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Development of Ultra performance Liquid Chromatography (UPLC) method for the Separation of Alfuzosin Hydrochloride and its organic impurities

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Abstract

For assessing alfuzosin hydrochloride in the presence of organic contaminants and degradants by forced breakdown products, a novel, quick, precise, sensitive, specific, and stability-indicating reverse-phase (RP-UPLC) approach was established. Acquity BEH C18 (50×2.1 mm,1.7), BEH C8 (50×2.1 mm,1.7), Acquity CSH C18 (50×2.1 mm,1.8), and Acquity BEH C18 (100×2.1 mm,1.7) are among the rapid liquid chromatography columns that have been investigated. Low and neutral pH buffers were also used. Furthermore, the best chromatographic separation was achieved with a Waters Acquity HSS T3 C18, 100 mm×2.1 mm, particle size 1.8, UV detection at As a mobile phase carrier, (acetonitrile, tetrahydrofuran) is used. The final technique conditions enable excellent impurity separation, which can be used to analyse the stability of alfuzosin hydrochloride commercial samples as well as for quality control throughout production. The gradient time was about 6.5 min, and the re-equilibration time was roughly 1.5 min, allowing for more than 100 samples each day to be analysed. Aside from that, the pH sensitive analytical approach addressed in both the US and European Pharmacopoeias was explored.

Introduction

With the empirical formula $C_{19}H_{27}N_5O_4$•HCl and a molecular weight of 425.91 g/mol, alfuzosin hydrochloride is known as N-[3-[(4-amino-6,7-dimethoxy-2-quinazolinyl)methylamino]propyl]tetrahydro-2-furamide monohydrochloride. In the treatment of benign prostatic hypertrophy, alfuzosin is a nonselective alpha-1 adrenergic antagonist. Alfuzosin is linked to a low rate of transient serum aminotransferase increases and a small number of cases of clinically obvious acute liver damage. This work describes a simple step gradient reverse phase UPLC technique for separating impurities reported in the US and European Pharmacopeias, as well as potential impurities and degradants throughout our laboratory's synthesis process. During the manufacture and storage of an API, organic contaminants can develop. To some extent, approval criteria set by the International Conference on Harmonization (ICH) are based on pharmaceutical research or existing safety data as described in the ICH guidelines [1], [2], [3]. The majority of alfuzosin hydrochloride uses the classic HPLC method. However, in this experiment, the proposed analytical method is compatible with LCMS, with a total run time of approximately 8.0 min.The developed method is sensitive to detecting impurities at low concentrations with showing the separation of 8 potential impurities and degradation products in a “one-shot” analysis using the UPLC method.

Section snippets

Chemicals

70% perchloric acid, sodium hydroxide purchased from Sigma Aldrich, hydrogen peroxide (30%) purchased from Thermo Fisher Scientific. LC grade methyl alcohol and ethanonitrile were used, the rest were analytical grade. During the experiment, HPLC grade water was purified using the MilliQ Reagent Water System (Millipore, Bedford, Massachusetts) and used to prepare aqueous solutions and mobile phases. Alfuzosin hydrochloride samples were sourced locally and the impurity A-F was sourced from the…

Results and discussion

During development trails, it was evident that these impurities are strongly retained in neutral conditions and hence under acidic modifier, it can be better retained. Additionally, the addition of 1% Tefrahydrofuan in both the mobile phases (Aqueous and Organic) allow the maintain the concentration of Tetrahydrofuran as 1% throughout the chromatographic run time., which can help to improve the elution of peaks much earlier and benefits to improve the selectivity. Additionally, the 11% carbon…

Conclusion

The UPLC method used to determine impurities (Process, degradation) in Alfuzosin hydrochloride and active pharmaceutical ingredient have been successfully developed. The method has been evaluated and sufficient results have been obtained for all the verification parameters tested. The proposed approach can be used to easily measure the characteristics of Alfuzosin Hydrochloride in bulk pharmaceuticals. Because of the short running time of 6.5 mn, the consumption of lower solvent results is more …

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 (11)

International Conference on Harmonization (ICH) guidance on Impurities in New Drug Substances Q3A(R2),...

International Conference on Harmonization (ICH), Validation of analytical procedures: text and methodology, Q2 (R1),...

International Conference on Harmonization (ICH), Photo stability testing of new drug substances and products, Q1B,...

United states Pharmacopeia USP 43 NF 18, Monograph for Alfuzosin...

European Pharmacopoeia 10.5 Monograph for Alfuzosin...

There are more references available in the full text version of this article.

Cited by (0)

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