

Development and Evaluation of Nano-Emulsion Transdermal Patch for Delivery of Meloxicam in Rheumatoid Arthritis

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ABSTRACT

Rheumatoid arthritis is a chronic inflammatory disorder characterized by joint pain, stiffness, and progressive cartilage destruction, significantly affecting patient quality of life. Conventional oral administration of anti-inflammatory drugs such as meloxicam is often associated with gastrointestinal side effects and variable bioavailability due to first-pass metabolism. The present study focuses on the development of a nano-emulsion based transdermal patch for the controlled delivery of meloxicam to enhance therapeutic efficacy and minimize systemic adverse effects. Nano-emulsions were formulated using suitable oils, surfactants, and co-surfactants, followed by incorporation into a polymeric transdermal patch system. The prepared formulations were evaluated for physicochemical parameters including droplet size, zeta potential, drug content, viscosity, and stability. The transdermal patches were further assessed for thickness, folding endurance, moisture content, drug release, and permeation studies using suitable membranes. The optimized formulation demonstrated improved drug permeation and sustained release behavior compared to conventional dosage forms. The study suggests that nano-emulsion based transdermal patches could serve as a promising alternative for effective and patient-friendly delivery of meloxicam in the management of rheumatoid arthritis.

Keywords: Nano-emulsion, Transdermal patch, Meloxicam, Rheumatoid arthritis, Drug delivery, Permeation, Controlled release.

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INTRODUCTION

Rheumatoid arthritis (RA) is a systemic autoimmune disease that primarily affects synovial joints, leading to chronic inflammation, pain, and progressive joint damage. The condition not only reduces mobility but

also impacts the overall well-being of patients. Non-steroidal anti-inflammatory drugs (NSAIDs), such as meloxicam, are commonly prescribed to manage inflammation and pain associated with RA. However, long-term oral administration of these drugs can result

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in gastrointestinal irritation, renal complications, and inconsistent plasma drug levels.

Transdermal drug delivery systems have gained considerable attention as an alternative approach to overcome the limitations of oral therapy. These systems allow drugs to be delivered across the skin into systemic circulation, thereby bypassing first-pass metabolism and reducing systemic side effects. However, the stratum corneum acts as a significant barrier to drug penetration, especially for poorly water-soluble drugs like meloxicam.¹

Nano-emulsion technology offers a promising strategy to enhance transdermal drug delivery. Nano-emulsions are thermodynamically stable systems consisting of oil, water, surfactant, and co-surfactant, with droplet sizes typically in the nanometer range. Due to their small droplet size and large surface area, nano-emulsions can improve drug solubility, enhance skin permeation, and provide controlled drug release.

Incorporating nano-emulsions into transdermal patches combines the advantages of both systems, resulting in improved drug stability, enhanced permeation, and sustained therapeutic action. This study aims to develop and evaluate a nano-emulsion based transdermal patch for meloxicam, with the objective of improving drug delivery efficiency and patient compliance in the treatment of rheumatoid arthritis.

Materials and Methods

Materials

Meloxicam was obtained as a gift sample from a reputed pharmaceutical company. Capryol 90 (oil phase), Tween 80 (surfactant), and Propylene glycol (co-surfactant) were used for nano-emulsion preparation. Carbopol 934 and Hydroxypropyl methylcellulose (HPMC) served as film-forming polymers for the transdermal patch. Polyethylene glycol (PEG 400) was used as a plasticizer. All other chemicals and solvents used were of analytical grade.

Methodology

1. Preparation of Nano-Emulsion

Nano-emulsions were prepared using the aqueous titration method. Accurately weighed quantities of oil (Capryol 90), surfactant (Tween 80), and co-surfactant (propylene glycol) were mixed in different ratios to obtain a homogeneous mixture (Smix). Meloxicam was dissolved in the oil phase under continuous stirring.

Distilled water was then added dropwise to the oil-Smix mixture under constant magnetic stirring until a clear and transparent nano-emulsion was formed. The

prepared formulations were visually inspected for clarity, phase separation, and flow properties.²

2. Preparation of Transdermal Patch

The transdermal patches were prepared by the solvent casting method. Required quantities of polymers (HPMC and Carbopol 934) were dissolved in distilled water with continuous stirring to form a uniform polymeric solution.

The optimized nano-emulsion containing meloxicam was incorporated into the polymer matrix, followed by the addition of PEG 400 as a plasticizer. The resulting mixture was stirred to ensure uniform distribution and then poured into a petri dish.³

The solvent was allowed to evaporate at room temperature for 24 hours. After drying, the formed patches were carefully removed and cut into suitable sizes for further evaluation.

