ABSTRACT

The aim of this diploma thesis was to develop and validate a high performance liquid chromatography (HPLC) method for purity and stability evaluation of fesoterodine.

The HPLC method development was carried out using design of experiments (DOE), which allows to find optimal separation conditions within small number of experimental analysis. Design was done by using L18 linear model. Chromatographic system of the developed method consisted of a C8 stationary phase (SF) XBridge BEH - C8 (100 x 4.6 mm, 2.5 μm), a binary mobile phase (MF) consisting of 10mM borate buffer pH 9.2 and MeOH in various ratios according to the gradient program. Flow rate was 0.7 ml/min, column temperature 35 °C and a diode-array detector (DAD) was applied for the detection at 227 nm. Analysis time was 22 min.

The optimized method was validated and the forced degradation study was performed. Studied effects were: the effect of elevated temperature (60 °C), humidity (10 and 75% relative humidity), acidic and basic conditions, oxidation and light. Peak purity of fesoterodine was evaluated for all experiments of forced degradation study. Additionally, the sensitivity of the active substance to hydrolysis was determined within the pH range of 2-10.