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Research

Formulation And Evaluation Of Tenoxicam Emulgel For Topical Application By Using Synthetic Polymer

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	Abstract
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2024 All rights reserved.  Creative Commons Attribution 4.0 International License.	Topical drug delivery systems offer advantages such as bypassing first-pass metabolism and avoiding intravenous administration risks. Emulgels, combining the properties of emulsions and gels, have emerged as effective vehicles for delivering hydrophobic drugs. This study aims to formulate and evaluate Tenoxicam emulgel for topical application using synthetic polymers. The emulgel was prepared by incorporating Tenoxicam into an oil-in-water emulsion system, which was then mixed with a gel base. The formulations were characterized for various parameters, including particle size, zeta potential, pH, viscosity, spreadability, drug content, and in vitro drug release. The optimized formulation (F9) exhibited desirable properties, including good homogeneity, appropriate pH (6.90), and high drug content (90.01%). The in vitro release studies showed a sustained release pattern, with formulation F9 achieving 91.43% cumulative drug release over 8 hours. The formulation followed the Higuchi model, indicating a diffusion-controlled release mechanism. Stability studies confirmed that the optimized emulgel was stable, with no significant changes in physical appearance, drug content, or release profile over time. In conclusion, the Tenoxicam emulgel formulation developed in this study demonstrates potential as an effective topical drug delivery system, providing sustained drug release and improved patient compliance. This study highlights the advantages of using emulgels for the topical application of hydrophobic drugs, making it a promising approach for future pharmaceutical formulations. Keywords: Tenoxicam, Emulgel, Topical Drug Delivery, Synthetic Polymer, Sustained Release.

INTRODUCTION

Topical drug delivery system is the dosage form which is administered on the skin and other routes of drug delivery get failed or for skin disorders. The topical drug delivery system has the advantage of negotiating the first pass metabolism. It also helps to avoid the risk and inconvenience of i.v route therapy. Topical formulations are prepared in different consistency such as solid, semisolid, and liquid. The topical delivery system

is fails in the administration of hydrophobic drug. In each formulation with the active ingredients many excipients are used. Sometimes more than one formulation can be combined to enhance the drug delivery. Emulgel is such a type of combination. It is the combination of emulsion and gel.

Emulgel is prepared as both in oil- in- water and water- in oil type emulsion mixed with gel. Oil- in- water type is used for lipophilic drugs and water- in- oil type is used for hydrophobic drugs' delivery. The emulgel have many advantages like thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, bio-friendly, pleasing appearance, transparent and cosmetically acceptable, which also have a good skin penetration and long shelf- life. The emulsion and gel preparations have their own properties. But the gels show some limitations for hydrophobic drug delivery, this limitation is overcome by emulgel. By the use of gelling agent classical emulsion can be converted in to emulgel. Two types of topical delivery products are available. They are external and internal products. As their name indicates, the external products are applied by spreading or spraying, and the internal products are applied orally, vaginally or rectally. The topical preparation can be classified by their consistencies, which are solid preparation, liquid preparation, semi-solid preparation and miscellaneous preparation.[1]

Ideal properties of Emulgels

- Being Greaseless
- Easily Spreadable
- Easily Removable
- Emollient
- Non - Staining
- Longer shelf life and Bio friendly
- Pleasing Appearance

Significance of Emulgels

Topical dosage forms like cream, lotion, ointment have many disadvantages. Some of which are greasiness and stickiness, causing problems to patients in application and having low spreading coefficient and requirement of rubbing is also considered as disadvantage. It may Also cause stability problems of hydrophilic drug formulation. Due to these shortcomings with the semisolid group of preparations, the use of gellified formulation has been expanded both in pharmaceutical preparations and in cosmetics. Gel is colloidal preparation containing 99 % part of liquid where macromolecular network of fibres built from a gelling agent and liquids are immobilized by surface tension between them. In spite of advantage a major problem is the delivery of hydrophobic natured drugs. Emulsion based strategies can be used to incorporate lipophilic therapeutic moiety in gel built system to overcome this problem.

