Development and Validation of Analytical Methods for Simultaneous Estimation of metoprolol succinate and chlorthalidone as API and Its formulation

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<u>ABSTRACT</u>

A First order derivative spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Metoprolol succinate and Chlorthalidone as API and its formulation. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Metoprolol succinate and Chlorthalidone. The method employed First order derivative method based on the measurement of absorbance at two wavelengths, 243.1 nm and 267.35 nm, ZCP of Metoprolol succinate and Chlorthalidone, respectively. The calibration curve was linear in a concentration range of 8-32 μg/ml for Metoprolol succinate and 2-8 μg/ml for Chlorthalidone. The RP-HPLC method has shown adequate separation of Metoprolol succinate and Chlorthalidone as API and its formulation. The separation was achieved on a Enable C18 (250mm X 4.6 mm i.d, 5 μm particle size) with an gradient system of Phosphate buffer (pH-5.0, 0.02M): Acetonitrile:

Water in the ratio of 60:20:20 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20 μl and wavelength of detection used was 232 nm. The retention time for Metoprolol succinate and Chlorthalidone was obtained as 2.978±0.1min and 3.711±0.1min, respectively. The linearity of the proposed method was investigated in the range of 10-60 μg/ml for metoprolol succinate and 2.5-15 μg/ml Chlorthalidone. Correlation coefficient was 0.997 for metoprolol succinate and 0.998 for Chlorthalidone. 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, simple and useful for estimation of Metoprolol succinate and Chlorthalidoneand are also applicable in research. It can also be adopted for quality control tests for these drugs in dosage form.

Key words: Metoprolol succinate ,Chlorthalidone, First order derivative
method, RP-HPLC, Validation.