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Research Article

Pharmacy for better health

Formulation and Characterization of Piroxicam Emulgel for Topical Drug Delivery

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Abstract: The aim and objective of this research work was to formulate and evaluate Piroxicam Emugel for topical drug delivery. Various concentration of gelling agent were used for preparation of Piroxicam Emugel along with emulsifiers Tween-80 and Span-80 with glycerine as a humectants. The Clove oil and eucalyptus oil were used as permeation enhancer. The formulated Emulgel was characterized for their physical appearance, pH determination, spreadability, extrudability, drug content, in vitro drug release and stability studies. According to our results, the range of pH of the formulations was from 5.6±0.2 to 6.8±0.3 for final batches which is considered acceptable. Formulation F3, F4, F6 and F7 spreadability was found to be 32.03 ± 0.54 g.cm/sec, 30.79±0.2 g.cm/sec, 26.41±0.51 g.cm/sec and 30.44±0.6 g.cm/sec respectively. The Formulation F5 and F8 was prepared with higher concentration of carbopol i.e. 1.5 g were of in stiff category and the spreadabilty value found to be 18.14±0.36 g.cm/sec and 20.30±0.34 g.cm/sec respectively. The percentage swelling index was (F5, F6, F7 and F8) found to be 44.24 %, 27.35%, 31.98 % and 46.38 respectively. Extrudability of Formulation F5 and F8 was less i.e. 17.32± 0.5 gm/cm^2 and 20.39±0.58 gm/cm^2 respectively as containing higher concentration of polymer. Formulation F3, F4, F6, F7 having optimum concentration of polymer extrudability was good i.e. 30.47±0.52 gm/cm^2, 27.39±0.6 gm/cm^2, 29.49±0.56 gm/cm^2 and 26.90±0.6 gm/cm^2 respectively. Extrudability was decreased with an increase in concentration of Carbopol. *Invitro* drug release (98.45% in 8h) from the Emulgel, batch F7 was concluded as optimized batch. Drug release was in following order F5< F1< F3< F2< F4< F8 < F6 < F7. Presence of two Penetration enhancer's Clove oil and Eucalyptus oil has resulted in better performance as compared to other formulations. All these developed emugel formulation have acceptable physical properties, hence F7 can be considered as the optimized formulation. From this research, the formulated Emulgel of Piroxicam would be an effective alternative to conventional delivery of Piroxicam for the management of pain and inflammation.

Keywords: Emulgel, Piroxicam, Clove oil , Eucalyptus oil, Topical drug delivery, Spreadability

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1. INTRODUCTION

The novel approach in the field of topical drug delivery is to introduce or deliver the hydrophobic drug that can enjoy the gelling property and whose rate can be controlled which is called as Emulgel, as it has dual release control system i.e. gel and emulsion [1]. Piroxicam is one of the most effective NSAIDs (non-steroidal, anti-inflammatory drugs) and is an Oxicam derivative whcih also has antipyretic activity for numerous types of pains such as in the treatment of rheumatoid arthritis, osteoarthritis and traumatic contusions [2]. Even though the drug is well absorbed through oral route, however its use has been associated with a number of undesirable side effects on the stomach and kidneys in addition to gastric mucosal damage[3]. Dermal delivery is an alternative route but requires a formulation which ensures deep skin penetration, allowing therapeutic effect at the localized site. Although Piroxicam is not easily absorbed after topical application, some studies have been carried out to predict the percutaneous absorption of Piroxicam using different substances as permeation enhancers[4]. Piroxicam belongs to the BCS Class II drugs means low solubility and high permeability, thus its oral absorption is considered to be dissolution rate limited. The objective of the current research work was to explore the potential of emulgel in enhancing the topical delivery of Piroxicam[5].

2. MATERIALS AND METHODS

Piroxicam (99.79%) was received as a gift samples from Curex Pharma Products Jalgaon. Carbopol 934, Xanthan gum, Liquid paraffin, Tween 80, Span 80, Glycerin, Ethanol, Methyl paraben, Propylparaben, Clove oil, Eucalyptus oil, Triethanolamine were purchased from Research Lab Fine Chem Industries, Mumbai. All other chemicals and reagents used were of analytical grade.

