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Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare
Director, Pharmaceutical Evaluation Division

Points to note (effects on human health) regarding "Implementation Guidelines for Chemical Substance-related GLP Inspection"

Implementation procedures, etc. of the chemical substance-related GLP inspection to test facilities which are subject to "Notice of the Good Laboratory Practice for test facilities conducting tests of New Chemical Substances etc." (31 March 2011/Yakushokuhatsu 0331 No.8/Heisei 23.03.29 Seikyoku No. 6/Kampo Kihatsu No. 110331010, which were jointly notified by the Director-Generals of the Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare, Manufacturing Industries Bureau of the Ministry of Economy, Trade and Industry, and Environmental Policy Bureau of the Ministry of the Environment; hereinafter, "chemical substance-related GLP") are specified in "Handling of the Study Results for determination in the Evaluation of New Chemical Substances etc." (Pharmaceutical and Food Safety Bureau (PFSB) Notification 0331 No.9 dated March 31, 2011/Ministry of Economy, Trade and Industry (METI) Manufacturing Industries Bureau Notification No. 7 dated March 29, 2011/ Ministry of the Environment (MOE) Environmental Health Policy Planning and Management Division Notification No. 110331011, which were jointly notified by the Director-Generals of Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare, Manufacturing Industries Bureau of the Ministry of Economy, Trade and Industry, and Environmental Health Policy Planning and Management Division of the Ministry of the Environment; hereinafter, "Test Result Handling Notification") and in "Guidelines for the Conduct of Laboratory Inspections under the Principles for Test Facilities Conducting Tests of New Chemical Substances" (PFSB Notification 1226 No.6 dated December 26, 2013, notified by the Director-General of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; hereinafter, "Inspection Implementation Guidelines Notification"), and points to note that inspectors, the notifiers, etc. should pay attention upon implementing inspection of chemical substance-related GLP (hereinafter, "Points to Note") are specified in "Points to note regarding 'Guidelines for Chemical Substance-related GLP Inspection'" (Yakusyokukahatsu Notification 1226 No.1 dated December 26, 2013, notified by the Director, Office of Chemical Safety, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; hereinafter, "Old Notification on Points to Note").

Based on the recent revision, etc. of the Test Result Handling Notification, the points to note are determined as follows.

For clarification, Old Notification on Points to Note is abolished with the issuing of this notification.

Notice

1. With regard to inspections of chemical substance-related GLP

(1) With regard to pre-inspection visits

If a testing facility that submitted an application based on 2(1) in the Annex to the Test Result Handling Notification, has never gone through confirmation on the compliance with the chemical substance-related GLP in the past, the inspector may visit the said facility before inspection in order to obtain necessary information.

(2) Timing of inspection

Inspection to test facility which has never gone through confirmation on compliance with chemical substance-related GLP shall be conducted in response to application submitted based on the prescription 2 (1) in the Annex to the Test Result Handling Notification. Inspections with respect to the 2nd application or later application shall be conducted, in principle, during the period from the date after two years and six months have passed since the date of the last confirmation until the date three years have passed, and during such period that one or more tests have completed or are in the course of implementation. If no test is conducted within three years since the date of the last confirmation, the first test conducted after three years shall be chosen as an object for inspection. But, if there are unavoidable circumstances, this is not applied to it.

(3) With regard to the checklist of chemical substance-related GLP

"Checklist of chemical substance-related GLP (Annex 1)" is supposed to be used as a guide of items etc. to be examined by inspectors at the time of the chemical substance-related GLP inspection. Because the items to be examined are different depending on the genre of object tests, organisation, etc. of the facility to be inspected, inspectors may add or delete the item to be examined as necessary.

(4) With regard to the tests, etc. that were not conducted as chemical substance-related GLP compliant tests for the past three years

When making an application on a test genre in which no chemical substance-related GLP test was conducted for recent three years going back from the date of application, though it was conducted previously, or when making application for the compliance confirmation on new test genre, the applicant is advised to consult the Office of Chemical Safety, Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare about the handling etc. of individual test to be inspected.

(5) With regard to computer validation

In the facility in which calculation and storage of data are carried out using computers, it is recommended to ensure the reliability of the computer with reference to "Checking Items in Computer

Validation (Annex 2)".

(6) With regard to the effective period of compliance confirmation

The effective period of the compliance confirmation specified in 8, 2) of the Annex to Inspection Implementation Guidelines Notification shall be, as for the case with testing facility which has not gone through any compliance confirmation in the past, or the case with testing facility which did not go through confirmation on compliance with standards continually, three years starting from the date of issuance of certificate on the compliance with standards, as for the case with testing facility which is going to go through confirmation on the compliance based on the 2nd or later application, three years starting from the day following the day when effective period of the last compliance confirmation ends.

2. With regard to the category of an inspection findings

The category and action to be taken for an inspection findings specified in Inspection Implementation Guidelines Notification Annex 5, 2) (4) shall be those specified in Annex 3.