Advantages of Emulgels

Emulgels are considered advantageous over the other drug delivery system for a number of reason including as follows:

- Hydrophobic drugs can be easily incorporated into gels using o/w emulsions. Most of the hydrophobic drugs cannot be incorporated directly into gel base because the solubility of the drug act as a barrier and problem arises during the release of drug. Emulgels helps in the incorporation of hydrophobic drugs into the oil phase and then oily globules are dispersed in aqueous phase resulting in o/w emulsion, and this emulsion can be mixed into gel base. This may be provided by better stability and release of drug than simply incorporating drugs into gel base.
- Better stability: Other transdermal preparations are comparatively less stable than Emulgels, like powders are hygroscopic, creams show phase inversion or breaking and ointments show rancidity due to oily base.
- Better loading capacity: Other novel approaches like niosomes and liposomes are of nano size and due to vesicular structures may result in leakage and result in lesser entrapment efficiency. But gels due to vast network have comparatively better loading capacity.
- Production feasibility and low preparation cost: Preparation of Emulgels comprises of simpler and short steps which increases the feasibility of the production. There are no specialized instruments needed for the production of Emulgels. Moreover materials used are easily available and cheaper. Hence, decreases the production cost of Emulgels.
- No intensive sonication: Production of vesicular molecules need intensive sonication which may result in drug degradation and leakage. But this problem is not seen during the production of Emulgels as no sonication is needed.
- Controlled release: Emulgels can be used to prolong the effect of drugs having shorter half life.[2]
- Emulgels as topical drug delivery system better to avoiding first pass metabolism.
- Emulgels is more selective for a specific site.

- Topical drug delivery of Emulgels is convenient and easy to apply.
- Emulgels are prepared to be capable of releasing the drug in a controlled manner and sustained pattern at the target site, thereby enhancing the therapeutic efficacy of the drug avoiding its adverse reactions.

Limitations of Emulgels

- Create problem in absorption of macromolecules.
- Entrapment of air bubble during formulation.
- Only hydrophobic drugs are the best choice for such delivery system.
- Skin irritation on contact dermatitis.
- The poor permeability of some drugs through the skin.

MATERIALS AND METHODS

Table 1: List of chemicals used

S. No	INGREDIENTS	VENDOR
1.	Tenoxicam	Techino laboratory
2.	Carbopol-940	Prakarti aroma care
3.	Span-80	S.D Finechem Ltd
4.	Tween-80	S.D Finechem Ltd
5.	Liquid paraffin	S.D Finechem Ltd
6.	Triethanolamine	S.D Finechem Ltd

Table 2: List of Equipments used

S. No	EQUIPMENTS	MODEL
1.	Digital weighing balance	Wensar
2.	Digital melting point apparatus	Selec TC 303
3.	UV spectrophotometer	Shimazu corporation
4.	FT-IR	Shimazdu
5.	PH meter	Systronics, PH system
6.	Mechanical stirrer	Remi motors
7.	Viscometer	Brookfield viscometer

Preformulation studies

Melting point

Digital melting point apparatus was used to determine the melting point of drug. A capillary tube was taken and fused at one side with the help of a Bunsen burner. The drug Tenoxicam was introduced into the capillary tube through the unsealed end and then placed in a melting point viewer. Then the degree at which the drug gets melted down was considered as the melting point of the drug.

Solubility studies

A test for the solubility becomes a test for purity only when a special quantitative test is given in the individual monograph and is an official requirement

Preparation of standard solution

The standard stock solution of Tenoxicam as prepared by accurately weighing & transferring 10mg of Drug to 100ml of volumetric flask. Then 2ml of the solution was added to 10ml volumetric flask and the final volume was made up with distilled water to get final standard stock solution (20ug/ml) was further diluted with distilled water to obtain 05- 25 ug/ml Tenoxicam solutions.

Calibration curve of Tenoxicam

The dilution were made from standard stock solution to get concentration of 2,4,6,8,10 & 12ug/ml respectively. The solutions were scanned in the range of 355nm. The calibration curve plotted between absorbance values against concentration.

Compatibility studies

A Physical mixture (1:1) of drug and polymer was prepared and analysed by FITR. The IR spectrum of the

physical mixture was compared with those of pure drug and polymer and matching was done to detect any appearance of peaks.

Preparation of phosphate buffer: 50ml 0.2 M Potassium dihydrogen phosphate was taken in 200ml volumetric flask, to which 39.1ml of 0.2M Sodium hydroxide was added and the volume was made up to the mark with distilled water.

Preparation of potassium dihydrogen phosphate (0.2M) solution: 27.219g of Potassium dihydrogen phosphate was added in to a 1000ml volumetric flask containing distilled water and the volume was made up to the mark with distilled water.

Preparation of sodium hydroxide (0.2M) solution: 8g of sodium hydroxide was taken in 1000ml volumetric flask containing distilled water and the volume was made up to the mark with distilled water.

