Abstract

The purpose of this study was to develop a new stability indicating method for the analysis of trandolapril in formulation and raw material. In the present study a rapid, simple, economical reverse phase HPLC-DAD procedure has been developed for the determination of trandolapril.

The trandolapril was separated isocratically on Hypersil-Gold C18 column (Length- 250 mm, Diameter- 4.6 mm, Particle size- 5 μm) with a mobile phase consisting of 50% acetonitrile, 50% water ( containing 0.25 mL triethylamine, final pH was adjusted to 3.0 ± 0.1), operated at 25 ± 1 °C with a retention time less than 6 min. The total run time of the stressed study was 20 mins. The eluted drug was identified and monitored on a Photo Diode- Array detector (PDA) at 210 nm.

The linearity of the method was excellent ($r^2 > 0.9999$) over the concentration range of 1 - 24 μg/mL; the LOD and LOQ were 0.0566 μg/ml and 0.1715 μg/ml respectively.

The statistical evaluation of the method was examined by performing intraday and interday precision analysis. The overall precision (% CV, RSD) was less than 2%. Mean recovery of trandolapril was more than 99%, no interference was found from the other ingredient or component present in the preparation. The result of stability studies indicates that the drug was stable when exposed to direct sunlight or UV light. The drug gives 6 different oxidative products on exposure to hydrogen peroxide (oxidative stress). Under alkaline condition it was converted to trandolaprilate and other degradative products. Slight degradation (less than 0.4%) was observed in acidic condition.

In conclusion the method presented here is sensitive, rapid, accurate, precise, economic, robust, rugged and selective for the routine analysis of the drug in formulation and raw material.

Stability Indicating High Performance Liquid Chromatographic (HPLC-DAD) Determination of Trandolapril in Bulk Drug and Formulation

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Dean of Graduate Studies and Scientific Research Al-Ahliyya Amman University Jordan
July, 2012

Detailed view of the monograph

Title: Stability indicating high performance liquid chromatographic (HPLC - DAD) determination of trandolapril in bulk drug and formulation

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Publishing info: Amman: Al-Ahliyya Amman University , Graduate Studies and Scientific Research, 2012

Descriptors: PHARMACOLOGY MEDICINE PHARMACEUTICAL ANALYSIS MEDICINAL CHEMISTRY

Classification: Diss 615.1909565/H389