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Research Article

Formulation and Evaluation of Ketoprofen Emulgel

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ABSTRACT

The present study aimed to develop and evaluate a topical Ketoprofen emulgel for effective management of pain and inflammation. Ketoprofen, an NSAID, shows poor oral bioavailability and gastrointestinal irritation when taken orally. To overcome these limitations, emulgels were prepared using carbopol 940 as a gelling agent and liquid paraffin, Span 20, and Tween 20 as emulsifiers. The formulations were evaluated for pH, viscosity, spreadability, drug content, and in vitro release. The optimized batch exhibited good homogeneity, suitable pH, and sustained drug release for up to 8 hours, following Higuchi kinetics. The formulation remained stable under accelerated conditions. The study concludes that Ketoprofen emulgel provides a stable and effective topical system with improved local action and reduced systemic side effects.

INTRODUCTION

Inflammation is a natural defence reaction of living vascular tissues against internal or external injury. The term originates from the Latin word “inflammare,” meaning “to set on fire.” Its main purpose is to eliminate harmful agents, remove damaged cells, and initiate tissue repair. Although protective in nature, excessive or prolonged inflammation may lead to tissue damage or disease.

TYPES OF INFLAMMATION:

1. By duration: Acute, Subacute, Chronic
2. By phase: Alterative, Exudative, Proliferative
3. By cause: Trivial, Specific

Signs of Acute Inflammation:

1. Redness – dilation of blood vessels
2. Heat – increased blood flow
3. Swelling – fluid accumulation
4. Pain – due to tissue damage and mediators
5. Loss of function – from pain and swelling

CHRONIC INFLAMMATION:

Chronic inflammation is a long-lasting process that continues for weeks or months. It occurs when

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tissue damage and repair happen simultaneously due to persistent injury or infection.

TYPES:

1. Non-specific inflammation
2. Specific inflammation

MECHANISM ACTION OF NSAIDs

NSAIDs work by inhibiting the enzyme cyclooxygenase (COX), which converts arachidonic acid into prostaglandins, thromboxanes, and prostacyclins. Blocking COX reduces prostaglandin synthesis, thereby decreasing pain, fever, and inflammation.

GEL:

A gel is a semi-solid or semi-rigid system consisting of a liquid phase trapped within a three-dimensional network of particles or polymers. It behaves like a solid but contains liquid within its structure. The term "gel" comes from gelatine, meaning "to freeze or solidify."

In pharmaceutical formulations, gels are used to enhance viscosity, improve consistency, and allow easy application on the skin or mucous membranes. They can be single-phase (uniform dispersion) or two-phase (with small solid particles dispersed in a liquid).

Common gelling agents include Carbopol, Hydroxypropyl cellulose, Hydroxypropyl methylcellulose, Tragacanth, Pectin, and Natural agar. Gels are often hydrophilic and can be reversible or irreversible depending on the polymer used [1,2].

TYPES OF GELS:

Elastic gels: Gels that exhibit elasticity are known as elastic gels. When a force is applied, they change shape, but when the force is released, Flexible and return to shape after deformation .(e.g., gelatin, starch).

Non-elastic gels: Gels that are rigid, like silica gel, are considered non-elastic gels. These are prepared using the proper chemical process. The nonelastic gels are rigid and irreversible like elastic gels. (e.g., silica gel)[3].

EMULGEL

An emulgel combines the properties of an emulsion and a gel. It includes a hydrophilic (water) phase and a hydrophobic (oil) phase stabilized by an emulsifier. It provides a smooth, non-greasy surface and promotes rapid absorption through the skin. Emulgels are ideal for topical drug delivery, offering controlled drug release, better spreadability, and patient compliance.[4].

