OMICS International conferenceseries.com SciTechnol

Mansi K Shah, J Pharm Drug Deliv Res 2015, 3:3
http://dx.doi.org/10.4172/2325-9604.S1.002

World Drug Delivery Summit

August 17-19, 2015 Houston, USA

Preparation, *in-vitro* evaluation, statistical optimization and application of Caco-2 cell line for *in-vitro* absorption mechanism of Carvedilol-loaded solid lipid nanoparticles for oral delivery

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The availability of reliable high throughput screening methods for rapid evaluation and prediction of the absorption mechanism is needed with lipid based drug delivery systems especially for solid lipid nanoparticles. Carvedilol-loaded solid lipid nanoparticles (SLN) were prepared using solubility parameter (δ) to select the lipid, and hot homogenization to fabricate SLN. The effect of concentration of Compritol 888 ATO (COMP) and Poloxamer188 (P-188) on particle size of blank SLN was studied using design of experiments (DOE). Further narrow concentration range of COMP and P-188 was selected and carvedilol-loaded SLN were prepared to obtain an optimized formulation which was lyophilized (L-SLN), transformed into enteric compression coated tablet and evaluated for drug release, x-ray diffraction and cellular uptake mechanism. To elucidate the absorption mechanism in detail, cells were subjected to different pretreatments and transport studies. COMP was chosen as lipid due to its least value of Δδ with carvedilol. The optimized formulation (7.5% COMP, 5.0% P-188 and 1.11% carvedilol) had 161 nm particle size and 94.8% entrapment efficiency. The enteric-coated carvedilol-loaded SLN tablet protected carvedilol from acidic environment and similar prolonged release profiles were obtained from L-SLN, core tablet and enteric coated tablet. Absence of crystalline carvedilol XRD peak indicated presence of amorphous carvedilol in SLN. Based upon the results of uptake, pretreatments and transport studies, the main absorption mechanism of carvedilol-loaded SLN could be endocytosis and, more specifically, clathrin mediated endocytosis. Higher carvedilol uptake from SLN compared to drug solution in Caco-2 cell line exhibited a potential prolonged drug release in the body following the lymphatic uptake of carvedilol-loaded SLN which will avoid first pass metabolism and hence higher oral bioavailability.

Biography

Mansi Shah is currently a Research Scientist at Amneal Pharmaceuticals, Prior to joining Amneal, Shah has also worked as a Formulation Scientist at Hi-tech Pharmacal-An Akorn Company, USA. At a very young age, she received her Ph.D. in Industrial Pharmacy, Pharmaceutical Sciences from St.John's University in 2013. Shah has done extensive research to develop an oral drug delivery system for drug molecules which suffers low bioavailability due to poor aqueous solubility and high first pass metabolism. She has completed her M.S. in the same major from the same university in 2009. She has also served as a Scientist in few other pharmaceutical companies. Shah has been recipient of several awards at International and local conferences including travel-ship award in AAPS-2012 from Merck. She is also a recipient of Graduate scholarship award by NJPhAST. She has presented her research at both national and international conferences. Shah is a very young, enthusiastic, and focused with a keen scientific knowledge.

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