2.1 Fabrication of Emulgel of Piroxicam[6,7,8]

Dissimilar formulations were formulated using altering amount of gelling agent and penetration enhancer. Gel base was prepared by dispersing Carbopol 934 in preheated distilled water at constant stirring at moderate speed using mechanical shaker Prepared dispersion was cooled and left overnight. Oil phase of emulsion prepared by dissolving Span 80 in liquid paraffin. Aqueous phase of emulsion was prepared by dissolving Tween 80 in purified water. Piroxicam was dissolved in ethanol . Methyl paraben and Propyl paraben were dissolved in Glycerin and these two solutions were added in aqueous phase. Clove oil was used as a penetration enhancer in first 3 batches and mixed in oil phase and for formulation F4, F5 and F6, Eucalyptus oil were used as penetration enhancer and mixed in oil phase. In formulation F7 and F8 both Clove oil and Eucalyptus oil were mixed in oil phase. Both oil and aqueous phase were separately heated to 70-80 °C then oil phase was added to the aqueous phase with constant stirring until it got cooled to room temperature, pH adjusted to 6-6.5 by using Triethanolamine (TEA).Prepared emulsion was mixed with gel in the ratio 1:1 .Different designed batches of Emulgel were shown in Table 1.

Table 1. Formulation composition of PiroxicamEmulgel (%W/W)

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Piroxicam	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Carbopol 934	0.6	0.8	1	1.25	1.5	1.25	1.25	1.5
Liquid paraffin	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Tween 80	1	1	1	1	1	1	1	1
Span 80	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Glycerine	5	5	5	5	5	5	5	5
Ethanol	3	3	3	3	3	3	3	3
Methyl paraben	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Propylparaben	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Clove oil	1.5	2	2.5	-	-	-	1.8	1.5
Eucalyptus oil	-	-	-	1.5	2	2.5	1.8	1.5
Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

2.2 *Characterization Of Prepared Formulation Of Emulgel* [9-14]

2.2.1 *Compatibility study*[9-14]

FT-IR spectra for pure Piroxicam and polymers was performed . FT-IR spectra for pure Piroxicam and polymer at room temperature was determined using FT-IR spectrophotometer (FTIR-8400S, Shimadzu, Japan) in transmittance mode. The samples were ground in a mortar, mixed with Nujol and placed between two plates of KBr and compressed to form a thin film. The sandwiched plates were placed in the infrared spectrometer and the spectra were obtained. Scanning was performed between wave numbers 4000-400 cm^{-1} at a resolution of 2 cm^{-1}.

2.2.2 Differential scanning calorimetric (DSC) analysis

DSC for pure Piroxicam and polymers was performed For determination of DSC drug polymer 3:1 ratio was taken .The DSC, test involves heating up a milligram-weighed sample of the material under investigation, and by detecting and measuring heat evolution or heat consumption by the sample, and quantifying the exothermic or endothermic reactions that occur while that sample is slowly heated up was analysed.

2.2.3 Physical appearance

The prepared emulsion preparations were examined visually for their color, homogeneity, Consistency, phase separation and Texture.

2.2.4 pH determination[12]

The pH of prepared emulgel was determined by using a digital pH meter. 1gm of the emulgel was stirred in distilled water until a uniform dispersion was formed. It was kept aside for 2 hours. The volume was then made up to 100 ml i.e. 1% solution of prepared formulation. By using digital pH meter pH was determined.

2.2.5 Spreadability[13]

Spreadability of the Emulgel was determined 48 hours after preparation of the Emulgel by using the wooden block and the glass slide apparatus. 1 g of the prepared Emulgel was placed between two 10 × 10 cm glass plates(125g each). About 25g of the sample was placed in a pan and the time required for the upper glass plate to completely separate from the fixed glass plate was recorded. The spreadability was then calculated from the following equation.

$$S = M \times L / T$$

Where,

S= Spreadability
M= Weight tied to upper slide (in gm)
L= Length of glass slide (in cm)
T= Time taken to separate the slide (in sec)
Spreadability was measured in terms of g.cm/sec.