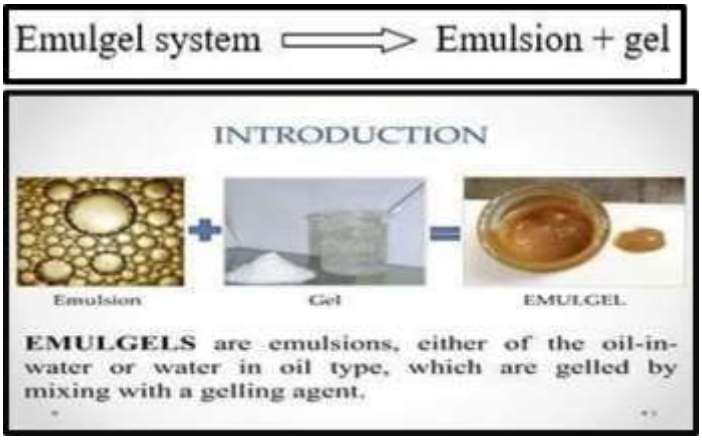


Fig no 1: - Emulgel

TYPES OF EMULGEL:

1. **Macroemulsion Gel** – Contains droplets larger than 400 nm; opaque and thermodynamically unstable but stabilized by surfactants.
2. **Microemulsion Gel –** Droplet size 100–400 nm; transparent, thermodynamically stable, but low viscosity; gelling agents (HPMC, Carbopol, guar gum) improve texture.
3. **Nanoemulgel –** Formed by combining nanoemulsions with gels (globule size <100 nm). Provides enhanced transdermal delivery, high drug loading, and faster therapeutic effect.[5]

GELLING AGENTS:

Gelling agents play a vital role in nasal drug delivery. They help make the formulation thicker, which means it stays in the nose longer and is less likely to drip out or be cleared away too. Materials that respond to the body's natural conditions to form a gel right where they're needed. These polymers are not only safe and biodegradable but also highly effective when used for delivering drugs directly to the brain through the nose. Smart polymers like poloxamer, chitosan, ethyl cellulose, pectin, and xylulose (which respond to temperature), Carbopol (which reacts to pH), and guar gum (which responds to ions) are especially useful. What makes them unique is their ability to change from a liquid (sol) to a gel when they come into contact with the body's natural environment— whether it's heat, pH levels, or even specific enzymes. This change makes it easier to administer the drug as a liquid, which then turns into a gel once inside the nasal cavity, helping the drug stay in place and be absorbed more effectively. For example, Pluronic (PF127), a thermoresponsive polymer, was used in a study to deliver selegiline hydrochloride—a drug for Parkinson's disease. The gel not only stuck to the nasal lining better but also released the drug steadily for up to 8 hours, significantly improving its effectiveness.

PROPERTIES OF GELLING AGENTS: -

Gels are semi-solid materials with characteristics ranging from soft and brittle to strong and tough.

1. **Hydration–** A completely dehydrated elastic gel can be regenerated by addition of water. - But once a nonelastic gel is freed from moisture, addition of water will not bring about gelation.
2. **Swelling –** Partially dehydrate elastic gels imbibe water when immersed in the solvent. – This causes increase in the volume of the gel and process is called Swelling.
3. **Syneresis –** Many inorganic gels on standing undergo shrinkage which is accompanied by exudation of solvent. This process is termed Syneresis.
4. **Thixotropy –** Some gels are semisolid when at rest but revert to liquid sol on agitation. – This reversible sol-gel transformation is referred to as Thixotropy. – Iron oxide and silver oxide gels exhibit this property. – The modern thixotropic paints are also an example [6].

The rationale of emulgel as topical drug delivery:-

Various semisolids and other preparations are available on the market for restoring the skin's fundamental role or pharmacologically altering an operation to the underline tissue 18. The formulations, such as lotions, ointments and creams have several drawbacks, including being sticky, having a low spreading coefficient, and having stability issues. Only transparent gels have exposure in pharmaceutical and cosmetic preparations due to overall limitations within the

semisolid preparations. As a result, an emulsion-based solution is used to address this limitation. Hence, the hydrophobic moiety of the drug should be incorporated and provided through gels. Drug/oil/water emulsions may be used to integrate hydrophobic drugs into emulgel. Since solubility acts as a barrier, most drugs cannot be inserted directly into gel bases, causing problems during drug release. The emulgel system helps to incorporate a hydrophobic drug into the oil phase, after which oily globules are easily dispersed into the aqueous phase, resulting in an oil/water emulsion. The emulsion can be mixed into the gel base. This may result in enhanced drug stability and release over simply incorporating the drug into the gel base[7].

