



Preclinical Technologies

FACTSHEET



Core Battery Services

Guidelines for Safety Pharmacology – ICH S7A

The ICH S7A guideline on the conduct of safety pharmacology studies was accepted by worldwide regulatory organizations and has been in operation in Europe since June 2001. Safety pharmacology packages should adopt the principles of this guideline, the elements of which are detailed below. Aptuit provides a fully comprehensive package of studies to cover ICH S7A regulatory requirements.

Core Battery

- **Central Nervous System** – Modified Irwin test or functional observation battery to detect effects on motor activity, behavior, coordination, sensory/motor reflex responses and body temperature.
- **Cardiovascular System** – Measurement of effects on blood pressure, heart rate and ECG preferably in conscious (telemetered) animals.
- **Respiratory System** – Assessment of effects on respiratory function measured using plethysmography (e.g. respiratory rate, tidal volume, minute volume) or from measurements of haemoglobin oxygen saturation.

Follow-up Studies

Further studies may be required to provide more in depth understanding of effects on vital functions. These may be required due to observations from core battery studies and would involve a more detailed investigation of effects on CNS, CVS and respiratory function (please enquire for further details).

Supplemental Studies

Supplemental studies are intended to evaluate potential adverse effects on organ systems not addressed in the core battery. These would include:

- Renal/Urinary System
- Autonomic Nervous System
- Gastrointestinal System
- Other organ systems e.g. skeletal muscle, drug dependency, immune and endocrine functions

GLP Compliance

All safety pharmacology studies are conducted in a GLP environment and may be monitored for compliance with OECD, FDA and JMOHW GLP guidelines by our independent QA group.

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

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