3. With regard to handling of testing facilities subject to the drug-related GLP or the Industrial Safety and Health Act-related GLP

Inspection of the testing facility that complys with the standards specified in "Ministerial Ordinance on Good Laboratory Practice for Nonclinical Safety Studies of Drugs" (Ministerial Ordinance No. 21, Ministry of Health and Welfare, 1997) (hereinafter, "drug-related GLP) or to "Standards that testing facilities should have based on the provisions of Article 34-3, Paragraph 2 of the Ordinance on Industrial Safety and Health" (Ministerial Notification No. 76, Ministry of Labor, 1988; hereinafter, "Industrial Safety and Health Act-related GLP") shall be handled as follows.

(1) With regard to handling of notifiers etc.

If the test results attached to a notification of production, import, or export of the new chemical substance based on Article 3 or Article 7 of the Act on the Evaluation and Regulation of Manufacture etc. of Chemical Substances (Act No. 117, 1973; hereinafter, "Act"), or submission of test results on the properties of the priority assessment chemical substance based on Paragraph 1 in Article 10 of Act, or reporting the results of study on the hazard of priority assessment chemical substances or the monitoring chemical substances pursuant to Paragraph 2 in Article 10 or Paragraph 1 in Article 14 of Act, fall under any one of the following, inspection of the chemical substance-related GLP shall not be conducted, in principle. However, if the Director General of the Pharmaceutical Safety and Environmental Health Bureau recognizes the necessity of conducting inspection to the test facility because of the reason such as doubt in reliability of the test results etc., inspection can be conducted.

i. The test results obtained from studies that were completed within 3 years from the date of compliance confirmation, and was carried out in the testing facility evaluated as compliant by the on-site inspection of the drug-related GLP, (however, this is limited to the test results within the test

genre confirmed to comply with the drug-related GLP by the said inspection)

ii. The test results obtained from the study that is completed within 3 years from the date of completion of the inspection, and was carried out in the testing facility evaluated as good by the Industrial Health and Safety Act-related GLP inspection (however, this is limited to the test results within the test genre confirmed to comply with the Industrial Health and Safety Act-related GLP by the said inspection)

(2) With regard to handling of applicants for confirmation

When a testing facility, relating to an application for confirmation submitted by an applicant to the Director-General of the Pharmaceutical Safety Bureau on the basis of "the Guidelines on GLP Compliance Confirmation of the Testing Facility", which is an Annex to the Test Result Handling Notification, is evaluated as compliant as a result of the on-site inspection of the drug-related GLP, or is evaluated as good as a result of the Industrial Health and Safety Act-related GLP inspection, the chemical substance-related GLP inspection shall not be conducted in principle. However, if the Director-General of the Pharmaceutical Safety Bureau recognizes the need of conducting inspection at the said test facility, inspection can be conducted.

(3) With regard to judgement result of the Chemical Substance-related GLP

With regard to the facility that did not undergo the chemical substance-related GLP inspection based on (1) or (2), the phrase "based on evaluation results of 2) in 7" under 2) in 8 of the Annex to Inspection Implementation Guidelines Notification shall be replaced with "based on the evaluation result of the drug-related GLP or of the Industrial Health and Safety Act-related GLP, as well as on the submitted information".

In that instance, if judged as compliant by the drug-related GLP or judged as good by the Industrial Health and Safety Act-related GLP, shall also be judged as "good" by the chemical substance-related GLP, and compliance shall be confirmed in principle.

Refer to Annex 4 for correspondence of the test genre between the chemical substance-related GLP and the drug-related GLP.

(4) Regarding the effective period of compliance confirmation

Regarding the testing facility that underwent the compliance confirmation of the chemical substance-related GLP based on (3), the effective period in the compliance confirmation document of the drug-related GLP or of the Industrial Health and Safety Act-related GLP, which was submitted at the time of application for confirmation, shall be deemed as the effective period of the compliance confirmation of the chemical substance-related GLP.

Besides, when conducting the compliance confirmation of the chemical substance-related GLP based on the evaluation results of the drug-related GLP and on the submitted documents (hereinafter, "current compliance confirmation"), because handling of the starting date of the effective period of the chemical

substance-related GLP is changed, if an empty period is generated between the expiry date of the effective period of the previous compliance confirmation and the effective period of the current compliance confirmation, the effective period shall be deemed to continue even in the said empty period only for the test genre whose compliance with the chemical substance-related GLP was confirmed as continuous from the previous compliance confirmation.

With regard to handling of the case where the confirmation on the compliance with the standards is not notified by the date one day before the expiration date of the effective period because of unavoidable circumstances such as a disaster in spite of the fact that the specified application for the confirmation of compliance with the standards concerning the testing facility was made, this shall follow the handling specified in (4) under 3 confirmation in “the Guidelines on GLP Compliance Confirmation of the Testing Facility” which is an Annex to the Test Result Handling Notification.