ADVANTAGES:

1. Emulgel matrix releases the incorporated drugs in a controlled manner over prolonged period. This result in sustained therapeutic effect, reduce dosing frequency and improved patient compliance.
2. Hydrophilic-lipophilic balance in emulgels helps in solubilizing drugs with poor aqueous solubility. This enhances absorption and bioavailability of such drugs.
3. It formulation provides a stable environment protecting labile drugs, peptides and proteins from degradation. This helps improving their effectiveness and stability. Emulgel bases provide a smooth, cushioned and emollient feel. this leads to better cosmetics elegance, spreadability and non-greasy feels which enhances patients' acceptance.
4. It can be designed as solid, semisolid or liquid formulations based on required consistency and dose. This permits flexible choices of dosage forms for various applications.
5. It matrix allows incorporation of drugs with synergistic effects or different mechanism of action. This provides combine therapeutic benefit in single formula [8].

KETOPROFEN

Ketoprofen is a non-steroidal anti-inflammatory drug. (NSAIDS)

Chemical name: - 2-(3-benzoylphenyl)-propionic acid

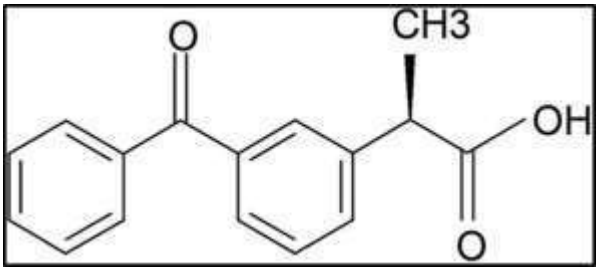


Fig No 2: - Structural formula of Ketoprofen

Molecular formula: - C16H14O3

Molecular Weight: 254.29

It has pKa of 5.94 in methanol: water (3:1) and an n-octanol: water partition coefficient of 0.97 (buffer -7.4)

Ketoprofen is a white or off white, odourless, non-hygroscopic, fine to granular powder, melting at about 95° C. It is freely soluble in ethanol, chloroform, acetone, and ethers and soluble in benzene and strong alkali, but practically insoluble in water at 20° C. Ketoprofen has a half-life of 1.5 hrs and the bioavailability of ketoprofen is 86%[9].

MECHANISM OF ACTION OF KETOPROFEN

It inhibits cyclo oxygenase enzymes both COX1 and COX2.These cyclooxygenase enzyme catalyses the synthesis of prostaglandins from arachidonic acid in the tissue. These inhibition produces its analgesic, antipyretic and anti-inflammatory effects. It can also stabilize the lysosomal membrane. It is a Non-Steroidal Anti-

Inflammatory Drug. It is a propionic acid derivative.

Pharmacodynamics:

Class: Nonsteroidal Anti-inflammatory Drug (NSAID) — Propionic acid derivative.

Other Effects: Inhibits leukocyte migration and decreases bradykinin activity.

May stabilize lysosomal membranes and reduce vascular permeability.

Pharmacokinetics:

Absorption- Well absorbed orally; bioavailability ≈ 90%. Peak plasma concentration in 0.5–2 hours after oral dose.

Distribution- Extensively bound to plasma proteins (~99%). Widely distributed in tissues, including synovial fluid (important for arthritis).

Metabolism- Primarily metabolized in the liver by conjugation (glucuronidation).

Excretion- Excreted mainly in the urine as glucuronide conjugates (≈80%).

