Waters™

アプリケーションノート

ACQUITY UPLC I-Class/Xevo TQD IVD System: Analytical Performance for Immunosuppressive Agents

Waters Corporation

For *in vitro* diagnostic use. Not available in all countries.

Introduction

The Waters ACQUITY UPLC I-Class/Xevo TQD IVD System enables the quantification of organic compounds in human biological liquid matrices.

This document describes a test of the analytical performance of the ACQUITY UPLC I-Class/Xevo TQD IVD System for the analysis of cyclosporine, everolimus, sirolimus, and tacrolimus in whole blood.

Experimental

The ACQUITY UPLC I-Class/Xevo TQD IVD System was controlled by MassLynx IVD (v4.1) and the data processed using the TargetLynx Application Manager. Whole blood Calibrators and Quality Controls were processed using the following conditions:

ACQUITY UPLC I-Class/Xevo TQD IVD System.

Sample Preparation Conditions

50 µL sample was processed with aqueous zinc sulphate, acetonitrile, and centrifuged. Each analyte was analyzed individually.

LC Conditions

Column:	ACQUITY UPLC HSS C_{18} SB 1.8 µm, 2.1 mm x 30 mm
Mobile phase A:	2 mM Ammonium acetate+0.1% formic acid in water
Mobile phase B:	2 mM Ammonium acetate+0.1% formic acid in methanol
Flow rate:	0.4 mL/min

Gradient:	50% B for 0.2 minutes, 50–100% B over 0.4 minutes, hold 100% B for 0.6 minutes, equilibrate with 50% B for 0.6 minutes at 0.6 mL/min

MS Conditions

Resolution:	MS1 (0.75 FWHM), MS2 (1.2 FWHM)
Acquisition mode:	MRM
Polarity:	ESI (+)

Results and Discussion

Performance characteristics of cyclosporine, everolimus, sirolimus, and tacrolimus on the ACQUITY UPLC I-Class/Xevo TQD IVD System are shown in Table 1. Analytical sensitivity of the system is illustrated in Figure 1.

Compound	Range (ng/mL)	LLOQ (ng/mL)	%RSD at LLOQ	Total precision	Repeatability	EQA mean bias
Cyclosporine	25–1500	5	7.0	≤5.7%	≤1.8%	-0.2%
Everolimus	1–30	0.5	6.5	≤7.7%	≤4.7%	-11.9%
Sirolimus	1–30	1	12.7	≤9.1%	≤6.1%	-6.1%
Tacrolimus	1–30	0.5	17.5	≤6.3%	≤2.6%	+1.6%

Table 1. Performance characteristics of cyclosporine, everolimus, sirolimus, and tacrolimus. Range defined by linear fit where r^2 >0.99. LLOQ defined by S/N (PtP) >10 and %RSD ≤20%. % RSD at LLOQ determined through analytical sensitivity experiments performed over five occasions (n=50). Total precision and repeatability of QCs performed over five occasions in whole blood (n=25). EQA mean bias determined by comparison of obtained values to the LC-MS all laboratories trimmed mean (LC-MS ALTM) value (n=33). Note: The EQA mean bias for everolimus (-11.9%) is based on the returned EQA results for just two laboratories.

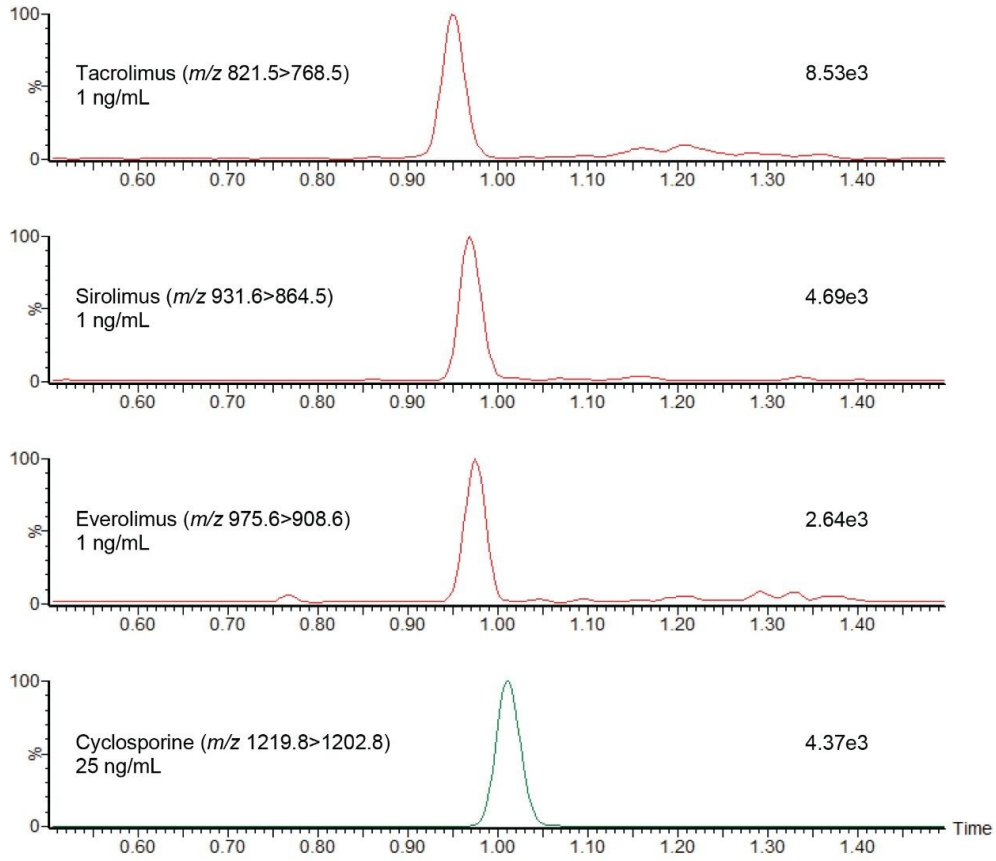

Figure 1. Chromatogram showing the analysis of 25 ng/mL cyclosporine and 1 ng/mL everolimus, sirolimus, and tacrolimus using the ACQUITY UPLC I-Class/Xevo TQD IVD System.

Conclusion

The Waters ACQUITY UPLC I-Class/Xevo TQD IVD System has demonstrated the capability to deliver analytical sensitivity, accuracy, and precision for the analysis of cyclosporine, everolimus, sirolimus, and tacrolimus in whole blood.

Disclaimer

The analytical performance data presented here is for illustrative purposes only. Waters does not recommend or suggest

analysis of the analytes described herein. These data are intended solely to demonstrate the performance capabilities of the system for analytes representative of those commonly analyzed using liquid chromatography and tandem mass spectrometry. Performance in an individual laboratory may differ due to a number of factors, including laboratory methods, materials used, intra-operator technique, and system conditions. This document does not constitute a warranty of merchantability or fitness for any particular purpose, express or implied, including for the testing of the analytes in this analysis.

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