ABSTRACT

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Title of thesis: **Evaluation of Stability of Gestodene Using HPLC**

The purpose of this thesis was to develop and validate the HPLC method and further evaluate the stability of gestodene under selected model conditions. Gestodene is highly effective new-generation gestagen that is a part of hormonal contraceptives that subsequently occurs in low concentrations in surface waters.

The default parameters set in Czech pharmacopoeia were used for the further development of the suitable evaluation method. The chromatographic parameters were optimized in order to obtain the method that would reduce time and costs. The developed isocratic method has shortened the retention time of gestodene by half without interfering with the dead retention time of the column and has met all prescribed validation requirements. The chromatographic parameters of the developed method are as follows: column (length 150 mm, internal diameter 4.6 mm), stationary phase (octadecylsilylated R (5 μm) spherical silica gel, mobile phase (water R, acetonitrile R1), elution (isocratic, 45 % water + 55 % acetonitrile), flow rate (1 ml/min), detection (spectrophotometric detector 254 nm and 205 nm).

The developed method was used in two stability studies. Degradation of gestodene molecule was observed in two types of experiments in aqueous medium and medium with oxidizing agent. The stability was evaluated under the natural conditions of heat, light and oxidation.

Gestodene is relatively stable substance in water and in the dark, without oxidizing agent is the degradation minimal. The degradation of the gestodene molecule is significantly accelerated by oxidation and further potentiated by heat and light.

Keywords: gestodene, HPLC, stability, surface waters, steroid hormones