Stability-indicating chromatographic methods for determination of flecainide acetate in the presence of its degradation products; isolation and identification of two of its impurities

Mohamed Mohamed ,Nariman A. El-Ragehya, Nagiba Y. Hassana, Mahmoud A. Tantawya

Abstract

In this work, two stability-indicating chromatographic methods have been developed and validated for determination of flecainide acetate (an antiarrhythmic drug) in the presence of its degradation products (flecainide impurities; B and D). Flecainide acetate was subjected to a stress stability study including acid, alkali, oxidative, photolytic and thermal degradation. The suggested chromatographic methods included the use of thin layer chromatography (TLC-densitometry) and high-performance liquid chromatography (HPLC). The TLC method employed aluminum TLC plates precoated with silica gel G.F254 as the stationary phase and methanol-ethyl acetate-33% ammonia (3:7:0.3, by volume) as the mobile phase. The chromatograms were scanned at 290 nm and visualized in daylight by the aid of iodine vapor. The developed HPLC method used a RP-C18 column with isocratic elution. Separation was achieved using a mobile phase composed of phosphate buffer pH 3.3-acetonitrile-triethylamine (53:47:0.03, by volume) at a flow rate of 1.0 mL/min and UV detection at 292 nm. Factors affecting the efficiency of HPLC method have been studied carefully to reach the optimum conditions for separation. The developed methods were validated according to the International Conference on Harmonization guidelines and were applied for bulk powder and dosage form.

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