2.2.6 Extrudability study[14-15]

The method adopted for evaluating emulgel formulation for extrudability which was based upon the quantity in percentage of emulgel extruded from lacquered aluminum collapsible tube on application of weight in grams required to extrude at least 0.5 cm ribbon of gel in 10 seconds. The extrudability was than calculated by using the following formula

$$\text{Extrudability} = \text{Applied weight to extrude gel from tube (in gm)} / \text{Area (in cm}^2\text{)}$$

2.2.7 Swelling Index[16]

To determine the swelling index of prepared topical emulgel,1gm of emulgel is taken on porous aluminum foil and then placed separately in a 50ml beaker containing 10ml 0.1N NaOH Sample were taken at specified interval from beaker and reweighted Swelling index is calculated as follows.

$$\text{Swelling Index (S.I\%)} = \{(wt-wo)/wo\} \times 100$$

Where,

S.I. = Swelling index
Wt. = Weight of swollen emulgel after time t.
WO = Weight of emulgel before placing in the Beaker

2.2.8 Viscosity determination[17]

In this present study, the Brookfield viscometer model-Brookfield Viscometer with spindle 07 was used to find out the rheological behavior of emugels. Proxicam Emugel batch whose viscosity was to be determined was added to the beaker and was allowed to settle down for 30 min. at temperature (25±1°C) before the measurement was taken. Spindle was lowered perpendicular in to the centre of Proxicam Emulgel taking care that spindle does not touch bottom of the jar and rotated at a speed of 50 rpm for 10 minutes. The viscosity reading was recorded.

2.2.9 Drug content[18]

Weigh accurately 1 gm of emulgel and it was dissolved in 100 ml of phosphate buffer 7.4. The volumetric flask was kept for 2 h and shaken well in a shaker to mix it properly. The solution was passed through the filter paper and filtered. The drug content was then determined after appropriate dilution at 242 nm using a UV spectrophotometer [21].

2.2.10 In vitro Drug Release Study[18]

The *Invitro* drug release studies of the emulgel were carried out in modified diffusion cell using dialysis membrane. The membrane was soaked in a phosphate buffer solution pH 7.4 for 9-12 hour and was clamped carefully to one end of the hollow glass tube of dialysis cell. Then emulgel (300mg) was spread uniformly on the dialysis membrane. 200ml of phosphate buffer solution pH7.4 used as dissolution media was added to receptor compartment. This whole assembly was kept on a magnetic stirrer and the solution on the receptor side was stirred continuously using a magnetic bead and temperature of the cell was maintained at 37±0.5°C. Sample (10ml) was withdrawn at suitable time intervals and replaced with equal amounts of fresh dissolution media. Finally, the withdrawn sampled solution was diluted suitably and the absorbance of the resultant solution was measured to determine the drug content spectrophotometrically at 242 nm using UV/Visible spectrophotometer Shimadzu 1800.

2.2.11 In vitro Drug release data Analysis[19]

The rate and mechanism of release of Piroxicam from formulated Emulgel were analyzed by fitting the dissolution release data into following release exponential equations.

Zero order release equation

$$Q= K0t$$

Where Q is the amount of drug released at time t and K0 is the zero order release rate constant.

The first order equation

$$\log (100 - Q) = \log 100 - K1t$$

Where, K1 is the first order release rate constant.

The Higuchi's equation

The drug release data was fitted to the Higuchi's equation

$$Q= K2t1/2$$

Where, K2 is the diffusion rate constant.

The Korsmeyer-Peppas equation

The drug release data was also fitted to the Korsmeyer-Peppas equation, which is often used to describe the drug release behavior from polymeric systems

$$\text{Log } (Mt/M\infty) = \log K + n \log t$$

Where,

Mt is the amount of drug released at time t,
M∞ is the amount of drug release after infinite time
K is a release rate constant and n is the diffusion exponent indicative of the mechanism of drug release.
Hixson-Crowell recognized that area of the particle is proportional to the cubic root of its volume, and derived an equation as follows.

$$Wo1/3-Wt1/3=Kst$$

Where,

Wo is the initial amount of drug,
Wt is the remaining amount of drug in dosage form at time t, Ks is a constant incorporating the surface volume relation. The graphs are plotted as cube root of percent drug remaining versus time.

3. RESULT AND DISCUSSION

3.1 Compatibility of drug with selected Polymers

The IR spectrum of pure drug was found to be similar to the reference standard IR Spectrum of Piroxicam given in official spectrum. Emulgel formulation showed Piroxicam is compatible with other ingredients. The IR spectrum depicted in Figure no. 1,2 and 3.

