Abstract

Objective: The purpose of this work was to convert conventional HPLC method to the conditions of UFLC for determination of related substances of Quetiapine Fumarate tablet; new method should need less organic solvents, shorten the analysis time and be validated to guarantee its suitability. Methods: The new chromatographic conditions were assigned using an online method transfer calculator to convert HPLC parameters to UFLC parameters. The suitability of the new method was validated by system suitability test, linearity, quantification limit, detection limit, selectivity, precision and accuracy. Results: The method was shown to be suitable as the tailing factor of the peaks was kept within the limit range of 0.8 – 1.5 and the resolution of each of the peak areas was in all cases greater than 2. In linearity testing, the correlation coefficient obtained from the procedure was 0.999, which showed that the two variables, the peak areas and the range of five different concentrations of the sample highly correlate with each other. The quantification limit obtained from the method was 0.03%, while the detection limit was 0.01%. The selectivity of the method was confirmed as the peak areas of two placebo solutions were shown not to interfere with the peak areas of quetiapine and the impurities dibenzo and triethoxy. The precision of the method was ensured as the relative standard deviation of multiple injections was 3.27% for dibenzo impurity and 4.42% for triethoxy impurity. The accuracy of the method was confirmed as the recovery of the added amount of impurity in the sample was 93.56% for dibenzo and 105.90% for triethoxy impurity. Conclusion: the new method was successfully validated as all the results obtained are within the range of Ph.Eur. and USP requirements; the new method provided shorter analysis, less organic solvent and a better separation efficiency.