Checklist under the Principles of Good Laboratory Practice (GLP) for Chemical Substances

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
[1] Organization/Personnel (Chapter 2) Purpose: To examine whether a test facility has an appropriate and sufficient number of personnel and is organized in such a way that it can conduct studies in accordance with the GLP for Chemical Substances.	(Comprehensive assessment of [1])		**II 1. Test Facility Organisation and Personnel**
1. Check how the organization of all the test facilities relates to the organization that responds to studies compliant with the GLP for Chemical Substances.	Compliant Others		
○ (Article 4 (2)) (Organization and Personnel) (Test Facility Management's Responsibilities) to confirm that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study.			II 1.1-2 b)
2. Check how the organization of all the test facilities relates to the organization of the quality assurance unit.	Compliant Others		
○ (Article 4 (6)) (Organization and Personnel) (Test Facility Management's Responsibilities) to designate quality assurance unit personnel and assure that the quality assurance responsibility is being performed in accordance with these Principles.			II 1.1-2 f) modified
3. Check the name, title, curriculum vitae (CV), etc. of the test facility management, and how the test facility management grasps activities of all the test facilities.	Compliant Others	Name of the test facility management: Job title:	
(Article 4) (Organization and Personnel) (Test Facility Management's Responsibilities) The test facility management should confirm that these Principles are complied with in its test facility and should, at a minimum, implement items which are prescribed in each of the following:			
○ (1) to have a statement which identifies the individual(s) within a test facility who fulfill the responsibilities of management as defined by these Principles;			II 1.1-2 a)
○(3) to confirm the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;			II 1.1-2 c)
○(4) to confirm that personnel clearly understand the functions they are to perform and, as necessary, provide training for these functions;			II 1.1-2 d)
○ (5) to confirm that appropriate and technically executable standard operating procedures are established and followed, and approve original and revised standard operating procedures;			II 1.1-2 e)
○ (8) to confirm that approval of the study plan is documented by the study director;			II 1.1-2 i)
○ (9) to confirm that the quality assurance unit personnel have obtained the approved study plan from the study director;			II 1,1-2 j)
○ (10) to confirm that all standard operating procedures are chronologically organized;			II 1.1-2 k) modified
○ (12) to prepare/maintain a master schedule;			II 1.1-2 m)
○ (13) to confirm that equipment and materials of the test facility meet requirements appropriate to their use in			II 1.1-2 n)

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
a study; ○ (14) to confirm that test substances and reference substances are properly identified and controlled.			II 1.1-2 p)
4. Check the methods of designating the study director, quality assurance unit personnel, and individual responsible for storage of archives.	Compliant Others	SOP (Exists/Not exists)	
○ For Article 4 (6) (Organization and Personnel) (Test Facility Management's Responsibilities), refer to [1] 2. ○ (Article 4 (7)) (Organization and Personnel) (Test Facility Management's Responsibilities) For each study, to designate an individual with the appropriate qualifications, training, and experience 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 and retained. ○ (Article 4 (11)) (Organization and Personnel) (Test Facility Management's Responsibilities) to designate an individual responsible for storage of samples and documents in the archive facilities.			II 1.1-2 f) modified II 1.1-2 g) II 1.1-2 l)
5. Check whether the test facility has a sufficient number of personnel (especially study personnel) for the conduct of its operations.	Compliant Others		
○ For Article 4 (2) (Organization and Personnel) (Test Facility Management's Responsibilities), refer to [1] 1.			II 1.1-2 b)
6. Check the name, job title, CV, etc. of the study director, and how the study director controls the overall conduct of the study.	Compliant Others		
○ (Article 6) (Organization and Personnel) (Study Director's Responsibilities) The study director is the single point of study control who has the responsibility for the overall conduct of the study and its final report. These responsibilities include, at a minimum, items which are prescribed in each of the following: (1) to approve the study plan and any amendments to the study plan by dated signature or seal. In case of amendments, to describe their details and reasons; (2) to confirm that the quality assurance unit has obtained a copy of the study plan and any amendments without delay and communicate closely with the quality assurance unit during the conduct of the study, as necessary; (3) to confirm that the study plans and their amendments and standard operating procedures are available to study personnel; (4) to confirm that the procedures specified in the study plan are followed; to record any deviations from the study plan and any deviations from the standard operating procedures during the conduct of the study, assess the impact of those deviations on the quality and integrity of that study, and take appropriate corrective action, as necessary; and to document them; (5) to confirm that all raw data generated are recorded completely by documents or appropriate electronic media etc.; (7) to date and sign or seal the final report to indicate acceptance of responsibility for the validity of the study data and to acknowledge that the study complies with these Principles; (8) to confirm that after completion (including termination) of the study, the study plan, the final report, raw data and the relevant supporting study materials are stored and retained in the archive facilities; (10) In the event of a multi-site study, to confirm that the study plan and the final report specify the roles of all principal investigators (only if appointed) and test facilities involved with the conduct of that study.			II 1.2-2 a) modified (Association II 8.1-2a)) II 1.2-2 b) II 1.2-2 c) II 1.2-2 e) modified II 1.2-2 f) II 1.2-2 h) modified II 1.2-2 i) II 1.2-2 d)