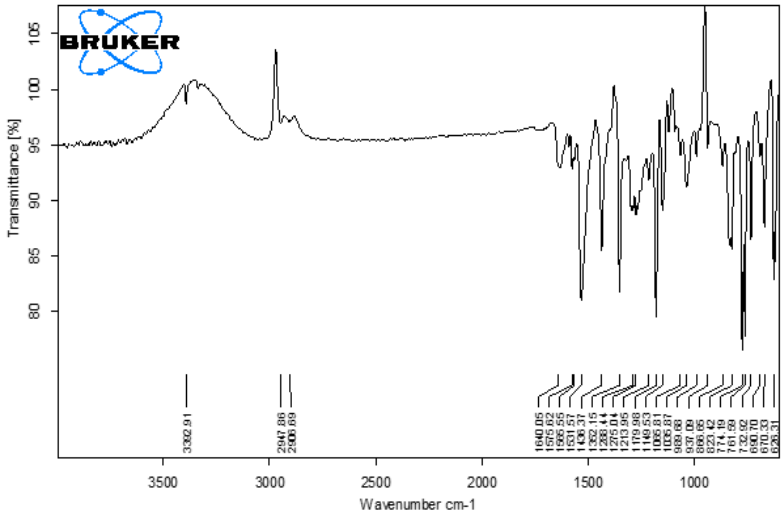

Fig 1. FTIR spectrum of Piroxicam

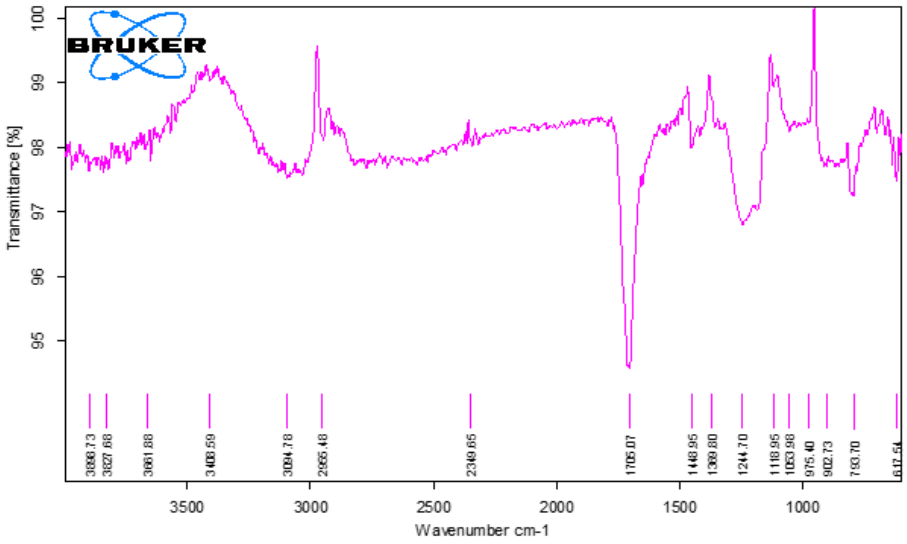

Fig 2. FTIR spectrum of Carbopol 934

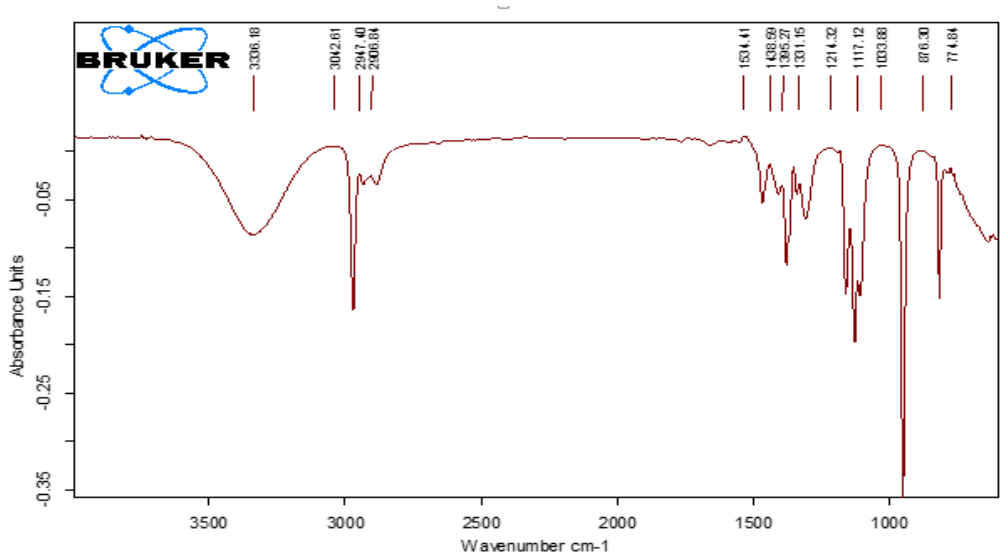

Fig 3. FTIR spectrum of spectrum of Piroxicam +Carbopol 934

All the characteristic peaks of Piroxicam appears in spectra represents the compatibility between drug and excipients. No appreciable change in the peaks of Piroxicam and in the mixture of polymers. Hence there is no interaction between pure drug and polymers. The unchanged functional peaks for the drug in the formulation is tabulated in Table 2.

Table 2. Showing the major peaks of functional groups obtained during FTIR

Sr. No.	Functional groups	Frequency (cm^{-1})
1	C=C	1630-1635
2	C=O	1800-1810
3	N-H	3392-3400
4	C-H(Aromatic)	3050-3065
5	C-N	1149-1155

3.2 Differential scanning calorimetric study

The Endothermic peaks of Piroxicam in formulation blend was in the range of 198-202 °C which corresponds to its melting point . The various thermograms are shown in figure no. 4 and 5.