In this buffer solution drug compatibility and excipients compatibility studies were discussed and detected with appearance of peaks.

Formulation of emulgel

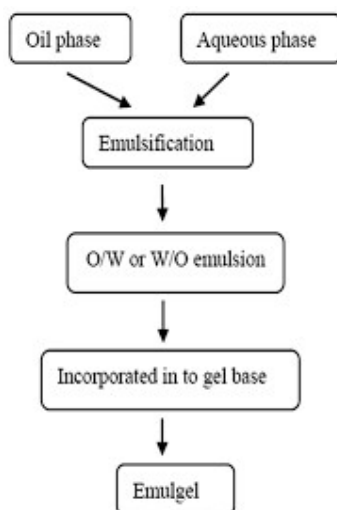


Fig 1: Emulugel preparation

Oil phase: Accurately weighed quantity of span-80 is dissolved in liquid paraffin.

Aqueous phase: Accurately weighed quantity of tween-80 is dissolved in water.

Emulsification: Both aqueous phase and oil phase are heated separately at 70°C then it mixed with to form emulsion. In this stage drug is dissolved in suitable solvent and mixed with the aqueous phase.

Gel base: Accurately weighed quantity of Carbopol-940 is mixed with water to form gel by using mechanical stirrer and make a clear gel.

Emulgel: The emulsion is incorporated into the gel base to make a emulgel. Triethanolamine is added to the emulgel.

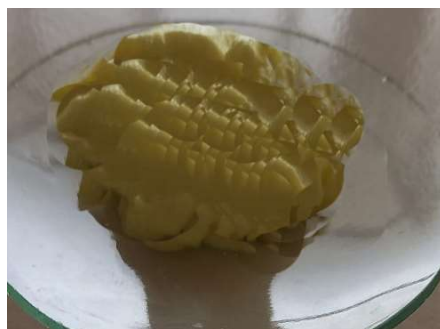


Fig 2: Tenoxicam Emulgel

Table 3: Formulation Of Emulgel

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Tenoxicam(mg)	1000	1000	1000	1000	1000	1000	1000	1000	1000
Carbopol-940(mg)	100	200	150	300	100	350	500	150	500
Span-80 (mg)	100	200	100	200	200	100	100	200	100
Tween-80 (ml)	2	4	2	2	2	4	2	4	4
Liquid paraffin (ml)	5	5	5	5	5	5	5	5	5
Water for aqueous phase(ml)	10	10	10	10	10	10	10	10	10
Water for gel form(ml)	5	5	5	5	5	5	5	5	5
Triethanolamine(ml)	1	1	2	1	1	1	1	1	1

Evaluation of Emulgels**Measurement of particle size and zeta potential of formulation**

The mean size of the selected emulgel were determined by using Malvern Rasterizer 2000 MS. The mean particle size was recorded.

Appearance

The prepared emulgel bases were inspected visually for clarity, colour and presence of any particles.

Homogeneity

All developed emulgels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.

PH measurement

The pH measurement was carried out by using calibrated digital type pH meter by dipping the glass electrode and the reference electrode completely into emulgel system so as to cover the electrodes.

Drug content

For the estimation of the drug in emulgel, sample was extracted from 1gm of gel formulation with 50ml of phosphate buffer 6.8 and mixture was filtered through membrane filter (pore size 0.4 μ m) From this, 2 ml was pipette out and made up to 10 ml. The absorbance of the sample was determined spectrophotometrically at 270 nm. The concentration of Tenoxicam was estimated from the calibration curve.

Viscosity

The viscosity of the formulations (emulgel) was determined at 25°C by using Brookfield viscometer with spindle no. S-96 at 1 RPM and viscosity was measured in cps. The measurement of each formulation was done in triplicate and average values are calculated.

Spread ability

Spread ability is determined by apparatus suggested by Multimer. It consists of wooden block, which is provided by a pulley at one end. By this method, spread ability by is measured on the basis of “Slip” and “Drag”. A ground glass slide is fixed on this block. A sample of 0.1 g of emulgel under study is placed on this ground slide. The gel is fixed on the beach formula was pressed between two slides and a 1 kg weight is placed on the top of two slides and left for about 5 min to expel air and to provide a uniform film of the emulgel between two slides. Excess of the gel is scrapped from edges. The top plate is then subjected to pull the weight. With help of string attaches to the hook and the time required by top slide to cover the distance is noted. A shorter interval indicates better spread ability, spread ability was calculated by using the formula,

$$S=M.L/T,$$

Where, S=spread ability, L=Length of glass slide, M=weight tied to upper slide, T=Time taken to separate the slides.

