IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

"Development of Celecoxib Emulgel: A Comprehensive Study on Formulation, Characterization, and In Vitro Evaluation"

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ABSTRACT

Background: The present research is based on formulation of celecoxib emulgel and determines in-vitro drug release and swelling index of prepared emulgel.

Material and Methods: Pure drug of celecoxib was identified by using FTIR spectroscopy and preformulation study of emulgel was performed by using various methods like determination of lamba max, drug solubility studies, melting point of pure drug etc. The present formulation is based on carbapol 934 polymer and other key ingredient and excipients which was used in preparation of anti emulgel.

Result: Evaluated the prepared emulgel by their physical appearance, PH, Rheology, Swelling index, microscopic studies, Drug content, % drug release. In all formulation batch, F3 batch formulation was give satisfactory result like that drug content 95.3%, cumulative drug release 92.9 %.

Conclusion: As a result, the current study's results unambiguously showed that celecoxib emulgel presents a promising alternative to the traditional dose form. Nevertheless, additional clinical research is required to evaluate the effectiveness of this technique. After taking into account everything mentioned above, it was determined that the current research study's goal could be effectively met.

Key Word: Emulgel, Celecoxib, Gel, Jelly Etc.

1. INTRODUCTION:

PHARMACEUTICAL GEL:

The word "gel" derives from the word "gelatin," and the Latin terms "gelu," which means "frost," and "gel are," which means "freeze" or "congeal," are the source of the words "gel" and "jelly." The fundamental idea of a liquid setting to a solid-like substance that is elastic and maintains some liquid characteristics but does not flow is demonstrated in this source. In the late 1800s, chemists attempted to classify semisolid materials more on the basis of their phenomenological characteristics than their chemical composition. This is when the term "gel" was first employed in classification. At the time, there was a lack of analytical procedures necessary to determine chemical structures.

EMULGEL:

The qualities of an emulsion and a gel are combined in a medicinal composition called an emulgel. It usually consists of an oil stage and a water stage that are adjusted by an emulsifying expert and a gelling expert to give it a gel-like consistency.

Emulgels are applied topically to deliver active pharmaceutical ingredients (APIs) through the skin. Compared to traditional measuring frameworks such as creams or treatments, the emulgel framework has a few advantages. Because of its excellent surface, it improves the stability of both hydrophilic and lipophilic APIs, increases the skin penetration of pharmaceuticals, provides regulated discharge characteristics, and offers further enhanced spreadability and patient consistency.

2. MATERIAL AND METHODS:

MATERIAL:

The standard raw material active pharmaceutical ingredient (Drug) of Celecoxib was obtained as a gift sample from Cheminor Drugs Limited, Hyderabad, India.

Chemical and solvent:

Methanol, KBr, Methyl Paraben, HCl, Ethanol, DMSO, Acetonitrile etc.\

METHODS:

A. PREFORMULATION STUDIES:

The preformulation testing is the first step in the rotational development of dosage form of a drug substance. It can be defined as an investigation of physiochemical properties of a new drug substance alone and when combined with the excipients, to generate data useful to the formulation safe, stable, potent, bioavailable and efficacious dosage form.

1. IDENTIFICATION OF DRUG AND POLYMER BY FTIR:

The drug Celecoxib was identified by Fourier Transform Infrared (FTIR) Spectroscopy. Drug sample and IR grade Potassium Bromide (KBr) in 1:100 was taken mortar and triturated. Then required quantity was placed in sample holder and placed in sample compartment. Whereas for liquid sample potassium bromide was replaced by nizole. The sample was scanned for 4000-400 cm^{-1} for 45 times. The spectra were recording by

Simadzu IR solution 1.50, DLATGS detector. The spectrum was matched with standard reference spectrum and the principal peak were matched with reference spectrum.

2. ORGANOLEPTIC CHARACTER:

Organoleptic character of drug substance was carried out the characteristics feature like taste, colour, odour etc were studies.

4. SOLUBILITY:

- **SOLUBILITY OF CELECOXIB IN VARIOUS SOLVENTS:**

Solubility of drug (Celecoxib) in different solvents like DMF, DMSO, Ethanol, Methanol, Acetonitrile and water was determined.

- **SOLUBILITY OF CELECOXIB IN VARIOUS OIL AND SURFACTANT:**

The spontaneous interaction of two or more substances to form a homogenous molecular dispersion is called as solubility in that solvent. The solubility of Celecoxib estimate in various oils, surfactants and co-surfactants. Excess amount of drug was added to 1gram of each excipient in cap vials and were cyclo-mixed immediately using cyclomixer

5. SELECTION OF SOLVENT:

The solubility of drug was determined in verity of polar and non-polar solvents as per IP specification. The common and stable solvent for celecoxib was found to be Methanol.

