Development and validation of a stability indicating HPLC method for determination of doxycycline hyclate in bulk and capsules

Phennapha Chancharoen[1]*, Chutima Phechkrajang[1]
Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Mahidol University, Thailand
**E-mail: phennaphaaa@gmail.com*

A stability indicating reverse phase high performance liquid chromatography (RP–HPLC) method was developed for the determination of doxycycline hyclate in bulk and capsules to support product development and quality control efforts. Chromatographic separation of doxycycline hyclate and its degradation products were achieved on a Symmetry C_8 column (150 mm x 4.6 mm, 5 μm) with an isocratic mobile phase composed of water and acetronitril in the ratio 88:12 (v/v) (pH adjusted to 3.00 with phosphoric acid) at a flow rate of 1.0 mL/min. The detection of analyze was carried out by UV detector at 273 nm. Doxycycline hyclate was subjected to stress conditions including hydrolysis (neutral, acidic and alkaline), oxidation, photolysis and thermal conditions. Significant degradation is observed in hydrolysis (neutral, acidic and alkaline) and oxidative conditions. The method was validated by evaluating linearity and range, accuracy, precision and specificity according USP guideline and was found it is acceptable in range of 50–150 μg/ml.

Keywords: Doxycycline hyclate; Stability; Force degradation; High performance liquid chromatography