In- vitro release studies

The drug release from the formulation was determined by using the apparatus known as Franz Diffusion Cell, which consist of a cylindrical glass tube which was opened at both the ends. 1 gm of emulgel was spread uniformly on the surface of cellophane membrane (previously soaked in medium for 24 hrs.) and was fixed to the one end of tube. The whole assembly was fixed in such a way that the lower end of tube containing gel was just touches (1-2 mm deep) the surface of diffusion medium i.e., 100 ml of pH 7.4 phosphate buffer contained in 100 ml beaker. The assembly was placed on thermostatic hot plate with magnetic stirrer and maintained at temperature 37 $\pm$ 2° the contents were stirred using magnetic bar at 100 rpm for a period of 8 hrs., 2 ml of samples were

withdrawn at different time intervals. This 2 ml was diluted up to 10 ml of fresh phosphate buffer (pH 7.4) and sample were analyzed at 270 nm in UV-Vis.

RESULTS AND DISCUSSION

Reformulation Studies

Melting point: Melting point is found to be 199°C which confirms Tenoxicam drug.

Solubility: Solubility of Tenoxicam in different solvent is carried out and this has been found

- Soluble in ethanol.
- Slightly soluble in chloroform.

Calibration curve

Standard curve of Tenoxicam

Standard curve of Tenoxicam was plotted by using UV spectrophotometer and the absorbance was noted as 355nm. A series of concentrations of solutions 2, 4, 6, 8, 10, 12µg/ml were prepared and the corresponding absorbance was noted. The calibration curve plotted between absorbance values against concentration.

Table 4: Standard curve data of Tenoxicam

S.NO	CONCENTRATION (ug/ml)	ABSORBANCE
1	0	0
2	2	0.151
3	4	0.393
4	6	0.701
5	8	0.793
6	10	0.832
7	12	0.997

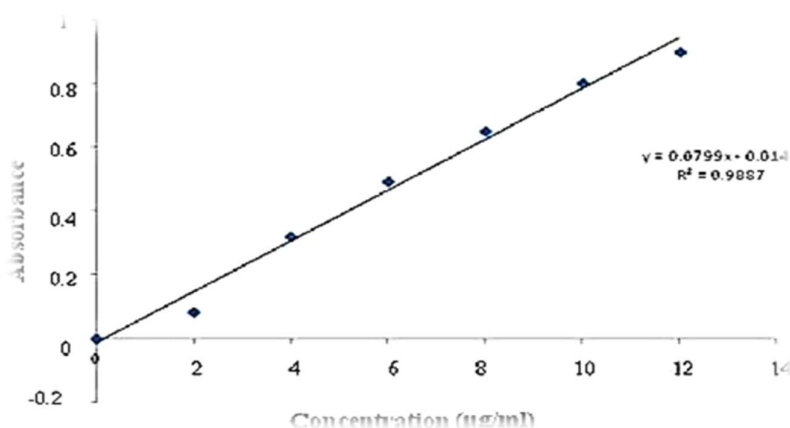
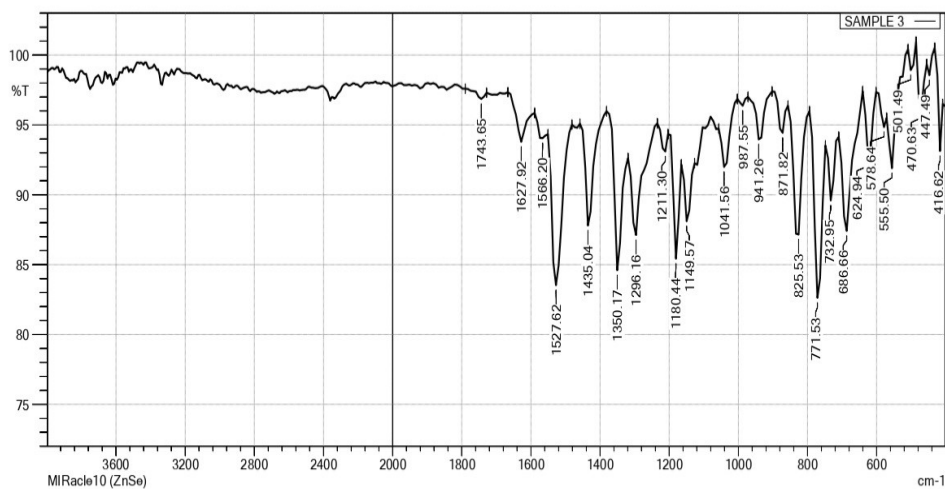


