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Stability Indicating RP-HPLC Method for Simultaneous Assay of Bisoprolol and Hydrochlorothiazide in Combined Tablet Dosage Form

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Abstract : A simple, sensitive, precise and accurate stability-indicating HPLC with photodiode array detection method has been developed and validated for simultaneous determination of bisoprolol and hydrochlorothiazide in its bulk and combined tablet dosage form. Chromatographic separation was achieved on an YMC Pack Pro C18 column (250 mm \times 4.6 mm; 5 µm particle size, maintained at a temperature of 30 °C) by a mobile phase consisted of 0.1% orthophosphoric acid and acetonitrile (55:45, v/v) with a flow rate of 1.0 ml/min. The detection wavelength was set at 259 nm. Bisoprolol and hydrochlorothiazide was subjected to different forced degradation conditions. In all the conditions, the degradation products were well resolved from the pure drugs with different retention time values. The method was linear $(R^2 = 0.9999)$ at a concentration range of 40-120 µg/ml (bisoprolol) and 50-150 µg/ml (hydrochlorothiazide). The limit of quantitation was 0.398 and 0.385 µg/ml for bisoprolol and hydrochlorothiazide, respectively. The precision of the method was satisfactory; the relative standard deviations did not exceed 1%. The accuracy of the method was proved; the mean recovery of both drugs was in the range of 99.67% to 100.28%. The proposed HPLC method would have a significant value when applied in quality control laboratories for the simultaneous assay of bisoprolol and hydrochlorothiazide.

Key words: antihypertensive, Bisoprolol, hydrochlorothiazide, stability-indicating, chromatographic analysis.

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