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

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FOREWORD

The OECD Working Group on Good Laboratory Practice, at its 27th meeting in 2013, established a drafting group to develop an Advisory Document on the characterisation of test items according to the principles of GLP. The purpose of the document was to consolidate existing guidance documents on test items which can be found in several OECD publications and to promote consistency in performing the characterisation of test items between OECD member countries. It would provide clarification and additional guidance on test item characterisation and test item retention.

A draft of the Advisory Document was posted on the GLP public web site on 4 May, 2017 and members of the public were invited to comment by 22 June 2017. (The deadline for comments was subsequently extended to 31 July, 2017.)

The drafting group has been led by Ms. Lesley Graham (UK - Medicines and Healthcare products Regulatory Agency) and Mr. Thomas Lucotte (France - Agence nationale de sécurité du medicament et des produits de santé). Other members of the drafting group included representatives from Brazil, Denmark (Pharmaceuticals), Finland, India Israel, Italy, Japan (Medical Products), South Africa, the US (EPA) and the US (FDA).

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

OECD GLP ADVISORY DOCUMENT NO. 19 ON THE MANAGEMENT, CHARACTERISATION AND USE OF TEST ITEMS

PREAMBLE

1. This guidance provides clarity for test facilities on the expectations of national Good Laboratory Practice (GLP) compliance monitoring authorities on how test items are transported, received, identified, labelled, sampled, handled, stored, characterised, archived and disposed. The document consolidates existing OECD guidance on test items that are used in studies conducted in compliance with the Principles of GLP. It also aims to promote a consistent approach that is appropriate to the objective of the study and the nature of the test item.

1. SCOPE

2. This document is designed to provide guidance on:

- the transportation, receipt, identification, labelling, sampling, handling, storage, characterisation, archiving and disposal of all test items used in GLP studies.

- the expectations on the characterisation of different types of test items that are used in the conduct of a broad range of non-clinical studies carried out in compliance with the Principles of GLP. Test items could be from different origins such as chemical, biological, synthetic, natural, living organisms, transgenic organisms, items from complex industrial or biological processes, complex mixtures or part of them. The final use of test items includes but is not limited to agrochemicals, industrial chemicals, pharmaceuticals (human and veterinary), cosmetics products, food/feed additives and medical devices.

3. The expectations in this guidance for "test facilities", "Test Facility Management" and "Study Directors", would equally apply to "test sites", "Test Site Management" and "Principal Investigators", where delegated study phases are conducted as part of a multisite study. (These terms are defined in the *OECD Principles on Good Laboratory Practice*[1].)

4. The amount of information required for transportation, receipt, identification, labelling, sampling, handling, storage, characterisation, archiving and disposal can vary from study-to-study. This is due to the wide variety of test items, the objectives of the study and the development stage of the test item. Because of the diverse nature of test items there is an expectation that Test Facility Management will undertake appropriate and proportionate risk-based assessments of the management, characterisation and use of each test item throughout their use on GLP studies. This should enable the test facility personnel to maintain a controlled approach in assessing whether information they have available on the test item is sufficient. Adoption of a risk-based approach to decision

[1] *OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring; Number 1* [ENV/MC/CHEM(98)17]

making should also serve to ensure that the test item is what it purports to be and is suitable to fulfil the objectives of the study.

2. DEFINITIONS OF TERMS

2.1. Test Item

5. Test item is defined as an article that is the subject of a study. The conclusion of a GLP study provides information on the properties of the test item which allows an assessment of the risk it presents to the safety of humans, animals or the environment. It should be noted that test item is also referred to as "test chemical" in some of the OECD Test Guidelines[2].

2.2. Batch

6. Batch (or lot) is defined as a specific quantity of a test item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform and homogeneous character and should be designated as such.

2.3. Vehicle

7. Vehicle is defined as any agent that serves as a carrier and is used to mix, disperse, suspend or solubilise the test item to facilitate the administration and/or application to the test system.

2.4. Formulation

8. A formulation (or mixture) is a combination of a test item and different ingredients such as excipients that are combined and administered and/or applied to the test system in a different form, e.g. tablet, capsule, solution.