- **DETERMINATION OF LAMBDA MAX (λ_{MAX}):**

Prepared solution of drug compound with methanol and checked the absorbance over a wide range of wavelengths (200-400 nm). The wavelength at which the highest signal (peak) is recorded is identified as the lambda max.

- **PREPARATION OF STANDARD STOCK SOLUTION:**

10mg drug (Celecoxib) was weighed accurately and dissolved with sufficient quantity of methanol solvent then solution was transfer in to a 100ml of volumetric flask and volume upto 100ml with methanol solvent in volumetric flask. Thus, the stock solution (100µg/ml) of Celecoxib drug in methanol solvent was prepared.

- **CALIBRATION CURVE OF PURE DRUG**

The stock solution (100µg/ml) was prepared to get concentration, 5-30µg/ml. The of concentration v/s peak area absorbance was plotted and data was subjected to linear regression analysis on the maximum absorbance (λ max= 252).

➢ **MELTING POINT**

Melting point of Celecoxib Nitrate was determined by using Thelie tube. Celecoxib drug sample are filled half in a sealed capillary tube, attached to a thermometer with thread, was immersed in the tube. Heating is commenced and the temperature ranges at which Celecoxib drug sample was melts was observed.

B. GEL PREPARATION:

Gel bases prepare by dispersing various concentrations of gelling agents (Carbomer934) in distilled water by constant stirring at moderate speed using mechanical shaker. These gel are prepare by dispersion method.

Dispersion method:

Stirring the gelling agent in water at 1200 rpm for 30 minutes dispersed the gelling agent. The nonaqueous solvent will used to dissolve the drug. The preservative was also added. Continuous stirring will be performed while adding this solution to the gel above.

C. EMULSION PREPARATION:

Oil phase: Span 20 dissolve in liquid paraffin.

Aqueous phase: Tween80 dissolve in water.

Methyl paraben dissolved in propylene glycol whereas drug dissolve in methanol and both solutions add to aqueous phase.

D. FORMULATION OF CELECOXIB EMULGEL:

Emulgel are prepared by incorporating gel and emulsion. The emulsion and gel are prepared separately and mix together. The optimization in the formulation is made mainly based on gelling agent and emulsifying agents. It was designed according to a 2^3 factorial design so total five Celecoxib emulgel formulations were prepared. The optimization in the formulation batches were made mainly based on gelling agent and emulsifying agents.

E. EVALUATION PARAMETERS FOR CELECOXIB EMULSION:

1. Organoleptic characteristics:

Freshly prepared emulsions were investigated Organoleptically for colour, and phase separation.

2. Microscopic Studies:

Determine by using optical microscope.

3. Dye test:

Emulsion was mixed with water soluble dye (amaranth red) and observed under microscope if continuous phase appears red then emulsion O/W type or if scattered globules appear red and continuous phase is colourless then W/O type.

4. Thermodynamic stability studies:

Centrifugation test: Emulsion subjected for centrifugation at 3500rpm for 30min.

Freeze-thaw test: Emulsion subjected to Freeze-thaw cycles for 48hrs.

5. Robustness to dilution:

Emulsions were subjected to dilution with water and pH phosphate buffer using magnetic stirrer

F. EVALUATION PARAMETERS FOR CELECOXIB EMULGEL:

1. Physical appearance:

Prepared emulgel formulations are examined visually for color, phase separation, consistency and homogeneity.

2. pH evaluation:

pH evaluation is important criteria especially for topical formulations. The pH of emulgel should be in between 5-7 to mimic the skin conditions. If the pH of prepared emulgel is acidic or basic, it may cause irritation to the patient. pH of prepared emulgel is measure by using digital pH meter by dipping the glass electrode into the emulgel.

3. Rheological studies (Viscosity):

The viscosity of gel during handling, transport and storage is an important criterion. The viscosity of different emulgel formulations determine at 25^0C using Brook field viscometer. The emulgels is rotate at 10 rpm and viscosities is measure.

4. Swelling index:

1g of prepared emulgel formulations taken on porous aluminium foil and then placed in the Petri dish containing 10 ml 0.1N Hcl. The samples taken from the Petri dish at a different time interval and left undisturbed in a dry place for some time so that the external liquid is remove and weigh.

