



Drug-Induced Phospholipidosis GLP and non-GLP Services for Safety Assessment

Phospholipidosis Assessment:



NextPL Assay

- Measurement of di-22:6-BMP

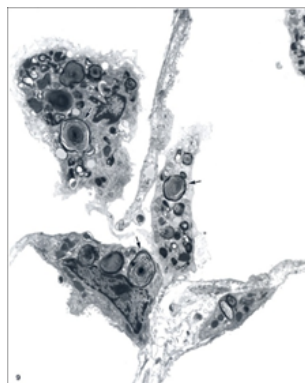
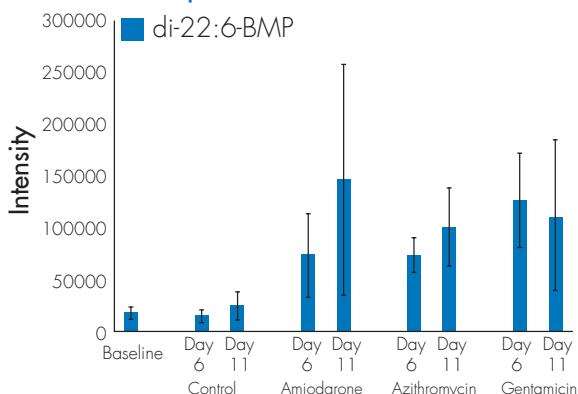
Samples Types

- Plasma
- Serum
- Urine
- Tissues
- Other fluids
- Cells
- Human
- Animal
- In vitro

Drug-induced phospholipidosis (PL) is a phospholipid storage disorder characterized by the accumulation of multi-lamellar bodies (myeloid bodies) in tissues. Many of the drugs that cause phospholipidosis in animals and humans are associated with clinical toxicities (e.g. myopathy, kidney injury, QT prolongation, and hepatotoxicity). As a result, the interpretation of phospholipidosis in risk assessment remains uncertain in preclinical and clinical development¹⁻⁶.

Nextcea identified di-docosahexaenoyl (22:6)-bis(monoacylglycerol) phosphate (di-22:6-BMP) as a validated marker of phospholipidosis for monitoring the onset and time course of tissue phospholipidosis in animal and human studies².

Levels of di-22:6-BMP in Sprague-Dawley rat urine compared to controls



Biological samples

Urine, serum, plasma, lung, liver, kidney, and lymph node from animal or human studies.

About Nextcea, Inc.

Nextcea, Inc. is a drug development service company dedicated to optimizing efficacy and minimizing toxicity in all phases of drug development. Nextcea integrates cross-species biomarker studies with traditional PK/PD and TK/TD. In-house platforms include HPLC/UPLC coupled to mass spectrometry LC-MS and LC-MS/MS (API-6500s and TripleTOF 6600).

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- 2 Hsieh F. Tengstrand E. Detecting Phospholipidosis and Diagnosing Lysosomal Storage Disorders. US Patent 8,313,949 and Japanese Patent 5702363.
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- 5 Tengstrand-Baronas E, Lee JW, Aiden C, Hsieh F. Biomarkers to monitor drug-induced phospholipidosis. *Toxicology and Applied Pharmacology* 2007;218:72-78