

(54) Title of the invention : A β -SITOSTEROL LOADED SOLID LIPID NANOPARTICLES FOR ENHANCED SOLUBILITY AND SUSTAINED DRUG RELEASE IN DIABETES

<p>(51) International classification :A61K0009510000, A61K0009000000, A61K0031167000, A61K0047380000, A61K0047320000</p> <p>(86) International Application No :NA Filing Date :NA</p> <p>(87) International Publication No : NA</p> <p>(61) Patent of Addition to Application Number :NA Filing Date :NA</p> <p>(62) Divisional to Application Number :NA Filing Date :NA</p>	<p>(71)Name of Applicant :</p> <p>1)DR. VARSHA TIWARI Address of Applicant :Pharmacy Academy, IFTM University, Lodhipur-Rajput, Moradabad, U. P. -----</p> <p>2)DR. ABHISHEK TIWARI</p> <p>3)MS. RAMSHA ASLAM</p> <p>4)DR. PRASHANT UPADHYAY</p> <p>5)DR. AJAY SHARMA</p> <p>6)DR. ARYA LAKSHMI MARISETTI</p> <p>7)DR. MANISH KUMAR</p> <p>8)DR. RENU KARWASRA</p> <p>9)DR. RAVINDER VERMA</p> <p>Name of Applicant : NA Address of Applicant : NA</p> <p>(72)Name of Inventor :</p> <p>1)DR. VARSHA TIWARI Address of Applicant :Pharmacy Academy, IFTM University, Lodhipur-Rajput, Moradabad, U. P. -----</p> <p>2)DR. ABHISHEK TIWARI Address of Applicant :Pharmacy Academy, IFTM University, Lodhipur-Rajput, Moradabad, U. P. -----</p> <p>3)MS. RAMSHA ASLAM Address of Applicant :Faculty of Pharmacy, IFTM University, Lodhipur-Rajput, Moradabad, U. P. -----</p> <p>4)DR. PRASHANT UPADHYAY Address of Applicant :School of Pharmaceutical Sciences, IFTM University, Lodhipur-Rajput, Moradabad, U. P. -----</p> <p>5)DR. AJAY SHARMA Address of Applicant :School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences and Research University, Pushp Vihar, New Delhi -----</p> <p>6)DR. ARYA LAKSHMI MARISETTI Address of Applicant :School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences and Research University, Pushp Vihar, New Delhi -----</p> <p>7)DR. MANISH KUMAR Address of Applicant :Department of Pharmaceutics, ISF College of Pharmacy, Moga, Punjab, India -----</p> <p>8)DR. RENU KARWASRA Address of Applicant :Central Council for Research in Unani Medicine (CCRUM) 3, Ministry of AYUSH, Government of India, Janakpuri - 110058, New Delhi, India -----</p> <p>9)DR. RAVINDER VERMA Address of Applicant :Department of Pharmaceutical Sciences, Chaudhary Bansi Lal University, Bhiwani, Haryana -----</p>
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(57) Abstract :

This research focuses on the design and optimization of solid lipid nanoparticles (SLNs) encapsulating β -sitosterol, a hydrophobic drug, to enhance solubility and enable sustained therapeutic action. The SLNs were prepared using melt emulsification followed by an ultrasonication technique, employing a randomized response surface Box-Behnken design (BBD) for optimization. The solubility of β -sitosterol was found to be highest at a drug-to-lipid ratio of 1:3 using Compritol ATO 888. The optimized SLN formulation exhibited a particle size of 210.20 nm, a polydispersity index (PDI) of 0.312, a zeta potential of -47.2 mV, and an entrapment efficiency (EE) of 60.12%. Differential scanning calorimetry (DSC) analysis confirmed the absence of chemical changes in the optimized formulation. In vitro drug release studies demonstrated sustained release of β -sitosterol over 28 hours. Scanning electron microscopy (SEM) revealed the formation of homogeneous, spherical particles. Overall, the β -sitosterol-loaded SLN, generated through the BBD approach, proved to be a promising strategy for enhancing drug solubility and achieving sustained release, while exhibiting long-term stability during storage.

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