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
7. Check the career history, work experiences, etc. of the study personnel, and check the provision of education and training for the performance of the study personnel's functions, and their records. ○ (Article 4 (3)) (Organization and Personnel) (Test Facility Management's Responsibilities) to confirm that records of qualifications, training, experiences and job descriptions for each professional and technical individuals related to the study are retained. ○ (Article 8) (Organization and Personnel) (Study Personnel's Responsibilities) Study personnel's responsibilities are as follows: (1) to be knowledgeable in those parts of these Principles which are applicable to his or her functions in the study.	Compliant Others		II 1.1-2 c) II 1.4-1
8. Check how to deal with a health problem that happens with the study personnel that may unfavorably affect the quality of the study, and its records (when applicable). ○ (Article 6 (9)) (Organization and Personnel) (Study Director's Responsibilities) The study director is the single point of study control who has the responsibility for the overall conduct of the study and its final report. These responsibilities include, at a minimum, the following functions: (9) when the study personnel has a health problem that may adversely affect the conduct of the study, to give consideration not to allow that study personnel to engage in the work that may adversely affect the conduct of the study until the health condition of that study personnel is improved. ○ (Article 8) (Organization and Personnel) (Study Personnel's Responsibilities) Study personnel's responsibilities are as follows: (4) to exercise health precaution to minimize risk to themselves and to endeavor to ensure the integrity of the study. Any person who has a health problem that may adversely affect the conduct of the study should share that fact with the appropriate person thereof.	Compliant Others	SOP (Exists/Not exists)	No correspondent Related to II 1.4-4 II 1.4-4 modified
9. Check that the test facility management and the study director fulfill their responsibilities in accordance with the GLP for Chemical Substances when the computerized system is used for the conduct of study. ○ (Article 4 (15)) (Organization and Personnel) (Test Facility Management's Responsibilities) to establish procedures to confirm that the computerized system meets the purpose and its effectiveness is verified, operated, maintained/administered in accordance with these Principles; ○ (Article 6 (6)) (Organization and Personnel) (Study Director's Responsibilities) The study director is the single point of study control who has the responsibility for the overall conduct of the study and its final report. These responsibilities include, at a minimum, items which are prescribed in each of the following: (6) To confirm that necessary measures have been taken so that the computerized system used for the study functions properly.	Compliant Others		II 1.1-2 q) II 1.2-2 g) modified
10. In the case of a test facility for a multi-site study, also check the following in addition to 1 through 9 above.			

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
(1) Check the name, job title, CV, etc. of the test facility management, and the scope of the test facility management's responsibilities.	Compliant Others		
○ (Article 5) (Organization and Personnel) (Test Facility Management's Responsibilities) When a certain phase of the study is conducted at more than one test facility, the management of each test site (only if appointed) will have the responsibilities as defined in Article 4 with the following exceptions: (6), (7), (8), (9), (16) and (17).			II 1.1-3 modified
(2) Check how the test site management grasps the overall activities of the test facility.	Compliant Others		
○ For Article 5 (Organization and Personnel) (Test Facility Management's Responsibilities), refer to [1] 10.(1).			II 1.1-3 modified
(3) Check the method of designating the principal investigator(s).	Compliant Others		
○ (Article 4 (16)) (Organization and Personnel) (Test Facility Management's Responsibilities) in the event of a multi-site study, to designate a principal investigator, as necessary, and confirm that the individual so designated is trained, qualified and experienced as required 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.			II 1.1-2 h)
(4) Check the name, job title, career history, etc. of the principal investigator, and the scope of the principal investigator's responsibilities.	Compliant Others		
○ (Article 3 (7)) (General Provisions) (Definitions) Principal investigator (only if appointed) 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; provided, however, that the study director's responsibility for the study overall cannot be delegated to the principal investigator(s). This responsibility that cannot be delegated includes approval of the study plan and its amendments, approval of the final report, and confirming that the study is compliant with these Principles.			I 2.2-7
(5) Check how the principal investigator controls the delegated parts of the study.	Compliant Others		
○ (Article 7) (Organization and Personnel) (Principal Investigator's Responsibilities) Principal Investigator (only if appointed) will confirm the delegated phases of the study are conducted in accordance with these Principles.			II 1.3
(6) Check that the communication network has been set up among the study director,	Compliant		

