DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF ETIZOLAM AND PROPRANOLOL HYDROCHLORIDE IN BULK AND ITS FORMULATION

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ABSTRACT

An Absorption ratio Method and RP-HPLC methods were developed and validated for simultaneous estimation of Etizolam and Propranolol Hydrochloride in bulk and synthetic mixture. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Etizolam and Propranolol Hydrochloride. The

method employed Absorption ratio method based on the measurement of absorbance at two wavelengths, 249 and 264.03 nm, λ_{max} of Etizolam and Isobestic Point, respectively. The calibration curve was linear in a concentration range of 1-6 µg/ml for Etizolam and 40-160 µg/ml for Propranolol Hydrochloride. The RP-HPLC method has shown adequate separation of Etizolam and Propranolol Hydrochloride in bulk and its synthetic mixture. The separation was achieved on a Nova-pack C_{18} (150mm X 4.6 mm i.d., 4 µm particle size) With an isocratic system of Phosphate buffer (pH): ACN at pH 5 in the ratio of 60:40 v/v. The mobile phase at a flow rate of 0.75 ml/min, Injection volume 20µl and wavelength of detection used was 264 nm. The retention time for Etizolam and Propranolol Hydrochloride was obtained as 4.33±0.1min and 8.83±0.2min, respectively. The linearity of the proposed method was investigated in the range of 0.5-3µg/ml and 20-120µg/ml for Etizolam and Propranolol Hydrochloride, respectively. Correlation coefficient was 0.9988 and 0.9998 for Etizolam and Propranolol Hydrochloride, 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 with good sensitivity for estimation of Etizolam and Propranolol Hydrochloride. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablets.

Key words: Etizolam, Propranolol Hydrochloride, Absorption ratio method, RPHPLC, Validation.