



Specific Accreditation Guidance

OECD GLP Program - Types of Studies Inspected

October 2021



© Copyright National Association of Testing Authorities, Australia 2018

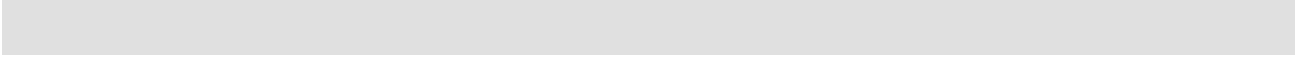
This publication is protected by copyright under the Commonwealth of Australia Copyright Act 1968.

NATA's accredited facilities or facilities seeking accreditation may use or copy this publication or print or email this publication internally for accreditation purposes.

Individuals may store a copy of this publication for private non-commercial use or copy a reasonable portion of this publication in accordance with the fair dealing provisions in Part III Division 3 of the Copyright Act 1968.

You must include this copyright notice in its complete form if you make a copy of this publication.

Apart from these permitted uses, you must not modify, copy, reproduce, republish, frame, upload to a third party, store in a retrieval system, post, transmit or distribute this content in any way or any form or by any means without express written authority from NATA.



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

Detailed below are the types of GLP studies which can be inspected by NATA. GLP studies are described by a combination of both the service and relevant determination(s).

The Services 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.*

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
Residue studies	Crop studies; Transfer feeding studies; Veterinary studies
Safety studies of medical devices	Acute studies; Biocompatibility; Bioequivalence studies; Subacute and chronic toxicity studies
Toxicity studies	Acute studies; Biocompatibility; Bioequivalence studies; Reproductive studies; Subacute and chronic toxicity studies; Target species safety studies; Toxicokinetic studies; Cytotoxicity studies
Virus reduction studies	Viral Load

Amendment Table

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

Amendment
Document revised to include Determinations available for each Service to enable a more complete description of studies to be audited.