4TH INTERNATIONAL PHARMACEUTICAL RESEARCH CONFERENCE 2018

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25 - 26 AUGUST 2018
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24 – 26 August 2018 | Cyberjaya, Malaysia

Development and Validation of LC-MSMS Method for the Analysis of Amlodipine and Perindopril in Tablet Dosage Form

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Keywords: Amlodipine, Perindopril, LC-MSMS, Validation

Abstract

Introduction: Amlodipine (AMLO) and Perindopril (PER) have been combined in one tablet dosage form which has been proven to be an effective and well tolerated antihypertensive. Many analytical methods were applied for the analysis of AMLO and PER in this combination but most of the methods are time and money consuming. A new sensitive, rapid, and specific LC-MS/MS analytical methods for the analysis of AMLO and PER was developed and validated. Chromatographic conditions for the best results were optimized using design of experiment method.

Method: The instrument used was Waters Aquity UPLC, and the column was Acquity BEH C18 (50 mm × 2.1 mm, 1.7 µm). The mobile phase consisted of solvent A which was 0.1% formic acid in water and solvent B which was ACN. The injected volume was 10 µl with a flow rate of 0.4 ml/min. samples were eluted following gradient program over 5 min. The column temperature was maintained at 35 °C. The detection was performed using Xevo TQD MS with ESI in positive mode. The method was validated according to ICH guidelines.
Result: The results showed that the retention times of AMLO and PER were 1.65 min and 1.78 min respectively. Method was linear for AMLO and PER over the range of 5-15 ng/ml with R^2 of 0.9988 and 0.9991 respectively. The accuracies of AMLO and PER were in the range of 98.1% -100.19%. LOD and LOQ were 50.28 and 152.78 pg/ml for AMLO respectively and 16.86 and 51.1 pg/ml for PER respectively. The developed and validated method was applied for the quantification of AMLO and PER at tablet dosage form which is available at the market with satisfactory results.
Conclusion: It can be concluded that this method is highly sensitive, rapid, selective and it can be used for the routine analysis of AMLO and PER in QC laboratories.