Swelling index is then calculated by using below formula,

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

Where (SW) % = Equilibrium percent swelling,

Wt = Weight of swollen emulgel after time t,

Wo = Original weight of emulgel at zero time

5. Drug content determination:

Drug concentration in emulgel was measured by UV spectrophotometer. Celecoxib content in emulgel was measured by dissolving Known quantity of emulgel in solvent (methanol) by Sonication.

6. ***In-vitro Diffusion Study***

In-vitro diffusion was carried out by modified Franz diffusion cell. A glass cylinder with both ends open, 10 cm height, 3.7 cm outer diameter and 3.1 cm inner diameter was used as diffusion cell. An egg membrane (soaked in phosphate buffer 24 hours before use) was fixed to one end of the cylinder with the aid of an adhesive. About 1gm of organogel was taken in the cell (donor compartment) and cell was immersed in a beaker containing 500 ml of phosphate buffer (pH 6.8) as receptor compartment. The entire surface of the cell was in contact with the receptor compartment which was agitated using magnetic stirrer and a temperature of 37±1°C was maintained. Sample of 5 ml of the receptor compartment was removed at 1 hour interval of time over a period 8 hours with same amount replaced to maintain sink condition. The sample was analyzed at 252 nm against blank using UV Spectrophotometer. Amount of celecoxib released at various time intervals was calculated with the help of calibration curve with phosphate buffer (pH 6.8) and plotted against time.

3. RESULTS:

A. PREFORMULATION STUDIES:

1. IDENTIFICATION OF DRUG BY FTIR:

It was found that the peak obtained by performing FTIR pure drug were found to be in between the rang of main principal peaks recorded previously as theoretical range, hence this indicate that the drug is pure. These observations were found to be in concurrence with the structure of the drug molecules.

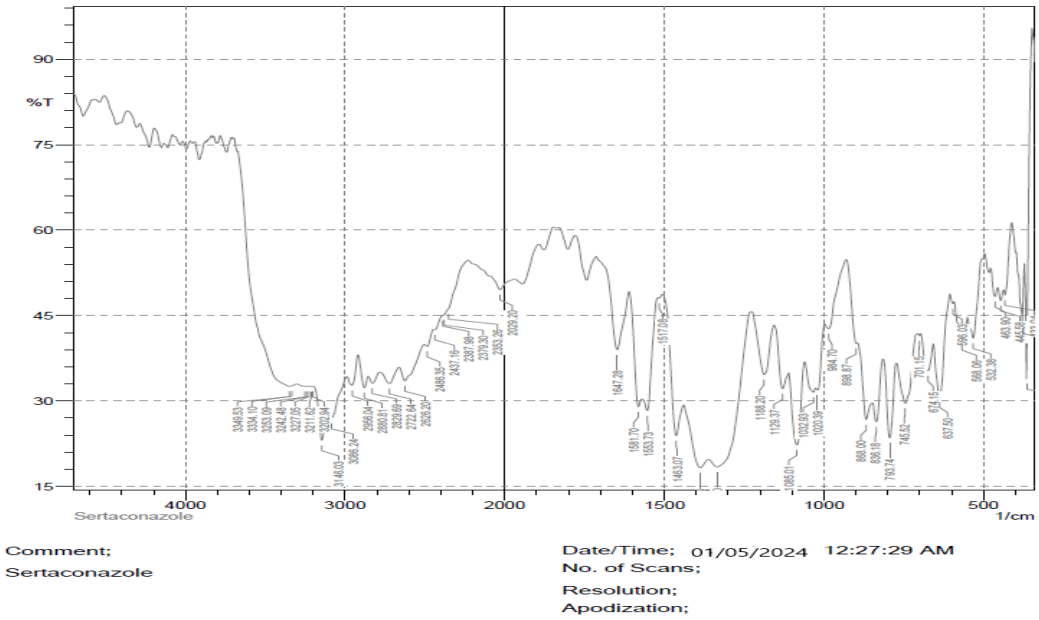

Figure 1: FTIR of Celecoxib

Table 6.1.: Peak table with principle peak of Celecoxib

S. No.	Functional Group	Theoretical Peak (Cm^{-1})	Practical Peak (Cm^{-1})
1.	OH Stretching	3700-3100 (Cm^{1})	3349.53 (Cm^{-1})
2.	Aliphatic C-H Stretching	2950-2850 (Cm^{1})	2880.81 (Cm^{-1})
3.	Aromatic C-H Stretching	3030 (Cm^{1})	2956.04 (Cm^{-1})
4.	C=O Stretching	1750-1735 (Cm^{1})	1647.28 (Cm^{-1})
5.	Aromatic C=C	1700-1750 (Cm^{1})	1581.70 (Cm^{-1})
6.	C=N Stretching	1335-1250 (Cm^{1})	1188.20(Cm^{-1})
7.	Amine NH binding	1650-1580 (Cm^{1})	1463.07 (Cm^{-1})

