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Analytical method validation of alfuzosin hydrochloride and its organic impurities by using ultra performance liquid chromatography

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Abstract

A low cost ultra-high performance reverse phase liquid chromatography (RPUPLC) method has been proven for the investigation of alfuzosin hydrochloride in the existence of organic pollutants and decomposition products due to forced decomposition products. Attempts have been made to develop several methods for separating drugs from organic impurities. In addition, the best chromatographic separation is Waters Acquity HSS T3 C18, 100 mm×2.1 mm, UV detection at particle size 1.8, 254 nm, and Perchloric acid (pH 3.5 with sodium hydroxide) with a mixture of organic solvents. This method was endorsed for specificity / selectivity, linearity / range, reproducibility, recovery, and reliability. They can be utilized for quality control during manufacturing and for assessing the stability of commercially available alfuzosin hydrochloride samples. With a gradient time of about 6.0 min and an equilibration time of about 2.0 min, it was possible to analyze more than 100 samples per day. In addition, the pH susceptibility analysis methods referred to in the United States Pharmacopeia and the European Pharmacopoeia were discussed. The Method was successfully validated as per ICH Q2R1 guideline.

Section snippets

. Introduction

Alfuzosin can be a nonselective alpha-1 adrenergic antagonist applied within side the remedy of benign prostatic hypertrophy. Alfuzosin is associated with a espresso price of brief serum aminotransferase elevations and with uncommon times of clinically obvious acute liver injury. Organic impurities are frequently fashioned at some stage in the producing and garage of an API. To a specific extent, International Conference on Harmonization (ICH) attractiveness standards are supported…

Chemicals

Hydrogen peroxide (30%) was procured from Thermo Fisher Scientific. Perchloric acid 70%, sodium hydroxide procured from Sigma-Aldrich, and Methyl alcohol and ethanolnitrile were

analytical grade Perchloric acid 70%, Sodium Hydroxide procured from Sigma-Aldrich, Hydrogen peroxide (30%) purchased from Thermo Fisher scientific. LC grade methyl alcohol and ethanenitrile were used, while remaining was analytical grade. Theaqueous solutions andthemobilephase were prepared withHPLC-grade waterpurifiedwitha…

Results and discussion

All the impurities were eluted individually with Alfuzosin hydrochloride analyte and No blank interference were observed at the retention time of analyte and each impurities. The method has been successfully validated as per ICHQ2R1 requirements [13], [14], [15]….

Conclusion

The UPLC method used to determine contaminants in Alfuzosin hydrochloride and active pharmaceutical ingredient is accurate, precise, linear and specific. The method shall be used for routine analysis and stability analysis for its intended purpose….

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.…

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References (9)

M.I. Walash *et al.*
Simultaneous HPLC determination of alfuzosin, tamsulosin and vardenafil in human plasma and pharmaceutical formulations using time programmed fluorescence detection
Ann. Pharm. Fr. (2019)

J.P. Ahtoy *et al.*
Alfuzosin, an alpha1-adrenoceptor antagonist for the treatment of benign prostatic hyperplasia
J. Clin. Pharmacol. Therap. (2002)

Shivprasad DS, Shwetha HS, Vaishali Musale V, Sunil DR. Development and Validation of RPHPLC method for simultaneous...

M. Sirisha *et al.*
Method Development and Validation of Simultaneous Estimation of Alfuzosin Hydrochloride and Dutasteride in Bulk and Pharmaceutical Dosage Form by RP-HPLC
Int. Res. J. Pharm. Appl. Sci. (2012)

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