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Simultaneous determination of Carvedilol and its metabolite in human plasma by liquid chromatography-tandem mass spectrometry with electrospray ionization method and its application to a bioequivalence study

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Carvedilol is an adrenergic blocking agent for the treatment of chronic heart failure, left ventricular dysfunction and hypertension. Several strengths of carvedilol tablets ranging from 3.125-25 mg are available in market. A Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS) method has been developed and validated for determination of Carvedilol and its metabolite (4'-hydroxyphenyl carvedilol) in the wide range of concentration using Carvedilol-d5 and 4'-hydroxyphenyl carvedilol-d5 as Internal Standards [ISs]. The analytes and ISs were extracted from human plasma via liquid-liquid extraction. The reconstituted samples were chromatographed on ACE5 C18 column using gradient mobile phase system composed of 0.01% formic acid solution (v/v): Acetonitrile and monitored in the positive ion mode by applying ESI probe. The calibration curves were linear over the range of around 0.1-100 ng/mL of carvedilol and around 0.05-10 ng/mL of the metabolite (r2>0.99). This method showed acceptable precision and accuracy, selective, good recovery and stability during the validation. The method was successfully applied to a bioequivalence study of Carvedilol 6.25 mg and 12.5 mg tablets formulations, Dilatrend® (reference product) and Carvolol GPO (test product) after oral administration to healthy Thai volunteers under fasting condition. The 90% confidence intervals of the least squares means ratios of the test to the reference product of $AUC_{0\text{-tlast}}$, $AUC_{0\text{-}\infty}$ and C_{max} of carvedilol were within the bioequivalence range of 80.00-125.00%.

Biography

Isariya Techatanawat is currently working as the Director of Bioequivalence Study Group, Research and Development Institute, the Government Pharmaceutical Organization (GPO), Bangkok, Thailand, responsible for method development, method validation and bio-analysis in biological fluids.

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