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
the principal investigator(s), the quality assurance unit personnel, and the study personnel. ○ (Article 4 (17)) (Organization and Personnel) (Test Facility Management's Responsibilities) For a multiple-site study, to confirm that clear lines of communication exist between the study director, the principal investigator(s) (only if appointed), the quality assurance unit personnel and the study personnel.	Others		II 1.1-2 o)
11. Confirm the following matters with respect to the completed study.			
(1) CVs, work experiences, etc. of the study director, principal investigator(s) (if appointed) and the study personnel, and documents on provision of education, training, etc., to them. ○ For Article 4 (3) (Organization and Personnel) (Test Facility Management's Responsibilities), refer to [1] 7. ○ For Article 4 (16) (Organization and Personnel) (Test Facility Management's Responsibilities), refer to [1] 10.(3). Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 1.1-2 c) II 1.1-2 h)
(2) Workload of the main study personnel, to judge whether their roles in the study stated in the study plan have been appropriately performed. ○ For Article 4 (12) (Organization and Personnel) (Test Facility Management's Responsibilities), refer to [1] 3. Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 1.1-2 m) modified
[2] Reliability Assurance Division (Chapter 3) Purpose: To examine the organization, functions, etc. of the quality assurance unit, and whether the quality assurance unit assures the test facility management of the conduct of studies in compliance the GLP for Chemical Substances.	(Comprehensive assessment of [2])		II **2. Quality Assurance Programme**

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
1. To check whether the test facility has the documented quality assurance rules to assure that studies performed are in compliance with these Principles. ○ (Article 9, 1.) (Quality Assurance Unit) (General) The test facility should have documented quality assurance rules to assure that studies performed are in compliance with these Principles.	Compliant Others		II 2.1-1
2. Check the organization of the quality assurance unit, and the names, job titles, CVs, etc. of the personnel. ○ (Article 9, 2.) (Quality Assurance Unit) (General) The quality assurance unit consists of an individual or individuals designated by and directly responsible to the test facility management and who are familiar with the test procedures.	Compliant Others		II 2.1-2
3. Check whether individuals in charge in the quality assurance unit are involved with the conduct of the study they are to assure. ○ (Article 9, 3.) (Quality Assurance Unit) (General) The above-mentioned individuals in charge must not be involved in the conduct of the study they are to assure.	Compliant Others		II 2.1-3
4. Check the procedures for planning, conducting, reporting, giving recommendations etc. regarding audit or inspections (including those related to a multi-site study). ○ (Article 9, 4.) (Quality Assurance Unit) (General) The standard operating procedures for the quality assurance should, at a minimum, specify the following matters: (1) study audit or inspection; (2) inspection of the facilities conducting the study and archiving facilities; (3) audit of final report; (4) preparation of the quality assurance report and other documents; (5) audit or inspections with a focus on process related to the quality.	Compliant Others	SOP (Exists/Not exists)	II 7.4-5 modified (Standard Operating Procedures)
5. Check the methods of auditing each phase of the study and the final report. ○ (Article 10) (Quality Assurance Unit) (Quality Assurance Unit Personnel's Responsibilities) The responsibilities of the quality assurance unit personnel include, at a minimum, each of the following functions: (3) to conduct audit or inspection and determine if all studies are conducted in accordance with these Principles; to confirm that study personnel make use of and follow study plans and the standard operating procedures; and to retain records of such audit or inspection.	Compliant Others	SOP (Exists/Not exists)	II 2.2-1 c)
6. Check whether copies of the master schedule, study plan and standard operating procedures are retained.	Compliant Others		

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (Article 10) (Quality Assurance Unit) (Quality Assurance Unit Personnel's Responsibilities) The responsibilities of the quality assurance unit personnel include, at a minimum, each of the following functions: (1) to maintain copies of all approved study plans and standard operating procedures in use in the test facility, and an up-to-date copy of the master schedule;			II 2.2-1 a)
7. Confirm that the study plan contains the information required for the compliance of these Principles, and check whether their results are documented.	Compliant Others		
○ (Article 10) (Quality Assurance Unit) (Quality Assurance Unit Personnel's Responsibilities) The responsibilities of the quality assurance unit personnel include, at a minimum, each of the following functions: (2) to confirm that the study plan contains the information required for the compliance with these Principles and document the results.			II 2.2-1 b)
○ (Article 25) (Performance of the Study) (Study Plan) For each study, a study plan should exist prior to the initiation of the study. The study plan should be approved by the dated signature or seal of the study director, and are confirmed based on these Principles by the quality assurance unit personnel under the provisions of Article 10.			Part of II 8.1-1, modified
○ (Article 26, 1.) (Performance of the Study) (Content of the Study Plan) Amendments to the study plan and their justifications should be documented and approved by dated signature or seal of the study director, and be maintained with the study plan before amendment.			II 8.1-2 a)
○ For Article 27 (Performance of the Study) (Content of the Study Plan), refer to [8] 2.(2).			II 8.2
8. Check the following matters with respect to the completed study.			
(1) Name of the quality assurance personnel who have conducted audit or inspections of the study.	Compliant Others		
○ For Article 9, 2. (Quality Assurance Unit) (General), refer to [2] 2.			II 2.1-2
Studies chosen for inspection ( ) study ( ) study			
(2) that periodical audit or inspections in each phase of the study, and audit of the final report have been conducted, and their contents and results have been recorded and reported thereon (including recommendations) to the test facility management and study director; and that those contents and results have also been reported to the test site management and the principal investigator(s), if appointed.	Compliant Others		
(Article 10) (Quality Assurance Unit) (Quality Assurance Unit Personnel's Responsibilities) The responsibilities of the quality assurance unit personnel include, at a minimum, each of the following			

