ABSTRACT:

The purpose of this present research work was, to enhance the solubility, dissolution rate and formulation and evaluations of the Fast dissolving tablets of Rosuvastatin calcium and Atorvastatin calcium. These two drugs are insoluble in water which leads to low bioavailability and incomplete absorption. The primary aim is to enhance the drug solubility and dissolution rate of Rosuvastatin Calcium and Atorvastatin Calcium by different solubility enhancement methods by complexation with β-cyclodextrins and HP-β-cyclodextrins. The Physical mixture, Kneading and Spray drying methods were used for the preparation of the inclusion complexes. The inclusion complexes of Atorvastatin calcium and Rosuvastatin calcium with β-CD and HP-βCD formulated in different molar ratios like 1:1, 2:1 and 1:2. The phase solubility study of Atorvastatin calcium and Rosuvastatin calcium was carried out. The study indicated that, there is formation of AL type curves for both the drugs at 1:1 stoichiometric ratios.

All formulated inclusion complexes of Rosuvastatin Calcium and Atorvastatin Calcium has showed increased dissolution rate when compared with the pure drug. The inclusion complexes of Atorvastatin Calcium and Rosuvastatin Calcium were characterized using X-ray diffraction study, Differential Scanning Colorimetry and Scanning Electron Microscopy studies, by these studies it has been concluded that, there was complete complexation of drug with complexing agents. Dissolution rate of Atorvastatin Calcium and Rosuvastatin Calcium with β-CD and HPβ-CD (1:1) by above methods showed higher than the pure drug. The Spray drying method showed increased dissolution rate compared with the physical and kneading method. The complexes of formulation RF16 and AF16 Prepared with Spray drying method was showed increased solubility and enhanced dissolution rate of Atorvastatin Calcium and Rosuvastatin Calcium. So, this inclusion complex was used to prepare the fast dissolving tablets using the method like, Direct Compression. The superdisintegrants such as Crosspovidone, Crosscarmellose and Sodium starch glycolate employed for the preparation of FDT tablets. The composition of Crosspovidone formulations of Rosuvastatin Calcium and Atorvastatin calcium showed faster results such as, wetting, disintegration, dispersion time and good water absorption ratio compared with another two superdisintegrants like, Sodium starch
glycolate and Croscarmellose. The in vitro drug dissolution studies of all formulations shows 85% to 99% drug release within 12 minutes. The formulation of Rp8 and AP8 showed the in vitro drug release as 98.22% and 95.42%. The formulation of Rp8 showed highest drug release, in vitro dispersion and in vitro disintegration compared to formulation Ap8. Hence it concludes that, the fast dissolving tablets of Rosuvastatin calcium and Atorvastatin calcium has the increased bioavailability and improved patient compliance. Keywords: Rosuvastatin calcium, Atorvastatin Calcium, Solubility enhancement, Cyclodextrins, Inclusion complexes.