Half-life (t½)- 1.5 to 4 hours (short half-life, so often given 2–3 times/day)[10].

METHODOLODY:

Ketoprofen and Carbopol 934, HPMC K15M are obtained as a gift sample from SVCP Laboratory, Warora, India. All other chemicals used were of analytical grade.

Preparation of Ketoprofen emulgels:

- Ketoprofen emulgel was prepared using Carbopol 940, HPMC K15M as gelling agents.
- The gels in formulations were prepared by dispersing Carbopol or HPMC in purified water with constant stirring at a moderate speed and then the pH is adjusted to around 6 using tri ethanol amine.
- The oil phase of the emulsion was prepared by dissolving Span 20 in light liquid paraffin while the aqueous phase was prepared by dissolving Tween 20 in purified water.
- Methyl and propyl parabens were dissolved in propylene glycol whereas drug was dissolved in ethanol and both solutions were mixed with the aqueous phase.
- Both the oily and aqueous phases were separately heated to 70° to 80°C; then the oily phase were added to the aqueous phase with continuous stirring until cooled to room temperature.
- Finally, the emulgel was prepared by mixing the both gel and emulsion in 1:1 ratio[11].

Table No. 1:- Components of Ingredients

Ingredients (%w/w)	F1	F2	F3	F4
Ketoprofen	1	1	1	1
Carbopol 934	0.25	0.5	-	-
HPMC K15M	-	-	2.5	5
Liquid paraffin	7.5	7.5	7.5	7.5
Tween 20	0.5	0.5	0.5	0.5
Span 80	0.5	0.5	0.5	0.5
Propylene glycol	5	5	5	5
Ethanol	2.5	2.5	2.5	2.5
Methyl paraben	0.003	0.003	0.003	0.003
Propyl paraben	0.001	0.001	0.001	0.001
Water	Q.S.	Q.S.	Q.S.	Q.S.

Fig No.3: - Preparation of aqueous phase and oil phase

EVALUATION OF EMULGEL

Physical evaluation of emulgels

The prepared ketoprofen emulgel formulations were inspected visually for their colour, clarity, homogeneity, pH and viscosity. All developed gels were tested for colour, clarity and homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance to identify the presence of any aggregates. The pH values of 1% aqueous solutions of the prepared emulgel were measured by a pH meter (Digital pH meter, Systronics). The pH of emulgel is adjusting to avoid the risk of irritation upon application to the skin and the acceptable pH is around 5.5. Viscosity measurements were carried out at room temperature (25- 27°C) using a Brookfield viscometer[11].

1. **Melting Point Determination:** The melting point of ketoprofen was determined by using the capillary tube method[12].
2. **Spreadability:** This is an important criterion for an Emulgel is that it should possess good spreadability. Spreadability is a term expressed to denote the extent of area on which the gel readily spreads on application to the skin[13].

The spreadability of various formulations from F1-F4 was mentioned in Table 4: Spreadability determination. It shows that the F2 formulation shows a higher spreading coefficient as compared to other formulations. Spreadability was then calculated by using the formula:

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

Where, S = Spreadability; M = Weight tide to upper slide; L = Length of glass slide; T = Time taken to separate the slide completely from each other[14,16].

3. Swelling index: To determine the swelling index of prepared emulgels, 1 gm of gel is taken on porous aluminum foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N sodium hydroxide. Then samples were removed from beakers at different time intervals and put it on dry place for some time after it reweighed. Swelling index is calculated as follows:

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

Where (SW) % = Equilibrium percent swelling, Wt = Weight of swollen emulgel after time t, Wo = Original weight of emulgel at zero time [15,16].

