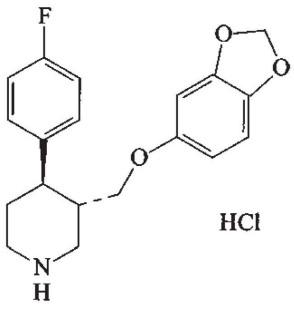
Method Summary

SAP.1070, revision 000
May 2007

Paroxetine
in K_3EDTA Human Plasma

Sample Matrix	K_3EDTA Human Plasma
Internal Standard	Paroxetine-d6
Instrumental Technique	LC-MS/MS
Extraction	Liquid/liquid
Regression Type and Weighting Factor	Quadratic regression with 1/concentration^2 weighting, quantitation by peak area ratio
Sample Volume	100 µL (for each analysis)
Calibration Curve	60.0 ng/mL to 0.100 ng/mL
Quality Control Samples	Over-range QC 500 ng/mL, 50.0, 25.0, and 0.300 ng/mL
LLOQ Bias	2%
LLOQ Precision	13.7%
Intra-day QC Bias	-3.2% to 6.4%
Intra-day QC Precision	2.8% or better
Inter-day QC Bias	-1.6% to 3.6%
Inter-day QC Precision	2.1% or better
Dilution Integrity	Dilution factor of 100 verified
Matrix Stability at Room Temperature	At least 48 hours
Extract Stability at Room Temperature	At least 48 hours
Freeze/Thaw Stability	4 cycles at approximately -80ºC
Long Term Matrix Stability	At least 47 days at approximately -80ºC
Stock Solution Stability at Room Temperature	At least 6 hours
Stock Solution Stability at -20°C	At least 52 days

Paroxetine



Features

- Selective liquid-liquid extraction using deep well plates.
- Large run sizes (3 plates per run).
- Study-specific QC samples.

Figure 1. Chromatogram of High Calibration Standard

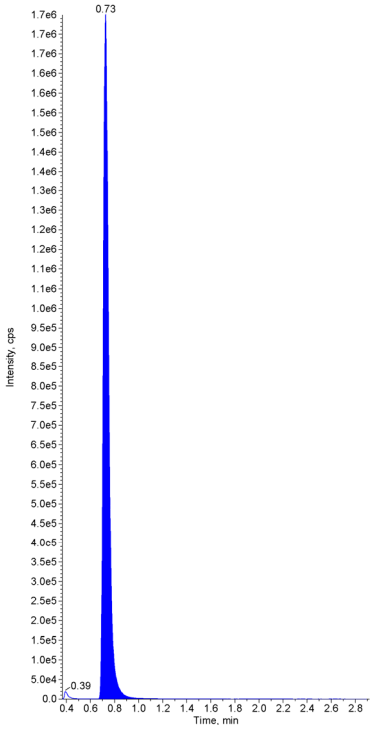


Figure 2. Chromatogram of Low Calibration Standard

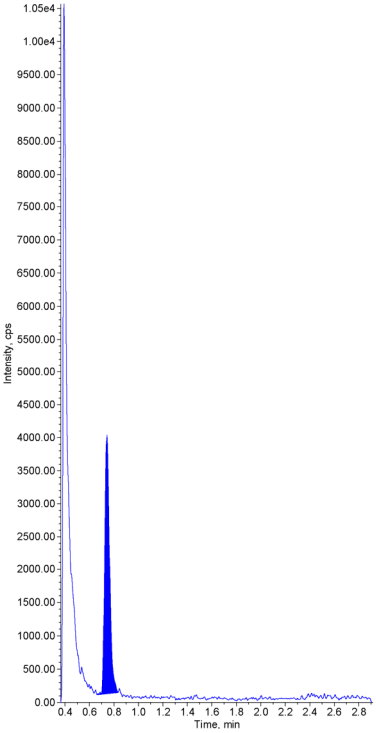


Figure 3. Chromatogram of Blank Matrix

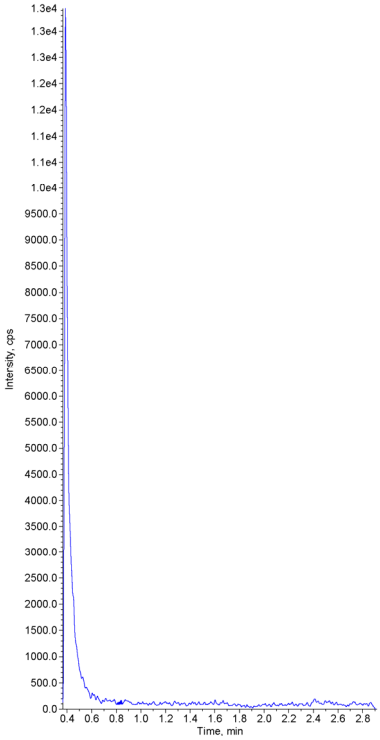


Figure 4. Typical Calibration Curve

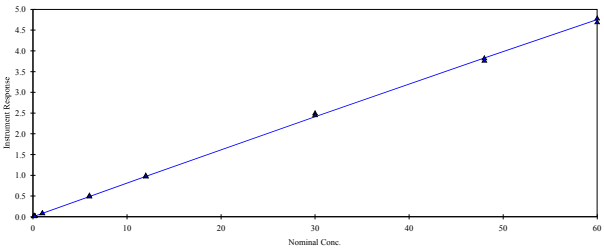


Table 1. Calibration Standard Statistics

	STD 0.100	STD 0.200	STD 1.00	STD 6.00	STD 12.0	STD 30.0	STD 48.0	STD 60.0
%CV	2.9	3	2.3	1.9	3.7	1.4	1.2	1.2
%Bias	1	-2.5	-0.2	2.7	-2.5	2.3	-0.8	-0.2
n	12	12	12	12	12	12	12	12

Table 2. Intra-Assay Quality Control Sample Statistics

	Curve Number	LLOQ 0.100 ng/mL	Low 0.300 ng/mL	Mid 25.0 ng/mL	High 50.0 ng/mL
Intrarun %CV	12	3.4	1.8	1.3	1.1
Intrarun %Bias		-0.5	1.3	3.6	-1
Intrarun %CV	13	3.7	2.8	1.1	1.2
Intrarun %Bias		1	2	3.6	-1.6
Intrarun %CV	14	5.4	1.2	1.2	1.2
Intrarun %Bias		3	2.3	1.6	-3.2
Intrarun %CV	15	3.3	1.2	0.7	0.9
Intrarun %Bias		2	5	6.4	-0.2
Intrarun %CV	16	2.1	1.1	1	0.9
Intrarun %Bias		3	2.3	4.4	-2.6
Intrarun %CV	21		2	0.8	1.2
Intrarun %Bias			4.7	0.8	-1.4

Table 3. Inter-Assay Quality Control Sample Statistics

	LLOQ 0.100 ng/mL	Low 0.300 ng/mL	Mid 25.0 ng/mL	High 50.0 ng/mL
%CV	3.7	2.1	2	1.4
%Bias	2	3	3.6	-1.6
n	30	36	36	36

Table 4. Between Subject Variability

Samples	BSAP 25.0 ng/mL
Subject A	24.6
Subject B	25.3
Subject C	23.6
Subject D	26.2
Subject E	24.8
Subject F	26.1
Intrarun Mean	25.1
Intrarun %CV	3.9
Intrarun %Bias	0.4
n	6

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