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Determination of Bromazepam from pharmaceutical formulations with reverse with reverse phase LC method for in vitro dissolution test

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Bromazepam is a benzodiazepine generally used for a number of medical reasons, it is an intermediate-acting tranquilizer, prescribed for the treatment of moderate to severe anxiety and panic attacks for the short-term treatment of insomnia. It has been widely used in psychiatry disorders for four decades, with selective anxiolytic, anticonvulsant, myorelaxant and hypnotic actions. It acts on the central neural system as an inhibitor of the neurotransmitter gamma aminobutyric acid (GABA).
The biotransformation from solid into absorbable form depends on its dissolution in organic liquids; therefore, dissolution tests became an essential parameter to determine the properties of pharmaceutical formulations in order to predict their quality. The quality of pharmaceutical formulations is important in financial and ethical terms because it is directly associated with the patient's health. Thus, there is a real need for the development of dissolution tests able to predict in vivo physiological behavior.

The present study is focused on minimizing limitations and developing a simple, precise, accurate and economic method for estimation of Bromazepam in tablet dosage forms.

Dissolution test is a standardized method for measuring the rate of drug release from a dosage form. For dissolution medium 0.1 M HCl was chosen, in volume of 500 ml, at 37ºC, performed on ERWEKA DT 700, apparatus 2 (paddle), with 75 rpm for 45 minutes. An analytical method for Dissolution by using High Performance Liquid Chromatography technique was validated for content of Bromazepam and the validation was carried out on Shimadzu Nexera HPLC system. To optimize chromatographic parameters several mobile phase compositions were tested. A satisfactory separation, good peak symmetry and optimal retention time was obtained with mobile phase consisting a mixture of methanol, acetonitrile and potassium dihydrogen phosphate buffer (KH_2PO_4) (pH 7.0; 11.33g/l KH_2PO_4) in ratio of 45:5:50 (v/v/v) that was set at flow rate of 1.0 ml/min was found to be optimum and further optimized by adjusting pH 7.0 by adding KOH 0.5M. A LiChrospher RP Select B column (125 × 4.0 mm, 5μm) is used as stationary phase with temperature of column oven, 50ºC.

The proposed method is simple, rapid, accurate, precise, and specific in relation to interference of excipients. Its chromatographic run time of 3.50 min allows the analysis of a large number of samples in short period of time. Therefore, it is suitable for the routine analysis of Bromazepam in pharmaceutical dosage forms.

Key words: Bromazepam, dissolution, HPLC