DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF BUPROPION AND NALTREXONE IN COMBINATION

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ABSTRACT

A simple, accurate, and precise UV spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Bupropion and Natrexone in Combination.

UV spectrophotometric method has been developed using Water as a solvent in First Order Derivative method determination was carried out at 262.33 nm λmax ZCP of Naltrexone and 227.19nm λmax ZCP of Bupropion. The calibration curves were linear 10-60 µg/ml and 1-6 µg/ml for Bupropion and Naltrexone at their respective wavelength. Both the drugs were found in good agreement with the label claimed in the marketed formulation. In Combination both the drugs were estimated as 98.6% and 99.4% Bupropion and Naltrexone respectively.

The RP-HPLC method has shown adequate separation of Bupropion and Naltrexone in Combination. The separation was achieved on a Phenomenex luna ODS C18 (250mm X 4.6 mm i.d., 5 µm particle size) with an gradient system of Buffer(pH 3.5) :Methanol in the ratio of (70:30% v/v). The mobile phase at a flow rate of 1.0 ml/min, injection volume 20µl and wavelength of detection used was 238nm. The retention time for Bupropion and Naltrexone was obtained as 7.060±0.05min and 2.550±0.1min respectively. The linearity of method was investigated in the range of 22.5-78.75µg/ml and 2-7µg/ml for Bupropion and Naltrexone respectively. R^2 was 0.9991 and 0.9991 for Bupropion and Naltrexone 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 rapid and simple for estimation of Bupropion and Naltrexone.

Key words: Bupropion, Naltrexone, First Order Derivative Method, RP-HPLC, Validation.