OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Pharmaceutics & Novel Drug Delivery Systems
April 08-10, 2013 Hilton Chicago/Northbrook, USA

Lipid based nanocarrier for the oral delivery of Decitabine: Production, characterization and optimization by using Box-Behnken design

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The aim of current study entails to develop an optimized solid lipid nanoparticle (SLN) as novel lipid nanocarrier for the oral delivery of Decitabine (DCB) using cold homogenization technique. A Box-Behnken design (33) with 17 experimental runs was constructed to identify the key independent variables influencing on dependent variables (particle size, polydispersity index and entrapment efficiency). The optimized batch (SLN-11) was further characterized with particle size and distribution, zeta potential, particle morphology, entrapment efficiency, drug content, rheological behavior, thermal analysis (DSC), *in vitro* drug release behavior and accelerated stability study to determine the shelf life of the formulation. The optimized batch (SLN-11) revealed spherical morphology with a smooth surface under TEM analysis with particle size of 136.6± 2.35 nm (n=3). The polydispersity index of particle and zeta potential was found to be 0.244± 0.002 (n=3) and -31.34±0.67mV (n=3) respectively. The rheological study revealed Hershel Bulkley plastic viscosity of 0.3291pas and the % EE was found to be 58.89 % ±0.78 (n=3). In vitro release studies of an optimized batch showed burst release at the initial stage followed by sustained release of DCB from SLN up to 24 hrs and the data was further studies using release kinetic models study which revealed Higuchi matrix as best fitted model for release mechanism. Finally, SLN made of precirol ATO5 as solid lipid and water soluble surfactants as poloxamer 188, tween 80 and solutol HS15 (2:1:2 ratio) posses high potential to entrap DCB in lipid nanoparticle demonstrated good stability for six months and shelf life of 2.087 years, showed better prospects for the oral delivery of DCB.

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