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응용 자료

ACQUITY UPLC I-Class/Xevo TQD IVD System: Analytical Performance for a Thymidylate Synthase Inhibitor

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 5-fluorouracil in plasma.

ACQUITY UPLC I-Class/Xevo TQD IVD System.

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. Calibrators and Quality Controls were prepared by spiking commercially available reference material in plasma and the samples were processed using the following conditions:

Sample Preparation Conditions

50 µL sample was processed in a liquid-liquid extraction with acidified ethyl acetate followed by a solvent exchange to 0.1% formic acid in water prior to analysis.

LC Conditions

Column:	ACQUITY UPLC HSS PFP 1.8 µm, 2.1

	mm × 100 mm
Mobile phase A:	Water
Mobile phase B:	Acetonitrile
Flow rate:	0.4 mL/min
Gradient:	2% B for 0.5 minutes, 2–60% B over 1.5 minutes, 98% B for 0.5 minutes, 98% A for 0.5 minutes

MS Conditions

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

Results and Discussion

Performance characteristics of 5-fluorouracil on the ACQUITY UPLC I-Class/Xevo TQD IVD System are shown in Table 1. A chromatogram illustrating the analytical sensitivity of the 5-fluorouracil analysis is shown in Figure 1.

Compound	Range (ng/mL)	LLOQ (ng/mL)	%RSD at LLOQ	Total precision	Repeatability	EQA mean bias
5-fluorouracil	20-2000	7.5	20	≤9.0%	≤7.2%	2.6%

Table 1. Performance characteristics of 5-fluorouracil. 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 plasma (n=25).

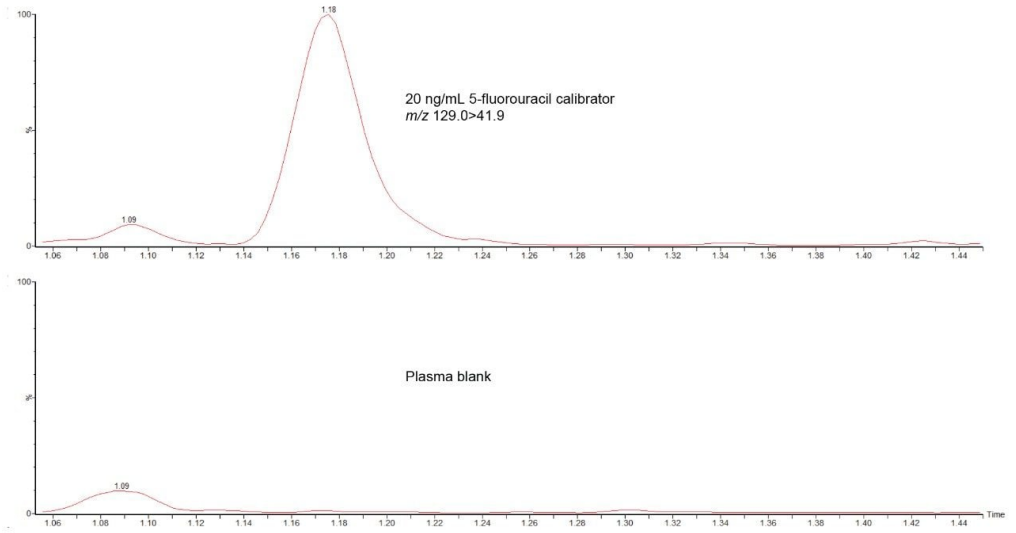

Figure 1. Chromatogram showing the analysis of 5-fluorouracil using the ACQUITY UPLC I-Class/Xevo TQD IVD System.

Conclusion

The Waters ACQUITY UPLC I-Class/Xevo TQD IVD System has demonstrated the capability to deliver analytical sensitivity and precision for the analysis of 5-fluouroracil in plasma.

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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