ABSTRACT

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Title of thesis: **Stability inducing HPLC method for evaluation of fluoxetine**

The purpose of this thesis was to develop and validate the stability – indicating HPLC method for evaluating Fluoxetine-hydrochloride. Fluoxetine-hydrochloride is a drug from the SSRI group used to treat depression of various etiologies. The basic method was adopted from the Czech Pharmacopoeia 2009. The given Pharmacopoeia method is not sufficient, as the peak of the degradation product Fluoxetine-hydrochloride interfered in the so – called dead retention time of the used column. Its quantitative determination was impossible for this reason. Development of the method consisted in adjustment of the mobile phase using gradient elution. The mobile phase was composed of a mixture of methanol, tetrahydrofuran and triethylamine solution, and it was divided into two containers. The container A consisted of the mixture (MeOH : THF) : TEA solution – 70: 30 (v/v) and the container B consisted of the mixture (MeOH : THF) : TEA solution – 5: 95 (v/v). The mixture (MeOH : THF) was prepared in the ratio of 8 : 30 (v/v). The chromatographic conditions were adjusted as follows: flow rate 1,0 ml/min, column temperature 24 °C, feed 10 and 50 μl; the detection was carried out using a spectrophotometric detector at the wavelength $\lambda = 215$ nm. The method was validated and subsequently applied in two stability studies. In the experiment no. 1 was demonstrated hydrolytic and photolytic stability of fluoxetine-hydrochloride in the aqueous medium. In experiment no. 2 was detected decomposition of fluoxetine-hydrochloride in a 3 % solution of hydrogen peroxide.