2.5. Preparation of test item

9. Preparation of test item (or prepared test item) could be a formulation (or mixture) containing the test item or the test item in a vehicle, where the combination is obtained by dilution, mixing, dispersion, suspension, solubilisation and/or another process with the intention to be administered to the test system. The test facility can be supplied with the

[2] *Terminology in OECD Test Guidelines to designate what is tested. In June 2013, OECD's Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology agreed that where possible with respect to Test Guidelines, a more consistent use of the term "test chemical" describing what is being tested should now be applied in new and updated Test Guidelines. However, it is important to note that previously adopted OECD Test Guidelines will still use the terms "test item", "test compound", "test substance" or other similar term to describe what is being tested." The intention of this proposal is not to provide a new definition of the term "chemical(s)", but rather to be consistent with the UN definition of it when applicable, i.e. in Test Guidelines that make reference to the UN GHS for Classification and Labelling where "chemical" means "substance and mixture".*

test item or with preparation(s) of the test item to be processed again or preparation(s) of the test item ready to be applied or administrated to the test system (also called "ready-to-use").

10. A test item which is encapsulated or packed in some other way, in the absence of excipients or a vehicle, for the purposes of delivery to the test system is not regarded as a prepared test item in this document.

2.6. Characterisation

11. Characterisation determines attributes of the test item and provides the evidence to support its suitability for use in GLP studies.

2.7. Identification

12. Identification of the test item is the process of checking and assessing the test item against the supplied information to determine whether the test item is as expected. Supplied information could be the shipping documents, emails from the supplier, the test item label, etc. Typical characteristics used to identify the test item would be the name, batch number, purity, concentration, composition, chemical, physical and biological parameters. Identification can also include a physical and/or analytical check. The process of identification should be carried out prior to the start of the experimental phase of a GLP study.

2.8. Test system

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

2.9. Expiry Date (or Expiration Date)

14. Expiry Date (or Expiration Date) is the designated date a test item is expected to remain within established shelf life specifications if stored under defined conditions and after which it should not be used.

2.10. Retest Date

15. Retest Date is the date a test item should be re-examined to ensure that it is still suitable for use.

3. RESPONSIBILITIES

3.1. Test Facility Management

16. Test Facility Management should ensure that test items are appropriately characterised and that there are procedures which describe how test items should be transported, received, identified, labelled, sampled, handled, stored, characterised, archived and disposed. These procedures should describe the actions and responsibilities required to ensure that the test item is suitable to fulfil the objectives of the GLP study. Test Facility Management should ensure that the test facility has an adequate number of qualified personnel, appropriate facilities, equipment and materials available, to ensure the integrity of the test item.

3.2. Study Director

17. The Study Director has overall responsibility for the compliance of the study with the Principles of GLP. Therefore, when designing the study the Study Director should assess whether the materials, the test system and the test methods which will be used are compatible and suitable for use with the expected test item. It is essential that the Study Director has confidence in the procedures used to characterise the test item and is sure that the test item is what it purports to be.

3.3. Quality Assurance personnel

18. The Quality Assurance personnel undertake the activities of the Quality Assurance Programme. The Quality Assurance Programme should include inspections to verify the implementation of relevant procedures and practices, such as transportation, receipt, identification, labelling, sampling, handling, storage, characterisation, archiving and disposal of test items.

3.4. Archivist

19. 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.

3.5 Sponsor

20. The Sponsor often provides the test facility with information about the test item which is needed to ensure the study to be performed is in compliance with the Principles of GLP. For example, information is often provided on storage conditions, stability, expiry date, homogeneity, purity, batch number, etc. The Sponsor is responsible for submitting the results and outcomes from GLP studies to regulatory receiving authorities in support of chemical safety.

