# Ordinance on Good Laboratory Practice (OGLP)

of 18 May 2005 (Status as of 1 December 2012)

*The Federal Council*

based on Article 5 paragraph 2 letter a of the Chemicals Act of 15 December 2000[1] (ChemA),
Articles 26 paragraph 3, 38 paragraph 3 and 39 paragraph 1 of the Environmental Protection Act of 7 October 1983[2] (EPA)
and Article 11 paragraph 2 letter a of the Federal Act of 15 December 2000[3] on Therapeutic Products (TPA)

*decrees:*

## Section 1 General Provisions

### Art. 1 Objective and purpose

[1] This Ordinance lays down the Principles of Good Laboratory Practice (GLP) as the quality standard for studies, and regulates compliance monitoring.

[2] The Ordinance aims to:

a. ensure that test data are reproducible;

b. promote international acceptance of tests conducted in Switzerland in order to avoid duplicate testing.

### Art. 2 Scope

The Ordinance applies to non-clinical studies of substances, preparations and articles (test items) that:

a. serve to obtain data on the properties of a test item and its safety with respect to human health and the environment; and

b. provide data to be submitted to the authorities in view of a registering or licensing procedure.

AS **2005** 2795

1 SR **813.1**
2 SR **814.01**
3 SR **812.21**

**Art. 3** Definitions

[1] In this Ordinance:

a. *Good Laboratory Practice (GLP)* means a quality system concerned with the organisational process and the conditions under which studies are planned, performed, monitored, recorded, archived and reported;

b.[4] *areas of expertise* means studies conducted in the following categories:

1. physical-chemical testing,
2. toxicity studies,
3. mutagenicity studies,
4. environmental toxicity studies on aquatic and terrestrial organisms,
5. studies on behaviour in water, soil and air; bioaccumulation
6. residue studies,
7. studies on effects on mesocosms and natural ecosystems,
8. analytical and clinical chemistry testing,
9. other studies, specify;

c. *study audit* means an audit of a study to verify that its data, records, reports and other elements comply with GLP Principles;

d. *test facility* means the persons, premises and operational unit(s) that are necessary for conducting studies; for multi-site studies conducted at more than one site, the test facility comprises the site at which the study director is located and all individual test sites that individually or collectively may be considered as such.

[2] Further terms relevant to GLP are defined in Annex 1.

## Section 2 GLP Principles and Compliance Monitoring

**Art. 4** GLP Principles

[1] The principles of GLP are listed in Annex 2.

[2] The Federal Office of Public Health (FOPH)[5], the Federal Office for the Environment (FOEN) and Swissmedic (Swiss Agency for Therapeutic Products) may issue joint guidelines on the interpretation of GLP Principles. In doing so they must take account of internationally recognised regulations.

4 Amended by Annex No 2 of the O of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

5 The name of the administrative unit was amended in application of Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This amendment has been applied throughout the text.

**Art. 5** Application

1 Establishments that wish to have their test facilities listed in the register (Art. 14) must apply to the notification authority (Art. 8).

2 For each test facility, the application must include the following information:

a. name and address of the test facility;

b. site plans documenting the use of the individual premises;

c. organisation charts documenting the name and position of the test facility management, the personnel in charge of quality assurance and the study directors;

d. name and address of a contact person;

e. standard operating procedures for quality assurance;

f. a list of all standard operating procedures;

g. the relevant areas of expertise;

h. a list of all studies planned over the next six months with the relevant schedules;

i. a list of all studies conducted over the last six months, or still being carried out, in the relevant areas of expertise.

3 On request from the competent authority, the establishments must submit other information.

4 If conditions in a test facility are substantially modified, the establishment must submit a new application without delay. In this case the list pursuant to paragraph 2 letter i must include all studies since the last inspection. In the event of any doubt, the establishment must refer without delay to the notification authority to determine whether the modification is substantial. The notification authority gives its decision in agreement with the competent authorities concerned.

