(12) PATENT APPLICATION PUBLICATION
(19) INDIA
(22) Date of filing of Application :24/03/2026

(21) Application No.202641035509 A
(43) Publication Date : 03/04/2026

(54) Title of the invention : A NANOPARTICULATE FORMULATION OF NERATINIB FOR BREAST CANCER THERAPY.

| | |
|---|---|
| (51) International classification | :A61P 35/00, A61K 31/4709, A61K 9/51, A61K 47/24, A61K 9/127 |
| (31) Priority Document No | :NA |
| (32) Priority Date | :NA |
| (33) Name of priority country | :NA |
| (86) International Application No<br>Filing Date | :<br>:01/01/1900 |
| (87) International Publication No | : NA |
| (61) Patent of Addition to Application Number<br>Filing Date | :NA<br>:NA |
| (62) Divisional to Application Number<br>Filing Date | :NA<br>:NA |

(71)**Name of Applicant :**
**1)JSS COLLEGE OF PHARMACY – JSS ACADEMY OF HIGHER EDUCATION & RESEARCH**
Address of Applicant :Mysore to Bangalore Main Road, Shivarathreeswara Nagar, Mysore, India Mysuru Karnataka India
(72)**Name of Inventor :**
**1)Dr. Madhugiri Prakash Venkatesh**
**2)Surabhi Chorappan**
**3)Purnima Sinha**
**4)Abirami Kaliappan**

(57) Abstract :
The present invention relates to a novel nanostructured lipid carrier (NLC) pharmaceutical formulation of neratinib for the treatment of breast cancer, particularly HER2-positive breast cancer. The formulation comprises neratinib encapsulated within an imperfect lipid matrix formed by a combination of a solid lipid and a liquid lipid, stabilized using a pharmaceutically acceptable surfactant. The nanostructured lipid carrier system provides nanoscale particle size, high drug entrapment efficiency, improved apparent solubility, and sustained drug release. The formulation overcomes limitations associated with conventional neratinib therapy, including poor aqueous solubility, erratic bioavailability, burst drug release, and dose-limiting gastrointestinal toxicity. The invention further provides a scalable and solvent-free method for preparing the formulation, resulting in improved stability, reduced adverse effects, enhanced patient compliance, and improved therapeutic efficacy. The invention is industrially applicable in the field of pharmaceutical manufacturing of anticancer drug delivery systems.

No. of Pages : 21 No. of Claims : 9