4. TEST ITEM TRANSPORTATION AND RECEIPT

21. To preserve the integrity of the test item, care should be taken to avoid it being exposed to environmental conditions which may be detrimental. Prior to sending the test item there should be a mechanism, developed in co-operation between the sponsor (or the sender) and the test facility, to establish the conditions the test item is expected to be subject to during transportation. Special care should be taken if the test item is temperature, light and/or humidity sensitive. Appropriate monitoring measures, such as the use of data loggers, max/min thermometers or the visual check of the presence of dry ice on arrival may be required commensurate to risk.

22. An assessment of the integrity of the test item upon receipt is essential to confirm that it is suitable for use in the study. The assessment should be recorded and retained by the test facility and should include a review of the shipping and environmental conditions, where monitored, during all stages of transportation, the physical condition of the test item and its container upon arrival and the date of receipt.

5. IDENTIFICATION, LABELLING AND SAMPLING

23. Verification of the identity of the test item is an integral part of ensuring the integrity of a GLP study, therefore great importance should be placed on the procedures used to confirm that the test item is what it is expected to be.

24. For each GLP study there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item. The identity of the test item should be verified upon arrival at the test facility. Verification should include ensuring that information on the container in which the test item is shipped and the labelling on the test item matches information recorded on the certificate of analysis, or other relevant information provided by the sponsor.

25. Checking that the physical characteristics of the test item, such as colour and consistency, match the physical characteristics detailed on the certificate of analysis or other associated documentation is an important part of the verification process. The extent and depth of what is checked can vary from test item to test item and should be justified; checks may include laboratory analysis. These checks can be performed immediately after reception or at the first opening of the container. Evidence of these checks should be documented and retained.

26. Containers used to hold the test item should carry unique identification information, expiry date and specific storage instructions. If a test item is stored in a container which is small or difficult to label, it would be appropriate to assign a unique reference number or identifier to the container which is traceable to more comprehensive information either in paper or electronic format.

27. Sampling procedures should be designed to prevent cross-contamination or potential confusion between test items.

28. To ensure retained and archived samples of test item are representative of the material used during the study, samples should be taken immediately after receipt or at the first opening of the container, and then stored in the appropriate conditions.

6. HANDLING AND STORAGE

29. Handling and storage facilities should be designed to ensure the integrity of the test item before and during its use on the study. Safety issues should also be taken into consideration. Some test items require special handling and storage conditions because of their physical/chemical/biological properties; for example, test items may be light sensitive, hygroscopic, require refrigeration or freezing.

30. To prevent cross contamination or potential confusion between test items, there should be separate rooms or areas for the receipt, storage and preparation of test items before administration or application to the test system. Methods used to prevent cross contamination, such as separation in terms of location and/or time, cleaning or decontamination, restricted access to the test items should be described in procedures.

31. Test item storage rooms or areas should be separate from rooms or areas housing the test systems.

32. Records of the quantity of test item received, the amount used during the conduct of the study, and the quantity remaining at the end of the study should be maintained. Quantities could be measured in weight, volume, unit or any other relevant way. Any discrepancies between the expected quantity and the actual quantity of stored test item should be investigated and justified. Responsibilities for the maintenance of those records should be defined by the Test Facility Management.

33. From the receipt of the test item by the test facility, the records of quantities of test item, handling conditions and storage conditions and locations should be maintained and retained in the archive by the test facility. Where multiple batches of a test item are used during a GLP study, such records should be available for each batch. Responsibilities for the maintenance of these records should be defined by the Test Facility Management.

7. CHARACTERISATION OF THE TEST ITEM

7.1. General information

34. The Principles of GLP require information on identity, such as name, code, CAS number, biological parameters, batch number, purity, composition, concentrations, and, in case of several batches of test item, characteristics to appropriately define each batch. Stability of the test item under storage and test conditions should also be available.

35. No or inadequate information on the characterisation of the test item constitutes a deviation from the Principles of GLP. The impact the deviation has on the validity of the study data and the extent of compliance with the Principles of GLP should be described by the Study Director in the GLP compliance statement of the final study report.

36. Consideration should always be given to whether information on the characteristics of the test item is needed in order to design the study and issue the study plan.

37. There is an expectation that test item administration or application only occurs when sufficient information is available that confirms the identity of the test item.