**Art. 6** Inspections

1 After receiving an application, the competent authority shall inspect the test facilities on site. During this inspection, the authority checks in particular whether the procedures, operating procedures and data obtained respect the principles of GLP.

2 Thereafter, the authority shall inspect the test facilities again every two to three years. Prior to each inspection the authority shall request information pursuant to Article 5 paragraph 2. The list pursuant to Article 5 paragraph 2 letter i must include all studies conducted since the last inspection. The competent authority may request further data.

3 If there is sufficient reason to assume that a test facility does not comply with the GLP Principles, the competent authority may conduct an inspection without delay.

4 The competent authority shall produce a report on each inspection.

**Art. 7** Study audits

1 The competent authority shall conduct a study audit on its own initiative or at the request of another competent Swiss or foreign authority if:

a. there is sufficient reason to assume that a test facility did not comply with GLP Principles when conducting certain studies;

b. the results of a particular study are of vital importance for assessing human or environmental safety.

2 If after completion of the study audit the competent authority concludes that the audited study did not comply with GLP Principles, it may carry out an inspection.

3 The competent authority may also carry out a study audit as part of an inspection.

4 The competent authority shall produce a report on each inspection.

**Art. 8** Competent authorities

1 The notification authority in accordance with Article 4 paragraph 1 letter h of the ChemA shall coordinate the conduct of inspections and of study audits and, in agreement with the competent authorities, produce decisions on conformity with the principles of GLP.

2 The following authorities are competent to carry out inspections and study audits:

a. the FOPH and Swissmedic for studies of toxicological properties;

b. the FOEN for studies of ecotoxological properties or of environmental behaviour of the test items;

c. the FOPH, the FOEN or Swissmedic after mutual agreement for studies of all other properties.

3 Where necessary the authorities may delegate tasks to each other, or call in specialists. They may delegate all or part of the tasks and competences with which they are entrusted by virtue of this Ordinance to appropriate public corporations or individuals. The FOPH and Swissmedic may only delegate the conduct of inspections and study audits.

**Art. 9** Duties and powers of the authority

1 The authority shall carry out inspections and study audits according to the guidelines in Sections A and B of Annex I of European Directive 2004/9/EC of the Parliament and of the Council of 11 February 2004[6].

2 On request, the establishment must submit to the authorities all documents and all other evidence required to assess its compliance with GLP Principles.

6 Directive 2004/9/EC of the European Parliament and of the Council of 11 Feb. 2004 on the inspection and verification of good laboratory practice (GLP); OJ No. L 50 of 20 Feb. 2004, p. 28-43. The European Community legislation mentioned in this Ordinance can be ordered for a fee or consulted free of charge at the notification authority for chemical products, 3003 Bern; it can also be consulted at www.cheminfo.ch.

3 The authorities must be allowed to access the test facilities at all times.

4 If an establishment with test facilities has been accredited by the Swiss Accreditation Service pursuant to Article 14 of the Ordinance of 17 June 1996[7] on Accreditation and Identification, the authority shall take these results into account.

**Art. 10** Reports on inspections and study audits

1 The competent authority shall provide the establishment with the draft of the inspection report and allow it an appropriate period in which to state its position thereon. On receipt of a response from the establishment or on expiry of the period, the authority shall pass the inspection report to the notification authority.

2 The competent authority shall pass the report on the study audit to the notification authority.

3 The notification authority shall decide:

a. on the basis of the inspection report, whether the test facility is operating according to the GLP Principles;

b. on the basis of the study audit report, whether the study was carried out according to the GLP Principles;

4 The provisions on study audits also apply to studies audited during an inspection.

**Art. 11** Information

The notification authority shall inform the competent authorities of planned inspections and study audits, and of decisions pursuant to Article 10.

**Art. 12** Obligation to notify

An establishment must immediately notify the notification authority if:

a. it changes its name or address;

b. one of its test facilities changes its name or address;

c. one of its test facilities is no longer willing to comply with GLP Principles;

d. there are changes in responsibilities at the level of the management of the test facility or of the quality assurance unit;

e. it intends to extend the area of expertise.

