TMP UNIVERSAL JOURNAL OF ADVANCES IN PHARMACEUTICAL SCIENCES

PEER REVIEWED | INTERNATIONAL | QUARTERLY JOURNAL | E-ISSN: 3139-2601

VOLUME 2 | ISSUE 4 | YEAR 2026 | OCT – DEC 2026

Research Article

FABRICATION AND IN VITRO CHARACTERIZATION OF A MELOXICAM FILM-FORMING TOPICAL SPRAY

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KEYWORDS:

Meloxicam; film-forming spray; topical delivery; polymeric film; Franz diffusion cell; in-vitro drug release

ARTICLE HISTORY

Received Date: 11/10/2026

Revised Date: 14/10/2026

Accepted Date: 20/11/2026

Published Date: 08/12/2026

DOI: 10.69557/8aevxx73

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ABSTRACT

Background: Film-forming topical sprays are polymer-based drug delivery systems that form a thin polymeric film on the skin following application and solvent evaporation. Such systems may offer advantages for localized drug delivery and may overcome certain limitations associated with conventional topical dosage forms. Meloxicam, a non-steroidal anti-inflammatory drug (NSAID), is a potential candidate for incorporation into topical delivery systems.

Objective: The present study aimed to formulate meloxicam-containing film-forming topical spray systems and evaluate their selected physicochemical characteristics and in-vitro drug release profiles.

Methods: Six formulations (F1–F6) were investigated. Preformulation studies included organoleptic characterization, melting-point determination, solubility assessment, UV spectrophotometric analysis, calibration-curve development, and Fourier-transform infrared (FTIR) spectroscopy for drug–excipient compatibility assessment. The prepared formulations were evaluated for appearance, weight uniformity, film thickness, folding endurance, and drug content. In-vitro drug release was assessed using a Franz diffusion cell, with phosphate buffer (pH 6.8) as the receptor medium, maintained at 37 ± 0.2 °C.

Results: Meloxicam exhibited a maximum absorption wavelength (λmax) of 365 nm and an experimentally determined melting-point range of 251–254 °C. The calibration curve was reported to be linear over the concentration range of 0–25 µg/mL, with a correlation coefficient (r) of 0.999. Film weight ranged from 0.123 ± 0.0085 to 0.139 ± 0.0063 g, while film thickness ranged from 0.54 ± 0.05 to 0.62 ± 0.05 mm. Drug content ranged from 92.31 ± 0.345% to 97.40 ± 0.425%. Formulation F6 was designated as the optimized batch in the source thesis. At the end of eight hours, the reported cumulative drug release ranged from 72.86% to 92.61%; F1 showed the highest release (92.61%), whereas F6 showed the lowest (72.86%).

Conclusion: Six meloxicam-containing film-forming topical spray formulations were reported to have been prepared and evaluated for selected physicochemical properties and in-vitro drug release. Formulation F6 was identified as the optimized batch in the source thesis. Nevertheless, confirmation of the formulation composition and verification of the in-vitro release dataset are necessary before definitive conclusions can be drawn regarding the comparative performance of the formulations.

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INTRODUCTION

Transdermal and topical drug delivery systems use the skin as an application site for localized or systemic delivery. Conventional oral administration may be limited by gastrointestinal exposure, enzymatic degradation and hepatic first-pass metabolism, whereas topical systems can deliver drug directly to the intended application area. Film-forming sprays are liquid formulations containing drug and film-forming excipients that form a polymeric layer after solvent evaporation.

The characteristics of a film-forming system depend on polymer identity and concentration, plasticizer content, solvent composition and the physical properties of the drug. These variables influence film integrity, flexibility, drug distribution and release. The thesis describes the development of Meloxicam-containing spray formulations using polymeric excipients and evaluates their physicochemical properties and in-vitro release.

The objective of the present work was to formulate Meloxicam film-forming topical spray systems and compare their selected preformulation and performance characteristics.

MATERIALS AND METHODS

Materials

Meloxicam was obtained from Cadila Pharmaceuticals Ltd. The thesis lists Eudragit L100 and ethyl cellulose among the materials, with PEG 400 and ethanol supplied by Lobachemie Pharmaceutical Pvt. Ltd. The formulation table, however, labels the first polymer series as methyl cellulose. This discrepancy is flagged for confirmation.

Formulation development

The thesis reports six formulations (F1–F6), each containing 50 mg Meloxicam, 5% PEG 400, 5 mL ethanol and 5 mL water. F1–F3 contained 100, 150 and 200 mg methyl cellulose, respectively, while F4–F6 contained 100, 150 and 200 mg Eudragit L100, respectively. The narrative preparation method additionally describes ethyl cellulose and a camphor–menthol eutectic mixture, which are not consistently represented in the formulation table. The exact composition and preparation sequence must therefore be reconciled with the laboratory formulation records.