38. The characterisation of the test item, including stability, should always be completed by the end of the study so that information can be detailed in the final study report.

39. Where multiple batches of test item are used during a GLP study, characterisation information should be available for each batch of the test item used.

7.2. Source of characterisation data

40. The characterisation of the test item may be carried out by the sponsor, a supplier or the test facility. If characterisation is performed by the sponsor or a supplier, Test Facility Management should ensure that documented procedures are in place to verify the integrity and quality of the information provided.

41. In every case, the final study report should describe who is responsible for test item characterisation and who performed it. The report may also provide other relevant information such as the quality system under which the characterisation was performed.

7.3. Data on identity

42. The Principles of GLP require that for each study, the identity, including batch number, purity, composition, concentrations, or other characteristics necessary to appropriately define each batch of the test item, should be known.

43. The test facility may be supplied with a certificate of analysis, which usually provides basic information on the physical characteristics of the test item. In the absence of a certificate of analysis, information needed to confirm the identity and properties of the test item may be supplied in alternative formats such as a laboratory report, safety data sheet, memorandum, letter or email from the sponsor. All information supplied about the identification of a test item should be retained.

7.4. Data on stability

44. The test facility should be provided with information on the stability of the test item under storage and test conditions, or the test facility should determine such information. The stability of the test item can only be assured if the material is handled and stored appropriately, and is used before expiration.

45. The available data (e.g. retest or expiry date or any other indicator of stability) should be reported in as detailed a fashion as possible in the final study report.

7.5. Characterisation data for specific test items

46. If characterisation data required by the Principles of GLP is not available before completion of a GLP study, the lack of such information should be outlined and justified in the final study report as a GLP deviation and its impact on the validity of the study assessed.

47. The lack of data on the characterisation of a test item - because it is difficult or impossible to collect - should be justified.

48. For some other specific test items, additional data on characterisation from those required by the Principles of GLP can be essential. Some examples of specific test items are given hereafter in the following chapters 7.5.1. to 7.5.8.

7.5.1. Test items in the early stage of development

49. The extent to which a test item will be characterised may be commensurate with the stage of product development. In the earlier stages of test item development there may be less characterisation information available. However, the Study Director should

always be able to demonstrate that the test item used in the study is what is required in the study plan.

7.5.2. Biochemical

50. If the test item is a biochemical, for example an antibody, a peptide, a protein, a viral vector or an enzyme, the need for information to verify biological activity should always be considered, including the determination method and its quantification (potency) as part of the characterisation process. If no information is provided to demonstrate the biological activity of the test item, the reasons why the test item is still considered suitable for use in the study should be clearly outlined in the study plan and in the final study report.

7.5.3. Living Organisms

51. If the test item is a living organism, for example a cell, a virus or a microorganism, the characterisation may require specific information on properties which are unique to the test item. For example, if the test item is a cell line, it may be appropriate to confirm passage number. Other biological properties that may have to be taken into consideration because they have an impact on the viability of the test item may include viability rate, proliferation rate, culture conditions or infectious titer determination. Information required to characterise living organisms should be considered on a case-by-case basis and the rationale for performing the tests described in the study plan.

7.5.4. Transgenic organisms

52. A test item may be a transgenic organism[3] . If a unique identifier is available (see for example ENV/JM/MONO(2002)7) this can be included. If information is available on seed certification this can be used and may include: the name of the host species, a description of the inserted genetic material, the trait and the name of the developer.

7.5.5. Medical devices

53. For studies on medical devices, characterisation data can include the description of the device, the lot number, the types of materials of which the device is made (and method of manufacture and name of the manufacturer of any polymers, colorants, metals), the methods of manufacture and synthesis of the final device (e.g. injection molding) and the location of manufacturing facilities.

[3] There are different terms for transgenic organisms in different countries. Commonly used terms include: genetically modified organism (GMO), genetically engineered organism (GEO) and living modified organism (LMO). There are other variations on this theme.

54. Illustrations or photos could be the best way to show the entire configuration of the medical device.

55. The date of manufacture, stability, and storage conditions should be known and documented. Where applicable, information on the sterilisation status of the device used as a test item should be provided by the supplier.