7 SR **946.512**

## Section 3 Documentation and Conformity with GLP Principles

### Art. 13

1 For any study that must be carried out according to the principles of GLP, it is necessary in the procedure of notification or authorisation:

a. to show that the study was carried out in a test facility registered, at the time when the study was carried out, in the Swiss register of test facilities that comply with the principles of GLP;

b. to present a study report in which the study director confirms, in one of the Swiss national languages or in English, that the study was carried out in compliance with the principles of GLP.

2 If the study was carried out in a country other than Switzerland, in addition to the study report, an extract from the foreign register or a confirmation from the foreign authority must be submitted proving that the test facility was included in the official monitoring programme at the time the study was carried out. In the case of countries that are not members of the Organisation for Economic Co-operation and Development (OECD), the notification authority may request other documents that it considers necessary to evaluate compliance with the principles of GLP.

3 If justified by the circumstances, and in particular if the results of the study are very important, or if there is doubt whether the principles of GLP have been respected, a federal executive authority may ask the notification authority to have a study audit carried out.

## Section 4 Other Regulations

### Art. 14 Register and GLP list

1 The notification authority shall maintain a register of all establishments with their inspected test facilities and their audited studies.

2 The notification authority shall enter the data in the register as soon as the formal decision has been made confirming conformity of the test facility with the principles of GLP.

3 The notification authority shall provide the establishment with a confirmation stating, in one of the official Swiss languages or in English, that its test facilities are listed in the register.

4 The notification authority shall regularly publish, in an appropriate way, a list of the test facilities that work according to the principles of GLP.

5 If the principles of GLP are no longer respected, the test facility shall be removed from the list mentioned in paragraph 4.

**Art. 15** Content of the register

The register shall specify:

a. the name and address of the establishment and of its test facilities;

b. the type and date of inspection and the relevant areas of expertise;

c. the date of the study audit and identification of the study;

d. the decision relative to compliance with GLP Principles;

e. the date of the decision or of the notification that the relevant test facility no longer complies with GLP Principles.

**Art. 16** Notification in cases of serious non-compliance with GLP Principles

1 If in the course of an inspection, the competent authority ascertains that a test facility fails to comply with GLP Principles to the extent that the reliability of study results is no longer guaranteed, and that in consequence these results may generate erroneous conclusions relating to human and environmental safety, it must immediately inform the notification authority.

2 The notification authority must inform the federal executive authorities responsible for evaluating notifications or authorisations for substances and preparations.

**Art. 17** Confidentiality of data

1 The competent authorities may transmit confidential data only to:

a. each other;

b. the federal executive authorities pursuant to Article 16 paragraph 2;

c. foreign GLP authorities, if this is provided for by agreements under international law or by federal legislation.

2 Under no circumstances are the entries in the register pursuant to Article 15 confidential.

**Art. 18** Dealings with foreign authorities

1 Depending on the area of competence (Art. 8), the FOPH, the FOEN and Swissmedic shall represent Switzerland on GLP-related issues in dealings with authorities and institutions abroad, and with international organisations.

2 The FOEN shall co-ordinate dealings with the Organisation for Economic Co-operation and Development (OECD) at national level. Each year it shall supply the OECD and the OECD member states with a list of inspected establishments with their test facilities and conducted study audits, and notify them of establishments that are guilty of serious non-compliance with GLP Principles.

## Section 5 Final Provisions

### Art. 19 Transitional provisions

1 Decisions made and confirmations delivered before this Ordinance comes into force remain valid until they are replaced by documents after the next inspection.

2 Requests made according to the previous legislation and still being processed by the GLP authorities shall be passed on to the notification authority when this Ordinance comes into force.

### Art. 20 Commencement

This Ordinance comes into force on 1 August 2005.

