Research Article

Formulation and Evaluation of Ibuprofen Gel

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ABSTRACT

Topical drug delivery systems are gaining increase in the popularity and several drugs have been successful delivered by this route for both local & systemic action. In recent years most NSAIDs have been designed to deliver the drug in the form of topical gels, to avoid gastrointestinal irritation, to overcome "first pass" effect and to maximize the drug concentration at the site of action. Ibuprofen have been shown to have potent analgesic effect & anti-inflammatory activities, similar to Indomethacin and Diclofenac and due to its preferential CO-X blockade, it has been better safety than conventional NSAIDs with respect to the adverse effects on gastrointestinal & cardiovascular system. Ibuprofen used in the treatment of osteoarthritis, rheumatoid arthritis, acute lumbago, & dental pain condition. Gels have a better potential as a vehicle to administer drug topically in comparison to ointment, because they are non-sticky requires low energy during the formulation. The formulated gel was evaluated for drug content, pH, spreadability, entrapment efficiency etc. Formulation of ibuprofen gel was prepared using HPMC/CMC, propylene glycol is used as permeation enhancer.

Keywords: Ibuprofen, gel, HPMC, triethanolamine, propylene glycol, evaluation.

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INTRODUCTION

Topical medications are applied on to the body to treat various ailments. Most commonly, a topical drug delivery system is applied to the skin, where the medicines either treat only the area of application or is absorbed into the blood stream through the dermis. Topical drug delivery systems are localized drug delivery system for local delivery of therapeutic agents via skin to treat the cutaneous disorders. These systems are generally used for local skin infection. The formulations are available in different forms, like from solid through semi solid to liquid.

Gels (sometimes called jellies) are semisolid systems consisting of either suspension composed of small inorganic particles or large organic molecules interpenetrated by a liquid. The gel mass consists of a network of small discrete particles and it is referred as magma. Both gels and magmas may be thixotropic forming semisolid after standing and becoming liquid when agitated. They should be shaken before use to ensure homogeneity and should be labeled to that effect (topical suspension).

IBUPROFEN gel on your skin usually takes 1 to 2 days to works, for arthritis it may take up to 7 days on the painful joint in order to feel the full effect. A gel is solid or semisolid system of at least two constituents, consisting of a condensed mass enclosing and interpenetrated by a liquid. The gels are used to achieve optimal cutaneous and percutaneous drug delivery. They can avoid gastrointestinal drug absorption difficulties caused by gastrointestinal pH. The main advantage of gel over a tablet is that it prevents first pass metabolism and also patient compliance is high and is to administer.[1]

The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to promptly achieve and then maintain the desired drug concentrations. The route of administration has a significant impact on the therapeutic outcome of a drug. Skin is one of the most readily accessible organs on human body for topical administration and is main route of topical drug delivery system. Topical delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorders (e.g. acne) or the cutaneous manifestations of a general disease (e.g. psoriasis) with the intent of containing the pharmacological or other effect of the drug to the surface of the skin or within the skin. Semi-solid formulation in all their diversity dominate the system for topical delivery, but foams, spray, medicated powders, solutions, as well as medicated adhesive systems are also in use.

- External topical that is spread, sprayed, or otherwise dispersed on to cutaneous tissues to cover the affected area.

- Internal topical that are applied to the mucous membrane orally, vaginally or rectal tissues for local activity.[2]

MATERIALS AND METHODS

Materials

Ibuprofen was procured from Yarrow chemical products, Mumbai, HPMC was procured from HI MEDIA Bangalore, Karnataka, Propylene glycol was procured from Spectrum reagents & chemical.pvt.ltd, kochin, Triethanolamine was procured from Merck specialties, pvt.ltd. worli, Mumbai, Propyl paraben was procured from Loba chemicals, colaba, Mumbai. All the chemicals and reagents used were of analytical grade.

Methods: Hydration and Precipitation Method

- Dissolve required amount of drug (ibuprofen) in propylene glycol by warming at about 40-50°C in a beaker
- Add HPMC into stirring for 15 min and mixture is heated to 90°C by constant stirring.
- Cool the mixture at room temperature by stirring for 15-30 minutes.
- Add 2 drops of triethanolamine and then add required quantity of preservative (paraben)[3]
- composition of Ibuprofen gel given in Table 1

Table 1: Composition of Ibuprofen gel

Formulation Code	Ibuprofen (mg)	HPMC (gm)	Propylene Glycol (ml)	Triethanolamine (ml)	Propyl Paraben (mg)
F1	10	1.5	1	0.1	200
F2	20	2.5	1	0.1	200

Characterization of GEL

Gels were evaluated for their clarity, pH, spreadability, drug content, *in vitro* diffusion studies.

Physical stability:

Inspected visually for its color, homogeneity, consistency.

PH measurement:

PH values of 1% aqueous solutions of the prepared gels were measured by pH meter.[4]

Spreadability:

For the determination of spreadability, excess of sample was applied in between two glass slides and was compressed to uniform thickness by placing 1kg weight for 5 min. Weight was added to the pan. In which the upper glass slide moves over to the lower plate was taken as measure of spreadability.

