DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF ALISKIREN HEMIFUMARATE AND AMLODIPINE BESYLATE IN BULK AND IN THEIR PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A simple, accurate, precise and stability indicating RP-HPLC method was developed and validated for estimation of Aliskiren Hemifumarate and Amlodipine Besylate in bulk and tablet dosage form. The RP-HPLC method has shown adequate separation for Aliskiren Hemifumarate and Amlodipine Besylate from its degradation products. The separation was achieved on a enable ODS C_{18} (250mm X 4.6mm i.d., 5µm particle size) with an isocratic mixture of water: acetonitrile pH-3.5 adjusted with o-phosphoric acid in the ratio of 45:55 v/v. The mobile phase at a flow rate of 1.0ml/min, Injection volume 20µl and wavelength of detection was kept at 235nm. The retention time for Aliskiren Hemifumarate and Amlodipine Besylate was 4.027 min and 7.36 min respectively. The linearity of the proposed method was investigated in the range of 30-150µg/mL and 2-10µg/mL for Aliskiren Hemifumarate and Amlodipine Besylate, respectively.

Correlation coefficient was 0.998 and 0.997 for Aliskiren Hemifumarate and Amlodipine Besylate respectively. The limit of detection was 1.01µg/mL and 0.48µg/mL for Aliskiren Hemifumarate and Amlodipine Besylate respectively and the limit of quantification was 3.06µg/mL and 1.47µg/mL for Aliskiren Hemifumarate and Amlodipine Besylate, respectively. Forced degradation study was carried out on combined dosage form as per ICH guideline and it was exposed to hydrolysis (acid and base hydrolysis), oxidative, thermal and sunlight conditions to apply stress. Proposed method was validated as per ICH guidelines for linearity, accuracy, precision, specificity and robustness for estimation of Aliskiren Hemifumarate and Amlodipine Besylate in commercially available pharmaceutical dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Key words: Aliskiren Hemifumarate and Amlodipine Besylate, Stability indicating RP-HPLC method, Forced degradation