

**Analytical method development and validation for the
estimation of Aliskiren Hemifumarate and Hydrochlorothiazide
in bulk and pharmaceutical dosage form**

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ABSTRACT

A simple, accurate, precise and sensitive UV spectrophotometry method namely absorption ratio and RP-HPLC methods have been developed and validated for estimation of Aliskiren Hemifumarate and Hydrochlorothiazide in combined tablet dosage form and can be used in routine analysis. In **UV spectrophotometry method** namely absorbance ratio method, absorbance measured at iso-absorptive point 275 nm (correlation coefficient was found to be 0.999 and 0.997 for Aliskiren Hemifumarate and Hydrochlorothiazide respectively) and 270 nm (correlation coefficient was found to be 0.999 and 0.997 for Aliskiren Hemifumarate and Hydrochlorothiazide respectively). Assay was found to be 102.86% and 97.60% for Aliskiren Hemifumarate and Hydrochlorothiazide respectively. The methods were found to be linear in the concentration range of 20-70 μ g/mL and 2.5-12.5 μ g/mL for Aliskiren Hemifumarate and Hydrochlorothiazide respectively.

In **RP-HPLC**, method was carried out by isocratic technique on a reversed-phase: Enable C₁₈ (250mm x 4.6 mm i.d., 5µm particle size) and UV detection at 275 nm with mobile phase containing a mixture of water : acetonitrile : triethylamine (35:65:0.25) at a flow rate of 1.0 mL/min. The average retention times for Hydrochlorothiazide and Aliskiren Hemifumarate were 5.03 and 8.38 min respectively. The calibration curves were linear in the concentration range of 30-150µg/mL and 2.5-12.5µg/mL for Aliskiren Hemifumarate and Hydrochlorothiazide respectively. Correlation co-efficient were found to be 0.997 and 0.998 for Aliskiren Hemifumarate and Hydrochlorothiazide respectively. Mean assay was found to be 100.79% and 98.93% for Aliskiren Hemifumarate and Hydrochlorothiazide respectively. These analytical methods are also applicable in ordinary laboratories . It can also be adopted for quality control tests for these drugs in tablets.

KEYWORDS: Aliskiren Hemifumarate, Hydrochlorothiazide, Absorption ratio and RP-HPLC.