2. ORGANOLEPTIC CHARACTERISTCS:

Table 2: Organoleptic Properties of Celecoxib

S.No.	Properties	Result
1.	Description	Crystalline fine powder
2.	Taste	Slightly Bitter
3.	Odour	Odourless
4.	Colour	Pale Yellow Colour

3. SOLUBILITY:

➢ SOLUBILITY OF CELECOXIB IN VARIOUS SOLVENTSL:

Solubility of pure drug sample Celecoxib with various solvents was found to be:

Table 3: Solubility of Celecoxib in various solvents

S.No.	Solvent Media	Solubility
1.	Water	Sparingly Soluble
2.	Methanol	Freely Soluble
3.	Ethanol	Soluble
4.	DMSO	Soluble
5.	Acetonitrile	Insoluble
6.	Tween 20	Soluble
7.	Span 60	Soluble

➢ SOLUBILITY OF CELECOXIB IN VARIOUS OIL AND SURFACTANT:

Solubility of pure drug sample Celecoxib with various Oil and surfactant was found to be:

In various oils:

4: Solubility of Celecoxib in various oils

S.No.	Oil Media	Solubility (mg/g)
1.	Liquid Paraffine	43.1
2.	Soyabean Oil	29.2
3.	Clove Oil	16.8
4.	Olive Oil	9.1
5.	Arachis Oil	7.2

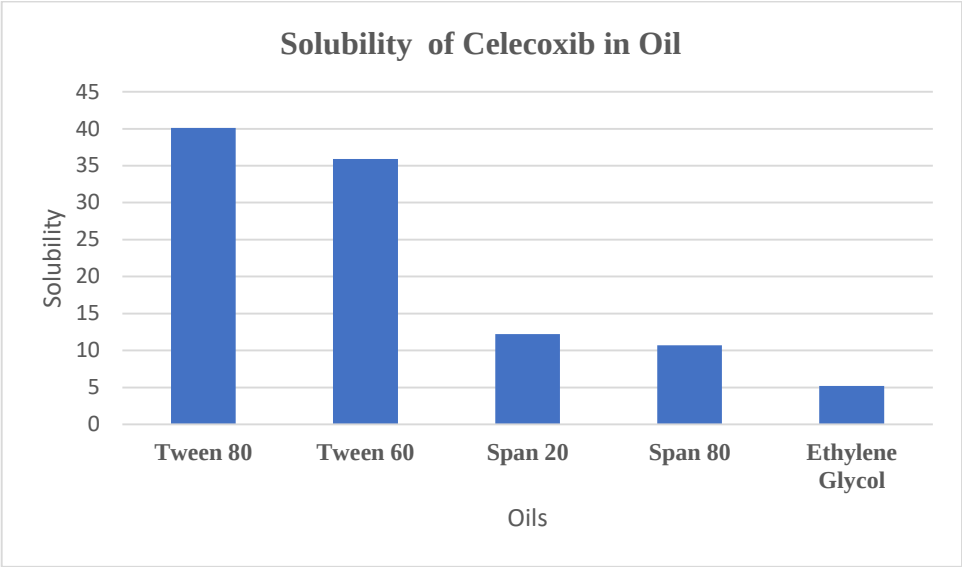

Figure 2: Solubility of Celecoxib in various oils

In various surfactants:

Table 6.5: Solubility of celecoxib in various surfactant

S.No.	Oil Media	Solubility (mg/g)
1.	Tween 80	40.1
2.	Tween 60	35.9
3.	Span 20	12.2
4.	Span 80	10.7
5.	Ethylene Glycol	5.2
6.	PEG	6.8

