



Design, Formulation and Characterization of an Emulgel Containing Microcapsules of NSAID Drug

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ABSTRACT

The emulgel, armed with microcapsules containing a nonsteroidal anti-inflammatory drug (NSAID) tailored for arthritis, presents a precise, regulated, and prolonged therapeutic avenue, holding the promise to elevate patient outcomes while mitigating the common side effects linked to the oral NSAID route. This emulgel, boasting microcapsules, orchestrates a methodical dissemination of the NSAID medication across time. This deliberate, protracted release extends the therapeutic impact, diminishing the need for frequent applications and curbing the side effects associated with sudden drug liberation. The artful engineering of microcapsules adds a layer of precision, facilitating the targeted delivery of the drug to the affected joints. This innovative formulation stands out in the realm of drug delivery, amalgamating the merits of both gels (easy spreadability and application) and emulsions (impressive stability and sustained release). Within this framework, microcapsules emerge as the unsung heroes, adept at encapsulating NSAID drugs, shielding them from degradation, and orchestrating a gradual and controlled release. The microcapsules were prepared by the conventional solvent evaporation method at room temperature (25-27°C) with different ratio of drug and different polymer (1:1, 1:2, 1:3). A total of nine formulations were formulated, where F6 showed spherical shape of microcapsules with good encapsulation efficiency, high recovery test and bet stability when dispersed in emulgel. By achieving a pH balance that corresponds to the skin's natural acidity, potential irritations are minimized, promoting a more comfortable and user-friendly experience with the emulgel.

Key words: Etoricoxib, Microcapsules, 2hydroxy propyl-beta cyclodextrin, Emulgel, Ethyl cellulose.

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INTRODUCTION

Ongoing research in the field of emulgel with microcapsules is focused on improving formulations to enhance drug release profiles and therapeutic efficacy [1]. Emulgel formulations containing microcapsules, particularly for NSAIDs used in arthritis treatment, offer controlled, sustained drug release, potentially improving patient outcomes and reducing the side effects common with oral NSAIDs. This sustained release ensures prolonged therapeutic effects, reduces the frequency of application, and minimizes abrupt drug release side effects. Microcapsules can also be engineered to target affected joints more effectively. These formulations combine the benefits of gels—such as spreadability and ease of application—with the stability and sustained release provided by emulsions. Microcapsules in the emulgel protect the active NSAID from degradation, allowing for controlled release and enhanced drug targeting [2-4]. In both pharmaceutical and cosmetic industries, emulgel with microcapsules offer a strategic formulation that optimizes stability, release kinetics, and the overall performance of active ingredients. The gel matrix plays a crucial role in providing a stable environment for the microcapsules, influencing the formulation's texture, rheology, and overall effectiveness. This combination enhances the formulation's versatility and functionality. Compared to traditional gels, incorporating microcapsules into an emulgel matrix offers unique advantages, such as improved bioavailability, controlled release, and targeted delivery. Microencapsulation protects the active ingredients, improving their solubility and absorption by the target tissues. Additionally, microcapsules can modify the gel's rheological properties, allowing for customized viscosity and spreadability, which can be valuable for combination therapies where multiple active ingredients are needed. Topical applications of emulgel microcapsules allow for localized delivery of active ingredients, offering targeted therapeutic effects, such as treating skin conditions, joint pain, or muscle inflammation. This approach also reduces skin irritation by preventing direct contact between the active substance and the skin, resulting in a milder formulation. The emulsion component of the emulgel provides a base for incorporating both hydrophobic and hydrophilic active ingredients, contributing to the formulation's texture and consistency [5-12]. The gel

component enhances the product's rheological properties, structure, and spreadability, contributing to overall stability. Microcapsules, embedded within the gel matrix, offer controlled and sustained release of the active ingredients, ensuring consistent therapeutic efficacy while protecting the encapsulated substances from degradation. This stability is key to maintaining uniform distribution and preventing separation within the product.

MATERIALS AND MEHODS

MATERIAL: Etoricoxib (East African Overseas, India), 2hydroxy propyl-beta cyclodextrin(East African Overseas, India), Chloroform (Merck international, Ahmedabad), Tween 20 (Swadesh life science, Ahmedabad), Ethyle cellulose (Global chemie, Mumbai).