Spreadability coefficient was determined by the formula

S=Ml/t

M- mass in gram

t-time in seconds

l- length moved on the glass

Homogeneity:

All developed gels were tested for homogeneity by visual inspection after the gels have been set in the container for their appearance and presence of any aggregate.[4]

Entrapment Efficiency:

Percentage entrapment efficiency was studied by centrifuge method. 100mg of gel formulation was weighed and dispersed in 10ml of PBS pH 7.4. The obtained gel dispersion was centrifuged at 10000 rpm for 30 min. The clear fraction (supernatant) was used for the determination of the free drug. The drug concentration in the resulting solution was assayed by UV spectrophotometer at absorption maxima. The percentage of drug encapsulation was calculated by the following equation[5]:

$$\text{Entrapment Efficiency \%} = \frac{\text{Total amount of drug} - \text{Unentrapped drug} * 100}{\text{Total amount of drug}}$$

Drug content:

Drug content of gel was determined by dissolving accurately weighed 1gm of gels in methanol. After suitable dilution absorbance was recorded by using UV visible spectrophotometer at 271.6nm.[6]

in vitro drug permeation study

The *in vitro* drug release studies were conducted by using Franz diffusion assembly.10 mg equivalent gel preparation was placed on dialysis membrane between donor and receptor compartment of diffusion cell assembly. The receptor compartment was filled with PBS pH 7.4, magnetically stirred at 200 rpm. The drug content was determined by collecting 2ml receptor fluid every hour. The volume withdrawn was replaced with equal quality of fresh buffer. After suitable dilution, the sample was a analyzed spectrophotometrically at λmax.[7]

RESULTS AND DISCUSSION

Table 2 shows the color and physical state for each formula.

Table 2: Physical Appearance of gel formulation

Formulation	Colour	Homogenity	Consistency
F1	Transparent yellow	good	Semi-solid
F2	Transparent yellow	good	Semi-solid

pH and spreadability

The pH of the formulation was determined in order to investigate the possibility of any side effects *in vivo.* The pH was found between 7-7.5 (Table 3). This range is within the physiological skin surface pH. The spreadability of each formulation was determined and it is found within the range of 20-28gcm/sec (Table 3).

Entrapment Efficiency (EE)

Entrapment efficiency was studied for seven formulations to find the best formulation in terms of entrapment efficiency. The entrapment efficiency was found between 60.5 to 93.6% (Table 3). The EE was found to be higher with formulation No F1.

Table 3: pH, Spreadability, Entrapment Efficiency and Drug content of Ibuprofen gel

Formulation code	Ph (*)	Spreadability (g cm/sec±SD)*	% Entrapment Efficiency	Drug content (%±SD)*
F1	7.45±0.03	28.9±0.05	92.7±0.3	93.5±0.35
F2	7.29±0.03	22.67±0.3	62.5±0.35	75.35±0.24

Drug content

Uniformity in content of gel was confirmed to assure uniformity in dosages. The results were reported in table 3. The drug content of the all formulation was found between 72.75 to 93.5%.

In vitro drug release

The diffusion method was used to investigate the *in vitro Ibuprofen* release from gels. The percentage of the drug released after 7 hrs from the gel vesicles are shown in table no 4. From the diffusion study it was found that formulation F1 shows the highest drug permeation (72.01%) as demonstrated in figure 1.

Table 4: *In vitro* release profile of Ibuprofen gel

Time (hr)	% CDR	
	F1	F2
0	0	0
1	14.02	14.43
2	21.50	21.45
3	32.47	27.49
4	49.05	30.15
5	57.29	45.23
6	64.31	56.01
7	72.01	63.45

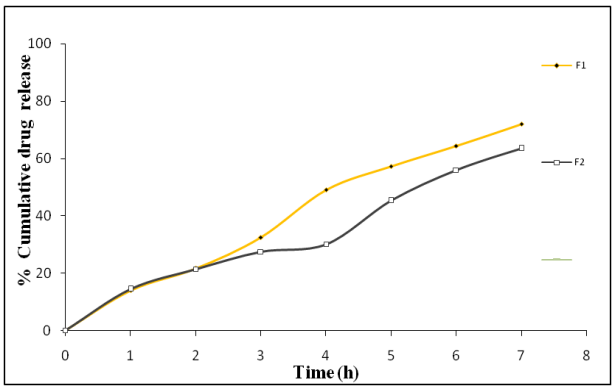

Figure 1: *In vitro* drug release profile for Ibuprofen formulation

CONCLUSION

In present study ibuprofen gel was prepared using hydration and precipitation method and used in the treatment of Analgesics, commonly known as painkillers, are substances which work in various ways to relieve different types of pain experienced in the body. Formulation F1 selected as optimized formulation and shows highest drug permeation of 72.01%, it also shows good sustained release properties.

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