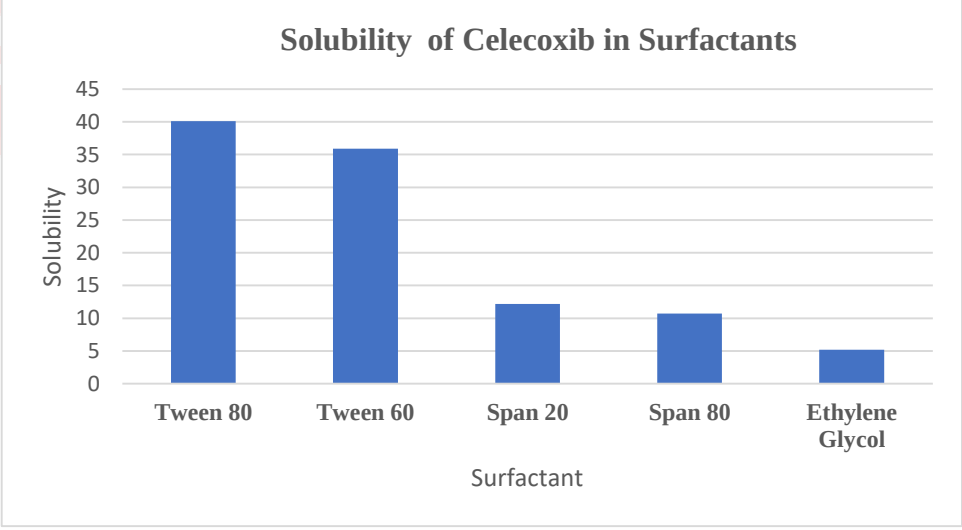

Figure 3: Solubility of Celecoxib in various surfactants

4. DETERMINATION OF λmax:

The absorption spectrum of pure drug was scanned 200-800 nm with 10µg/ml prepared in methanol. The λmax of pure drug (Celecoxib) was to be found to be 252 nm.

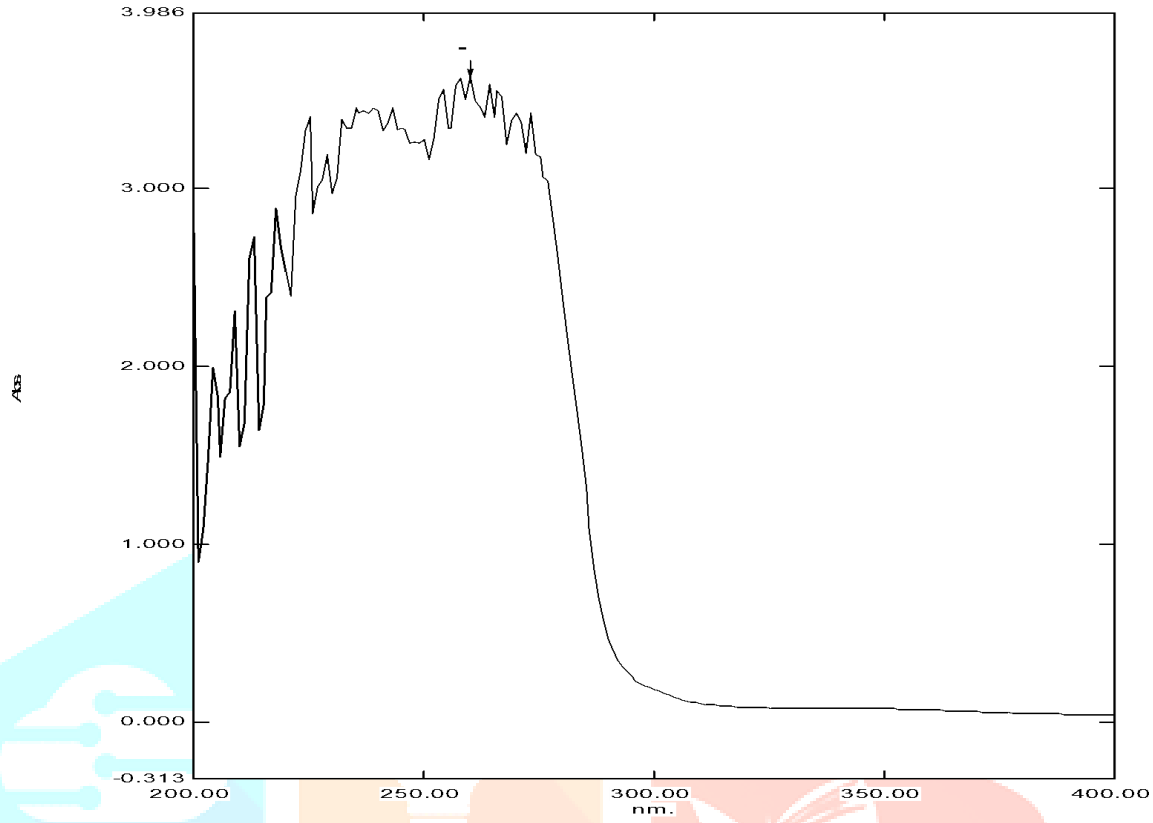

Figure 4: λ max of pure drug (Celecoxib)

5. PREPARATION OF STANDARD CALIBRATION CURVE:

Standard calibration curve of sertaconazole was carried out in methanol at 252 nm. The absorbance value obtained are shown in table. Using concentration and absorbance data, a beer lumbert's plot was obtained. The plot in the given figure. The R^2 value of Sertaconazole was found to be 0.996, which is near to1, which signifies linearity.