METHODS: The selected polymers were dissolved in an organic solvent (e.g. dichloromethane) to create a homogeneous polymer solution. The active ingredient was added to the polymer solution and uniformly dispersed. The polymer-drug solution was then poured into an aqueous phase containing a surfactant or emulsifier (e.g. Tween 80). The mixture was stirred vigorously to form an oil-in-water emulsion, where the organic solvent formed droplets containing the polymer and active ingredient. Rotation speed of the Rotary evaporator with stirring mechanism was adjusted to a moderate level to increase the surface area of the liquid droplets, promoting efficient solvent evaporation. The water bath was heated to a temperature 20-40°C below the boiling point of the organic solvent at atmospheric pressure, controlling the evaporation rate and preventing the formation of large pores in the microcapsules. The rotation mechanism was then activated to ensure consistent mixing and droplet formation. The process continued until most of the solvent had evaporated, leaving behind hardened microcapsules suspended in the aqueous phase.

Table 1: Microcapsules formulation of NSAID

Formulation Code	F1	F2	F3	F4	F5	F6	F7	F8	F9
Etoricoxib	10g	10g	10g	10g	10g	10g	10g	10g	10g
2hydroxy propyl-beta cyclodextrin	10g	20g	30g	-	-	-	-	-	-
Ethyle cellulose	-	-	-	10g	20g	30g	-	-	-
Polyvinyl Alcohol	-	-	-	-	-	-	10g	20g	30g
Dichloromethane	50ml	50ml	50ml	-	-	-	-	-	-
Chloroform	-	-	-	50ml	50ml	50ml	-	-	-
Acetone	-	-	-	-	-	-	50ml	50ml	50ml

Microcapsules characterization [13-16]

Microcapsules recovery test: The assessment of microcapsule recovery was conducted by contrasting the weight of the acquired microcapsules against the combined mass of the active ingredient and coating materials employed in the formulation under consideration.

$$\% \text{ Microcapsules recovery test} = \frac{\text{Microcapsules weight}}{\text{Microcapsule material foring weight}} \times 100$$

Microcapsules morphology and physical appearance: Microcapsule samples were placed on a sample holder and coated with gold particles using a fine coater to improve conductivity and imaging quality. Observations were made at 500x magnification, allowing detailed examination of microcapsule morphology and size. The gold coating enhanced conductivity for better SEM imaging, indicating the use of a high-performance SEM model for precise and detailed observations.

Encapsulation efficiency: The microcapsules were dissolved or broken down using an appropriate solvent, and the encapsulated drug is extracted. The amount of drug released was quantified using techniques like UV spectroscopy. Determining the entrapment efficiency of microcapsules involved a specific procedure. Isolated an encapsulated substance from microcapsules by dissolution process and followed by following formula:

$$\text{Encapsulation efficiency} = \frac{\text{Amount of drug entrapped}}{\text{Total amount of drug added}} \times 10$$

Swelling index: A sample of dry microcapsules was weighed, and microcapsules were immersed in a

solvent or exposed to specific conditions until they reached equilibrium.

The swelling index was calculated using the formula:

$$\text{Swelling index}(\%) = \frac{W_1 - W_0}{W_0} \times 100$$

Where W_0 was the initial weight and W_1 was the weight after swelling.

Preparation of emulgel consisting microcapsules of NSAID drug: The formulation process involved preparing a Carbopol gel by dispersing varying concentrations (1%, 1.5%, 2%, 2.5%) of Carbopol 934 and 940 in water and soaking it overnight. An emulsion was created by separately preparing the oil phase (Span 20 in olive oil) and aqueous phase (Tween 20 in water and ethanol), both heated to 200°C. Methylparaben and propylparaben were dissolved in propylene glycol, then added to the aqueous phase. The oil and aqueous phases were combined, and the final emulsion was blended with the Carbopol gel. Triethanolamine was mixed into the gel base using a homogenizer at 1500 rpm for 45 minutes. The mixture was adjusted to 50g with water. Microcapsules were gradually added to the gel base using gentle stirring to ensure uniform distribution without damaging the microcapsules, resulting in a homogeneous dispersion.

Table 2: Emulgel containing microcapsules

Formulationcode	F1	F2	F3	F4	F5	F6	F7	F8	F9
Microcapsules	5g	5g	5g	5g	5g	5g	5g	5g	5g
Olive oil	2 ml	2 ml	2 ml	2 ml	2 ml	2 ml	2 ml	2 ml	2 ml
Tween 20	1 ml	1 ml	1 ml	1 ml	1 ml	1 ml	1 ml	1 ml	1 ml
Span 20	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
Propylene Glycol	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
Methyl Paraben	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg
Propyl Paraben	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg
Carbopol 934	1.0 %	1.5%	2%	2.5%	3%	-	-	-	-
Carbopol 940	-	-	-	-	-	1.0 %	1.5%	2%	2.5%
Ethanol	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
Water (q.s)	50g	50g	50g	50g	50g	50g	50g	50g	50g

Evaluation of emulgel consisting microcapsules of NSAID drug [17, 18]:

Determination of pH: The pH of the gel was assessed using a digital pH meter. Initially, the electrode underwent calibration using standard buffer solutions of pH 4 and pH 7. A gel sample weighing 1 g was dissolved in 10 ml of distilled water, and the electrode was immersed in the solution until a stable reading was obtained. The constant pH value was recorded, and this measurement process was repeated three times to ensure accuracy and reliability.