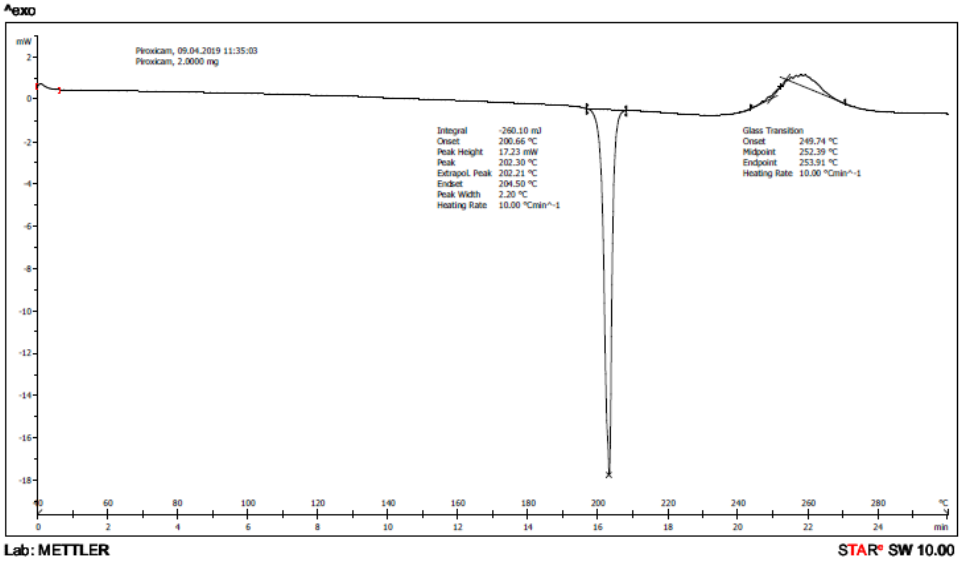

Fig 4. Differential Scanning Calorimetry (DSC) of Piroxicam

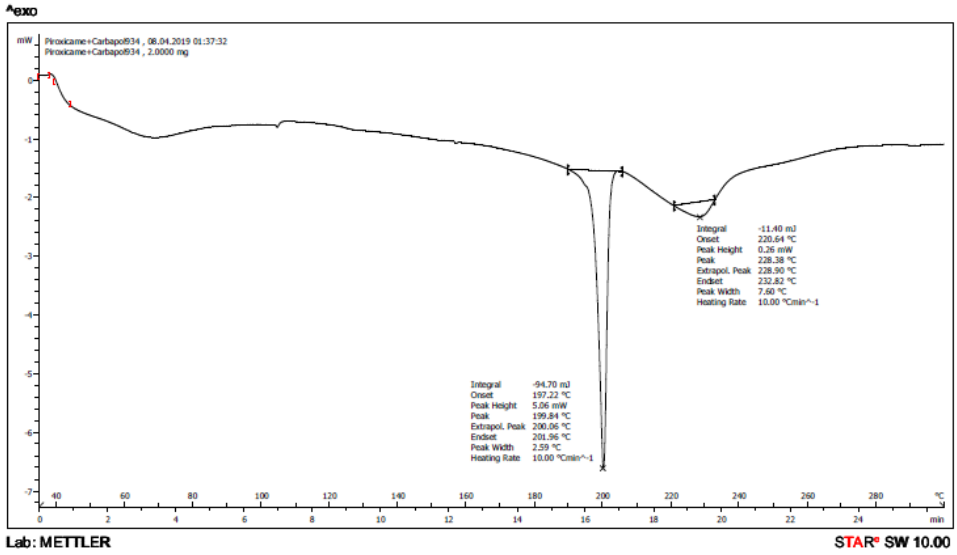

Fig 5. DSC of Piroxicam +Carbopol 934

In the FTIR and DSC study for the compatibility of Piroxicam with polymers Carbopol 934 , it showed that all above characteristic peaks of Piroxicam observed near their respective values. There were no significant changes in drug peaks when compared with the peaks of the mixture of drug and excipients.This confirms absence of incompatibility of drugs with the excipients .

Characterization of prepared Emulgel of Piroxicam

3.2.1 Physical Appearance

The results of various physical parameters evaluated are given in Table 3. All parameters were in acceptable range and the carbol concentration effects consistency of emugel. Not single prepared batches showed phase separation in emugel. Formulation F1 and F2 were fluid due to the presence of low carbopol concentrations. Formulation F3,F4, F6 and F7 which had similar carbopol concentration were white creamy in color. Formulation F5 and F8 thick white in color due to higher Carbopol concentration.

Table 3 Physical parameter of prepared Emulgel

Sr no.	Formulation codes	Colour	Consistency	Homogeneity	Phase separation	Texture
1	F1	White fluid	Uniform	Good	None	Smooth
2	F2	White fluid	Uniform	Good	None	Smooth
3	F3	White creamy	Uniform	Good	None	Smooth
4	F4	White creamy	Uniform	Good	None	Smooth
5	F5	Thick white	Uniform	Excellent	None	Smooth
6	F6	White creamy	Uniform	Excellent	None	Smooth
7	F7	White creamy	Uniform	Excellent	None	Smooth
7	F8	Thick white	Uniform	Good	None	Smooth

3.2.2 pH determination

