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Intranasal delivery of asenapine loaded nanostructured lipid carriers for treatment of schizophrenia

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Schizophrenia is severe chronic disabling brain disease affecting about 24 million people worldwide and 4 million people in India as WHO 2011 report. Asenapine maleate (ASN) is a novel psychopharmacologic agent recommended for treatment of Schizophrenia and Bipolar disorder. ASN suffers with the problems of poor aqueous solubility, very low oral bioavailability (1-2%) and high patient non-adherence. Therefore, objective of the present study was to prepare Nanostructured Lipid Carriers (NLCs) of Asenapine maleate to improve the bioavailability and enhance the uptake of ASN to the brain via intranasal route. Asenapine loaded NLCs (ASN-NLCs) were prepared by melt emulsification-high shear homogenization method. For preparation of NLCs, Glyceryl monostearate, Oleic acid and Tween 80 were used as solid lipid, liquid lipid and surfactant, respectively. ASN-NLCs were characterized for particle size, zeta potential, entrapment efficiency, *in-vitro* drug release study, XRD and DSC. Stability study was performed at 25°C/60% RH for three months. Further, pharmacodynamic studies (paw test and l-dopa induced locomotor activity test) were performed on rat model to evaluate the efficacy of formulation. ASN-NLCs were successfully prepared and optimized with particle size below 200 nm, zeta potential -15.38 ± 2.17 mV, EE $82 \pm 3.5\%$ and more than 85% drug release in 24 h. The XRD and DSC analysis indicate that Asenapine was present in amorphous state in NLCs. The ASN-NLCs were stable over 3 month studies. In pharmacodynamic studies, significant increase ($p < 0.05$) in antipsychotic potential was observed in ANS-NLCs as compared to pure drug. These results indicate that the NLCs are having a potential to deliver drug into the brain from the non-invasive intranasal route.

Biography

Sanjay Kumar Singh is a research fellow at Indian Institute of Technology (Banaras Hindu University), Varanasi. His current area of research is lipid based nanoparticulate drug delivery system. Before joining as doctoral research, he had worked in IPMG-Formulation department with R&D center of Lupin Pharmaceutical Limited (Pune) India. He has six publications with cumulative impact factor 20.303 and has presented/co-authored 7 research/review works in national/international conferences. He has qualified GATE-2008 with 99.78 percentile. He received UGC-JRF for his post graduation research work and awarded Institutional fellowship, from MHRD, Gov. of India for continuing his doctoral research.

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