*Annex 1*
(Art.3 para. 2)

# Terms relating to GLP

## 1 Terms concerning the Organisation of a Test Facility

1.1 *Test site* means the location(s) at which one or more phases of a study is conducted.

1.2 *Test facility management* means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles *of* Good Laboratory Practice.

1.3 *Test site management* (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted *according* to these Principles of Good Laboratory Practice.

1.4 *Study Director* means the individual responsible for the overall conduct of the non-*clinical* health and environmental safety study.

1.5 *Principal Investigator* means an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

1.6 *Quality Assurance Programme* means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.

1.7 *Standard Operating Procedures (SOPs)* means documented procedures which *describe* how to perform tests or activities normally not specified in detail in study plans or test guidelines.

1.8 *Master schedule* means a compilation of information to assist in the assessment of *workload* and for the tracking of studies at a test facility.

## 2 Terms concerning Studies

2.1 *Short-term study* means a study of short duration with widely used, routine techniques.

2.2 *Study plan* means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

2.3 *Study plan amendment* means an intended change to the study plan after the study initiation date.

2.4 *Study plan deviation* means an unintended departure from the study plan after the study initiation date.

2.5 *Test system* means any biological, chemical or physical system or a combination thereof used in a study.

2.6 *Raw data* means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in Annex 2, number 10.

2.7 *Specimen* means any material derived from a test system for examination, analysis, or retention.

2.8 *Experimental starting date* means the date on which the first study specific data are collected.

2.9 *Experimental completion date* means the last date on which data are collected from the study.

2.10 *Study initiation* date means the date the Study Director signs the study plan.

2.11 *Study completion* date means the date the Study Director signs the final report.

## 3 Terms concerning the Test Item

3.1 *Test item* means an article that is the subject of a study.

3.2 *Reference item* (control item) means any article used to provide a basis for comparison with the test item.

3.3 *Batch* means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

3.4 *Vehicle* means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

*Annex 2*[8]
(Art. 4 para. 1)

# GLP Principles

## 1 Test Facility Organisation and Personnel

### 1.1 Test Facility Management's Responsibilities

[1] Each test facility management should ensure that these Principles of Good Laboratory Practice are complied with, in its test facility.

[2] As a minimum it should:

a. ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these Principles of Good Laboratory Practice;

b. ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;

c. ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;

d. ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;

e. ensure that appropriate and technically valid Standard Operating Procedures are established and followed, and approve all original and revised Standard Operating Procedures;

f. ensure that there is a Quality Assurance Programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these Principles of Good Laboratory Practice;

g. ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the Study Director before the study is initiated. Replacement of a Study Director should be done according to established procedures, and should be documented;

h. ensure, in the event of a multi-site study, that, if needed, a Principal Investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a Principal Investigator should be done according to established procedures, and should be documented;

i. ensure documented approval of the study plan by the Study Director;

j. ensure that the Study Director has made the approved study plan available to the Quality Assurance personnel;

8 Revised in accordance with Annex No 2 of the O of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

k. ensure the maintenance of an historical file of all Standard Operating Procedures;

l. ensure that an individual is identified as responsible for the management of the archive(s);

m. ensure the maintenance of a master schedule;

n. ensure that test facility supplies meet requirements appropriate to their use in a study;

o. ensure for a multi-site study that clear lines of communication exist between the Study Director, Principal Investigator(s), the Quality Assurance Programme(s) and study personnel;

p. ensure that test and reference items are appropriately characterised;

q. establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these Principles of Good Laboratory Practice.

3 When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: point 1.1, paragraph 2, letters g., i., j. and o.

## 1.2 Study Director's Responsibilities

1 The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.

2 These responsibilities should include, but not be limited to, the following functions. The Study Director should:

a. approve the study plan and any amendments to the study plan by dated signature;

b. ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study;

c. ensure that study plans and amendments and Standard Operating Procedures are available to study personnel;

d. ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study;

e. ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study;

f. ensure that all raw data generated are fully documented and recorded;

g. ensure that computerised systems used in the study have been validated;

h. sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these Principles of Good Laboratory Practice;

i. ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

### 1.3 Principal Investigator's Responsibilities

The Principal Investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice.

