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High performance thin layer chromatographic resolution of the enantiomers of some racemic β-blockers using β-cyclodextrin as chiral selector

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Statement of the Problem: Large number of β-blockers' marketed formulations contain racemic mixtures except for levobunolol and betaxolol. As the two enantiomers have different stereoselective mechanisms, they should be considered as different drugs. Taking into consideration the numerous side effects of these drugs and that the only pharmacologically active enantiomer is the levo- one whereas the dextro- enantiomer is inactive or harmful in some cases, there is no doubt that reliable and rapid methods should be developed for monitoring the stereoselective synthesis or checking enantiomeric purity.

Methodology: The present work involves economic novel procedure for separation of the two (+) and (-) enantiomers of the drugs sotalol, carvedilol and betaxolol using β-cyclodextrin as chiral mobile phase additive. Chromatographic separation was performed on Fluka HPTLC silica gel plates 60 F254 (20×10 cm). The mobile phase used consists of acetonitrile-methanol-acetic acid-water (4:3:0.2:1 v/v) and containing 0.3 mM β-cyclodextrin. Detection of the spots was performed using iodine vapor or densitometrically at 245 nm for carvedilol or at 220 nm for both betaxolol and sotalol.

Findings: Using the proposed method, linear calibration graphs were obtained for (-) and (+) enantiomers of betaxolol in the ranges 0.5-6.0 and 0.4-6.0 μg/band, respectively ($r>0.998$, $n=6$) with good accuracy and precision (%Er and %RSD <2.0%). Limits of detection for (-) and (+) enantiomers were 0.15 and 0.13 μg/band, respectively. The sensitivity for the detection of sotalol and carvedilol racemates was 0.3 and 0.2 μg/band, respectively.

Conclusion & Significance: The proposed method is selective and simple for separation of the enantiomers of carvedilol and sotalol and quantitation of both (-) and (+) betaxolol enantiomers in the bulk and in pharmaceutical preparatio.

Biography

Eman I El Kimary is an Associate Professor of Pharmaceutical Analytical Chemistry and Quality Control at the Faculty of Pharmacy, Alexandria University, Egypt. She received BSc in Pharmacy in 2003, Master's degree in Pharmaceutical Analysis in 2007 and PhD in Pharmaceutical Analysis in 2011 from Faculty of Pharmacy, Alexandria University. Currently, she is teaching general and physical chemistry, analytical chemistry, instrumental analysis and pharmaceutical quality control to pharmacy students at Alexandria University. She has the practical experience in working with devices such as: High performance liquid chromatography, polarograph, spectrofluorimeter, spectrophotometer, etc. She attended about 22 scientific and professional workshops and training courses and published about 18 research papers in peer reviewed scientific journals and about 8 abstracts in national and international conferences. She served as a Reviewer for more than 5 journals specialized in analytical chemistry and its applications.

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