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Test item – OECD guideline No 19

Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items

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Agenda

- Background
- Definitions
- Roles and responsibilities
- Transport and receipt
- Identification, labelling and sampling
- Characterisation
- Handling and disposal
- Archiving
- Inspection findings

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Background

- Purpose to provide clarity for test facilities on monitoring authority expectations
- The document was designed to consolidate existing guidance
  - OECD Series on Principles of GLP and Compliance Monitoring
    - No 1
    - No 6 (guideline on field studies)
    - No 7 (guideline on short time studies)
- Development started 2013 by the Working Group on GLP with lead UK and FR
- Public consultation 2017
- Approved by consensus at the Working Group on GLP March 2018
- Published by the Joint Meeting of the Chemicals Committee of the OECD 2018

GLP covers many sectors

Test item vary in terms of characteristics

Field studies:

- Described in Guideline No 6
- Active ingredient + inert compound
- Stored and mixed on site

GLP studies take place at different stages in the development process for different industrial sectors. Information required differs at each stage.

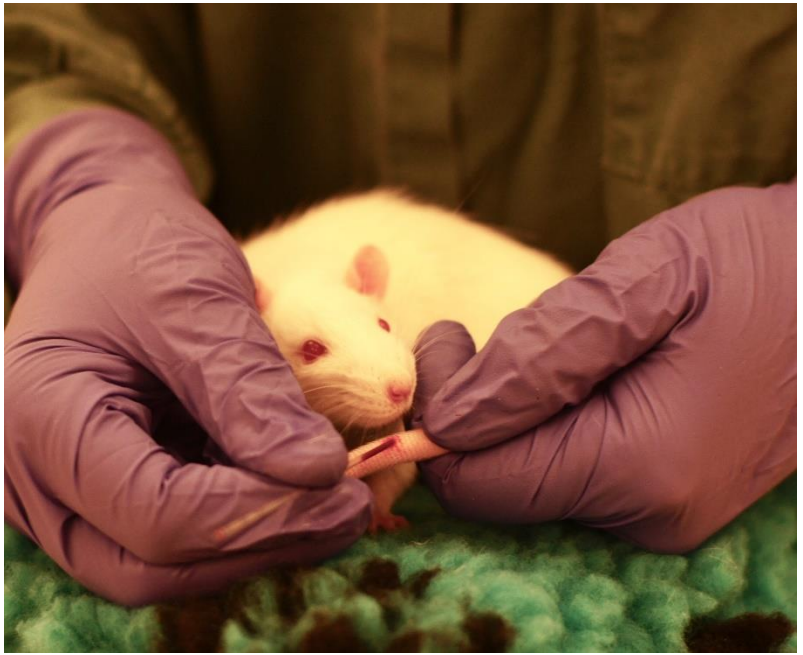
GLP covers many sectors

Pharmaceutical development process include:

- Early stages prior to clinical trials (toxicology studies including mutagenicity studies)
- Late stages (reproductive toxicology and long term carcinogenicity)

The quality and depth of information needed varies depending on the study type

The data needed varies depending on the stage in the development



GLP covers many sectors

- Not possible to write guidance that would cover all potential situations
- A risk based approach is needed depending on the nature of test item
- The guideline No 19 covers new test items…

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Guideline 19 provides full range of test items

→ Test items described in GLP No 1, 6, 7

- Agrochemicals (pesticides/biocides)
- Industrial chemicals including detergents
- Human pharmaceuticals
- Veterinary pharmaceuticals
- Cosmetics
- Food/Feed additives

→ Test items described in guideline 19

- Biochemical (antibody, peptide, protein, viral vector, enzyme)
- Living organism (cell, virus, microorganism)
- Transgenic organisms
- Medical devices
- Test items with complex composition
- Radiolabeled test items

→ Risk assessment to determine suitability for use in the study

Updated definitions

- **Test Item** – “an article that is the subject of a study”
- **Batch** – “a specific lot of test item during a defined cycle of manufacture that is expected to be uniform of character”
- **Vehicle** – “any agent that serves as a carrier and is used to mix, disperse or solubilize the test item”
- **Formulation** – “a combination of a test item and different ingredients such as excipients that are combined and administered to a test system in different form”
- **Characterisation** – “Determines attributes of the test item and provides the evidence to support it’s suitability for use in GLP studies”

Roles and responsibilities

Sponsor – submits the results from GLP studies to receiving authorities and often provides the test facility with information on test item

Test Facility Management should ensure that written procedures are in place to verify the integrity and quality of the information provided. Delegates responsibility to…

Study Director – has the knowledge of the impact of test item characterisation. What information is needed to demonstrate that a test item is suitable for use?

The **Archivist** is responsible for archiving records and test item

Transport and receipt

Test facility management are responsible for the integrity and traceability of test item

Responsibility can be delegated

Procedures should describe the transport of test item depending on:

- Length of travel
- Exposal to environmental condition
  - Temperature, light, humidity
- Nature of the test item

- Receipts should be retained

Identification, labelling and sampling

Consider the following when the test item is received to the facility:

Communication with sponsor should be documented

Sampling procedures should prevent cross-contamination

Assessment of integrity (transport has not impacted the suitability)

Verification of the test item identity should be recorded

- Match between labelling and certificate of analysis, checking physical characteristics)

Handling, storage and disposal

- Facilities should be designed to ensure the integrity of the test item
  - Some test items require special handling
- Cross contamination should be prevented
  - Separate storage rooms between test item and test systems
  - Separate rooms between preparation of test item and administration to test system
- Safety issues regarding hazardous test items should be considered
- Records of used quantities of test item should be maintained (available for all batches)

- Disposal ot test items according to written procedures complying with national requirements

Characterisation

OECD principles require:

- Identity
- Batch number
- Purity
- Composition
- Concentrations
- Expiry date
- Other characteristics

➢ Use risk based approach

Characterisation

Can be carried out by sponsor, supplier or test facility

Inadequate information on the characterisation of test item is a deviation from the principles

No requirement of GLP compliance but require assurances of quality

There is an expectation that data on homogeneity, concentration and stability of the test item in vehicle are generated in compliance with the Principles of GLP

Test item stability testing should be completed by the end of the study

All batches should have available characterisation information

The final study report should describe who performed and was responsible for characterisation

Archiving

The test facility should archive…

- Test item documentation
- A sample from each batch of test item (except for short-term studies)
  - Archieved samples should be representative
  - Archiving period depending on expiry date

The Archivist is responsible for the management, operations and procedures for archiving records and materials, including the test item, in accordance with established procedures and the Principles of GLP.

Inspection findings

Test and Reference Items	Reference to OECD GLP number 1
Records of used quantities of test item is missing	Section II, 6.1.1
Test item is not appropriately identified	Section II, 6.2.1

Conclusions

Test facilities…

- → Are responsible for transportation of test items
- → Are responsible to ensure that test items are suitable to use in a GLP study
- → For test items that fall outside of the document will be considered on a case by case basis
- → Characterisation is performed by risk based approach

Thank you!

- Questions?

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