Table 6.: Standard calibration curve data of Celecoxib

S. No.	Actutal Concentration (µg/ml)	Absorbance (λ Max= 252)
1	0.5	0.083
2	1	0.143
3	1.5	0.221
4	2	0.273
5	2.5	0.348

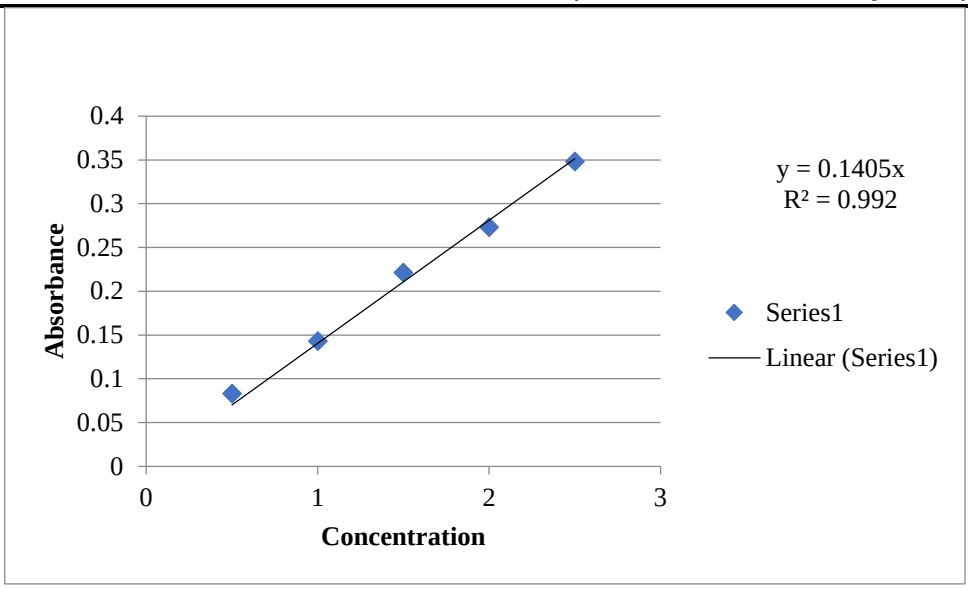

Figure 5: Calibration curve of celecoxib

6. MELTING POINT:

The melting point of celecoxib was obtained to be 162 ^{0}C, which compiles the indian pharmacopoeia so it was conformed that it is Celecoxib drug.

B. FORMULATION OF CELECOXIB EMULGEL:

Emulgel was designed according to a 2^3 factorial design so total five Celecoxib emulgel formulations were prepared. The optimization in the formulation batches were made mainly based on gelling agent and emulsifying agents. Composition of celecoxib emulgel show in table 6.7

Table 7: Composition of celecoxib emulgel formulation

S. No.	Ingredients (% w/v)	Formulation Code				
		F1	F2	F3	F4	F5
1.	Celecoxib (Mg)	100	100	100	100	100
2.	Carbapol 934 (Mg)	75	75	75	100	100
3.	Liquid Paraffin (ml)	7.5	7.5	7.5	7.5	7.5
4.	Ethylene Glycol (ml)	5	5	5	5	5
5.	Tween 80	0.5	1	0.5	1	0.5
6.	Span 20	1	1.5	1	1.5	1
7.	Methyl Paraben	40	40	40	40	40

8.	Ethanol	4	4	4	4	4
9.	Purified Water	q.s	q.s.	q.s.	q.s.	q.s.

C. EVALUATION PARAMETERS FOR CELECOXIB EMULSION:

1. Organoleptic characteristics:

Freshly prepared emulsions were investigated. Organoleptically for homogeneity, colour, and phase separation. All the emulsions were found to be homogenous, creamy white; no phase separation was observed.

2. Microscopic Studies:

Tween 80 and Span 20 based organogel were prepared by fluid filled structure mechanism by varying the composition of organogel. The microstructures of organogel were study by light microscope. The variation in microstructure of the organogel was studies as the gelator proportion in the oil was changed. The results was shown in figure

Figure 6: Microscopic Studies of Celecoxib Emulsion

Emulsions when subjected for centrifugation and followed by freeze thaw were found to be stable

3. Dye Test:

The prepared emulsion was found to be oil in water type emulsion.

4. Thermodynamic stability studies:

Emulsions when subjected for centrifugation and followed by freeze thaw were found to be stable.

