Abstract

Introduction: The validation concept refers to the statistical evaluation of the results obtained in the application of analytic technics, by appropriately documented and demonstrative tests that a method is sufficiently reliable to produce the result foreseen under defined conditions, like they are: analytic system, concentration interval, infrastructure and human talent. Objective: To describe the validation process of the analytic method for the valsartan quantification in human plasma by HPLC/UV and its application in pharmacokinetic, bioavailability and bioequivalence studies of products that contain the active principle valsartan. Methodology: A method for detection and quantification of valsartan in human plasma has been developed using an isocratic elution on reversed phase liquid chromatography with ultraviolet detection at a single wavelength (265 nm) and the addition standard method. Losartan was used as an internal standard. This method involves a solid-phase drug extraction (valsartan and losartan) from plasma using C8 cartridges. Separation was achieved on a C18 reversed phase column and the mobile phase consisted of 45% acetonitrile and 55% phosphate buffer (adjusted to pH 2.7 ± 0.1 with phosphoric acid). The assay has been validated over a concentration range of 0.05 to 20 µg/ml with addition of valsartan 2.5 µg/ml. Results and conclusions: Calibration curve was linear in the described concentration range. The reproducibility, stability and recovery of the method were evaluated. Determination of valsartan in human plasma by HPLC/UV method was accurate and precise with a quantitation limit of 1.485 µg/ml. The method was sufficiently sensitive for pharmacokinetic studies of valsartan in human plasma.

Keywords

Valsartan; Losartan; Solid-phase extraction; Addition standard method; HPLC/UV