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A Fully Validated UHPLC–MS/MS Method for the Estimation of Pimavanserin in Human (K2EDTA) Plasma and its Application to a Clinical Pharmacokinetic Study †

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Abstract: A simple, fast, and extremely sensitive for estimating Pimavanserin in human (K2EDTA) plasma using ultra-high-performance liquid chromatography combined with tandem mass spectrometry (UHPLC–MS/MS) was newly developed and validated. Sample extraction was accomplished using a partition liquid extraction (LLE—liquid-liquid extraction) procedure utilizing extraction solvent, methyl tertiary butyl ether. Separation of the components, chromatography, was done using a C18 chromatographic analytical column employing acetonitrile:methanol: 0.1% formic acid solution (40:40:20 volume by volume) pumped with 0.800 mL/min as the flow rate. For Pimavanserin, the established methodology was linear throughout the calibration curve range from 0.25ng/mL to 50.0 ng/mL. Results of intraday and interday accuracy and precision of Pimavanserin met recent regulatory requirements. This methodology was effectively used to estimate Pimavanserin in vivo human (K2EDTA) plasma concentration for a clinical pharmacokinetic study.

Keywords: Pimavanserin; liquid-liquid extraction (LLE); UHPLC; MS/MS; bioanalytical method validation; pharmacokinetics.

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Conflicts of Interest

The authors declare no conflict of interest.