Table 8: Thermodynamic Stability Studies

Formulation	**Centrifugation test (3500rpm for 30min)**	**Freeze-thaw test (2cycles NLT 48hrs)**
Emulsion	Passed	Passed

5. Robustness to dilution:

Emulsions when subjected to dilution with water and 6.8pH phosphate buffer were found to be stable.

Table 9: Robustness to dilution

Formulation	Distilled Water		6.8 pH Phosphate Bffuer	
	10 ml	100 ml	10 ml	100 ml
Emulsion	Stable	Stable	Stable	Stable

D. EVALUATION PARAMETERS FOR CELECOXIB EMULGEL:

1. Physical parameters:

All the formulations were evaluated for colour, homogeneity, phase separation and consistency. The formulations were found to be white in colour, homogenous, with no phase separation and smooth consistency.

Table 10: Physical parameter of celecoxib emulge

Formulation Code	Color	Phase Separation	Homogenity	Consistency
F1	White	No	Homogenous	Smooth
F2	White	No	Homogenous	Smooth
F3	White	No	Homogenous	Smooth
F4	White	No	Homogenous	Smooth
F5	White	No	Homogenous	Smooth

2. pH evaluation:

The pH value of prepared emulgel was found to be:

Table 11: PH measurement of Celecoxib Emulgel

S. No.	Formulation Code	pH Value
1.	F1	6.02
2.	F2	6.34
3.	F3	6.23
4.	F4	5.93
5.	F5	5.95

4. Rheology:

The viscosity values were determined by using Brookfield's viscometer emulgel formulation viscosities was found to be:

Table 12: Viscosity measurement of prepared emulgel (EG)

S. No.	Formulation Code	Viscosity (cps)			
		4 (RMP)	5 (RMP)	6 (RMP)	10 (RMP)
1	F1	88000	81600	74700	65700
2	F2	98000	86900	73500	59700
3	F3	65800	63000	56800	47600
4	F4	54700	51000	45600	38600
5	F5	53000	47900	39600	32500

5. Swelling index:

Swelling index for all the formulations were determined at various time intervals i.e., 10, 20 and 30minutes. Swelling index for all the formulations were in between 90-114. Among all formulations F4 formulation exhibited highest swelling index value

Table 6.13: Swelling Index of Celecoxib

Formulation Code	At 10min	At 20min	At 30min
F1	51.1	80.5	92.2
F2	47.9	78.1	96.8
F3	46.1	79.2	102.1
F4	57.6	91.2	113.6
F5	53.2	89.3	108.2

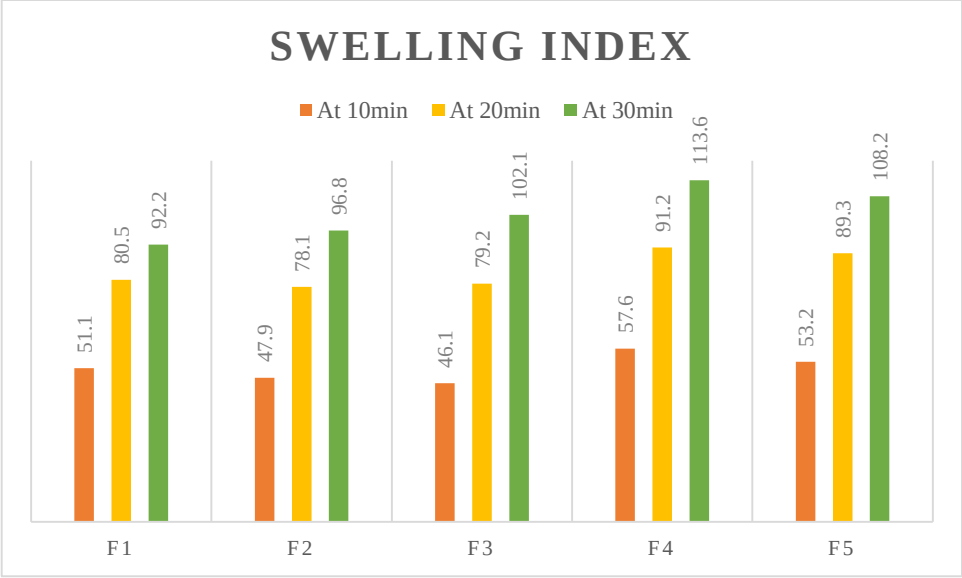

Figure 7: Graph for swelling index of Celecoxib emulgel

5. Drug content determination:

Drug content of all the formulations were carried out as per procedure stated in the methodology section. Drug content of all the formulations was found to be in the range 92.2 - 95.2 % as indicates in the table 14

