

CILNIDIPINE-LOADED TRANSDERMAL NANOEMULSION-BASED GEL: SYNTHESIS, OPTIMISATION, CHARACTERISATION AND PHARMACOKINETIC EVALUATION

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ABSTRACT

Objective: The aim of the study was to enhance transdermal flux and bioavailability, thereby reforming the effectiveness of drug delivery by synthesising and characterising cilnidipine-loaded nanoemulsion-based gel.

Methods: The research was conducted with meticulous planning and execution. After preformulation studies, cilnidipine-loaded nanoemulsions were synthesised using probe sonication and optimised by a 2-factor central composite design. The optimised nanoemulsions were loaded in Carbopol 940 and HPMC K₄M gelling system. The optimised nanoemulsions were characterised for droplet size, zeta potential, viscosity, refractive index, pH and TEM, and cilnidipine-loaded nanoemulsion gels were characterised for clarity, homogeneity, consistency, spreadability, extrudability, pH, viscosity, *in vitro* diffusion study, dermal toxicity, and pharmacokinetic profiling. The process was accurately planned and accomplished at each step to ensure the precision and reliability of the results.

Results: The findings of this research are not just significant; they are groundbreaking. The steady-state flux values observed ranged from $35.71 \pm 1.27 \mu\text{g}/\text{cm}^2/\text{h}$ to $107.7 \pm 2.04 \mu\text{g}/\text{cm}^2/\text{h}$ for DOE_CiL_1 to 9 and $40.88 \pm 1.44 \mu\text{g}/\text{cm}^2/\text{h}$ to $80.64 \pm 1.38 \mu\text{g}/\text{cm}^2/\text{h}$ for NEn_CiL_GeL_1 to 4. These results underscore the diverse efficacy of different formulations in facilitating drug delivery through the skin. The pharmacokinetics profile of cilnidipine also showed remarkable changes. The C_{max} for the cilnidipine tablet was $332.3 \pm 14.2 \text{ ng/ml}$, whereas it significantly increased ($p < 0.05$) to $593.00 \pm 24.8 \text{ ng/ml}$ in the nanoemulsion gel, demonstrating a substantial enhancement in drug concentration. Additionally, the AUC_{0-12} showed a significant ($p < 0.05$) increase from $1279 \pm 34.1 \text{ ng/ml} \cdot \text{h}$ with the tablet to $1922.50 \pm 162.8 \text{ ng/ml} \cdot \text{h}$ with the nanoemulsion gel. The $\text{AUC}_{0-\infty}$ also increased from $1395.5 \pm 156.7 \text{ ng/ml} \cdot \text{h}$ for the tablet to $1962.30 \pm 174.9 \text{ ng/ml} \cdot \text{h}$ for the nanoemulsion gel, further confirming the improved bioavailability of cilnidipine with the nanoemulsion gel. These significant bioavailability improvements cause excitement about the potential impact of this research, which could revolutionise transdermal drug delivery systems in the pharmaceutical business, leading to more effective and efficient drug delivery methods.

Conclusion: The results of this novel study are not only promising but also hold the potential to be transformative. The significant improvement in transdermal flux from the cilnidipine-loaded nanoemulsion gel reveals a substantial increase in the drug's bioavailability. This breakthrough could eliminate several drawbacks of cilnidipine, like first-pass fate and poor solubility, and provide a safer, more convenient delivery method for managing hypertension.

Keywords: Cilnidipine, Pseudo-ternary phase diagram, Transdermal flux, Bioavailability, Pharmacokinetics, Dermal toxicity

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It has come to our attention that there was an error in the published article regarding the corresponding author details. The name of the corresponding author was incorrectly mentioned as **Raman Rajesh Kumar**.

The correct corresponding author is: **Mahesh T. Gaikwad**

We apologize for this oversight and any inconvenience it may have caused.

The authors