



Cloe Select Bioanalytical Method Development and Validation Service

experts in **ADME**

Background Information



'Validation involves documenting, through the use of specific laboratory investigations, that the performance characteristics of the method are suitable and reliable for the intended analytical applications.'

FDA Guidance for Industry –
Bioanalytical Method Validation
(May 2001)

What can Cyprotex offer?

- State of the art highly sensitive instrumentation (Applied Biosystems Sciex QTRAP® 5500 LC-MS/MS)
- Highly trained and experienced bioanalytical scientists
- Networked data management system and data archive / back-up facilities
- Close customer consultation and interaction

Service Offering

- Bioanalytical method development
- Comprehensive bioanalytical method validation service (partial or full validation available)
- Bioanalytical method transfer
- Study plans based on FDA guidance on bioanalytical method validation



Protocol

LC Systems

- 3 x Waters Acquity UPLC and sample organiser systems
- 3 x Agilent HP 1100 binary LC systems one with UV diode array detection
- 1 x Shimadzu UFLC XR with UV-Vis (dual wavelength) spectrophotometric detection

Mass Spectrometers

- 1 x Applied Biosystems Sciex QTRAP® 5500 LC-MS/MS
- 5 x Waters Quattro™ Micro LC-MS/MS

All our LC-MS/MS systems are protected by an uninterrupted power supply system ensuring power input fluctuations are smoothed out / reduced and the systems are offered a limited battery backup power supply in case of mains power failure.

‘Our bioanalytical facility is equipped with an Applied Biosystems Sciex QTRAP® 5500 LC-MS/MS which is one of the most sensitive and fastest scanning linear ion trap and triple quadrupole instruments in the industry’



Cyprotex offers the latest state of the art equipment. Our Applied Biosystems Sciex QTRAP® 5500 LC-MS/MS provides:

- One of the most sensitive and fastest scanning linear ion trap and triple quadrupole instruments in the industry
- A combination of exceptional quantitative and qualitative analytical potential with no sacrifice in performance for either capability
- MS³ quantification offering superior selectivity which in turn may improve detection limits.
- Precise ion detection over a wide dynamic range – with no loss in sensitivity up to its maximum mass cut off.

Bioanalytical Method Development Service

Understanding the chemistry of your compound is important for designing the method development studies. The service consists of 3 main steps:

- Step 1: MS/MS optimisation
- Step 2: Chromatographic method development
- Step 3: Sample preparation

Bioanalytical Method Validation Service

There are 2 options available depending on the level of detail required. These can be tailored depending on customer requirements;

Partial Validation	Full Validation
Linearity and sensitivity	Linearity and sensitivity
Accuracy and precision	Accuracy and precision
Selectivity	Selectivity
Report**	Stability* (Stock solution, freeze thaw, short term, post preparative)
	Recovery
	Report**

* Long term stability available on request.

** Example reports available on request.