Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense)*
Lat. Am. J. Pharm. **32** (9): 1298-303 (2013)

Regular Article
Received: July 9, 2013
Revised version: August 12, 2013
Accepted: August 18, 2013

Development and Validation of an LC-MS method for Determination of Erlotinib in Rat Plasma and Applied in Pharmacokinetic Study

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***SUMMARY*. Erlotinib is a drug used to treat non-small cell lung cancer, pancreatic cancer and several other types of cancer. It is a reversible tyrosine kinase inhibitor, which acts on the epidermal growth factor receptor. After addition of linezolid as internal standard (IS), protein precipitation by acetonitrile-methanol (9:1, v/v) was used as sample preparation. Chromatographic separation was achieved on a Zorbax SB-C18 (2.1 mm × 150 mm, 5 μm) column with acetonitrile-0.1% formic acid as mobile phase with gradient elution. Electrospray ionization source was applied and operated in positive ion mode; selective ion monitoring (SIM) mode was used for quantification. Calibration plots were linear over the range of 5-2000 ng/mL for erlotinib in plasma. Mean recovery of erlotinib from plasma was in the range 90.9-95.6%. Coefficient of variation (CV) of intra-day and inter-day precision were both less than 10%. This method is simple and sensitive and applied successfully in pharmacokinetic of erlotinib in rat plasma.**

KEY WORDS: LC-MS, Erlotinib, Pharmacokinetics, Rat plasma.

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ISSN 0326-2383