Abstract

Aim of this thesis was to develop and validate a method for determination of pharmaceutical active substance abiraterone acetate for UHPLC and also to perform forced degradation with 0,3 % hydrogen peroxide and elevated temperatures. Because of poor solubility of abiraterone acetate in water, mixture of acetonitrile of water in ratio of 1:1 was chosen as solvent.

Opimized separation was performer on the column Acquity CSH PHENYL-HEXYL (1.7 µm, 100 × 2.1 mm) and its temperature was 45 °C. Mobile phaze was composed of acetonitrile and 0.1 % aqueous solution of formic acid, flow of mobile phase was 0,3 ml/min, sample injection volume was 1 µl and gradient elution was used. UV/VIS detector with diode array was used at the 265 nm wavelenght. Quadrupole mass detector was used as well.

For validation of the method repeatability, recovery and limits of detection and quantitation were tested. Calibration dependence was tested in the concentration in range of $0.1\text{-}1\cdot10^{-4}$ mg/ml.

Forced degradation was carried out on two sets of samples. Hydrogen peroxide of 0.3 % mass concentration was added to one set. Both of the sets were exposed to laboratory temperature and to temperature o 50 °C for 1, 2, 3 days. Abiraterone acetate exhibited small extent of degradation without hydrogen peroxide in laboratory conditions as well as in increased temperature. On the other hand, samples with hydrogen peroxide showed more significant extent of degradation in both conditions.

Key words

UHPLC, degradation, abiraterone acetate