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Application of UPLC-MS/MS for separation and quantification of carvedilol and 4-hydroxyphenyl carvedilol and comparative bioavailability of two carvedilol formulations in healthy volunteers

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In the present study, a novel, fast, sensitive and robust method, to separate the two Carvedilol stereo isomers i.e. 4-Hydroxyphenyl Carvedilol and 5-Hydroxyphenyl Carvedilol and quantify the Carvedilol and 4-Hydroxyphenyl Carvedilol in human plasma using UPLC-ESI-MS/MS is described. Carvedilol D5 and 4-Hydroxyphenyl Carvedilol D5 were used as internal standards (IS). The analytes and IS were extracted from human plasma by Solid Phase extraction. Extracted samples were analyzed by Ultra performance Liquid Chromatography coupled to atmospheric pressure electro spray ionization (UPLC-ESI-MS/MS). Chromatography was performed using gradient on ACQUITY UPLC® BEH C18 1.7 μ (2.1mm x 100mm) analytical column. The temperature of auto sampler was set to 5°C and run time was 7.5 minutes. A linear calibration curve over the range of 0.500 to 100.000 ng/mL for Carvedilol and 0.050 to 10.000 ng/mL for 4-Hydroxyphenyl Carvedilol was obtained. This method was successfully applied to a pharmacokinetic study in order to compare a test Carvedilol 12.5 mg formulation vs. a reference 12.5 mg Carvedilol tablet formulation in 50 human volunteers under fast conditions. It is concluded that test formulation of Carvedilol is bioequivalent to reference formulation of Carvedilol.

Biography

P K Patel is Associate Professor & Research Scientist in M. G. Science Institute, one of the reputed organizations of Ahmedabad. He has 27 yrs. of teaching and research experience. He has completed his Bachelors, Masters from the Gujarat University and PhD from HNGU. He has made his significant contribution in analytical chemistry and organic chemistry. He has published more than 35 papers in reputed journal and serving as a reviewer of many PhD theses. He is a reputed guide in more than 3 universities. 3 students have already obtained their PhD award and 5 students are working under his guidance. He has actively participated in various organizations of academic and government bodies of India. He has contributed in many small plant industries.

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