

# Metabolite Profiling & Identification

*Understand the metabolism of your compound by identifying which metabolites are formed during in vitro or in vivo studies. Metabolite profiling and identification is included in Cyprotex's portfolio of ADME services. Cyprotex delivers consistent, high quality data in line with regulatory guidelines, and can adapt protocols based on specific customer requirements.*

- ▶ Tailored work packages
- ▶ Scientific excellence & consultancy
- ▶ High quality data delivery
- ▶ Sensitive & selective analytical instrumentation
- ▶ Small & large molecule expertise
- ▶ Metabolite profiling is carried out on our high resolution mass spectrometry instrumentation:
  - Waters Vion® IMS QTOF
  - Waters Xevo® G2-S QTOF
- ▶ Data is processed using Waters Connect UNIFI software
- ▶ Ion mobility capabilities of our Vion instrumentation provides an ion mobility measurement of the rotationally-averaged collision cross section (CCS)





## Available Matrices

### In Vitro

- ▶ Hepatocytes
- ▶ Microsomes
- ▶ S9
- ▶ Plasma
- ▶ Expressed enzymes
- ▶ H<sub>9</sub>rel co-culture model

### In Vivo

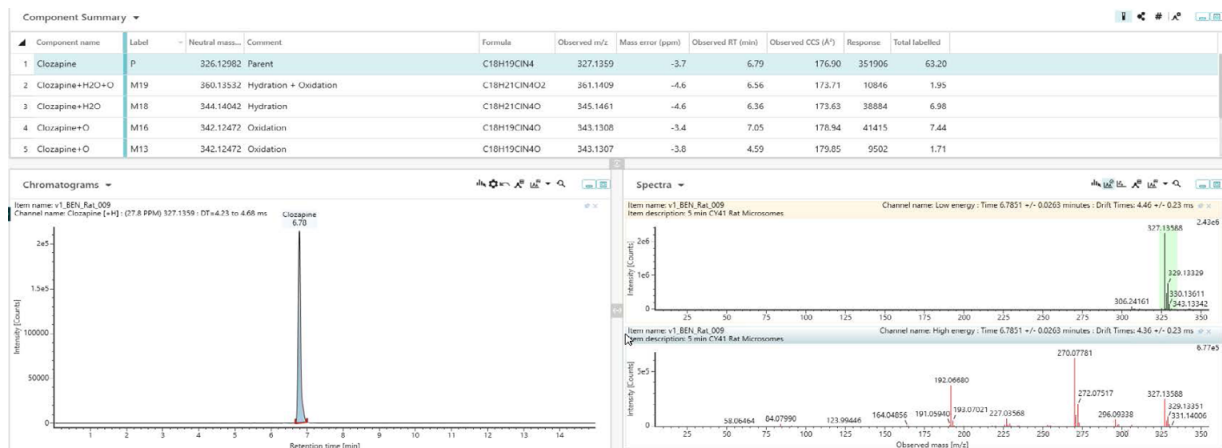
- ▶ Samples from PK analysis
- ▶ Supplied pre-clinical matrices
- ▶ Non GLP clinical matrices

## Soft Spot Metabolite Identification

- ▶ Soft spot identification – Top 3 metabolites reported and elucidated per species/ variable

## Comprehensive Metabolite Profiling

- ▶ **Tier 1:** Down to 1% of drug related material in each species/variable
- ▶ **Tier 2:** Down to 1% of drug related material in each species/variable with cross species/variable reported where observed down to the limit of detection (LOD) or 0.1% of drug related material if this is higher than the LOD
- ▶ **Tier 3:** Metabolite profiling down to the LOD or 0.1% of drug related material if this is higher than the LOD



## Data Delivery

- ▶ Initial tailored PDF report generated from instrument software per species/variable
- ▶ Elucidation of reported metabolites (Top 3 in Soft Spot and Top 5 in Comprehensive Metabolite Profiling)
- ▶ Comprehensive eCTD report combined all species/ variables
- ▶ Inclusion of clearance results into reports for *in vitro* matrices

## Additional Deliveries

- ▶ Analysis in both ionisation modes for greater understanding of metabolism
- ▶ Semi-quantification using in-line PDA detector (assuming selective chromophore)
- ▶ Comparison to supplied analytical standards

*Higher tier deliveries and deliveries following initial PDF can be decided in step wise approach following initial results*

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