LC-MS METHOD FOR DETERMINATION OF OLMESARTAN IN HUMAN PLASMA

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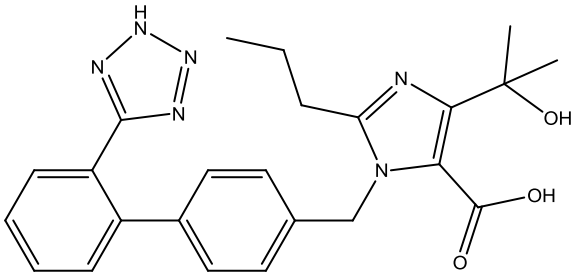

Olmesartan belongs to a class of drugs called angiotensin II receptor blockers (*ARBs*). It works by relaxing blood vessels so that blood can flow more easily and is used to treat high blood pressure (hypertension). Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems [1].

Olmesartan medoxomil is an ester prodrug that is hydrolysed during absorption from gastrointestinal tract to the active form olmesartan. Due to rapid metabolism determination of the concentration of the prodrug in plasma is impossible. Previous human pharmacokinetic studies indicated that olmesartan is the only metabolite of olmesartan medoxomil. The aim of the study was to develop a method for the determination of olmesartan in human plasma.

The developed LC-MS method is linear within the range of 5.00-2500.00 ng/mL which is suitable for pharmacokinetic studies after administration of 40 mg olmesartan medoxomil single oral dose. The sample preparation procedure is fast and allows examination of large numbers of samples in a short time.

The method was validated according to European Medicines Agency (*EMA*) [2, 3] and Food and Drug Administration (*FDA*) [4] guidelines, in compliance with the principles of Good Laboratory Practice (*GLP*). All of the validation parameters met acceptance criteria and the method was successfully applied in the pharmacokinetic study in humans.

[1] Summary of Product Characteristics – OLMETEC® Tablets, (Daiichi Sankyo UK Limited), Access date 25 September 2015, www.medicines.org.uk/emc/medicine/15152
[2] *Guideline on the Investigation of Bioequivalence.* Committee for Medicinal Products for Human Use (CPMP/EWP/QWP/1401/98/ Rev. 1 Corr.**). London, 20 January 2010.
[3] *Guideline on bioanalytical method validation*. European Medicines Agency (EMEA/CHMP/EWP/192217/2009 Rev.1 Corr.*). London, 21 July 2011.
[4] *Guidance for Industry. Bioanalytical Method Validation*. U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research (CDER). Center for Veterinary Medicine (CVM). May 2001.

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