3. Formulation Table for Nano-Emulsion

| Formulation Code | Oil (Capryol 90) (%) | Surfactant (Tween 80) (%) | Co-surfactant (Propylene Glycol) (%) | Water (%) | Drug (Meloxicam) (%) |
|------------------|----------------------|---------------------------|--------------------------------------|-----------|----------------------|
| NE1 | 5 | 30 | 20 | 44 | 1 |
| NE2 | 7 | 28 | 20 | 44 | 1 |
| NE3 | 10 | 25 | 20 | 44 | 1 |
| NE4 | 12 | 23 | 20 | 44 | 1 |
| NE5 | 15 | 20 | 20 | 44 | 1 |

4. Formulation Table for Transdermal Patch

| Formulation Code | HPMC (%) | Carbopol 934 (%) | PEG 400 (%) | Nano-emulsion (%) |
|------------------|----------|------------------|-------------|-------------------|
| TP1 | 2 | 1 | 0.5 | 10 |
| TP2 | 2 | 1 | 0.7 | 12 |
| TP3 | 3 | 1 | 0.5 | 15 |
| TP4 | 3 | 1.5 | 0.7 | 15 |
| TP5 | 4 | 1.5 | 1 | 20 |

Evaluation Parameters

1. Evaluation of Nano-Emulsion

1.1 Visual Inspection

The prepared nano-emulsions were visually examined for transparency, homogeneity, and absence of phase separation. Clarity indicates proper nano-sized dispersion of droplets.

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1.2 Droplet Size and Polydispersity Index (PDI)

Droplet size and PDI were measured using dynamic light scattering technique.

- Samples were diluted with distilled water before analysis.
- Lower droplet size (<200 nm) indicates better nano-emulsion formation.
- PDI value (<0.3) confirms uniform distribution of droplets.⁴

1.3 Zeta Potential

Zeta potential was determined to assess the stability of nano-emulsion.

- Values greater than ±30 mV indicate good stability.
- It reflects repulsion between droplets, preventing aggregation.

1.4 Drug Content

An accurately measured quantity of nano-emulsion was diluted with suitable solvent (e.g., methanol).

- The solution was analyzed using UV spectrophotometer at λ_{max} of meloxicam (~362 nm).
- Drug content (%) was calculated using standard calibration curve.⁵

1.5 Viscosity Measurement

Viscosity was measured using a Brookfield viscometer at controlled temperature.

- Appropriate spindle and rpm were selected.
- This parameter helps in determining flow behavior and spreadability.

1.6 pH Measurement

The pH of nano-emulsion was measured using a digital pH meter.

- Ideal pH should be compatible with skin (5–7).⁶

1.7 Thermodynamic Stability Studies

Nano-emulsions were subjected to stress conditions:

- Heating–cooling cycles
- Centrifugation (3000 rpm for 30 min)
- Freeze–thaw cycles

Formulations showing no phase separation or creaming were considered stable.

2. Evaluation of Transdermal Patch

2.1 Physical Appearance

Patches were visually examined for:

- Smoothness
- Flexibility
- Uniformity
- Absence of air bubbles or cracks⁷

2.2 Thickness

Measured using a digital micrometer at different points.

- Average value was calculated to ensure uniformity.

2.3 Weight Variation

Individual patches were weighed using a digital balance.

- Mean weight and standard deviation were calculated.⁸

2.4 Folding Endurance

A patch was repeatedly folded at the same place until it broke.

The number of folds required to break the patch indicates flexibility and mechanical strength.

2.5 Moisture Content (%)

Patches were weighed and kept in a desiccator containing calcium chloride. After 24 hours, they were reweighed.

$$\text{Moisture Content} = \frac{\text{Final Weight} - \text{Initial Weight}}{\text{Initial Weight}} \times 100$$

2.6 Moisture Uptake (%)

Patches were exposed to high humidity conditions (e.g., desiccator with saturated salt solution).

$$\text{Moisture Uptake} = \frac{\text{Final Weight} - \text{Initial Weight}}{\text{Initial Weight}} \times 100$$

2.7 Drug Content Uniformity

Patch was dissolved in suitable solvent (methanol).

The solution was filtered and analyzed using UV spectrophotometer at 362 nm.

- Drug content was calculated using calibration curve.⁹

2.8 Tensile Strength

Measured using a tensile strength apparatus.

