Development and Validation of UV Spectrophotometric and RP-HPLC Methods for Estimation of Aliskiren Hemifumarate and Valsartan in bulk and Pharmaceutical Dosage Form

Submitted By

Hitesh Chandubhai Gorwadia

Supervised By

Dr. Suresh M. Jain

M. Pharm., PhD.

Associate Professor and HOD, Dept. of Pharmaceutical Quality Assurance

Baroda College of Pharmacy

Limda, Ta. Waghodia, Dist. Vadodara 391760

ABSTRACT

A First order derivative spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Aliskiren hemifumarate and Valsartan in bulk and synthetic mixture. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of aliskiren hemifumarate and valsartan. The method employed First order derivative method based on the measurement of absorbance at two wavelengths, 280 and 255 nm, ZCP of Aliskiren hemifumarate and valsartan, respectively. The calibration curve was linear in a concentration range of 8-26 µg/ml for Aliskiren hemifumarate and 6-24 µg/ml for valsartan. The RP-HPLC method has shown adequate separation of Aliskiren hemifumarate and valsartan in bulk and its synthetic mixture. The separation was achieved on a Phenomenex luna ODS C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with an gradient system of Water: Methanol in the ratio of 60:40 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and

wavelength of detection used was 250nm. The retention time for Aliskiren hemifumarate and valsartan was obtained as 1.843±0.1min and 3.197±0.2min, respectively. The linearity of the proposed method was investigated in the range of 5-25µg/ml and 5-25µg/ml for Aliskiren hemifumarate and valsartan, respectively. Correlation coefficient was 0.998 and 0.999 for Aliskiren hemifumarate and valsartan, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Aliskiren hemifumarate and valsartan. These analytical methods are also applicable in ordinary laboratories . It can also be adopted for quality control tests for these drugs in tablets.

Key words: Aliskiren hemifumarate, Valsartan, First order derivative method, RP-HPLC, Validation.