Novel sublingual tablets of Atorvastatin calcium/Trimetazidine hydrochloride combination; HPTLC quantification, in vitro formulation and characterization


Abstract:

Background: Ischemic heart disorders and accumulation of lipids in blood vessels could contribute to angina pectoris. Therefore, the aim of this study was to formulate sublingual tablets containing a novel combination of Atorvastatin calcium (ATOR) and Trimetazidine HCl (TMZ) for efficient treatment of coronary heart disorders. Methods: The dissolution rate of water-insoluble ATOR was enhanced via complexation with sulfobutyl ether-b-cyclodextrin (SBE-b-CD) and addition of soluplus as a polymeric solubilizer excipient. The solubilized ATOR and TMZ were compressed into a sublingual tablets by direct compression technique and evaluated for their tableting characteristics. In addition, a new validated method based on High Performance Thin Layer Chromatography (HPTLC) was developed for simultaneous determination of both drugs in pure forms and sublingual tablets. Results: The developed HPTLC method showed LODs of 0.056 and 0.013 lg/band and LOQs of 0.17, 0.040 lg/band for TMZ and ATOR, respectively and proved to be linear, accurate, precise and robust. The optimum formulation containing mixture of superdisintegrants; Ac-Di-Sol and crospovidone (4.8% w/w, each) showed the shortest disintegration time (65 s) and enhanced release profiles of both drugs. Conclusions: The prepared sublingual tablets combining ATOR and TMZ will be a promising dosage form for coronary heart disease patients with an instant action and improved patient compliance.

Keywords:

Atorvastatin; Trimetazidine; Sublingual tablets; HPTLC; Sulfobutylether-b-Cyclodextrin

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