Analysis of Loratadine and Related Substances Using the ACQUITY UPLC H-Class System

Develop a method that is approximately five times faster and produces data of equal or better quality than current HPLC methods by using the ACQUITY UPLC H-Class System. This system provides an ideal solution for laboratories running USP compendial HPLC methods or that are looking to migrate current methods to the efficiency and cost-effectiveness of UPLC.

GOAL

Successfully transfer the compendial HPLC method for the analysis of Loratadine, as written, to the ACQUITY UPLC® H-Class System and subsequently migrate to a UPLC®-optimized method.

BACKGROUND

Drug substances and drug products are routinely analyzed for impurities and related substances and for assay of active pharmaceutical ingredient (API) content to ensure efficacy and safety of the pharmaceutical product. The U.S. Pharmacopeia (USP) compendial methods used for these analyses typically employ HPLC utilizing long columns resulting in excessive run times. In the case of Loratadine and Loratadine Tablets, an antihistamine drug used to treat allergies, the USP method for Related Substances (RS) and Assay uses a 4.6 mm x 15 cm L7 column at 1.0 mL/min with an isocratic run time of approximately 20 minutes. A second RS method (designated Test 2) for Loratadine prepared by a different synthetic route calls for a 4.6 mm x 25 cm L1 column at 1.2 mL/min with a gradient run time of 50 minutes in order to separate an additional impurity. Any reduction in analysis time can correspond to significant cost savings for an analytical lab.

SOLUTION

The method provided from the USP was run on a traditional HPLC system (Alliance® HPLC with a 2998 Photodiode Array Detector) exactly as written in the monograph. The entire analysis was then run, exactly as written, on the ACQUITY UPLC H-Class System. Results from these two assays (retention time reproducibility, relative retention time, and impurity levels) were compared to show the ACQUITY UPLC H-Class System has the ability to perform compendial methods of this type equally or better than traditional HPLC technology.

The compendial HPLC method was transferred to a UPLC method using the instrument's built-in ACQUITY UPLC Columns Calculator. Using this newly calculated method, the entire sample set was analyzed, and the results compared (retention time reproducibility, relative retention times, and impurity levels) to the HPLC results. Using this significantly shorter run time method with a reduction from 20 minutes for the isocratic run to 4 minutes, the results compared favorably to those obtained both from the ACQUITY H-Class System running the HPLC method and the traditional HPLC system (*Figure 1*).

SUMMARY

A compendial HPLC method for the assay of Loratadine and Related Substances was successfully run as written on the Waters ACQUITY UPLC H-Class System. Results obtained on the system were equivalent to those obtained on the Alliance HPLC System, meeting the requirements of the USP method.

With the help of the ACQUITY UPLC Columns Calculator, the method was transferred to UPLC on the ACQUITY UPLC H-Class System. This new UPLC method was approximately five times faster and produced data of equal or better quality than the current HPLC method. When high quality results are produced more quickly, laboratory productivity increases and cost-per-sample decreases.

The Waters ACQUITY UPLC H-Class System is an ideal solution for laboratories running USP compendium HPLC methods or that are seeking to migrate their current HPLC methods to the more efficient and cost-effective UPLC technology platform.

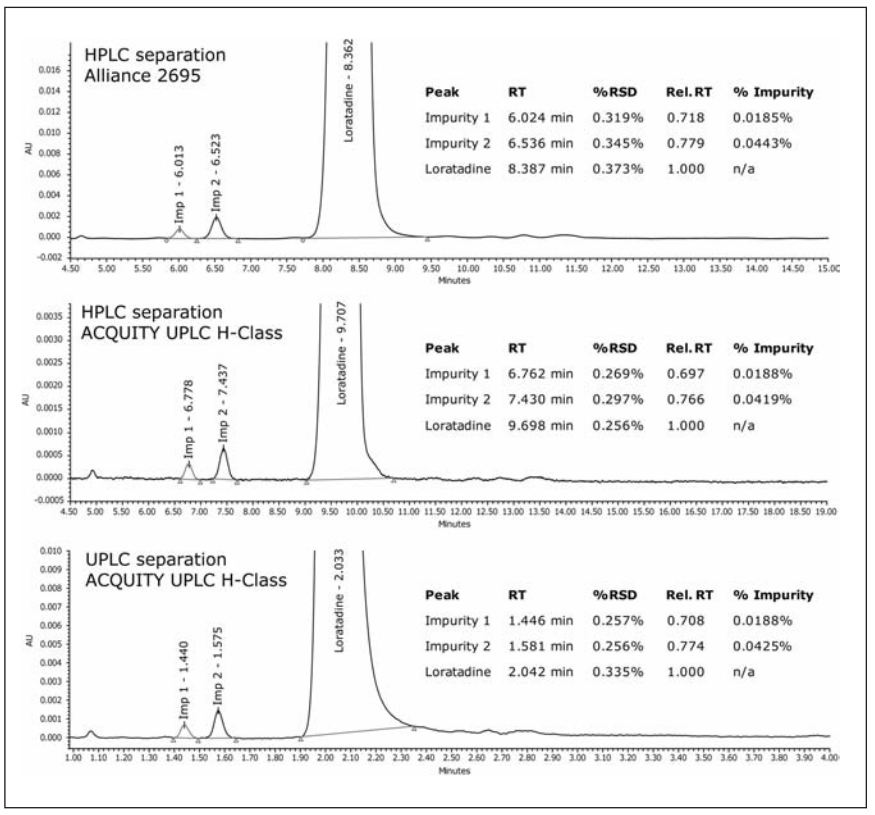

Figure 1. Comparison of Loratadine and Related Substances run by HPLC on Alliance HPLC System vs. HPLC run on ACQUITY UPLC H-Class and UPLC run on the same.