Spreadability: The spreadability test for the evaluation of etoricoxib emulgel involved measuring the diameter of 2 grams of gel placed between two plates for 3 minutes. The gel formed a uniform layer between the plates through spreading. Subsequently, the weight of the gel tied to the upper plate was measured, and the spreadability was calculated using the formula below:

$$S = \frac{M \times L}{T}$$

Viscosity and Flow property: Viscosity was measured by Brookfield viscometer with spindle no. 4. Lowered the viscometer into sample until the surface of sample was levelled with the groove mark on the spindle. The temperature was maintained at 28.6 C and seed was selected at 30RPM after trial and error.

Diffusion study: Ensured the membrane is properly installed between the donor and receptor chambers. Prepared the receptor fluid (Phosphate buffer 7.4) and placed it in the receptor chamber. Applied a known amount of emulgel to the donor chamber. Seal the donor chamber to prevent leakage. Placed the Franz diffusion cell in a water bath or temperature-controlled environment to maintain the desired temperature. Allowed the system to equilibrate. At specified time intervals, withdraw samples from the receptor chamber. Replace the withdrawn sample with fresh receptor fluid to maintain volume. Analysed the withdrawn samples using appropriate analytical methods (spectrophotometry) to quantify the amount of drug or

active ingredient that has diffused. Plot the cumulative amount of drug released versus time to generate a release profile.

Stability study: Accelerated Stability Testing conducted at elevated temperatures (e.g., 40°C ± 2°C) and humidity (e.g., 75% ± 5% RH) to predict long-term stability.

RESULT

Microcapsules recovery test: The Microcapsules Recovery Test Value indicates the efficiency of the microcapsule preparation process. Higher values suggest better material utilization and minimal waste. The recovery test values ranged from 61% to 88%, with F6 showing the highest recovery at 88%, indicating the most efficient preparation. In contrast, F7 had the lowest recovery at 40%, highlighting variability in the effectiveness of different formulations.

Microcapsules swelling index: Table 3 presents the swelling index of microcapsules in distilled water over 120 minutes, with values ranging from 58% to 85%. The microcapsules for the gel formulation were selected based on their spherical shape, highest entrapment efficiency, and largest particle size distribution to ensure visibility and effective dispersion in the gel.

Encapsulation efficiency: Entrapment efficiency measures the effectiveness of drug encapsulation within microcapsules coated with different polymers, reflecting the efficiency of the preparation method. Table 3 shows that entrapment efficiency values for various formulations ranged from 65.6% to 94.1%. Formulation F7 had the lowest efficiency at 65.6%, while F6 had the highest at 94.1%. This variability underscores the importance of selecting the most effective formulation to achieve optimal drug encapsulation within microcapsules.

Table 3: Recovery test, Entrapped efficiency and swelling index.

Formulation	Recovery test (%)	Entrapped efficiency (%)	Swelling index (%)
F1	62	66.2	58
F2	67	79.3	62
F3	78	82.9	73
F4	69	74.5	61
F5	79	86.3	77
F6	88	94.1	85
F7	61	65.6	62
F8	68	76.8	73
F9	79	81.5	79

Microcapsules morphology and physical appearance: Microscope (SEM) was employed for a thorough investigation, as depicted in Figure 1. The examination of the F6 formulation microcapsule has unveiled a noteworthy characteristic – the absence of pores.

