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Authors: Henrik Harnisch, Gerhard K.E. Scriba

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Henrik Harnisch, Gerhard K. E. Scriba*

Department of Pharmaceutical and Medicinal Chemistry, School of Pharmacy, Friedrich Schiller University Jena, Philosophenweg 14, 07743 Jena, Germany

*Corresponding author

Department of Pharmaceutical and Medicinal Chemistry

School of Pharmacy

Friedrich Schiller University Jena

Philosophenweg 14

07743 Jena, Germany

Phone: +49 / 3641-9-49830

Fax: +49 / 3641-9-49802

Email: gerhard.scriba@uni-jena.de

Highlights

- Validated method for purity determination of dapoxetine
- Simultaneous determination of enantiomer and related substances
- Application of analytical quality by design in method development
- Application to the analysis of drug substance and tablets

Abstract

A capillary electrophoresis method was developed and validated for the determination of the purity of dapoxetine with regard to the related substances (3*S*)-3-amino-3-phenylpropan-1-ol, (3*S*)-3-(dimethylamino)-3-phenylpropan-1-ol, 1-naphthol and the enantiomer (*R*)-dapoxetine. The separation was based on a dual selector system, which was optimized by a fractional factorial resolution V+