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
functions: ○ (4) to promptly report results of such audit or inspection in writing to the test facility management and to the study director, and when appointed, to the test site management and principal investigator(s). When serious problem that may affect the reliability of the study is found, the quality assurance unit personnel should give the test facility management and the study director recommendations to resolve the problem, and record the content, accompanied by a re-audit or re-inspection schedule. ○ (5) to audit the final report to confirm that the methods, procedures, and observation results are accurately and completely described, and that the reported study results accurately and completely reflect the raw data of the studies; ○ (6) when the content of the final report is appropriate, to submit a written report on the results of the audit or inspections to the test facility management and the study director, and when appointed, to the test site management and the principal investigator(s); ○ (7) to prepare, sign or seal a quality assurance statement, and attach with the final report. This quality assurance statement specifies types of audit or inspections and dates they were conducted, the phase(s) of the study audited or inspected, and the dates on which inspection results were reported to the test facility management, the study director and, if appointed, principal investigator(s). This quality assurance statement is used to confirm that the final report reflects the raw data. Studies chosen for inspection ( ) study ( ) study			II 2.2-1 e) modified II 2.2-1 d) II 2.2-1 e) modified II 2.2-1 f)
[3] Facilities (Chapter 4) Purpose: To examine that the facility is appropriate and the study can be conducted in accordance with the GLP for Chemical Substances.	(Comprehensive assessment of [3])		II **3. Facilities**
1. Check that the scale, structure and layouts etc. of the test facility are suitable for the kind of the tests being conducted based on the items presented in Article 1 of Annex 4 to the GLP for Chemical Substances, and that different activities are properly separated. ○ (Article 11, 1.) (Facilities) (General) The test facility should meet the requirements necessary for the conduct of the study and should be of suitable size, construction and location to minimize obstacles that might impair the validity of the study. ○ (Article 11, 2.) (Facilities) (General) In the test facility, an adequate degree of separation of the different activities should be provided to assure the proper conduct of each study. * (Annex 4: Article 1) (Test Facilities) Test facilities conducting chronic toxicity of chemical substances, test on effects on reproductive ability and subsequent generations, teratogenicity test, mutagenicity test, carcinogenicity test, in-vivo fate test, pharmacological test, and repeated dose toxicity test using mammals (hereinafter "toxicity or other test") should have the following facilities and areas: (1) Animal breeding facilities, etc. ○ 1) A test facility should be of suitable size and construction and have animal breeding facilities with equipment or apparatus necessary to set temperature, humidity, ventilation, lighting and other environmental conditions;	Compliant Others		II 3.1-1 modified II 3.1-2 Related to II 3.1-1

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ 2) Animal breeding facilities should have a sufficient number of animal rooms or areas with the following functions, as necessary: (i) Separate breeding by species or test system; (ii) Separate breeding for each study plan; (iii) Quarantine of animals.			Related to II 3.2-1, II 3.2-2
○ 3) A test facility should have special animal rooms or areas that are capable of conducting a test using test substances or reference substances such as volatile substances, aerosol and other radioactive substances and a test using what is known as a biological hazard such as infection factors as the test system separately from other tests.			Related to II 3.2-1
○ 4) A test facility should have facilities in which sick animals can be isolated and remedied, when necessary.			Related to II 3.2-2
(2) Facilities Supplying Animal Goods ○ 1) A test facility should have storage premises for feed, bedding, supplies and apparatus, when necessary. In this case, the storage premises for feed and bedding should be separated from the storage premises for test systems, and take measures to avoid contamination, and be equipped with refrigerating equipment for perishable supplies or feed.			Related to II 3.2-3
(3) Test operational areas ○ 1) A test facility should have separated operational areas, when necessary, for periodical measurement and various operations such as biochemical examinations, pathological examination, operation and anatomies.			Related to II 3.1-2
○ 2) A test facility should have special areas for the use of animal or microbe components, if applicable.			Related to II 3.2-1
○ 3) A test facility should have separated areas for cleansing, sterilization or disinfection and storage of supplies and apparatus used during the conduct of the study.			Related to II 3.2-3
2. Check whether rooms or areas needed to be separated or isolated have been separated or isolated corresponding to the purpose of use.	Compliant Others		
○ (Article 12) (Facilities) (Test System Facilities) Test system facilities should comply with each of the following: (2) to have appropriate rooms, areas or spaces, or facilities or structures to assure the isolation of test systems according to the nature of the study in order to prevent any adverse effect on the test system. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases or pathological conditions, when necessary, in order to prevent any unacceptable degree of deterioration in quality of test systems.			II 3.2-1 modified, II 3.2-2
○ For Article 1(1)2) of Annex 4, refer to note(*) to [3] 1.			Related to II 3.2-1, II 3.2-2
3. Check the environmental controls and their monitoring procedures in important areas, such as animal breeding facilities, facilities supplying goods for animal, areas for storage of test substances and reference substances, test operation areas, and special test areas including responses to chemical hazard and biological hazard.	Compliant Others	SOP (Exists/Not exists)	
○ For Article 11, 1. (Facilities) (General), refer to [3] 1.			II 3.1-1 modified
○ For Article 11, 2. (Facilities) (General), refer to [3] 1.			II 3.1-2
(Article 12) (Facilities) (Test System Facilities) Test system facilities should comply with each of the following: ○ (1) to have a sufficient number of rooms, areas or spaces to ensure the proper conduct of each study.			II 3.2-1 modified

