"ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF AZILSARTAN MEDOXOMIL AND AMLODIPINE BESYLATE HYDROCHLORIDE IN BULK AND PHARMACEUTICAL DOSAGE FORM."

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Guide

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ABSTRACT

A First order derivative spectroscopic method, and RP-HPLC method were developed and validated for simultaneous estimation of Azilsartan medoxomil and Amlodipine Besylate HCl in pharmaceutical dosage form. First order derivative method based on the measurement of absorbance at two wavelengths, 248.66 nm and 228.16 nm, ZCP of Azilsartan medoxomil and Amlodipine Besylate HCl respectively. The calibration curve was linear in a concentration range of 12-28 µg/ml for Azilsartan medoxomil and 3-7 µg/ml for Amlodipine Besylate HCl. The RP-HPLC method has shown adequate separation of Azilsartan medoxomil and Amlodipine Besylate HCl in its Dosage form. The separation was achieved on a Enable C18 H (250mm X 4.6 mm i.d., 5 µm particle size) with an Isocratic system of Acetonitrile : Phosphate Buffer (pH 3.8) in the ratio of 80:20 v/v at flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 242 nm. The retention time for Azilsartan medoxomil and Amlodipine Besylate HCl was obtained as 3.24±0.01min, and 6.18±0.01 min respectively. The linearity of the proposed method was investigated in

the range of 12-52 µg/ml and 3-13µg/ml for Azilsartan medoxomil and Amlodipine Besylate HCl. respectively. Correlation coefficient was 0.997 and 0.998 Azilsartan medoxomil and Amlodipine Besylate HCl 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 for estimation of Azilsartan medoxomil and Amlodipine Besylate HCl.

Key words: Azilsartan medoxomil and Amlodipine Besylate HCl, First order derivative method, RP-HPLC Method.