Ingredient	F1	F2	F3	F4	F5	F6
Meloxicam (mg)	50	50	50	50	50	50
Methyl cellulose (mg)	100	150	200	—	—	—
Eudragit L100 (mg)	—	—	—	100	150	200
PEG 400 (%)	5	5	5	5	5	5
Ethanol (mL)	5	5	5	5	5	5
Water (mL)	5	5	5	5	5	5

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Preformulation studies

Organoleptic properties were recorded by visual and sensory description. Melting point was determined by the capillary method. Solubility was assessed qualitatively in distilled water, ethanol, PEG 400 and aqueous buffers. The UV absorption maximum was determined by scanning the standard solution from 200 to 400 nm. A calibration curve was prepared in the reported concentration range of 0–25 µg/mL. FTIR spectra of the drug and drug–polymer mixtures were compared to assess possible drug–excipient interactions.

Evaluation of formulations

Appearance and surface texture were assessed visually and by touch. Film weight was measured using an electronic balance. Thickness was measured using a screw gauge. Folding endurance was determined by repeatedly folding a film strip at the same position until breakage. Drug content was determined by dissolving a measured film portion in phosphate buffer (pH 6.8), followed by UV spectrophotometric analysis. The thesis reports triplicate determinations for drug content.

In-vitro drug release

In-vitro release was evaluated using a Franz diffusion cell and a cellulose membrane. The receptor compartment contained 25 mL phosphate buffer (pH 6.8), maintained at 37 ± 0.2 °C and stirred at 50 rpm. Samples were withdrawn at scheduled intervals, diluted where required and analyzed by UV spectrophotometry at 365 nm. The thesis reports sampling through eight hours.

Data presentation

Results are presented using the mean and standard deviation were reported in the thesis. The number of replicates is stated only where explicitly described in the source document.

RESULTS AND DISCUSSION

Preformulation characteristics

The drug was described as a pastel-yellow/yellow solid with characteristic odour and bitter taste. The reported absorption maximum was 365 nm. The experimental melting point was stated as 251–254 °C, while the thesis table also gives 252–253 °C as the official value. Meloxicam was reported insoluble in distilled water, soluble in ethanol and most soluble in PEG 400, with sparing solubility in aqueous buffers.

UV calibration and FTIR compatibility

The calibration data were reported as 0, 5, 10, 15, 20 and 25 µg/mL with absorbance values of 0.0000, 0.0783, 0.1650, 0.2718, 0.3659 and 0.4985, respectively. The thesis reports a correlation coefficient of 0.999, slope of approximately 0.016 and intercept of 0.005. FTIR comparison was interpreted in the thesis as showing no interaction between Meloxicam and the listed polymers.

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Concentration (µg/mL)	Absorbance
0	0.0000
5	0.0783
10	0.1650
15	0.2718
20	0.3659
25	0.4985

Physical evaluation

Batch	Weight (g; mean ± SD)	Thickness (mm)	Folding endurance	Drug content (%; mean ± SD)
F1	0.131 ± 0.0052	0.55 ± 0.05	88.33 ± 4.50	97.40 ± 0.425
F2	0.135 ± 0.0025	0.56 ± 0.05	69.00 ± 1.25	95.27 ± 0.380
F3	0.127 ± 0.0036	0.54 ± 0.05	99.56 ± 2.36	93.29 ± 0.281
F4	0.133 ± 0.0045	0.58 ± 0.01	54.33 ± 4.36	92.31 ± 0.345
F5	0.139 ± 0.0063	0.62 ± 0.05	64.00 ± 1.25	94.39 ± 0.488
F6	0.123 ± 0.0085	0.57 ± 0.05	95.00 ± 1.25	93.29 ± 0.281

All six batches were described as having smooth, elegant surfaces and uniform weight. The reported thickness values were within 0.54–0.62 mm. Folding endurance ranged from 54.33 ± 4.36 to 99.56 ± 2.36, and drug content ranged from 92.31 ± 0.345% to 97.40 ± 0.425%. The thesis conclusion identifies F6 as the optimized formulation, citing uniform thickness, folding endurance and controlled release; however, the reported folding-endurance values do not establish F6 as the highest-performing batch on that parameter alone.

In-vitro drug release

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
0	0	0	0	0	0	0
1	11.35	8.83	9.67	5.71	4.80	4.32
2	19.36	17.11	17.23	17.76	13.96	12.90
3	29.63	26.78	28.69	25.31	24.22	21.78
4	47.43	36.20	40.11	39.23	37.99	34.56
5	57.82	56.06	53.41	48.32	46.93	45.80
6	73.40	68.34	62.12	57.03	54.65	54.34
7	80.57	77.19	75.97	67.17	64.49	63.65
8	92.61	90.41	87.12	79.59	76.79	72.86

The reported cumulative release increased with time in all batches. At eight hours, release was 92.61% for F1, 90.41% for F2, 87.12% for F3, 79.59% for F4, 76.79% for F5 and 72.86% for F6. This pattern is consistent with slower release at higher polymer loading in the reported series. However, the identical release values appear in the Naproxen buccal-patch thesis. The Meloxicam release dataset must be checked against original records before publication and should not be represented as independently validated.

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CONCLUSION

The thesis reports the preparation and in-vitro evaluation of six Meloxicam-containing film-forming topical formulations. The batches showed generally acceptable appearance, weight uniformity, thickness and drug content. F6 was designated as the optimized formulation in the source thesis on the basis of its overall evaluation and controlled-release profile. The manuscript's conclusions remain provisional until the polymer identity and preparation method are confirmed and the in-vitro release dataset is verified.

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