56. If the test item is only a component part or a representative sample of a medical device, information of the full medical device should be available when possible.

7.5.6. Test items with complex composition

57. Substances of unknown or variable composition, or biological materials (UVCBs), complex reaction products or products from animal or vegetable or natural origin cannot be sufficiently identified by their chemical composition because the number of their constituents is relatively large and/or the composition is, to a significant part, unknown and/or the variability of composition is relatively large or poorly predictable. In such cases, the composition could then be defined by the manufacturing process and/or by the origin description.

7.5.7. Radiolabeled test items

58. Radiolabeled test items are generally unstable; however, their exact stability characteristics are not normally known so it is not possible to provide a retest or expiry date or any other stability indicator for them. Therefore, their radiopurity should be checked at the start of the study and be reported. Characterisation data should also include the amount of radioactivity per unit mass or volume – i.e. specific activity and/or specific concentration.

7.5.8. Other specific test items

59. The above examples of specific test items do not constitute an exhaustive list. The need for specific data to ensure characterisation of an unusual or unique test item should be defined on a case-by-case basis.

8. PREPARED TEST ITEM

8.1. Preparation of the test item

60. Before administration or application to the test system, the test item may undergo some preparation steps. The most frequent operation is the mixing with a vehicle, but further steps could be required.

61. The preparation steps are usually part of the GLP study. If the test item is supplied to the test facility pre-prepared, the final study report should describe where it was prepared and by whom. The final study report may also provide other information on the quality system under which the preparation was performed. If the test item is supplied prepared, the characterisation data on the active test item ingredient should also be available and reported in the final study report.

8.2. Data on homogeneity, concentration and stability of the preparations

62. As required by the Principles of GLP, if the test item is administered or applied in a vehicle, homogeneity, concentration and stability of the test item in that vehicle should be determined and reported. Most of time, the determination is part of the study. For test items used in field studies (e.g., tank mixes), these may be determined through separate laboratory experiments.

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

64. If the test item is supplied prepared as a mixture, as a formulation or in a vehicle, and the data on homogeneity, concentration and stability is not generated in a GLP test facility, the impact on the validity of the study and the integrity of the test item should be assessed and made clear in the final study report.

65. It is recognised that it may not always be technically possible to generate information on homogeneity, concentration and stability for a test item administrated or applied in a vehicle. The lack of such data and its impact on the validity of a study should be justified in the final study report.

8.3. Separation steps

66. Separation steps could be required, for example to remove particles or to ensure the sterility of a prepared test item dedicated to an intravenous route of administration on animals. When separation steps such as centrifugation, decantation, filtration or chromatography are carried out during the preparation of the test item, those steps should be documented and the impact of such steps on the integrity, homogeneity, concentration and stability of the prepared test item should be assessed and documented.

8.4. Extraction steps

67. For some specific test items, as the test item cannot be administrated and/or applied, an extract of the test item is processed. For example, dosing preparation for medical devices could be either the intact medical device, mixture with a vehicle or extract from the device using adequate solvent and conditions.

68. For extracts from medical devices, data on the concentration may not be relevant. However, the stability and homogeneity of the extract might be relevant and it may be necessary to determine these before administration. In case of repetition of the extraction step, there may be a mechanism to confirm the extracts from the different extractions are equivalent (for example, description of aspect, monitoring of pH, osmolality).

9. ARCHIVING

69. The test item documentation should be archived by the test facility.

70. The Principles of GLP require that a sample from each batch of test item should be retained and archived for analytical purposes for all studies except short-term studies.

71. The Principles of GLP require that a test item be archived for as long as its quality permits evaluation.

72. Therefore, the archive period should be defined based on an evaluation that considers the stability of the test item, the recommended retention time and existing national safety and regulation requirements (e.g. hazardous or regulated test item).

10. DISPOSAL

73. Disposal of the test item at the end of the study or after the archiving period should be documented and performed according to established procedures and should comply with national requirements for the disposal of chemicals and biological products.