Fast and Reliable: Enhanced AMES Testing for Nitrosamine Mutagenicity

Nitrosamines are concerning due to their potential mutagenic effects, which can lead to cancer. Understanding their mutagenicity is crucial for ensuring safety of pharmaceuticals and consumer products.

At INTOX, an Aragen company, our Enhanced Ames Test (EAT) is designed to comprehensively evaluate the mutagenicity of nitrosamines, ensuring the highest standards of safety and compliance. Adhering to the rigorous EMA/409815/2020 Rev.19 [European Medicines Agency. (2024). Appendix 3: Q&A on nitrosamine impurities in human medicinal products (EMA/120337/2024).] and ICH S2 (R1) guidelines, our study employs advanced analytical testing methods to deliver precise and reliable results.

What sets us apart is our commitment to a thorough and multifaceted approach. We utilize multiple tester strains combined with metabolic activation of both hamster and rat liver S9, allowing us to accurately simulate biological conditions and reflect real-world scenarios. With INTOX, you can trust that our Enhanced Ames Test provides the insights necessary to safeguard your products and uphold public health standards.

Key Features

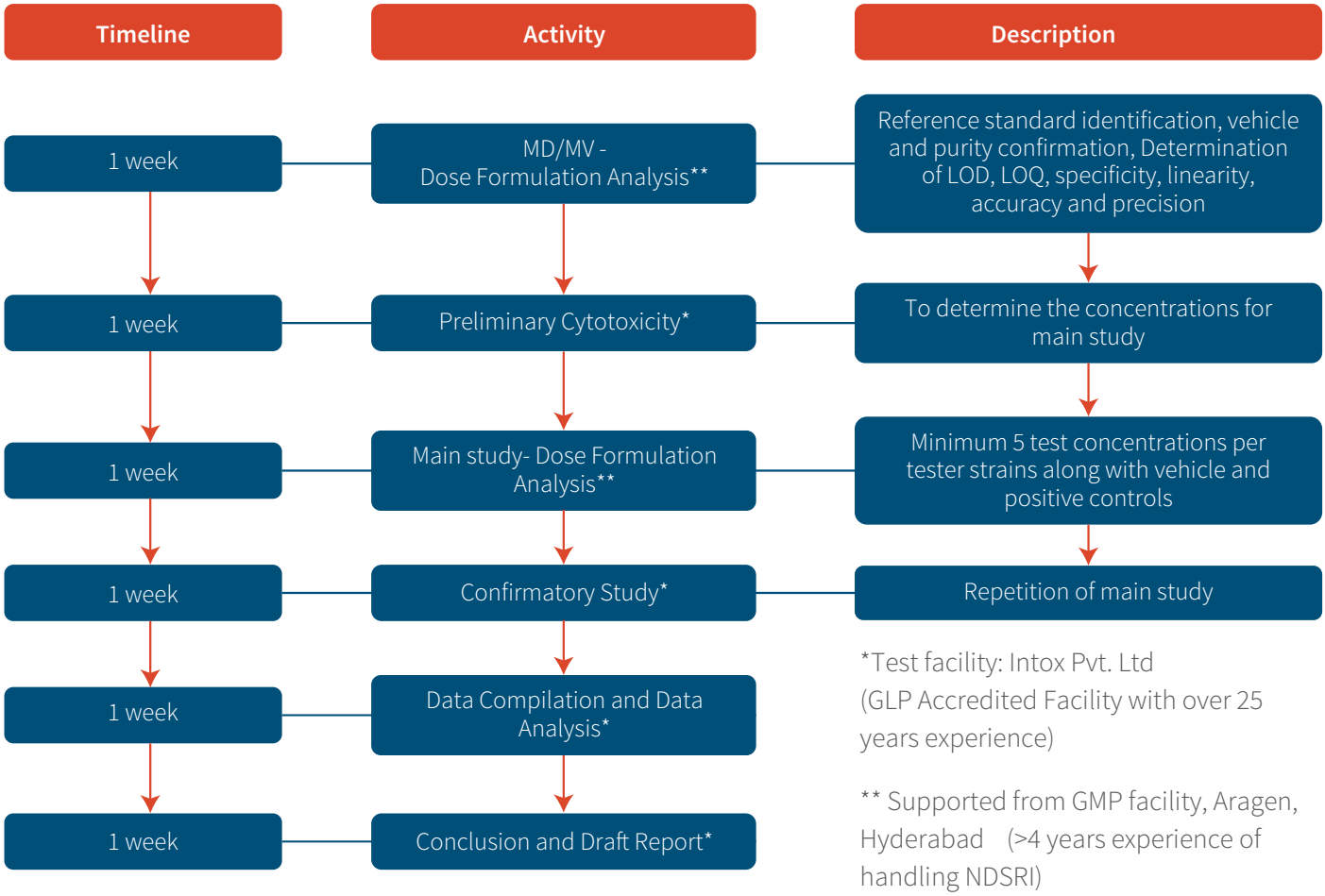
- **Tester Strains Used:** *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537); *Escherichia coli* WP2 uvrA (pKM101)
- **Control Groups:** Appropriate vehicle controls to ensure accurate baseline readings and at least two N-Nitrosamine positive controls are used.
- **S9 Metabolic Activation:** Utilization of 30% rat and hamster liver S9 extracts for metabolic activation.

Our Analytical Workflow

Our Enhanced Ames Test is supported by robust analytical expertise, ensuring reliable and reproducible results **within 6 weeks.** Key steps include:

- **MD/MV - Dose Formulation Analysis:** Confirm accurate dosing of nitrosamines.
- **Preliminary Cytotoxicity:** Assess cytotoxic effects for safe exposure levels.
- **Main Study:** Demonstrate mutagenic potential of nitrosamines.
- **Confirmatory Study:** Validate results through repeated testing.
- **Data Compilation, Analysis, and Reporting:** Analyze data and summarize findings in a detailed report.

Enhanced AMEs Test



*Test facility: Intox Pvt. Ltd (GLP Accredited Facility with over 25 years experience)

** Supported from GMP facility, Aragen, Hyderabad (>4 years experience of handling NDSRI)

Enhanced AMES study validation study was performed as per EMA guideline with tester strains of *Salmonella typhimurium* TA98, 100, 1535, 1537 and *E.coli* WP2 uvrA (pKM101), vehicle controls and two nitrosamine standards with 30% rat as well as hamster liver S9.

Why Choose INTOX?

- **Unmatched Proficiency:** With 25+ years and 18,000+ GLP studies, proficient in safety pharmacology and toxicology for pharmaceuticals, biologics, vaccines, and nutraceuticals.
- **Certified Excellence:** OECD and GLP certified, and AAALAC accredited, ensuring top-quality, compliant research.
- **Regulatory Compliance:** Adhere strictly to EMA and ICH guidelines, guaranteeing high standards of reliability.
- **Nitrosamine Analytical Expertise:** Use advanced techniques for the isolation, identification, and characterization of nitrosamines.
- **Rapid Turnaround:** Prioritize efficiency, delivering results within 6 weeks to meet your project timelines.

intox
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