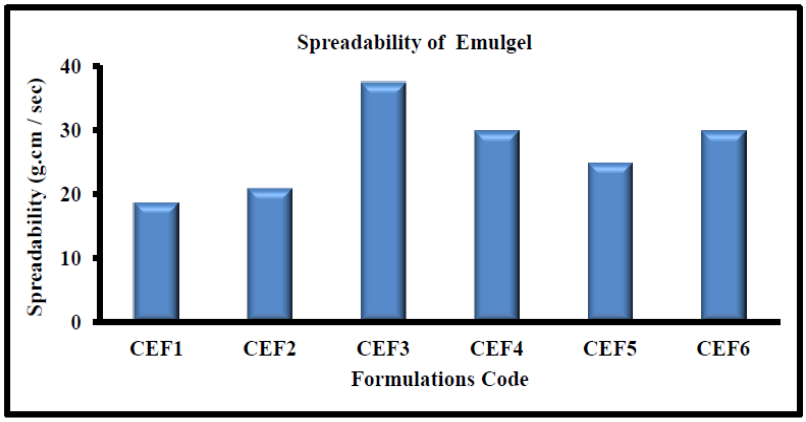

Fig-9: Spreadability of Emulgel

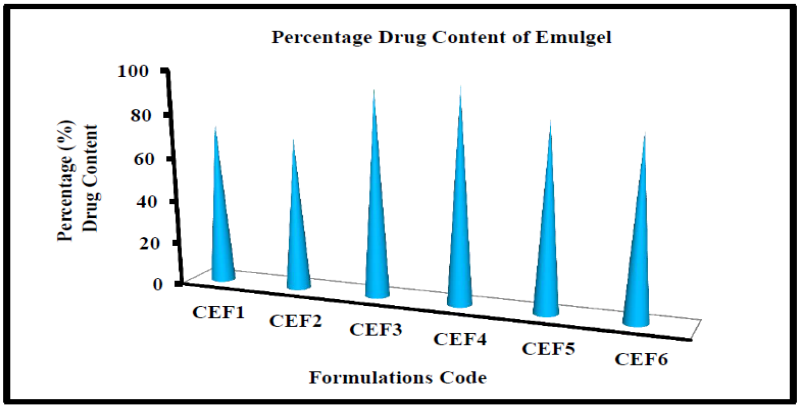

Fig 10: Percentage Drug Content of Emulgel

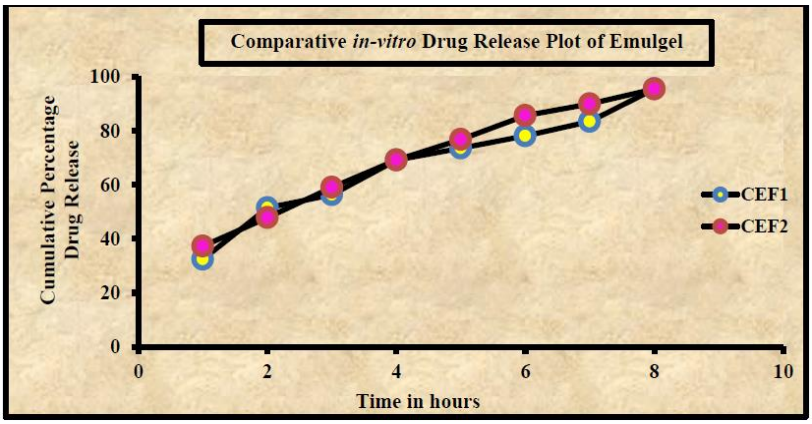

Fig 11: Comparative *In-vitro* Drug Release Plot of Emulgel (CEF1 & CEF2)

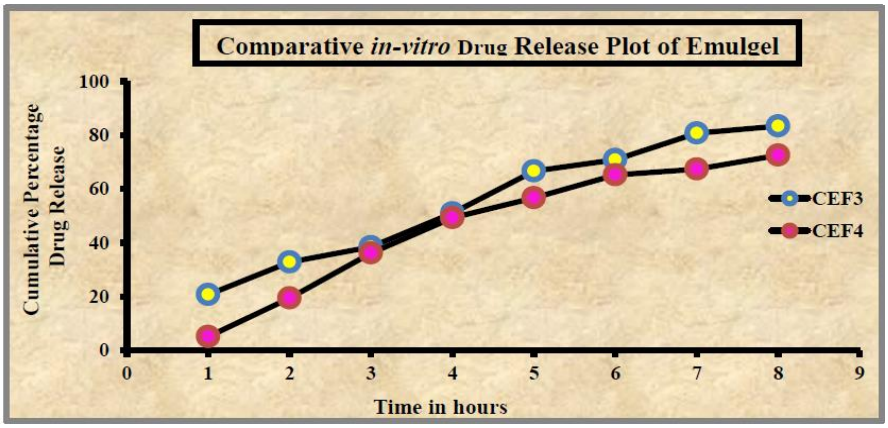

Fig 12: Comparative *In-vitro* Drug Release Plot of Emulgel (CEF3 & CEF4)

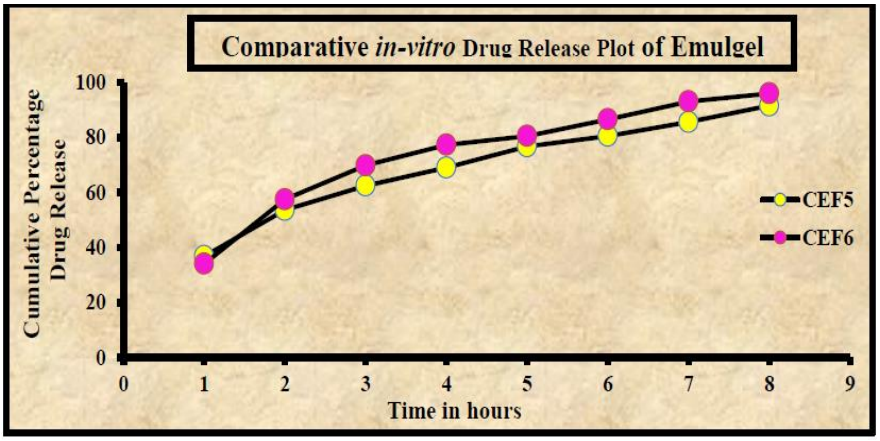

Fig 13: Comparative *In-vitro* Drug Release Plot of Emulgel (CEF5 & CEF6)

CONCLUSION

The development of Emulgels as a practical semisolid drug delivery technology enhanced emulsion stability by integrating it into a gel matrix. Emulsion based approach is being used so even a hydrophobic therapeutic moiety can employ the property of gels. Different polymers with varying concentrations were effectively used to manufacture of CP antibiotic emulgel. All formulations were evaluated of various parameters including *in-vitro* diffusion studies and microbiological studies. Over all, it's concluded that, type and concentration of polymers used are important factors that can affect the permeability of drug release studies and physico-chemical properties of emulgels. All things considered, CEF4 formulation was discovered to be the best to demonstrate a goal of this current effort.

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