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Capillary Electrophoresis Method for the Determination of (*R*)-Dapoxetine, (3*S*)-3-(Dimethylamino)-3-phenyl-1-propanol, (3*S*)-3-Amino-3-phenyl-1-propanol and 1-Naphthol as Impurities of Dapoxetine Hydrochloride

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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+

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