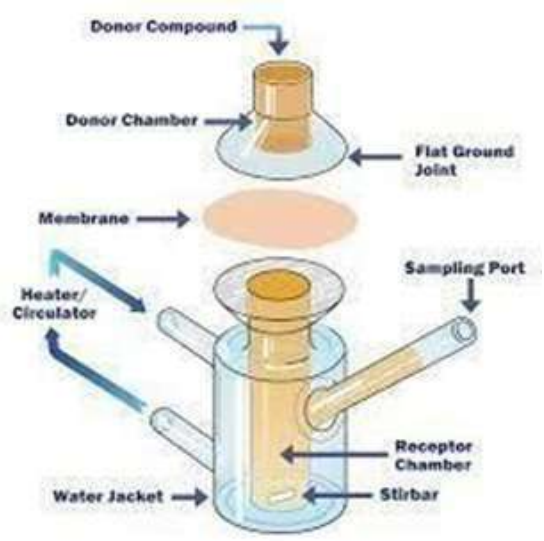
4. pH: pH values of all prepared formulations ranged from 5.5 to 6.5 near skin pH i.e., 5.5[17].

5. Viscosity: The viscosity of gel during preparation and stability should be given an almost importance [19]. Using Falling sphere viscometer the viscosity of different formulations were measured at 25°C[20].

6. Determination of drug content: The prepared emulgels were tested for the drug content uniformity. Accurately weighed quantity of formulation was transferred to a 100 ml volumetric flask containing 50 ml of methanol and allowed to stand for 5 h with intermittent sonication to ensure complete solubility of the drug. The mixture was made up to volume with methanol. The solution was suitably diluted and the absorption was determined by UV-Visible spectrophotometer at 260nm[18,16].

7. Stability studies: Formulation were kept at 40°C, 25°C & room temperature for 45 days & evaluated for following parameters[18,21].

8. In -Vitro Diffusion Study: The test was performed by using Franz diffusion cell. Egg membrane was plant between donor and receptor compartment. The receptor compartment was filled with 100 ml of 7.4 pH phosphate buffer maintained at room temperature and stirred by using magnetic stirrer. Pre weight (1.0 gm) emulgel was taken on the egg membrane. The sample (5ml) was collected for an interval of every one hour and analyse for drug content by UV visible spectrophotometer 1700 at 261nm after appropriate dilution[16,18].



No.4: - Franz Diffusion cell

RESULT AND DISCUSSION

Physical evaluation of Ketoprofen emulgel

Table No. 2: - Physical evaluation tests

Formulations	Clarity	Colour	Homogeneity	pH	Viscosity (cps)
F1	+++	Off White	Good	5.1+/- 0.26	11200
F2	+++	Off White	Good	5.2+/- 0.16	13500
F3	+++	Off White	Good	5.3+/- 0.31	9400
F4	+++	Off White	Good	5.5+/- 031	9750

Melting point: -

The Melting point was determined using the capillary method and it was found to be as per the following

Table No. 3: Melting point determination

Sr.no	Formulation	Physical constants
1.	F1	141°C
2.	F2	140 °C
3.	F3	130 °C
4.	F4	132 °C

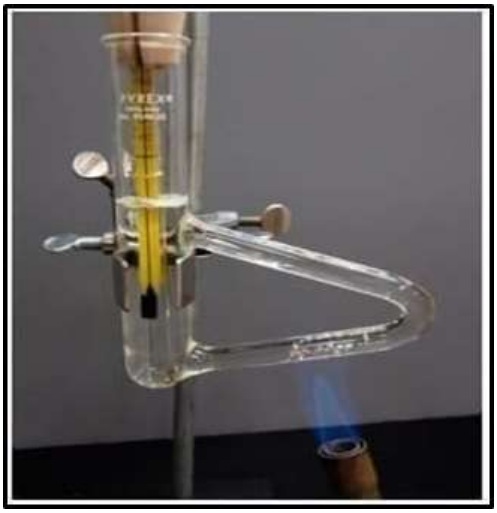


Fig No.5: - Melting point

pH

The pH of ketoprofen emulgel formulation of F4 was found to be 5.5.