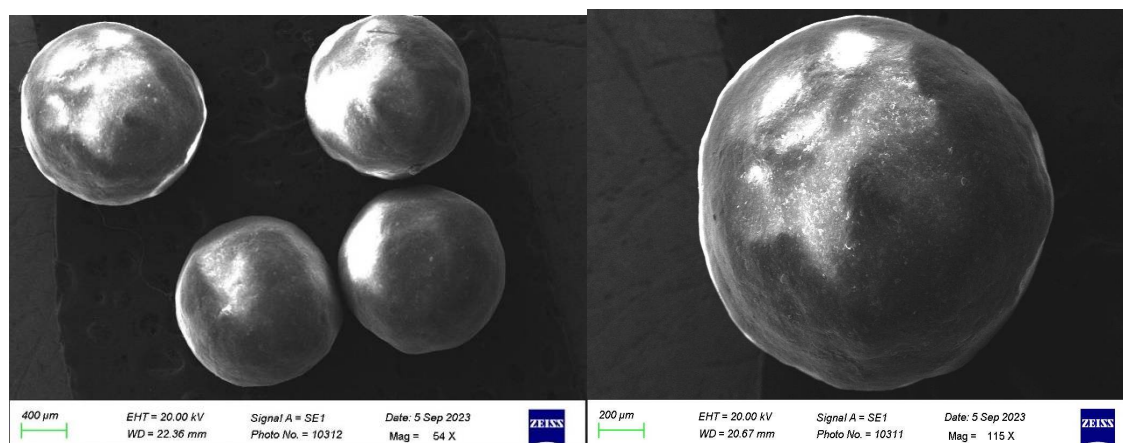


Figure 1: SEM images of F6 formulation.

Microcapsules incorporated emulgel evaluation:

Physical appearance of Emulgel consisting of microcapsule (NSAID): NSAID microcapsules gel revealed a distinctive appearance—translucent white powder resembling scattered microcapsules seamlessly dispersed throughout the gel formulation which is shown in table 4.

Determination of pH: The gel exhibited a pH range of 5.48-6.18, aligning closely with the natural pH balance of the skin (4.5-6.5) which is shown in table 4. This harmony ensures that the gel is gentle on the skin, minimizing the likelihood of irritation and enhancing overall comfort during use.

Determination of spreadability test: The spreadability of Carbopol based emulgel consisting of microcapsules formulations is depicted in table 4. The spreadability of gel preparations is defined as the ability of the gel to spread on the surface of the skin. The greater the scatter diameter, the greater the surface area that can be reached by the gel.

Determination of Viscosity and Flow properties: Viscosity and flow properties of the gel were assessed using spindle 4 at a rotational speed of 30 rpm. The recorded viscosity is shown in table 4. Viscosity is a measure of the thickness of a fluid and gel preparation refers to fluid's high viscosity of 2000–4000 cps.

Table 4: Physical appearance, pH, spreadability (gm.cm/sec), viscosity

Formulations	Physical appearance	pH	Spreadability (mean ± S.D, n= 3)	Viscosity (cp±S.D, n=3)
F1	White, translucent	5.67	15.7±0.3	2356
F2	White, translucent	5.23	15.9±0.2	2789
F3	White, translucent	5.76	18.4±0.4	3156
F4	White, translucent	6.31	19.6±0.1	2989
F5	White, translucent	6.56	21.2±0.4	3278
F6	White, translucent	5.99	24.6±0.3	2890
F7	White, translucent	5.11	23.1±0.3	3378
F8	White, translucent	5.42	20.1±0.1	3812
F9	White, translucent	5.39	19.5±0.2	3164

Permeation study: Table 5 shows permeation study of F1-F9 through Franz diffusion cell demonstrated a consistent and controlled release of drug over different time hours and figure 2 represents the graph plot between permeability and different time intervals.

Table 5: Diffusion study

Formulation	% Drug Released at 0 h	1h	2h	3h	4h	5h	6h	7h	8h
F1	0%	20%	35%	57%	60%	65%	70%	83%	98%
F2	0%	16%	27%	51%	62%	67%	78%	85%	95%
F3	0%	21%	38%	56%	61%	56%	63%	67%	97%
F4	0%	20%	29%	54%	59%	60%	64%	67%	97%
F5	0%	23%	32%	44%	63%	54%	59%	74%	94%
F6	0%	32%	41%	59%	62%	78%	82%	88%	99%
F7	0%	21%	36%	46%	61%	66%	71%	76%	96%
F8	0%	14%	47%	55%	60%	67%	70%	77%	97%
F9	0%	16%	28%	48%	63%	72%	79%	83%	98%

