



Specific Accreditation Guidance

OECD GLP Program - Types of Studies Inspected

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NATA scope of recognition for compliance with the OECD Principles of GLP covers all non-clinical health and environmental safety studies conducted within Australia for regulatory purposes.

Outlined below are the types of GLP studies subject to NATA inspection. GLP studies are defined by a combination of the service and the corresponding determination(s).

The Services outlined below are in accordance with the Appendix to Annex III to C(89)87(Final)/Revised in C(95)8(Final) of Document No 2 - *Guidance for GLP Monitoring Authorities. Revised guides for Compliance monitoring procedures for Good Laboratory Practice.*

In addition to referencing the OECD Principles of Good Laboratory Practice, the activity type(s) that reflect the relevant industry groupings (e.g. agribusiness, environment, food & beverage, etc.) and the applicable services and determinations listed below, the types of studies inspected will include the material/item/product tested. The types of studies inspected will also include the techniques and procedures used, however this information will not be made public and is only available to the recognised facility.

Service	Determination
Analytical and clinical chemistry associated with non-clinical studies	Histopathology; Clinical pathology; Analysis of dose formulations; Analytical chemistry; Immunology
Behaviour in water, soil and air, and bioaccumulation studies	Behaviour in air; Behaviour in soil; Behaviour in water; Bioaccumulation studies
Effects on mesocosms and natural ecosystems studies	Fauna count; Flora count
Environmental toxicity studies on aquatic and terrestrial organisms	Acute environmental studies; Reproductive environmental toxicity studies; Subacute and chronic environmental toxicity studies
Mutagenicity studies	Genotoxicity studies
Physical and chemical studies	Analysis for active constituents and/or impurities; Stability studies; Characterisation of test items; Homogeneity, stability and concentration of prepared test items
Residue studies	Crop studies; Transfer feeding studies; Veterinary studies
Safety studies of medical devices	Acute studies; Biocompatibility; Bioequivalence studies; Subacute and chronic toxicity studies

Service	Determination
Toxicity studies	Acute studies; Biocompatibility; Bioequivalence studies; Reproductive studies; Subacute and chronic toxicity studies; Target species safety studies; Toxicokinetic studies; Cytotoxicity studies; Analysis of toxicokinetic data
Virus reduction studies	Viral Load

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
All	The document was revised to include the following Determinations: Analysis of toxicokinetic data, Homogeneity, stability and concentration of prepared test items
All	Security classification label added