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RP-HPLC Method Development and Its Validation for Simultaneous Estimation of Metoprolol Succinate and Olmesartan Medoxomil Combination in Bulk and Tablet Dosage Form

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Abstract : A simple, accurate, precise, sensitive and specific RP-HPLC method was developed and validated for simultaneous estimation of Metoprolol Succinate and Olmesartan Medoxomil in bulk and tablet dosage form. The RP-HPLC method has shown adequate separation for Metoprolol Succinate and Olmesartan Medoxomil from its degradation products. The separation was achieved on a Phenomenex luna ODS C18 (250mm X 4.6mm i.d., 5µm particle size) with an isocratic mixture of acetonitrile: 50mM phosphate buffer pH 4.0 adjusted with glacial acetic acid in the ratio of 55:45 v/v. The mobile phase at a flow rate of 1.0ml/min, Injection volume 20µl and wavelength of detection was kept at 225nm. The retention time for Metoprolol Succinate and Olmesartan Medoxomil was 2.451±0.1min and 6.167±0.1min, respectively. The linearity of the proposed method was investigated in the range of 5-50µg/ml and 2-20µg/ml for Metoprolol Succinate and Olmesartan Medoxomil, respectively. Correlation coefficient was 0.999 and 0.9996 for Metoprolol Succinate and Olmesartan Medoxomil, respectively. The limit of detection was 0.2847µg/ml and 0.1251µg/ml for Metoprolol Succinate and Olmesartan Medoxomil, respectively and the limit of quantification was 0.8630µg/ml and 0.3793µg/ml for Metoprolol and Olmesartan, respectively. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision, specificity and robustness for estimation of Metoprolol Succinate and Olmesartan Medoxomil in commercially available tablet dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Keywords : metoprolol succinate, olmesartan medoxomil, RP-HPLC method, validation, ICH
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