Table 14: Drug content of prepared formulations

S. No.	Formulation Code	Drug Content (%)
1	F1	94.2
2	F2	92.2
3	F3	95.1
4	F4	94.3
5	F5	94.2

6. *In- Vitro* Diffusion Study:

Table 6.15 are displaying the Celecoxib in-vitro release characteristics for each of its several emulgel formulations. At the conclusion of the experiment, it was noted that all formulations had inflated as a result of diffusing medium penetrating into the gel matrix, which broke the gel matrix and allowed the drug to be released. Formulations F3 were shown to have a greater drug release. This can be the result of the smallest quantity of carbopol 934, the gelling agent. Compared to other emulgel formulations, the smallest amount of carbopol 934 causes the formulation to be less viscous. This results in a less packed gel matrix that is more easily broken, which increases the drug's release. At the conclusion of eight hours, the formulations F3 demonstrated cumulative drug release of 92.9%, as seen in Table 6.15. For every composition, an initial burst release and a control release were noted. Linear plots were produced when zero-order kinetics was used to plot the data. The zero-order values, which ranged from 0.997 to 0.994, had the highest regression coefficient values, indicating that zero-order kinetics was the mechanism of release for all formulations.

Table 15: Cumulative Amount of Celecoxib Diffused (%) from emulgel Formulations

S. No.	Time (Hr)	F1	F2	F3	F4	F5
1	1	10.7	9.7	11.8	10.6	9.4
2	2	17.3	15.9	22.6	21.3	20.1
3	3	28.9	26.1	34.3	33.1	32.8
4	4	39.1	39.8	46.4	44.5	43.1
5	5	47.8	51.5	55.7	54.7	54.3
6	6	59.2	63.8	68.3	67.1	67.3
7	7	68.2	76.8	79.2	77.1	78.3
8	8	78.1	87.7	92.9	89.5	86.9

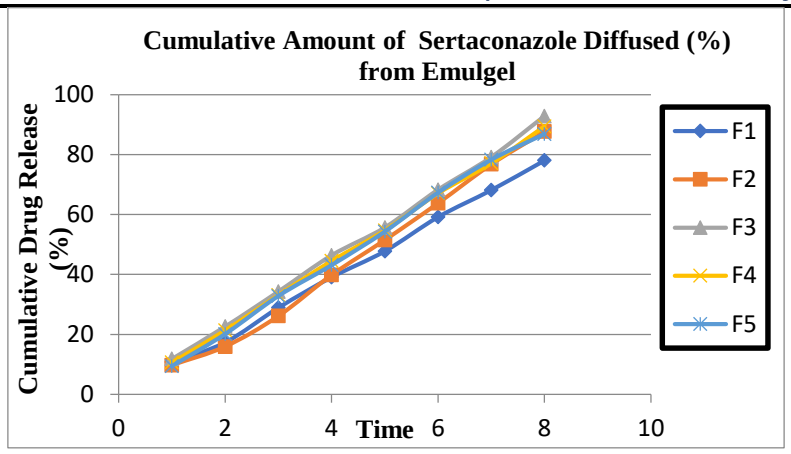

Figure 8: Cumulative Amount drug release of Celecoxib Diffused (%) from emulgel

Table 16: Drug release kinetics

Formulation Code	Drug release kinetics, correlation cofficient "R2"			
	Zero Order Model	First Order Model	First Order Model	Best Fit Model
	R2	R2	R2	
F1	0.9931	0.8543	0.9356	Zero Order
F2	0.9921	0.9131	0.9468	Zero Order
F3	0.9972	0.9576	0.9535	Zero Order
F4	0.9943	0.9486	0.9545	Zero Order
F5	0.9932	0.9345	0.9457	Zero Order

CONCLUSION:

The creation of emulgel based on Tween 80-PEG 400 is the subject of this investigation. In terms of overall product attributes, the emulgel formulations made with liquid paraffin, ethylene glycol, carbopol 934 and water outperformed the others. Drug release from the emulgel was found to be both prolonged and enhanced when compared to the commercial gel. The drug release formulations adhered to the zero ordered kinetic model, which included control release. Emulgels have the potential to be employed as a matrix for controlled delivery systems, according to in vitro diffusion experiments. Following an anti-fungal investigation, it was discovered that created emulgel (F3) had superior anti-fungal effectiveness compared to previous generated celecoxib oemulgel formulations. Nevertheless, additional clinical research is required to evaluate the effectiveness of this technique. After taking into account everything mentioned above, it was determined that the current research study's goal could be effectively met.

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