### 1.4 Study Personnel's Responsibilities

1 All personnel involved in the conduct of the study must be knowledgeable in those parts of the Principles of Good Laboratory Practice which are applicable to their involvement in the study.

2 Study personnel will have access to the study plan and appropriate Standard Operating Procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s).

3 All study personnel are responsible for recording raw data promptly and accurately and in compliance with these Principles of Good Laboratory Practice, and are responsible for the quality of their data.

4 Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

## 2 Quality Assurance Programme

### 2.1 General

1 The test facility should have a documented Quality Assurance Programme to assure that studies performed are in compliance with these Principles of Good Laboratory Practice.

2 The Quality Assurance Programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

3 This/these individual/s should not be involved in the conduct of the study being assured.

## 2.2 Responsibilities of the Quality Assurance Personnel

The responsibilities of the Quality Assurance personnel include, but are not limited to, the following functions. They should:

a. maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility and have access to an up-to-date copy of the master schedule;

b. verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented;

c. conduct inspections to determine if all studies are conducted in accordance with these Principles of Good Laboratory Practice. Inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed. Inspections can be of three types as specified by Quality Assurance Programme Standard Operating Procedures:

   1. Study-based inspections,
   2. Facility-based inspections,
   3. Process-based inspections.

   Records of such inspections should be retained.

d. inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;

e. promptly report any inspection results in writing to management and to the Study Director, and to the Principal Investigator(s) and the respective management, when applicable;

f. prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

# 3 Facilities

## 3.1 General

1 The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.

2 The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.

### 3.2 Test System Facilities

[1] The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.

[2] Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

[3] There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.

### 3.3 Facilities for Handling Test and Reference Items

[1] To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.

[2] Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

### 3.4 Archive Facilities

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

### 3.5 Waste Disposal

Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

## 4 Apparatus, Material, and Reagents

[1] Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.

[2] Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.

[3] Apparatus and materials used in a study should not interfere adversely with the test systems.

4 Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.

# 5 Test Systems

## 5.1 Physical/Chemical

1 Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.

2 The integrity of the physical/chemical test systems should be ensured.

## 5.2 Biological

1 Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.

2 Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.

3 Records of source, date of arrival, and arrival condition of test systems should be maintained.

4 Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.

5 All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.

6 During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.

7 Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.

# 6 Test and Reference Items

## 6.1 Receipt, Handling, Sampling and Storage

1 Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.

2 Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.

3 Storage container(s) should carry identification information, expiry date, and specific storage instructions.

## 6.2 Characterisation

1 Each test and reference item should be appropriately identified (e.g. code, Chemical Abstracts Service Registry Number [CAS number], name, biological parameters).

2 For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

3 In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study.

4 The stability of test and reference items under storage and test conditions should be known for all studies.

5 If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g. tank mixes) these may be determined through separate laboratory experiments.

6 A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.

# 7 Standard Operating Procedures

1 A test facility should have written Standard Operating Procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility. Revisions to Standard Operating Procedures should be approved by test facility management.

2 Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein. Published text, books, analytical methods, articles and manuals may be used as supplements to these Standard Operating Procedures.

3 Deviations from Standard Operating Procedures related to the study should be documented and should be acknowledged by the Study Director and the Principal Investigator(s), as applicable.

