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. Hassan, Mahmoud A.
Tantawya

Professor of Analytical Chemistry

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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