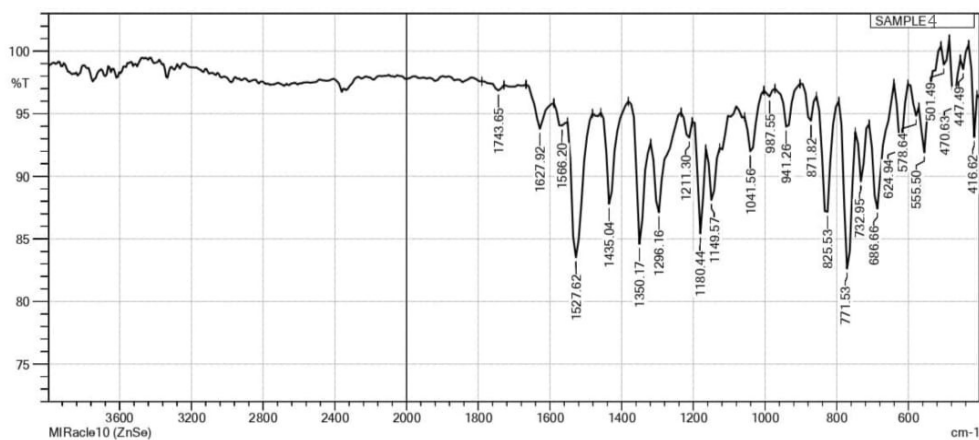
Fig 3: Standard curve

FT-IR Studies

Drug excipients compatibility was checked by comparing the IR spectra of pure drug and physical mixture of drug with excipients. No significant changes in the functional group between the spectra were observed. This ensures that there was no interaction between drug and excipients.

Tenoxicam**Fig 4: IR spectrum of Tenoxicam****Table 5: FT-IR data of Tenoxicam**

S. No	Standard wavenumber	Test wavenumber	Assignment
1	1500-1700	1627.92	N-H stretching
2	700-1000	987.55	C-H bending
3	1700-1800	1743.65	C=O bending
4	1200-1500	1435.04	OH stretching

Mixture of tenoxicam and carbopol-940**Fig 5: Mixture of Tenoxicam and Carbopol****Table 6: FT-IR data of Tenoxicam and Carbopol**

S. No	Standard wavenumber	Test wavenumber	Assignment
1	1500-1700	1627.92	N-H stretching
2	700-1000	987.55	C-H bending
3	1700-1800	1743.65	C=O bending
4	1200-1500	1435.04	OH stretching

The FT-IR studies conclude there is no major interaction occurred between drug and the polymer.

Particle Size And Pdi

Particle size of optimized formulation is 98.19nm and PDI is 0.444 as the smaller particle size may in turn bring about more bioavailability. ZETA POTENTIAL. The reduced zeta potential value of 0.0204mV indicated that prepared emulgel posses a good degree of long -term stability.

Physical Appearance

All the formulation shows clear yellow appearance all the formulations were homogenous and free of grittiness.

pH

The PH values of all prepared formulations were ranged between 6.40-6.94 which is considerable to avoid the skin irritation of the skin after application.

Spreadability

Spread ability diameter for different formulation F1-F9 showed good spread ability i.e., emulgel is easily spreadable.

Viscosity

All the formulations of Emulgel were subjected to Brookfield viscometer used to measure the viscosity (in cps) by dropping a cone attached to a holding rod from distance of 10cm in such a way that, it should fall on center of the glass cup filled with Emulgel.

Drug content determination

The drug content of Tenoxicam from its various emulgel formulations are represented in the F9 showed better drug content as compared to other formulations. The percent drug content of these formulation was 90.01% respectively.

Table 7: pH data

Formulation	pH	Spread ability (cm)	Viscosity (cps)	Drug content
F1	6.40	2.5	3459	55%
F2	6.68	3.2	3356	67%
F3	6.80	2.9	3268	71%
F4	6.84	3.4	3498	69%
F5	6.50	2.6	3295	73%
F6	6.72	2.9	3501	70%
F7	6.62	3.2	3340	77%
F8	6.55	2.8	3351	80%
F9	6.90	3.5	3528	90.01%