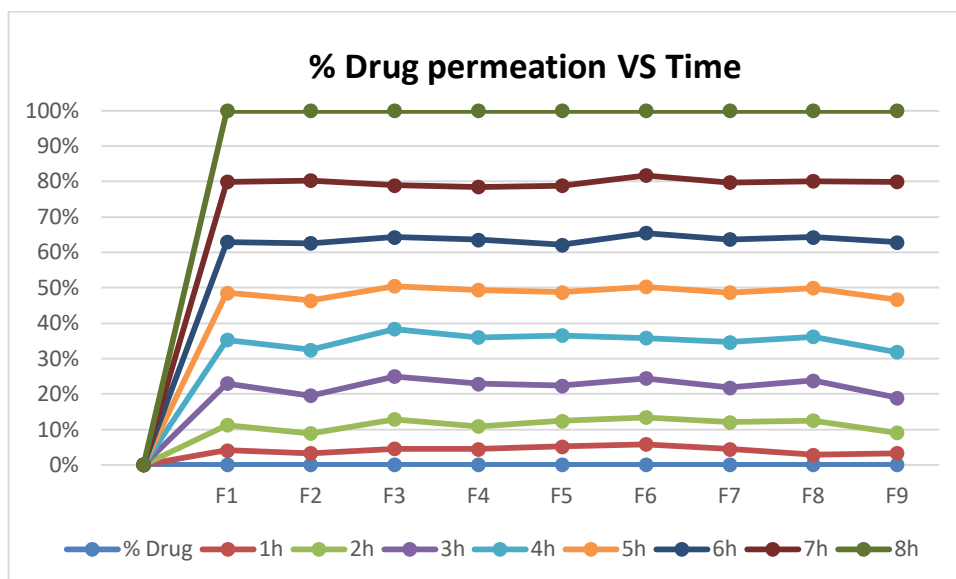


Figure 2: Drug permeation of formulations

Stability study: Table 6 shows the drug content of each formulation at different time points. Formulations (F3, F5, F7, F9) exhibited a significant decrease in drug content, with a more than 5% reduction observed by the end of the study. In contrast, Formulations 6 remained stable, with minimum reduction in drug content.

Table 6: Stability studies of formulations

Formulation	Storage Conditions	Initial Drug Content	After 3 Months (25°C / 60% RH)	After 3 Months (40°C / 75% RH)	After 6 Months (25°C / 60% RH)	After 6 Months (40°C / 75% RH)
F1	25°C / 60% RH; 40°C / 75% RH	100%	100%	98%	97%	95%
F2	25°C / 60% RH; 40°C / 75% RH	100%	100%	97%	96%	93%
F3	25°C / 60% RH; 40°C / 75% RH	100%	100%	98%	97%	95%
F4	25°C / 60% RH; 40°C / 75% RH	100%	100%	98%	98%	95%
F5	25°C / 60% RH; 40°C / 75% RH	100%	100%	96%	97%	94%
F6	25°C / 60% RH; 40°C / 75% RH	100%	100%	99%	99%	97%
F7	25°C / 60% RH; 40°C / 75% RH	100%	100%	95%	96%	92%
F8	25°C / 60% RH; 40°C / 75% RH	100%	100%	96%	98%	95%
F9	25°C / 60% RH; 40°C / 75% RH	100%	100%	97%	98%	93%

DISCUSSION

The preparation of NSAID microcapsules was achieved using the solvent evaporation method, which utilized volatile solvents like dichloromethane, chloroform, and acetone to prevent microcapsule aggregation. Tween 80, a surfactant, helped reduce interfacial tension, forming a continuous film that further prevented aggregation. Formulations F1, F4, and F7 exhibited lower entrapment efficiency due to the lower polymer concentration, leading to irregular microcapsules and insufficient active ingredient encapsulation. Stirring speed was found to be critical, with slower speeds producing larger, less spherical microcapsules. F1, with a 1:1 ratio of NSAID to 2-hydroxypropyl-beta-cyclodextrin, showed nonspherical forms due to insufficient polymer coverage, contrasting with the more spherical microcapsules in formulations F3, F6, and F9, which had higher polymer concentrations. Increased polymer concentration

improved entrapment efficiency by reducing microparticle porosity and preventing drug diffusion. Stirring speed also influenced microcapsule size, with higher speeds leading to smaller droplets and microcapsules. F3 formulation using ethyl cellulose demonstrated non-hygroscopic properties, making it stable in an emulgel formulation, while 2-hydroxypropyl-beta-cyclodextrin and polyvinyl alcohol were more hygroscopic, affecting their stability. The Permeation study suggests that the formulation can deliver the drug at a therapeutically relevant rate, with potential for effective transdermal or topical application [13, 18, 21].

The emulgel formulation included Carbopol as a gel base, with triethanolamine added to neutralize its acidity, aligning the pH with the natural skin balance for enhanced comfort and reduced irritation in topical application. The stability study of [F1-F9] indicated that the formulation remains stable up to 6 months under standard storage conditions (25°C/60% RH), with no significant changes in physical appearance, pH, assay, or dissolution profile. However, under accelerated conditions (40°C/75% RH), slight discoloration and an increase in degradation products were observed at 6 months, though these remained within acceptable limits [22]. Based on these results, a shelf life of 24 months is recommended when stored under controlled room temperature conditions.

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