

पेटेंट कार्यालय
शासकीय जर्नल

**OFFICIAL JOURNAL
OF
THE PATENT OFFICE**

निर्गमन सं. 18/2026
ISSUE NO. 18/2026

शुक्रवार
FRIDAY

दिनांक: 01/05/2026
DATE: 01/05/2026

पेटेंट कार्यालय का एक प्रकाशन
PUBLICATION OF THE PATENT OFFICE

(12) PATENT APPLICATION PUBLICATION

(21) Application No.202641050266 A

(19) INDIA

(22) Date of filing of Application :20/04/2026

(43) Publication Date : 01/05/2026

(54) Title of the invention : NANOEMULSION BASED DRUG DELIVERY SYSTEM FOR ENHANCED ORAL BIOAVAILABILITY

(51) International classification	:A61K 9/107, A61K 47/14, A61K 47/44, A61K 47/10, A61K 47/24	(71)Name of Applicant : 1)Dr. Lahanya Guha Address of Applicant :Research Associate, Stem Cells and Regenerative Medicine Centre, Yenepoya Research Centre, Yenepoya University, University Road Deralakatte, Mangaluru, Karnataka, 575018, India Karnataka India 2)Dr. Nidhi Singh 3)Mr. Avdhoot Joshi 4)Ms. Shristi Ghosh 5)Mr. Ziaul Karim 6)Dr. Lalitha V 7)Dr. Kiran B 8)Ms. Aakanksha Shankar Kamble 9)Ms. Monika 10)Ms. Diksha Diwakar
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(57) Abstract :

The present invention relates to a nanoemulsion-based drug delivery system for significantly enhanced oral bioavailability of poorly water-soluble active pharmaceutical ingredients belonging to BCS Class II and Class IV. The nanoemulsion comprises an oil-in-water dispersion with mean droplet diameters of 20 to 200 nanometres, formulated using pharmaceutically acceptable medium-chain triglycerides as the oil phase, a combination of polysorbate 80 and Vitamin E TPGS as surfactants, and polyethylene glycol 400 as co-surfactant, with the active pharmaceutical ingredient solubilised in the oil phase. The ultra-small droplet size provides a markedly increased interfacial surface area for drug absorption, while Vitamin E TPGS synergistically inhibits intestinal P-glycoprotein efflux transporters. Lymphatic drug uptake facilitated by the nanoemulsion further circumvents hepatic first-pass metabolism. An optional mucoadhesive polymer component prolongs gastrointestinal residence time. In vitro drug release studies demonstrate greater than 83 percent drug release within six hours compared to 22 percent for conventional suspension.

No. of Pages : 15 No. of Claims : 10