The pH values of all emulgel formulations of Piroxicam were measured using a calibrated digital pH-meter at room temperature and results were recorded as average of three measurements which was depicited in Table 4, pH of the emulgel formulations was in the range of 5.6 ± 0.2 to 6.8± 0.3, which lies in the normal pH range of the skin and would not fabricate any skin irritation

3.2.3 Spreadability values

The results of spreadability values were reported in Table 4,concentration of carbopol effect spread ability values. Lower concentration of carbopol in F1 and F2 shows gel having spreadability values since gel is fluid in nature & vice versa.

3.2.4 Extrudability study

The emulgels were filled into collapsible tubes after formulating them. The extrudability of the formulation has been checked. The extrudability of the prepared Piroxicam emulgel trial batches was found to vary from 17.47±0.2 gm/cm^2 to 33.43± 0.32 gm/cm^2. It was found that extrudability of emulgel was found to be function of concentration of carbopol acting as gelling agent. Extrudability decreased with an increase in concentration of carbopol. Formulation F1 and F2 were fluid category extrudability was found to be 39.52± 0.4 gm/cm^2 and 33.43±0.2 gm/cm^2 respectively. Extrudability of Formulation F5 and F8 was less i.e. 17.32±0.5 gm/cm^{2}and 20.39±0.58 gm/cm^2 respectively as containing higher concentration of polymer. Formulation F3, F4, F6, F7 having optimum concentration of polymer extrudability was good i.e. 30.47±0.52 gm/cm^2, 27.39±0.6 gm/cm^2, 29.49±0.56 gm/cm^2 and 26.90±0.6 gm/cm^2 respectively. The results are reported in Table 4.

