



## Development and Validation of LC-ESI-MS Method for the Quantification of Dapoxetine in Rat Plasma

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**SUMMARY.** A sensitive and simple liquid chromatography/electrospray mass spectrometry (LC-ESI-MS) method for determination of dapoxetine in rat plasma using one-step protein precipitation was developed and validated. After addition of midazolam as internal standard (IS), protein precipitation by acetonitrile was used in sample preparation. Chromatographically separation was achieved on an SB-C18 (2.1 mm × 150 mm, 5 μm) column with acetonitrile-0.1 % formic acid as the mobile phase with gradient elution. Electrospray ionization (ESI) source was applied and operated in positive ion mode; selected ion monitoring (SIM) mode was used to quantification using target fragment ions m/z 306 for dapoxetine and m/z 326 for the IS. Calibration plots were linear over the range of 5-1000 ng/mL for dapoxetine in rat plasma. Lower limit of quantification (LLOQ) for dapoxetine was 5 ng/mL. Mean recovery of dapoxetine from plasma was in the range of 92.4-98.6 %. CV of intra-day and inter-day precision were both less than 15 %. This method is simple and sensitive enough to be used in pharmacokinetic research for determination of dapoxetine in rat plasma.

**KEY WORDS:** Dapoxetine, LC-MS, Rat plasma.

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