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (2) Refer to [3] 2. ○ (3) To have rooms or areas as needed for the storage of supplies and equipment. Those storage rooms or areas should be separated from rooms and areas housing the test systems and should be provided with adequate protection against infection, contamination, and/or deterioration of the environment. ○ (Article 13, 1.) (Facilities) (Facilities for Handling of Test Substances and Reference Substances) To prevent contamination or mix-ups, the test facilities should be adequately separated from each test system facility and have separate rooms or areas with the functions mentioned in each of the following: (1) receipt and storage of the test substances or reference substances; (2) mixing of the test substances or reference substances with a vehicle; (3) storage of mixture of the test substances or reference substances with a vehicle. ○ (Article 13, 2.) (Facilities) (Facilities for Handling of Test Substances and Reference Substances) The above-mentioned storage rooms or areas should be adequate to preserve identity, concentration, purity, and stability of the test substances and reference substances, and their mixtures with a vehicle, and ensure safe storage for hazardous substances that may adversely affect the test systems by securely separating those substances from the test systems. ○ For Article 1(2)1), 1(3) of Annex 4, refer to note (*) to [3] 1.			II 3.2-1 modified, II 3.2-2 II 3.2-3 II 3.3-1 modified, II 3.3-2 modified II 3.3-2 modified Related to II 3.1-2 Related to II 3.2-1 Related to II 3.2-3
4. Check the physical layouts of the archive facilities, and that the archive facilities have design and environmental conditions capable of providing secure storage and retrieval of archives (including cases of storage by outsourcing). ○ (Article 14) (Facilities) (Archive Facilities) Archive facilities should provide secure storage and retrieval of study plans, raw data, final reports, samples of test substances and specimens, and their design and archive conditions should protect contents from deterioration (including cases of storage by commission).	Compliant Others		II 3.4 modified
5. For the handling and disposal of waste, check that proper gathering, storage and disposal facilities, decontamination, and means of transportation have been developed so as not to impair the reliability of the study. ○ (Article 15) (Facilities) (Waste Disposal Facilities) Handling and disposal of waste should be carried out in such a way as not to jeopardize the reliability of studies. This includes development of appropriate collection, storage and disposal facilities of waste, and development of means of decontamination and transportation.	Compliant Others		II 3.5
[4] Equipment, Apparatus, Materials, and Reagents (Chapter 5) Purpose: To examine that the test facility has appropriate and sufficient equipment, apparatus, etc. to conduct the study, and that equipment, apparatus, etc. are maintained, inspected and otherwise operated so as to obtain reliable results, and that reagents, etc. are properly labeled and stored.	(Comprehensive assessment of [4])		II **4. Apparatus, Material, and Reagents**

