ABSTRACT

The aim of this work was to develop and optimize liquid chromatography method with spectrophotometric detection applicable to assay and purity of vemurafenib in solid dosage form and perform its stability study.

The optimized separation conditions consisted of Poroshell HPH-C18 (3 × 100 mm, 2.7 μm) column tempered at 30 ºC, mobile phase composed of 10 mM ammonium phosphate, pH 3,0/acetonitrile. Flow rate was set at 0.6 mL/min and gradient elution was performed. Detection wavelength was 250 nm.

The calibration curve of vemurafenib was constructed in the concentration range 0.4 – 1.2 mg/mL. Limit of detection was 5.0 μg/mL and limit of quantitation was 16.5 μg/mL.

Stability and stress tests of vemurafenib were performed under several conditions: Heat (80 ºC), heat combined with humidity (80 ºC/75 % relative humidity), hydrochloric acid (0,1 M), sodium hydroxide (0,1 M) and hydrogen peroxide (3% and 0,3% solution). The significant degradation of vemurafenib was observed under acid condition. Vemurafenib also degradated under oxidation condition. No degradation was observed under base condition and under heat and heat combined with humidity. Degradation of vemurafenib was not effected by tested excipients.

Judging based on experiments vemurafenib is stable from the point of view of chemical stability.