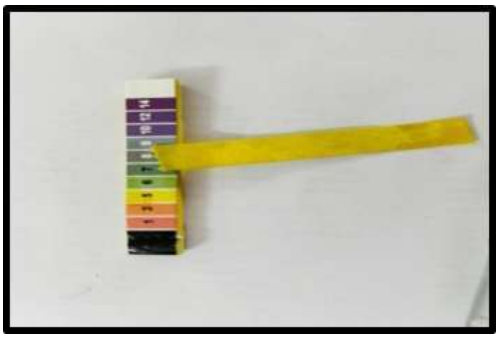


Fig No 6: - pH

Skin irritation test

No irritation occurred.

Centrifugation

The prepared emulgel were subjected to centrifugation test to determine the physical stability and there was no phase separation or creaming observed during this test which indicated that the formulation.

Viscosity

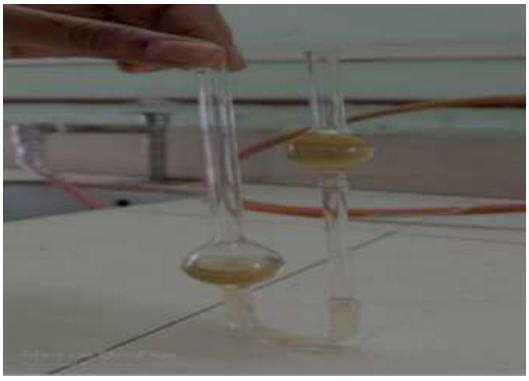


Fig No 7: - Oswald Viscometer

Spreadability:

Fig No 8: - spreadability

Table No. 4:- Spreadability test

Sr no	Formulation	Spreadability
1	F1	55cm
2	F2	65cm
3	F3	50cm
4	F4	70cm

Swelling index

Table No.5:- Swelling Index

Sr no.	Formulation	Swelling index
1	F1	10
2	F2	14
3	F3	15
4	F4	17

Fig No .9: - swelling index

Stability studies for f4 emulgel formulation-physical evaluation

Table No. 6:- Stability study test

Time Period	Clarity	Homogeneity	pH	Spreadability	Viscosity	% Drug content
Before storage	+++	Good	5.5+/- 0.31	70+/-0.64	9750+/-11	99.87+/- 0.50
After 1 months	++	Good	5.00+/- 0.18	69+/-0.48	9749+/-11	99.12+/- 0.36

In vitro % Drug Release for Carbopol

Table No. 7:- In vitro % drug Release for Carbopol

Sr. No	Time (min)	Formulation F1	Formulation F2
1	0	0	0
2	20	10	15
3	40	25	20
4	60	40	35
5	80	61	55
6	100	75	70
7	120	97	95

