J Pharm Drug Deliv Res 2017, 6:3 (Suppl)
http://dx.doi.org/10.4172/2325-9604.C1.018

Development and validation of high performance liquid chromatography method for Atorvastatin calcium in pharmaceutical dosage forms

M Diril, G Yıldız Türkyılmaz and H Y Karasulu
Ege University, Turkey

Atorvastatin calcium (AtrCa) is a BCS class 2 classification group and displays low resolution with high permeability. AtrCa has almost 14% bioavability absolutely. The aim of this study is to develop and validate an analytical method for oral delivery of AtrCa in pharmaceutical dosage form. The HPLC system consisted of a gradient pump, thermo stable column department and a UV detector supplied by Agilent 1100. The column was a C18 column (5 µm, 150x4,6 mm) (ACE). All UV-Vis spectrums were monitored between 200-400 nm and quantification was performed at 238 nm. The injection volume was 20µL and the retention time of AtrCa was about 7.1 min. The mobile phase was mixture of acetonitrile and 0.1 M sodium di-hydrogen phosphate (55:45) (v/v) and adjusted to pH 3 with trifluoroacetic acid (1 mL) pumped at 1 mL/min. The HPLC method was validated partially with respect to linearity, limit of detection (LOD) and quantitation (LOQ), precision and accuracy. The linearity between peak area and concentration was analyzed using three calibration curves obtained in the different days with standard solutions of AtrCa at 11 different concentrations ranging from 0.065 to 20 ppm for AtrCa. Data indicate that AtrCa peak area is linear over concentration range of 0.065-20 ppm. The R2 for regression line is 0.999 with slope of 61.428 and y+ intercept of 15.33. LOD was found 0.429 µg /mL and LOQ was found 1.30 µg/mL. In conclusion, an efficient high performance liquid chromatographic method was developed and validated method described is suitable for oral delivery of AtrCa.

mine.diril@gmail.com

Development and evaluation of Self-Emulsifying Drug Delivery System (SEDDS) pellet for Atorvastatin calcium

M Diril[1], H Y Karasulu[1] and I Nikolakakis[2]
[1]Ege University, Turkey
[2]Aristotle University of Thessaloniki, Greece

Atorvastatin calcium is poorly soluble in water and anti-hyperlipidemic drug, having a biological half-life of 14 hours. Lipid-based formulations have attracted attention in recent years because it improves the solubility of active substances showing low solubility and low bioavailability in gastrointestinal tract. These formulations have many advantages such as easy to prepare, can reduce the impact of food and reduce interpersonal variation. Self-emulsifying pharmaceutical pellets combine the advantages of emulsions and solid dosage forms, improved absorption of low solubility drugs and better stability in the gastric fluids. Among the approaches to improve the oral bioavailability, the use of self-emulsified drug delivery pellet systems (SEDDS-pellet) has been shown to be reasonably successful in improving the oral bioavailability of poorly water-soluble and lipophilic drugs. The aim of this study is to develop a new dosage form, alternative to the classical tablet forms of Atorvastatin. In this study, oleic acid was used as the oil phase, Tween 20 and Span 80 were used as the surfactants, N-methylpyrrolidone was used as the co-surfactant and both avicel and aerosol were used as the solid phase. The prepared SEDDS-pellet formulations are characterized for size, shape, density and stability and dissolution studies. Permeation studies were examined with caco-2 cell culture. According to results, SEDDS-pellet formulation had a higher permeability value than the conventional tablet formulation.

mine.diril@gmail.com