3.2.5 Swelling Index

Swelling Index is increased as the concentration of polymer increased and directly proportional to the rate of hydration. The percentage swelling index of trial batches was found to be 20.51% to 44.34 % and swelling index of final batches like (F5, F6, F7 and F8) found to be 44.24%, 27.35%, 31.98% and 46.38% respectively, because these four formulation batches contains higher concentration of polymers. The results were reported in Table 4.

3.2.6 Viscosity determination[17]

In this present study, the Brookfield viscometer model-Brookfield Viscometer was used to find out the rheological behaviour of emugels. Viscosity is F1-2765 mPas, F2-2870 mPas,F3- 2869 mPas,F4-2932 mPas,F5-2966 mPas,F6-3044 mPas,F6-3142 mPas,F7-30333 mPas, F8-3378 mPas. Results were given in highest viscosity which was found in formulation F8 and this may be due to high level of the carbopol and liquid paraffin concentration.

3.2.7 Drug Content[18]

Percentage drug content estimation of various Emulgel Formulations was done by UV spectrophotometer. The absorbance was measured and percentage drug content of various Emulgel formulations are reported in Table 4.

Table 4. Characterization Of Prepared Emulgel

Sr no.	Formulation codes	pH	Spreadability (g.cm/sec)	Extrudability (gm/cm^2)	Swelling index (%)	Drug content (%)
1	F1	5.9±0.3	38.81±0.5	39.52±0.4	10.03	89.20
2	F2	5.8±0.5	33.68±0.4	33.43±0.2	14.05	90.30
3	F3	5.6±0.2	32.03±0.54	30.47±0.52	17.28	87.12
4	F4	6.2±0.1	30.79±0.2	27.39±0.6	28.25	88.90
5	F5	6.3±0.3	18.14±0.36	17.32±0.5	44.24	83.39
6	F6	6.8±0.3	26.41±0.51	29.49±0.56	27.35	96.24
7	F7	6.5±0.2	30.44±0.6	26.90±0.6	31.98	95.60
8	F8	6.1±0.2	20.30±0.34	20.39±0.58	46.38	90.80

±SD, n=3

3.2.8 In vitro Drug Release Study[19]

The percent drug release of Piroxicam from emulgels in 8 hours is shown in figure no. 6. The percent cumulative drug release was found to be in the range 63.24% to 98.45 %. The higher drug release from emulgels was attributed to the presence of permeation enhancers in the formulations. Highest drug release is seen in Batch F7 95.60 % compare to other batches and having acceptable pH , sufficient swelling index, good Spreadability, Extrudability highest viscosity was found in formulation F7 it may be due to high level of the carbopol and liquid paraffin concentration thus F7 formulation was selected as optimized formulation.

