



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

Phospholipidosis Assessment:



NextPL Assay

 Measurement of di-22:6-BMP

Samples Types

- Plasma
- Tissues
- Human

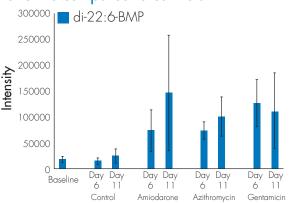
- Serum
- Other fluids
 Animal

- Urine
- Cells
- In vitro

Drug-induced phospholipidosis (PLD) 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, lung injury, and hepatotoxicity). As a result, the interpretation of phospholipidosis in risk assessment remains uncertain in preclinical and clinical development¹⁻⁵.

Nextcea identified di-docosahexaenoyl (22:6)-bis(monoacylglycerol) phosphate (di-22:6-BMP) as a validated marker of phospholipidosis to monitor 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







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 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.
- 3 Hsieh F. Tengstrand E. Drug-induced phospholipidosis assessment from nonlcinical to clinical studies. Dokusei Shitsumon-Bako 2015, 17: 24-36.
- 4 Tengstrand E, Miwa G, and Hsieh F. Bis(monoacylglycerol)phosphate as a non-invasive biomarker to monitor the onset and time-course of phospholipidosis with drug-induced toxicities. Expert Opin. Drug Metab. Toxicol. 2010 6(5):555-570
- 5 Tengstrand-Baronas E, Lee JW, Alden C, Hsieh F. Biomarkers to monitor drug-induced phospholipidosis. Toxicology and Applied Pharmacology 2007;218:72-78