ABSTRACT

Validation of a Stability-Indicating HPLC Method for Domperidone in Pharmaceutical Dosage Form

Anindya Kharisma Putri

The objective of this study was to obtain HPLC analysis method that could separate domperidone from its degradation product. A stability-indicating HPLC method has been developed and subsequently validated for Domperidone in tablets. The proposed HPLC method utilizes LiChrospher® C_{18} column (250 x 4.6 mm i.d., 5 µm) and mobile phase consisting of methanol-water (40:60, v/v) at a flow rate of 1.0 mL/min with column temperature of 30ºC. The retention time of Domperidone was found to be 1.235 min. Quantitation was achieved with UV detection at 233 nm based on peak area with linear calibration curves at a concentration ranges 25 – 150 µg/mL. The regression equation and coefficient of correlation were 9.61191x – 38.47770 and 0.9999 respectively. The method was validated in terms of selectivity, accuracy, precision, linearity, and robustness. The method has been successively applied to pharmaceutical formulation and no interference from the tablet excipients was found. Domperidone drug product was exposed to acid and base hydrolysis, oxidation, dry heat, and photolytic stress conditions and the stressed samples were analyzed by the proposed method. As the proposed method could effectively separate the drug from its degradation products, it can be employed as a stability-indicating method for the determination of instability of domperidone in tablets.

Keywords: Domperidone, Stability-indicating method, HPLC, Forced degradation