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應用手冊

ACQUITY UPLC I-Class/Xevo TQD IVD System: Analytical Performance for an Inosine-5'-Monophosphate Dehydrogenase Inhibitor

Waters Corporation

這是一篇應用簡報，不含詳細的實驗內容章節。

用於體外診斷用途。並非在所有國家/地區均可使用。

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 mycophenolic acid 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 Software (v4.1) and the data processed using the TargetLynx Application Manager. Commercial calibrators and Quality Controls were used as well as in-house calibrators prepared by spiking commercially available reference material in plasma. The samples were processed using the following conditions:

Sample Preparation Conditions

50 µL sample was processed with zinc sulphate/methanol and centrifuged. The supernatants were transferred to a collection plate for analysis.

LC Conditions

Column:	ACQUITY UPLC HSS C_{18} SB 1.8 µm,

	2.1 mm × 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:	0.7 mL/min
Gradient:	30–40% B over 0.75 minutes, 40–75% B over 0.85 minutes, 98% B for 0.4 minutes

MS Conditions

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

Results and Discussion

Performance characteristics of mycophenolic acid on the ACQUITY UPLC I-Class/Xevo TQD IVD System are shown in Table 1. A chromatogram illustrating the selectivity of the mycophenolic acid analysis is shown in Figure 1.

Compound	Range (µg/mL)	LLOQ (µg/mL)	%RSD at LLOQ	Total precision	Repeatability	EQA mean bias
Mycophenolic acid	0.1–20	0.075	5.6%	≤5.3%	≤3.6%	≤5.1%

Table 1. Performance characteristics of mycophenolic acid. 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 three occasions (n=30). Total precision and repeatability of QCs performed over five occasions in plasma (n=25). EQA mean bias determined by comparison of obtained values to HPLC-MS method mean.

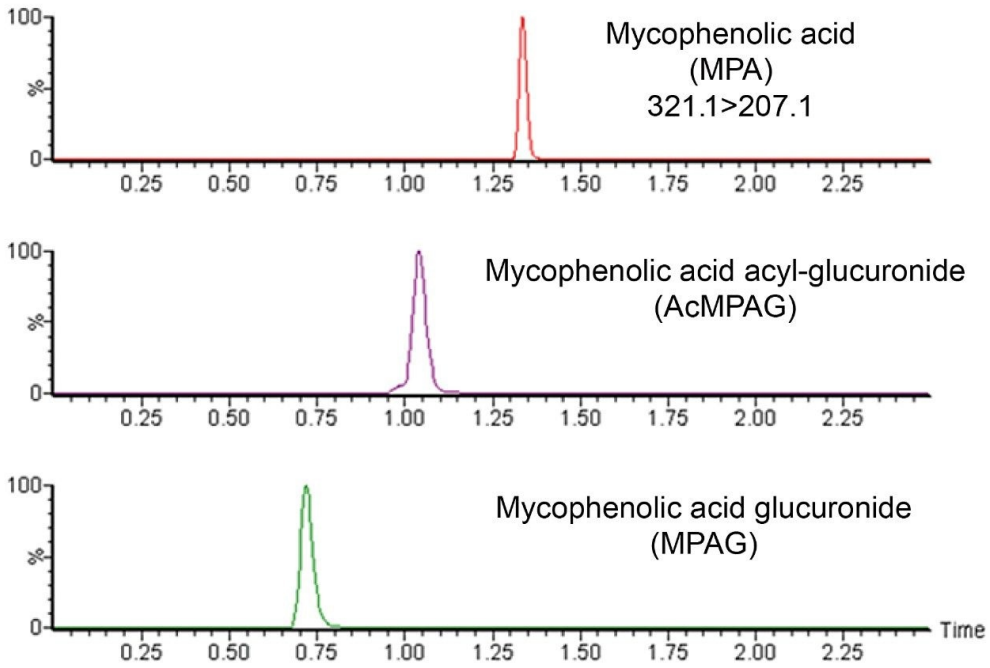

Figure 1. Chromatographic separation of mycophenolic acid from its metabolites using the ACQUITY UPLC I-Class/Xevo TQD IVD System.

Conclusion

The Waters ACQUITY UPLC I-Class/Xevo TQD IVD System has demonstrated the capability to deliver analytically sensitive, accurate, and precise performance for mycophenolic acid 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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