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Development and validation of bioanalytical method for the quantitative estimation of Duloxetine in human plasma using ICMS/MS

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A simple, sensitive and accurate liquid chromatography positive ion atmospheric pressure ionization tandem mass spectrometry method was developed and validated for the quantification of duloxetine in human plasma. Following liquid-liquid extraction, the analyte was separated using an isocratic mobile phase on a reverse phase column (Xterra MS C18 (5 μ m,100 \times 3.0mm)) at a column oven temperature of 30°C and analysed by MS/MS (Sciex API 3000) in the multiple reaction monitoring mode using the respective [M+H]⁺ ions, m/z 298.2 to 154.10 and 298.2 to 44.0 for duloxetine and m/z 310.0 to 44.0 for fluoxetine (internal standard). The isocratic mobile phase composition was a mixture of acetonitrile:0.1% formic acid (50:50 v/v), which was pumped at a flow rate of 1.0mL/min with split ration of 60:40(v/v). The assay exhibited a linear dynamic range of 0.345 to 185.463ng/ml for duloxetine in human plasma. The lower limit of quantification was 0.345 ng/ml with the relative standard deviation of less than 2.41% (n=4). Acceptable precision and accuracy were obtained for concentrations over the standard curve range. No significant degradation was observed for duloxetine in human plasma when stored at room temperature (4h), when subjected to freeze and thaw cycles (3 cycles). The overall absolute recovery is 76.92 % to 85.89%. No matrix suppression was found in the method (94.64%to 100.33%). Because of short run time of 2.0 minutes per sample, the maximum throughput of approximately 500 human plasma samples can be analysed per day in compliance with the current regulatory requirements, which makes it more economical and rapid method of analysis.

Biography

S. P. Pattanayak is working as an Assistant Professor in the University, Birla Institute of Technology (BIT), Mesra, a technical university under UGC, India established in 1955 and has done his master's and doctoral research on preclinical breast cancer research. He has published more than 24 research papers and 25 conference proceedings and serving as an editorial board member and reviewer of repute in some National (including India Government official publications) and International journals. He has hands on experience in clinical research. He also works as a visiting professor and external examiner in some reputed organizations of India.