

Novel liquid chromatographic methods for the determination of varenicline tartarate

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Abstract

Two simple, sensitive, rapid, and stability-indicating liquid chromatographic (LC) methods have been developed for the determination of varenicline tartrate. They comprised the determination of varenicline (VRC) in the presence of its oxidative degradates and related impurity (N-formyl varenicline) (NFV). The first method was a LC with diode array detection (DAD) at 235 nm using Ristek-Ultras C18 column (100 mm × 2.1 mm, 5 mm). Isocratic elution of VRC was employed using a mobile phase consisting of buffer mixture (1.2% potassium dihydrogen phosphate and 0.08% octane sulphonic acid): acetonitrile (86:14, v/v), pH (5.0). In the second method; a fluorimetric detection technique was developed, based on precolumn derivatization of VRC using 7-chloro-4-nitrobenzo-2-oxa-1, 3-diazole (NBD-Cl). The fluorescence detector (FLD) was operated at 474 nm for excitation and 539 nm for emission. Isocratic elution was applied with a mobile phase consisting of methanol-distilled water (70:30, v/v). Separation was achieved using Symmetrys Waters C18 column (150 mm × 4.6 mm, 5 mm). Linearity, accuracy and precision were found to be acceptable over the concentration ranges of 0.5620.0 mg mL⁻¹ and 0.2620.0 mg mL⁻¹ with the first and the second method, respectively. The optimized methods were validated and proved to be specific, simple, and accurate for the quality control of the drug in its pharmaceutical preparation.

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