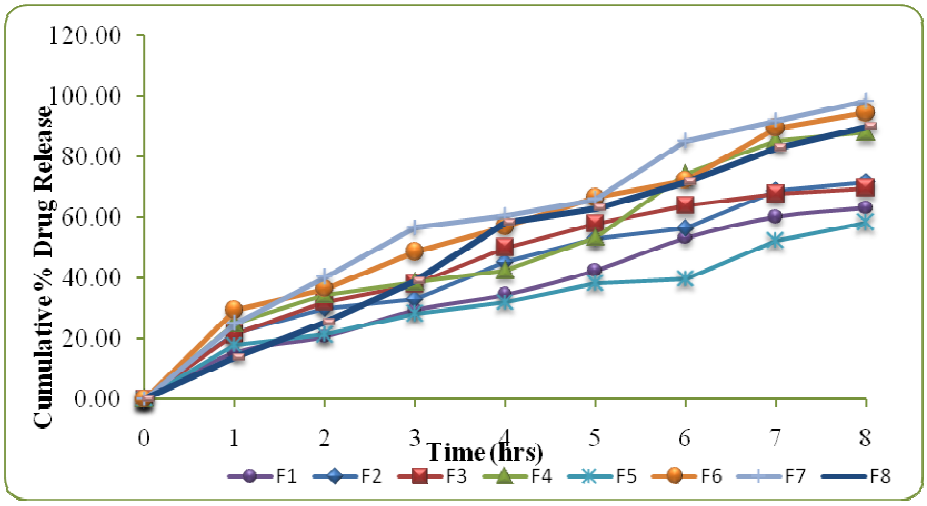

Fig 6. In Vitro % Drug Release Profile of Prepared Emulgel

3.3 Data analysis[19]

3.3.1 In vitro Drug release data Analysis

Table 5 Release kinetics of the formulations

Formulation code	Higuchi	Zero order	First order	Hixon Crow.	KorsmeyerPeppas	
	r^2	r^2	r^2	r^2	r^2	N
F1	0.948	0.957	0.913	0.949	0.980	0.921
F2	0.974	0.981	0.892	0.676	0.977	0.593
F3	0.981	0.952	0.868	0.960	0.962	0.574
F4	0.947	0.981	0.947	0.921	0.970	0.965
F5	0.970	0.946	0.893	0.674	0.972	0.582
F6	0.981	0.974	0.898	0.673	0.978	0.594
F7	0.982	0.956	0.869	0.954	0.981	0.574
F8	0.97	0.952	0.868	0.960	0.980	0.571

All the formulations were fitted for zero order release, first order release, Higuchi matrix model, Hixson-Crowell powder dissolution model and Korsmeyer-Peppas model analysis of release kinetics depicted Table 5. The *invitro* release profiles of drug from F7 the formulations could be best expressed Korsmeyer's equation. For the best formulation F7, the R^2 value was found to be 0,9872. Peppas as best fit model showed that the drug release was probably by "combination of swelling, erosion, and diffusion. A set of 8 different Emulgel formulation batches were prepared (with permeation enhancers). These Emulgel formulations were then evaluated for their appearance, pH, Viscosity, Spreadability, Extrudability, Drug Content, Swelling Index andIn-vitroDrug Release profiles. The pH of all emulgel formulations was found in range of 5.6±0.2 to 6.8 ±0.3. The values of Extrudability, Swelling index, Viscosity and Spreadability coefficient of Emulgel were found to be satisfactory. Shankar D et.al[20] previously reported that high level of Carpools and low level of liquid paraffin was the choice of effective formula, since it showed the highest drug release and activity. Our findings such as hightest drug release was seen in Batch F7 95.60 % compared to other batches and this may be due to high level of carbopol and low level of liquid paraffin concentration and having acceptable pH, sufficient swelling index, good Spreadability, Extrudability. Outcome of this study was that these developed Emulgel formulations of Piroxicam would be very effective for the management of pain and inflammation.

4. SUMMARY AND CONCLUSION

Aim and objective of this research work was to formulate and evaluate Piroxicam Emugel. A set of 8 different Emulgel formulation batches were prepared (with permeation enhancers). These Emulgel formulations were then evaluated for their appearance, pH, Viscosity, Spreadability, Extrudability, Drug Content, Swelling Index and In-vitro Drug Release profiles. The pH of all emulgel formulations was found in range of 5.6±0.2 to 6.8 ±0.3. The values of Extrudability17.32±0.5 to39.52±0.4(gm/cm$^{2)}$,Swelling index 10.03to46.38%,Viscosity 2765mPas to3378mPas, Drug content 83.39 to 96.24 % and Spreadability18.14±0.36 to 38.81±0.5 **(**g.cm/sec**)** coefficient of emulgel were found to be satisfactory. The drug release data revealed that formulation F7with optimum concentration of Carbopol and two types of penetration enhancers such as clove oil and Eucalyptus oil exhibited 98.45% drug release after 8 hrs. Emulgels exhibited a good potential for topical delivery of Drugs. The usefulness of Emulgel can be further explored with long term Pharmacokinetic and Pharmacodynamic studies.

5. ACKNOWLEDGEMENTS

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6. AUTHORS CONTRIBUTION STATEMENT

Dr. Shaikh Siraj N conceived the presented idea. He provided intellectual content, performs part of research work and guided the entire work. Shahid Raza Mohd Aslam Ansar did the literature search & perform research work. All other authors evaluated the results and reviewed the manuscript.

7. CONFLICT OF INTEREST

Conflict of interest declared none.

8. REFERENCES

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