



OECD Good Laboratory Practice Compliance Monitoring Program

Notification of GLP Recognition

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Notification of GLP Recognition document

The scope of all GLP recognised facilities i.e. Notification of GLP Recognition, includes reference to the principles as detailed below.

This facility complies with the OECD Principles of Good Laboratory Practice (1997)

The conduct of non-clinical health and environmental safety studies in Australia of test items contained in, but not limited to, pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and industrial chemicals.

List of studies

The Notification of GLP Recognition document also includes a list of the types of studies and processes associated with studies that were reviewed or discussed at assessment.

The types of studies detailed 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.*

Physical-chemical testing

- Analysis for active constituents and/or impurities
- Characterisation of test items
- Stability studies

Toxicity Studies

- Acute toxicity studies
- Subacute and chronic toxicity studies
- Reproductive toxicity studies
- Cytotoxicity studies
- Toxicokinetic studies
- Target species safety studies
- Bioequivalence studies

Mutagenicity studies

- Genotoxicity studies

Environmental toxicity studies on aquatic and terrestrial organisms

- Acute environmental toxicity studies
- Subacute and chronic environmental toxicity studies
- Reproductive environmental toxicity studies

Studies on behaviour in water, soil and air

- Behaviour in water
- Behaviour in soil
- Behaviour in air
- Bioaccumulation studies

Residue studies

- Crop studies
- Veterinary studies
- Transfer feeding studies

Studies on effects on mesocosms and natural ecosystems

- Effects on mesocosms
- Effects on natural ecosystems

Analytical and clinical chemistry associated with non-clinical studies

- Histopathology
- Clinical pathology
- Analytical chemistry
- Immunoassay

Other (example only)

- Statistical analysis of data
- Validation of virus inactivation studies
- Safety Studies on Medical Devices