

In vitro ADME & PK

Advanced Bioanalytical Method Development and Sample Analysis Service

Background Information



'Bioanalysis is a term generally used to describe the quantitative measurement of a compound (drug) or their metabolite in biological fluids, primarily blood, plasma, serum, urine or tissue extracts.'

¹Pandey *et al.*, (2010) *Pharm Methods* **1(1)**; 14-24

What can Cyprotex offer?

- State of the art highly sensitive instrumentation (AB Sciex QTRAP® 5500 and AB Sciex TripleTOF® 6600, Waters Xevo® TQ-MS and Waters Xevo® G2-S QToF LC-MS/MS systems).
- Highly trained and experienced bioanalytical scientists with over 120 years combined experience.
- Networked data management system and data archive/back-up facilities.
- Close customer consultation and interaction.

Service Offering

- Advanced bioanalytical method development and qualification.
- Bioanalytical method transfer.
- Small molecules and peptide bioanalysis (proteins and other biotherapeutics can be supported on request).

Protocol

LC Systems

- 11 x Waters Acquity UPLC (1 with 2D technology)
- 4 x Agilent 1290 Infinity 2D uHPLC
- 2 x Agilent 1200 uHPLC

GC Systems

- 1 x Waters Atmospheric Pressure Gas Chromatography (APGC)

UV and Radiochem Detectors

- 2 x Acquity UPLC PDA detectors
- 1 x Agilent DAD
- 1 x LabLogic β-RAM® radiochemical detector

Mass Spectrometers

- 11 x Waters Xevo® TQ-MS
- 4 x Applied Biosystems Sciex QTRAP® 5500
- 2 x Applied Biosystems Sciex TripleTOF® 6600
- 1 x Waters Xevo® G2-S QToF
- 2 x Agilent 6410
- 1 x Waters QDa

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 supported by a limited battery backup power supply in case of mains power failure.

‘Our bioanalytical facility combines highly sensitive state of the art equipment with a wealth of experience allowing delivery of robust bioanalytical methods for a range of different types of chemistry.’



Cyprotex has expertise in a wide range of bioanalytical techniques including:

- sensitive small molecule detection and quantification
- high resolution metabolite ID studies
- peptide biotherapeutic bioanalysis

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 (if preferred method of detection is mass spectrometry)
- Step 2: Chromatographic method development
- Step 3: Sample preparation

Advanced Bioanalytical Method Development Service

Our advanced bioanalytical method development service is a non-GLP service which can evaluate any of the following parameters to assess robustness of the bioanalytical method. These parameters can be tailored based on customer requirements.

- Linearity and sensitivity
- Accuracy and precision
- Selectivity
- Matrix effects
- Stability (freeze thaw, short term, post preparative)
- Recovery

Data are presented in a written report. Example reports are available on request.

References

- ¹ Pandey S, Pandey P, Tiwari G and Tiwari R (2010) Bioanalysis in drug discovery and development. *Pharm Methods* **1**(1); 14-24