ChemPartner
Dedicated to LifeScience

DMPK BIOANALYSIS

CAPABILITIES OVERVIEW

SMALL MOLECULES

- Mass spectrometry-based analysis
  - » Parent and metabolites from PK, PK/PD, in vitro ADME, metabolite identification
  - » Matrices: biological fluids and tissues

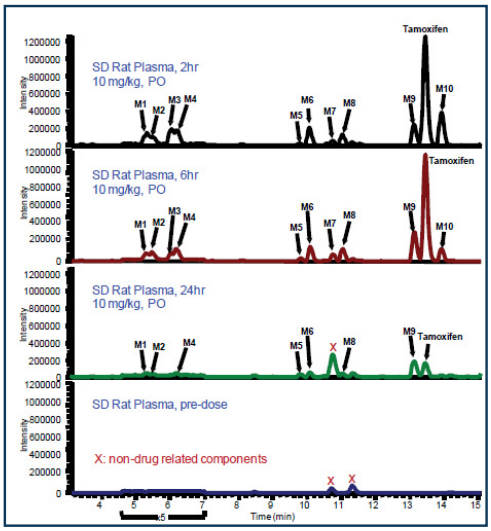
LARGE MOLECULES

- ELISA and MSD and mass spectrometry-based analysis
  - » PK, PK/PD, biomarker test and immuno-genicity test
  - » Bioassay

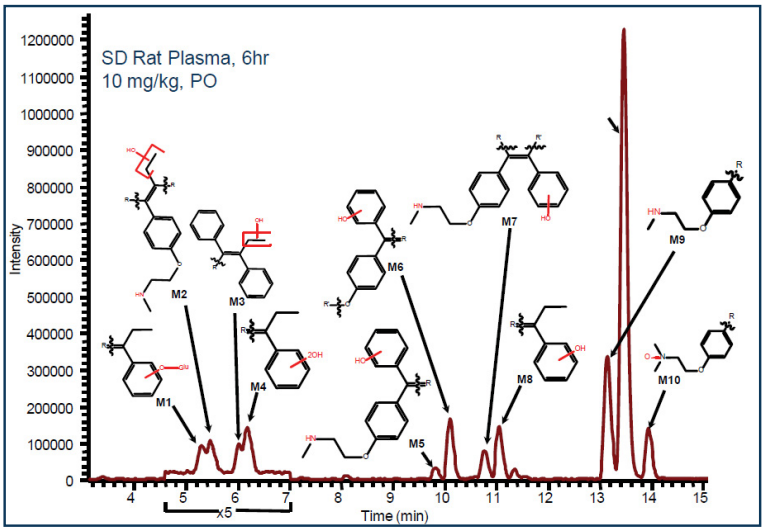
METABOLOMICS AND BIOMARKER ANALYSIS

CASE STUDIES

TAMOXIFEN METABOLITE PROFILES IN RAT PLASMA



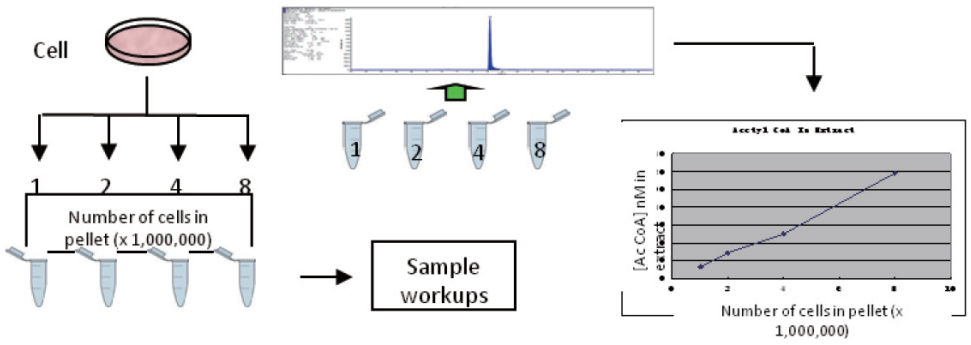
IDENTIFICATION OF TAMOXIFEN METABOLITES IN RAT PLASMA



BIOMARKER ANALYSIS

- A set of cell pellets produced with known numbers of cells
- Extracts made and analyzed by LC-MS/MS
- Resulting acetyl CoA in extract plotted against numbers of the cells loaded
- LC-MS/MS signal responses correlated with cell numbers
- Optimized cell numbers, washing factor evaluated and cell handling time optimized

ANALYSIS OF CANCER METABOLISM BIOMARKERS ACoA AND MCoA



REGULATED BIOANALYSIS

VALIDATION RESULTS				
QUALIFICATION ELEMENT			RESULTS	CRITERIA
Accuracy	Calibration curve (n=12)	Std 1-7	92.3-104.6%	Recovery: 80.0-120.0% for >3/4 of concentrations
Accuracy	Intra-assay (n=5)	Low	107.8-123.6%	Recovery: 70-130% for >4/5 determination per QC level
		Medium	97.2-119.1%	
		High	84.8-102.9%	
	Inter-assay (n=3)	Low	113.9%	
		Medium	105.4%	
		High	93.9%	
Precision	Intra-assy (n=5)	Low	3.0-5.1%	CV: <25% for >4/5 determination per QC level
		Medium	2.1-3.4%	
		High	1.1-2.9%	
	Inter-assay (n=3)	Low	7.3%	
		Medium	9.9%	
		High	8.4%	
Selectivity	Plasma (n=6)		No interference	Recovery: 70.0-130.0% for >5/6 of matrices
Specificity	Protein		No interference	Recovery: 70.0-130.0% for >4/6 of samples
Dilution linearity	Spiking standard samples		MRD-2	Recovery: 70.0-130.0%, CV <25.0% for >5/6 samples
Robustness	Short-term stability	RT 4.-20, -80°C	85.3 to 115.5%	Accuracy: 70.0-130.0% of day 0 value for >4/6 of samples
	Freeze and thaw stability	5 F/T cycles	84.8 to 110.7%	

ASSAY METHOD FOR DOXORUBICIN QUANTIFICATION

- Objective
  - » Due to in vivo PK difference, seperation of free and ecapsulated drug in plasma is needed
- Challenge
  - » Liposome is fragile
  - » Heat exposure, non-isotonic condition and thawing can produce premature bursting of the lipsome
  - » Sample preparation
- SPE Procedures
  - » SPE plate selection
  - » SPE procedure optimization
- LC-MS/MS Conditions
  - » Column: Waters Xbridge C18 (2.1X50 mm, 3.5 um)
  - » Mobile phase: Water: Acetonitrile: Formic Acid (10:90:0.2, v/v/v/)
  - » API 4000, TIS, positive

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