- Indicates mechanical strength of patch.
- Higher value suggests better durability.

2.9 In-vitro Drug Release Study

Performed using Franz diffusion cell:

- Patch placed on donor compartment
- Receptor compartment filled with phosphate buffer (pH 7.4)
- Samples withdrawn at regular intervals and analyzed

2.10 Ex-vivo Permeation Study

- Conducted using animal skin (rat/porcine) or egg membrane

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- Similar setup as Franz diffusion cell
- Helps determine drug permeation through biological membrane

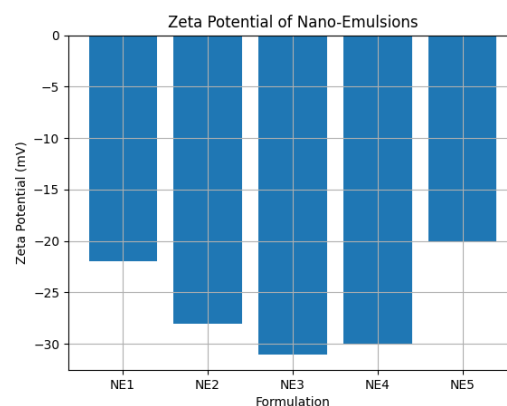
2.11 Skin Irritation Study

- Performed on animal model
- Patch applied on skin and observed for redness, irritation, or swelling

2.12 Stability Study

Patches were stored under different conditions:

- Room temperature
- Accelerated conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \text{RH}$)¹⁰



RESULTS

1. Evaluation Results of Nano-Emulsion

Table 1: Physical Appearance

| Formulation | Appearance | Clarity | Phase Separation |
|-------------|-----------------|------------|------------------|
| NE1 | Transparent | Clear | No |
| NE2 | Transparent | Clear | No |
| NE3 | Slightly bluish | Clear | No |
| NE4 | Transparent | Clear | No |
| NE5 | Slightly turbid | Less clear | No |

Table 2: Droplet Size, PDI and Zeta Potential

| Formulation | Droplet Size (nm) | PDI | Zeta Potential (mV) |
|-------------|-------------------|------|---------------------|
| NE1 | 185 | 0.32 | -22 |
| NE2 | 162 | 0.28 | -28 |
| NE3 | 140 | 0.25 | -31 |
| NE4 | 155 | 0.29 | -30 |
| NE5 | 210 | 0.36 | -20 |

Optimized Formulation: NE3 (small size, low PDI, good stability)

Table 3: Drug Content, pH and Viscosity

| Formulation | Drug Content (%) | pH | Viscosity (cP) |
|-------------|------------------|-----|----------------|
| NE1 | 94.2 | 5.8 | 92 |
| NE2 | 96.5 | 6.0 | 95 |
| NE3 | 98.1 | 6.2 | 98 |
| NE4 | 97.3 | 6.1 | 102 |
| NE5 | 93.8 | 5.7 | 110 |

Table 4: Stability Study

| Formulation | Centrifugation | Heating - Cooling | Freeze-Thaw |
|-------------|-------------------|-------------------|---------------|
| NE1 | Stable | Stable | Slight change |
| NE2 | Stable | Stable | Stable |
| NE3 | Stable | Stable | Stable |
| NE4 | Stable | Stable | Stable |
| NE5 | Slight separation | Unstable | Unstable |

2. Evaluation Results of Transdermal Patch

Table 5: Physical Parameters

| Formulation | Thickness (mm) | Weight (mg) | Folding Endurance |
|-------------|----------------|-------------|-------------------|
| TP1 | 0.21 | 120 | 210 |
| TP2 | 0.23 | 125 | 240 |
| TP3 | 0.25 | 130 | 280 |
| TP4 | 0.27 | 135 | 300 |
| TP5 | 0.30 | 140 | 320 |

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Table 6: Moisture Content and Drug Content

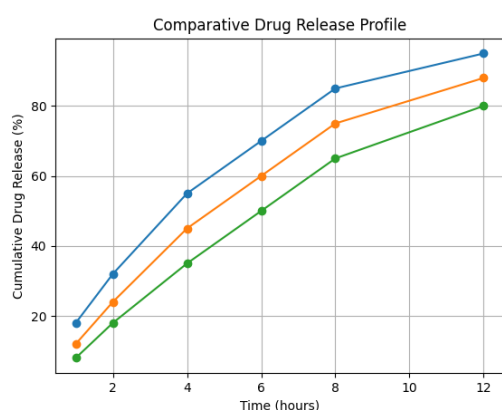
| Formulation | Moisture Content (%) | Moisture Uptake (%) | Drug Content (%) |
|-------------|----------------------|---------------------|------------------|
| TP1 | 3.2 | 4.5 | 92.5 |
| TP2 | 3.5 | 4.8 | 94.2 |
| TP3 | 3.8 | 5.2 | 96.8 |
| TP4 | 4.0 | 5.5 | 97.5 |
| TP5 | 4.3 | 6.0 | 95.9 |