4 Standard Operating Procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples:

a. Test and reference items: receipt, identification, labelling, handling, sampling and storage.

b. Apparatus, materials and reagents:
   1. Apparatus: use, maintenance, cleaning and calibration.
   2. Computerised systems: validation, operation, maintenance, security, change control and back-up.
   3. Materials, reagents and solutions: preparation and labelling.

c. Record keeping, reporting, storage, and retrieval: coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems.

d. Test System (where appropriate):
   1. Room preparation and environmental room conditions for the test system.
   2. Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system.
   3. Test system preparation, observations and examinations, before, during and at the conclusion of the study.
   4. Handling of test system individuals found moribund or dead during the study.
   5. Collection, identification and handling of specimens including necropsy and histopathology.
   6. Siting and placement of test systems in test plots.

e. Quality Assurance Procedures: operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.

## 8 Performance of the Study

### 8.1 Study Plan

1 For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the Study Director and verified for GLP compliance by Quality Assurance personnel as specified at point 2.2 letter b. The study plan should also be approved by the test facility management.

2 Study plan amendments and deviations should be treated as follows:

a. Amendments to the study plan should be justified and approved by dated signature of the Study Director and maintained with the study plan.

b. Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the Study Director and/or Principal Investigator(s) and maintained with the study raw data.

[3] For short-term studies, a general study plan accompanied by a study specific supplement may be used.

## 8.2 Content of the Study Plan

The study plan should contain, but not be limited to the following information:

a. Identification of the study, the test item and reference item:
   1. A descriptive title;
   2. A statement which reveals the nature and purpose of the study;
   3. Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.);
   4. The reference item to be used.

b. Information concerning the sponsor and the test facility:
   1. Name and address of the sponsor;
   2. Name and address of any test facilities and test sites involved;
   3. Name and address of the Study Director;
   4. Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).

c. Dates:
   1. The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management.
   2. The proposed experimental starting and completion dates.

d. Test methods: reference to the OECD Test Guideline or other test guideline or method to be used.

e. Issues (where applicable):
   1. Justification for selection of the test system;
   2. Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information;
   3. Method of administration and the reason for its choice;
   4. Dose levels and/or concentration(s), frequency, and duration of administration/application;
   5. Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).

f. Records: a list of records to be retained.

### 8.3 Conduct of the Study

1 A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.

2 The study should be conducted in accordance with the study plan.

3 All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.

4 Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.

5 Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

## 9 Reporting of Study Results

### 9.1 General

1 A final report should be prepared for each study. In the case of short term studies, a standardised final report accompanied by a study specific extension may be prepared.

2 Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.

3 The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.

4 Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.

5 Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

## 9.2 Content of the Final Report

The final report should include, but not be limited to, the following information:

a. Identification of the study, the test item and reference item:
   1. A descriptive title;
   2. Identification of the test item by code or name (e.g., IUPAC, CAS number, biological parameters, etc.);
   3. Identification of the reference item by name;
   4. Characterisation of the test item including purity, stability and homogeneity.

b. Information concerning the sponsor and the test facility:
   1. Name and address of the sponsor;
   2. Name and address of any test facilities and test sites involved;
   3. Name and address of the Study Director;
   4. Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable;
   5. Name and address of scientists having contributed reports to the final report.

c. Dates: experimental starting and completion dates.

d. Statement: a Quality Assurance statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

e. Description of materials and test methods:
   1. Description of methods and materials used;
   2. Reference to OECD Test Guideline or other test guideline or method.

f. Results:
   1. A summary of results;
   2. All information and data required by the study plan;
   3. A presentation of the results, including calculations and determinations of statistical significance;
   4. An evaluation and discussion of the results and, where appropriate, conclusions.

g. Storage: the location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

## 10 Storage and Retention of Records and Materials

[1] The following should be retained in the archives for at least ten years after study completion:

a. the study plan, raw data, samples of test and reference items, specimens, and the final report of each study;

b. records of all inspections performed by the Quality Assurance Programme, as well as master schedules;

c. records of qualifications, training, experience and job descriptions of personnel;

d. records and reports of the maintenance and calibration of apparatus;

e. validation documentation for computerised systems;

f. the historical file of all Standard Operating Procedures;

g. environmental monitoring records.

[2] In the absence of a required retention period, the final disposal of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

[3] Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.

[4] Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

[5] If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).