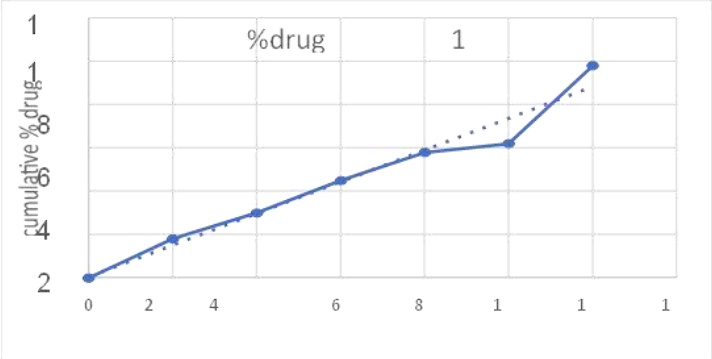


Fig No.10:- Batch 1

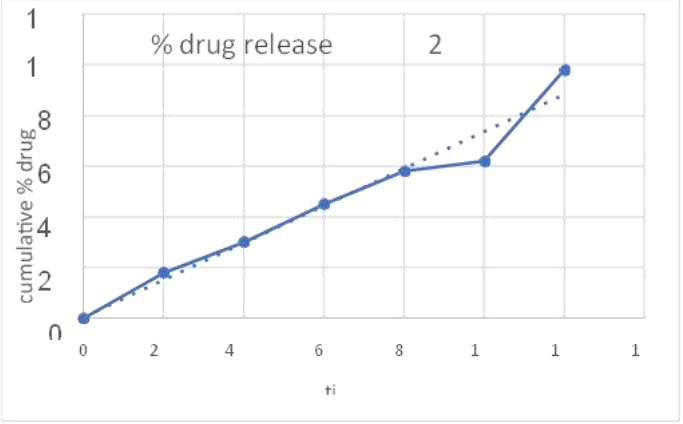


Fig No.11:- Batch 2

In vitro % Drug Release for HPMC

Table No. 8:- in vitro % drug Release for HPMC

Sr.no	Time (min)	Formulation F3	Formulation F4
1	0	0	0
2	20	10	18
3	40	20	30
4	60	75	45
5	80	63	58
6	100	78	62
7	120	96	98

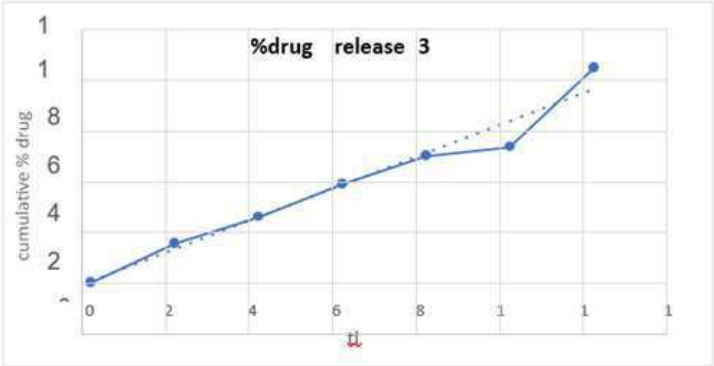


Fig No. 12:- Batch 3

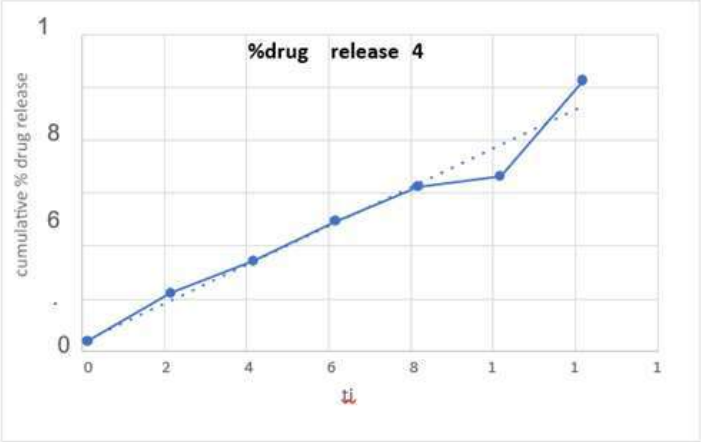


Fig No. 13:- Batch 4

CONCLUSION

To survey of the various literatures for selection of research domain and studied to get appropriate information about selected domain. Main aim of this study to formulation and evaluation of emulgel Ketoprofen, Emulgel was prepared by using super gelling agents i.e. Carbopol and HPMC. Prepared Emulgel of Ketoprofen (F1, F2, F3, F4,) was evaluated for test such as spreadability, viscosity, pH, swelling index, Skin irritancy, centrifugation, In vitro % drug Release, % drug content etc. In Conclusion, batch F4 showed the best result as compared to others. HPMC showed good absorbing properties in skin.

The topical emulgel of ketoprofen (F1, F2, F3, F4,) containing HPMC (hydroxy Propyl methyl cellulose) and Carbopol were use as gelling agent in the 1:1 ratio was prepared and evaluated. Where F4 shows better absorbance of drug. About 98.46% was released in 8 hours. There for based

on evaluation parameter and in vitro Drug release profile, F4 containing HPMC is optimised as the best formulation with dissolution rate.

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