VALIDATED BIOANALYTICAL METHOD

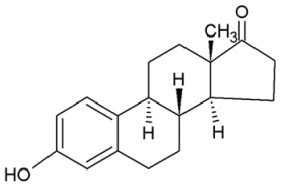
Bioanalytics, Metabolomics and Pharmacokinetics Shared Resource (BMPK)

Director: Dr. James Mohler

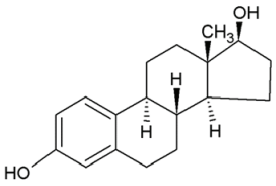
Estrogens in Human Serum

(Sensitivity: 2.00 pg/mL for E1 and 1.00 pg/mL for E2)

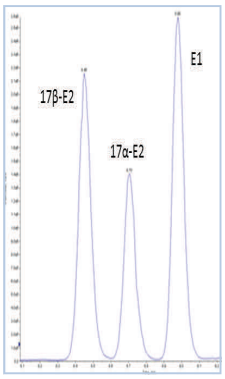
BMPK has validated a highly sensitive liquid chromatographic tandem mass spectral assay (LC-MS/MS) for the analysis of estrone (E1) and 17β-estradiol (E2). These steroidal sex hormones are secreted in both males and females and exhibit a wide range of physiological activity from development and regulation of the female reproductive system and secondary sex characteristics to gene regulation (genomic effects) and cell signaling (epigenomic effects) via estrogen receptors ERα and ERβ. The validated method was applied to the analysis of 823 serum samples obtained during a 5 year flaxseed study of postmenopausal women (performance data shown below). The assay was also adapted to the analysis of heparinized human plasma and breast tissue (benign and malignant) samples examining the mechanistic response of tamoxifen in a breast cancer study.



Estrone (E1)



17β-Estradiol (E2)



Specifications and Performance	
Matrix:	Human Serum
Required Volume:	600 µL
Preparation Procedure:	Solid Phase Extraction
HPLC Column:	$C18^{+}$
Mobile Phase:	Acetonitrile with Acetic Acid
Flow Rate:	300 µL/min
Detection Type:	Tandem Mass Spectral (MS/MS)
Calibration Range:	2.00 to 250 pg/mL for E1 1.00 to 250 pg/mL for E2
QC Concentrations:	6.00, 30.0 and 180 pg/mL for E1 3.00, 30.0 and 180 pg/mL for E2
Calibrator Accuracy:	100% (97.3 - 106%; n=14) for E1 100% (97.4 - 102%; n=13) for E2
Calibrator Precision:	3.26% CV (1.70 - 5.06%; n=14) for E1 3.17% CV (1.74 - 5.36%; n=13) for E2
QC Accuracy:	92.8% (91.1 - 94.6%; n=40) for E1 96.9% (96.2 - 98.3%; n=37) for E2
QC Precision:	5.42% CV (4.06 - 7.67%; n=40) for E1 4.78% CV (2.92 - 6.54%; n=37) for E2

BMPK offers a wide range of bioanalytical and PK/PD modeling services to assist investigators in their basic research, preclinical, and clinical study objectives. For information on services and pricing, contact John Wilton, Ph.D., Associate Director, at (716) 845-3258 or John.Wilton@RoswellPark.org.

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