Invitro release studies

Table 8: In-vitro release data

TIME	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	7.9	19.7	24.2	12.8	12.8	11.77	6.701	13.46	15.05
2	13.4	26.1	28.9	16.17	28.0	22.55	13.44	25.77	26.59
3	24.8	34.7	33.6	21.35	33.45	32.49	23.72	31.71	37.66
4	32.6	41.3	38.2	22.35	41.7	49.95	36.09	42.68	48.20
5	41.9	45.2	42.1	32.45	47.4	55.60	48.95	52.75	59.28
6	46.3	49.2	46.3	38.91	52.8	58.14	59.46	63.93	67.83
7	51.3	52.2	47.5	42.71	59.4	63.78	68.71	69.05	75.31
8	52.6	53.1	54.7	56.71	63.71	67.42	71.90	79.45	91.43

Comparative invitro release of Tenoxicam emulgel

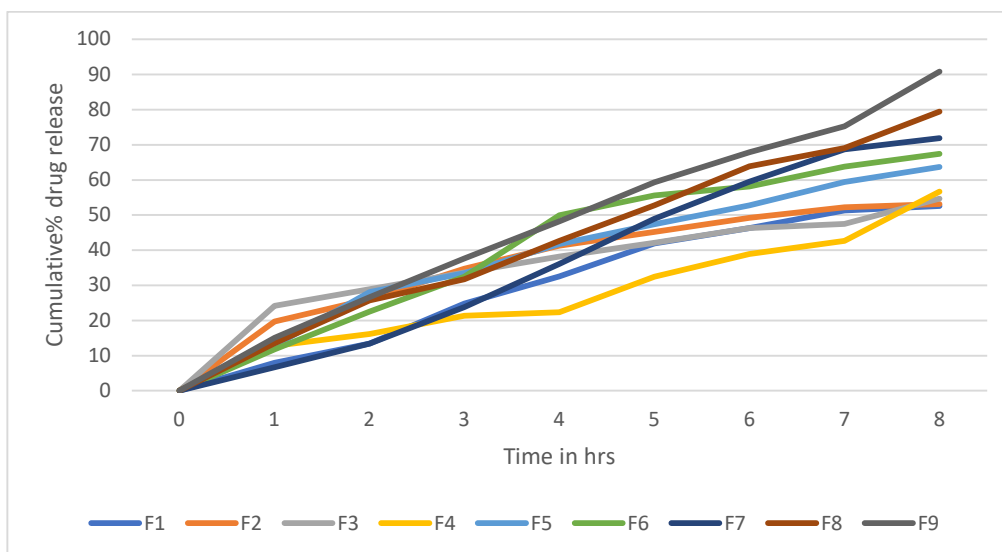


Fig 6: Overall cumulative release of Tenoxicam for various formulation

In vitro release was studied for all the formulation of emulgel. The studies were performed up to 8 hours for all formulations. The cumulative percentage release of formulation (F1, F2, F3, F4, F5, F6, F7, F8, F9) was found to be 52.6, 53.1, 54.7, 56.71, 63.71, 67.42, 71.90, 79.45, 91.43. Thus optimized formulation F9 has high amount of drug release due to good entrapment efficiency.

Invitro release kinetic studies

Table 9: Kinetic study data

Formula Tion Code	Time (InHrs)	S.Q.R.T.Of Time	Log Time	CumulatiVe % Drug Release	Log Cumulative % Drug Release
F9	0	0	0	0	0
	1	1	0	15.05	1.177
	2	1.414	0.301	26.59	1.425
	3	1.732	0.477	37.66	1.575
	4	2	0.602	48.20	1.683
	5	2.236	0.698	59.28	1.773
	6	2.449	0.778	67.83	1.831
	7	2.645	0.845	75.31	1.876
	8	2.828	0.903	91.43	1.961

SUMMARY AND CONCLUSION

In this study, Tenoxicam loaded emulgel was formulated and formulations were quite stable, it may be concluded that the formulation F9 was good showing high percentage of entrapment with desired sustained release of drug. The FTIR studies concluded there is no major interaction occurred between the drug and polymer. The formulation F9 with Tenoxicam emulgel showed good result. The percentage of drug release was found 91.4%. Malvern zeta sizer was used to explore the particle size of Tenoxicam emulgel. The average particle size of emulgel was 98.19 nm. Malvern zeta sizer was used to explore the zeta potential of Tenoxicam emulgel. The average particle size of emulgel was 0.0204. The presence of stabilizer made the emulgel formulation more stable with high entrapment efficiency 91%. The optimized formulation was found to be Higuchi order pattern. We can consider the emulgel could be used as a drug carrier for Tenoxicam and also to sustain the effect of drug for a longer duration of action.

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