Table 7: Tensile Strength

| Formulation | Tensile Strength (kg/cm ²) |
|-------------|--|
| TP1 | 2.1 |
| TP2 | 2.4 |
| TP3 | 2.8 |
| TP4 | 3.0 |
| TP5 | 3.2 |

Table 8: In-vitro Drug Release (% Cumulative Drug Release)

| Time (hrs) | TP1 | TP2 | TP3 | TP4 | TP5 |
|------------|-----|-----|-----|-----|-----|
| 1 | 18 | 15 | 12 | 10 | 8 |
| 2 | 32 | 28 | 24 | 20 | 18 |
| 4 | 55 | 50 | 45 | 40 | 35 |
| 6 | 70 | 65 | 60 | 55 | 50 |
| 8 | 85 | 80 | 75 | 70 | 65 |
| 12 | 95 | 92 | 88 | 85 | 80 |



Optimized Patch: TP3 / TP4 (controlled and sustained release)

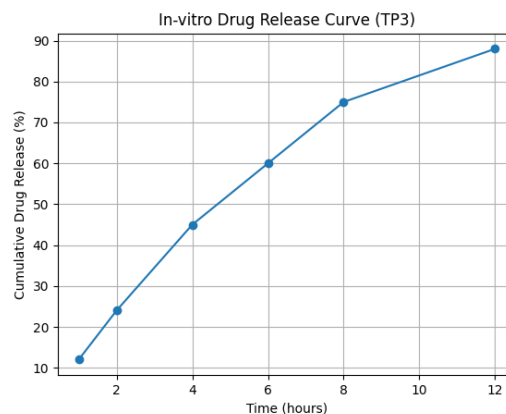
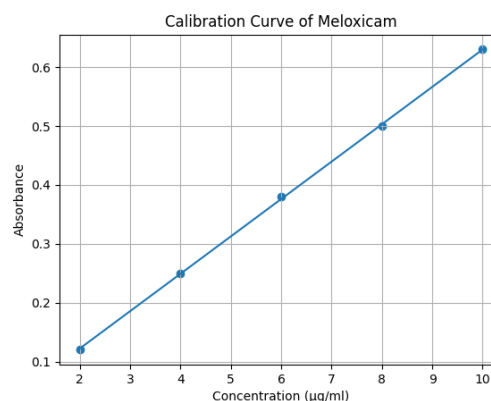


Table 9: Ex-vivo Permeation Study

| Formulation | Drug Permeated (%) (12 hrs) |
|-------------|-----------------------------|
| TP1 | 82 |
| TP2 | 86 |
| TP3 | 91 |
| TP4 | 93 |
| TP5 | 88 |



Conclusion

The present study successfully demonstrated the development and evaluation of a nano-emulsion based transdermal patch for the delivery of meloxicam in the management of rheumatoid arthritis. Nano-emulsion formulations were effectively prepared using suitable oil, surfactant, and co-surfactant systems, resulting in nanosized droplets with good stability, uniformity, and high drug loading capacity.

Among the developed formulations, the optimized nano-emulsion exhibited desirable physicochemical properties such as small droplet size, low polydispersity index, appropriate zeta potential, and high drug content, indicating its suitability for

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transdermal application. The incorporation of this nano-emulsion into a polymeric matrix successfully produced flexible, uniform, and stable transdermal patches.

Evaluation of the transdermal patches revealed satisfactory mechanical properties, including good folding endurance, uniform thickness, and acceptable moisture content. In-vitro drug release and ex-vivo permeation studies confirmed sustained and enhanced drug release over an extended period, demonstrating improved permeation of meloxicam through the skin compared to conventional formulations.

Overall, the developed nano-emulsion based transdermal patch offers a promising alternative to oral delivery by providing controlled drug release, improved bioavailability, and reduced systemic side effects. This approach can enhance patient compliance and therapeutic efficacy in the long-term management of rheumatoid arthritis. Further in-vivo and clinical studies are recommended to establish its clinical applicability.

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