

عنوان مقاله:

New HPLC method for determination of Donepezil hydrochloride assay and impurities content in Pharmaceutical Dosage Forms

محل انتشار:

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تعداد صفحات اصل مقاله: 11

نویسندگان:

Maryam Hosseini - *Yong researchers club, Islamic azad university, North Tehran branch, Tehran, Iran*

Erfan Ziarifar - *Young researchers club, Islamic Azad University of Ahwaz*

Eskandar Alipour - *Faculty of Chemistry, Islamic Azad University, North Tehran branch, Tehran, Iran*

خلاصه مقاله:

Donepezil hydrochloride is a reversible inhibitor of acetylcholinesterase, indicated for treatment of mild to moderate dementia of the Alzheimers type. A rapid, specific reversed phase HPLC method has been developed and validated for assaying of donepezil hydrochloride, also related substances was determined. The assay involved an isocratic elution in Perfectsil Target C18 column using a mobile phase composition of water (pH: 3.5 ± 0.05 , 25 mM potassium dihydrogen phosphate), methanol, Acetonitril and triethylamine (20: 65: 15:0.5 v/v). Typical retention time for donepezil was 6 min. The method was statistically validated for linearity, accuracy, precision and selectivity. The flow rate was 1ml / min and analyte monitored at 268nm. The best results for determination of impurities were obtained using buffer, Acetonitril and triethylamine (70:30:2 v/v). The assay method was found to be linear from 50 to 150 g / ml. All the validation parameters were within the acceptance range. It was also found to be stability indicating, and therefore suitable for the routine analysis of donepezil hydrochloride and related substances in Pharmaceutical formulation.

کلمات کلیدی:

Donepezil hydrochloride; HPLC; Assay; Related substances; Pharmacy

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