

Accepted Manuscript

Title: A new, rapid, stability-indicating UPLC method for separation and determination of impurities in amlodipine besylate, valsartan and hydrochlorothiazide in their combined tablet dosage form

Author: Jiří Vojta Aleš Jedlička Pavel Coufal Lucie Janečková

PII: S0731-7085(15)00112-0
DOI: <http://dx.doi.org/doi:10.1016/j.jpba.2015.01.059>
Reference: PBA 9958

To appear in: *Journal of Pharmaceutical and Biomedical Analysis*

Received date: 26-11-2014
Revised date: 16-1-2015
Accepted date: 19-1-2015

Please cite this article as: J. Vojta, A. Jedlička, P. Coufal, L. Janečková, A new, rapid, stability-indicating UPLC method for separation and determination of impurities in amlodipine besylate, valsartan and hydrochlorothiazide in their combined tablet dosage form, *Journal of Pharmaceutical and Biomedical Analysis* (2015), <http://dx.doi.org/10.1016/j.jpba.2015.01.059>

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



A new, rapid, stability-indicating UPLC method for separation and determination of impurities in amlodipine besylate, valsartan and hydrochlorothiazide in their combined tablet dosage form

Jiří Vojta^{a,b}, Aleš Jedlička^a, Pavel Coufal^b, Lucie Janečková^{a,*}

^a Zentiva, k.s., Praha, U Kabelovny 130, 102 37 Praha 10, Czech Republic

^b Department of Analytical Chemistry, Charles University in Prague, Faculty of Science, Hlavova 8, 128 43 Praha 2, Czech Republic

* Corresponding author, E-mail address: Lucie.Janeckova@zentiva.cz, tel: +420 267 242 354

Abstract

A new rapid stability-indicating UPLC method for separation and determination of impurities in amlodipine besylate, valsartan and hydrochlorothiazide in their combined tablet dosage form was developed. The separation of Ph. Eur. related substances of amlodipine besylate (A, B, D, E, F, G), hydrochlorothiazide (A, B, C), valsartan (B, C), two other valsartan impurities (S)-2-(N-([2'-cyanobiphenyl-4-yl]methyl)pentanamido)-3-methylbutanoic acid and (S)-3-methyl-2-([2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methylamino)butanoic acid and several unknown impurities was achieved by reversed phase liquid chromatography with UV detection. The detection wavelengths were set as follows: 225 nm for valsartan, its impurities and for the impurity D of amlodipine, 271 nm for hydrochlorothiazide and its impurities and 360 nm for amlodipine and its impurities except for impurity D. Zorbax Eclipse C8 RRHD (100 x 3.0 mm, 1.8 µm) was used as a separation column and the analytes were eluted within 11 minutes by a programmed gradient mixture of 0.01M phosphate buffer pH 2.5 and acetonitrile. The method was successfully validated in accordance to the International Conference of Harmonization (ICH) guidelines for amlodipine besylate and its impurity D,

Download English Version:

<https://daneshyari.com/en/article/7629587>

Download Persian Version:

<https://daneshyari.com/article/7629587>

[Daneshyari.com](https://daneshyari.com)