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
1. Check that the test facility has appropriate and sufficient equipment, apparatus, etc. necessary to conduct the study, and that those equipment, apparatus, etc. are properly designed and have sufficient processing capabilities to conduct the study.	Compliant Others		
○ (Article 16, 1.) (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus) Equipment and apparatus, including validated computerized systems, used for the generation, storage and retrieval of data, and for controlling test environments should be suitably located and of appropriate design and adequate processing capacity.			II 4-1
2. Check that equipment, apparatus, etc. are properly arranged.	Compliant Others		
○ For Article 16, 1. (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus), refer to [4] 1.			II 4-1
3. Check how the equipment, apparatus, etc. are inspected, cleaned, maintained, calibrated and otherwise controlled.	Compliant Others		
○ (Article 16, 2.) (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus) Equipment and apparatus used in a study should be periodically inspected, cleaned, maintained and calibrated according to the standard operating procedures, and records of these activities should be maintained. Calibration should, when necessary, be traceable to national or international standards of measurements.			II 4-2 Related to II 4-2
○ (Article 16, 3.) (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus) For equipment or apparatus repaired due to a malfunction or breakage, the date, details and the handler of the repair should be recorded, and those records should be stored.			
○ (Annex 4: Article 2) For materials and others used for toxicity or other tests, the following should be complied with: (1) Necessary measures should be taken for cages, hutches, racks and attached equipment at an appropriate frequency so that those items are kept clean and hygienic; (2) Bedding used for cages or hutches of animals should not interfere with the purpose or conduct of the test and should be replaced at an appropriate frequency to keep animals in a dry and clean environment; (3) Feed and water of animals should be periodically analyzed to verify that there exist no adulterates, that may interfere with the test and that presence of which is supposed to be predicted, in them more than the level preset in the study plan. In this case, records of such analysis should be retained as raw data. (4) Cleansers, pesticides, etc. that may interfere with the test should not be used. When used, the use of cleansers, pesticides, etc. should be recorded.			II 5.2-6, modified
4. Check the following items by picking out typical examples of equipment, apparatus, etc. used for the completed studies: (1) Standard Operating Procedure	Compliant Others		
○ For Article 16, 2. (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus), refer to [4] 3.			II 4-2

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (2) Equipment and Apparatus Operation, inspection, cleaning, maintenance, and calibration. Studies chosen for inspection ( ) study ( ) study			II 7.4-2 a)
(2) Methods of inspection, cleaning, maintenance and calibration of equipment, apparatus, etc., and their records.	Compliant Others		
○ For Article 16, 2. (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus), refer to [4] 3. Studies chosen for inspection ( ) study ( ) study			II 4-2
(3) Records of failures or breakage of equipment, apparatus, etc. and their repairs, and whether or not the failure or breakage has interfered with the conduct of the study.	Compliant Others		
○ For Article 16, 3. (Equipment, Apparatus, Materials, and Reagents) (Equipment and Apparatus), refer to [4] 3. Studies chosen for inspection ( ) study ( ) study			Related to II 4-2
5. Check whether the name and other appropriate labels (information on source, concentration, date of preparation, expiry date, and concrete storage conditions of reagents, etc.) in light of the nature and purpose of use of the relevant reagents, etc. are attached to the containers of reagents, etc.	Compliant Others		
○ (Article 17, 1. (Equipment, Apparatus, Materials, and Reagents) (Reagents) Containers, etc. of chemicals, reagents, and prepared solutions should be labeled to appropriately and explicitly indicate name, source of supply, concentration, date of preparation, expiry date, concrete storage conditions, and other information.			II 4-4 modified
○ (Article 17, 2. (Equipment, Apparatus, Materials, and Reagents) (Reagents) Make it a rule not to use reagents which have been deteriorated or expired, but the expiry date can be extended based on results of documented evaluation or analysis.			II 4-4 modified

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
6. Check that the reagents etc. are properly stored.	Compliant Others		No correspondent
7. Check that materials, etc. used for the study meet the condition shown in Article 2 in Annex 4 to the GLP for Chemical Substances and will not adversely affect the test systems. ○ (Article 18) (Equipment, Apparatus, Materials, and Reagents) (Materials) Materials, equipment, apparatus, etc. used in a study should not adversely affect the test systems. ○ For Article 2 of Annex 4, refer to [4] 3.	Compliant Others		II 4-3 II 5.2-6 modified
[5] Test Systems (Chapter 6) Purpose: To examine that biological test systems (animals, bacteria strains or cells) are properly bred, cultivated, stored, treated, housed or otherwise controlled so as not to interfere with the purpose or conduct of the study.	(Comprehensive assessment of [5])		II **5. Test Systems**
1. To check that the conditions of breeding, cultivating, storing, treating, housing or otherwise controlling biological test systems are properly specified given the items shown in Article 5 of Annex 4 to the GLP for Chemical Substances. ○ (Article 20) (Test Systems) (biological) Systems used for the generation for biological data should comply with each of the following: (1) Proper conditions should be established and maintained for the breeding, cultivation, handling or housing of biological test systems in order to ensure the reliability of data; (Annex 4: Article 5) (Breeding and Management of Animals) For the handling of animals used for toxicity or other tests, those animals should be properly bred and managed in accordance with each of the following. ○ (1) Assess the health conditions of animals newly received externally and isolate animals, in which any disease or pathological condition that would interfere with the purpose or conduct of the study is found during the observation, from healthy animals, and do not use those animals for the study. ○ (2) Isolate an animal from other animals when any disease or pathological condition that would interfere with the purpose or conduct of the study during the process of the study is found in the animal. For clarity, remedial treatment can be given to animals that have been isolated from other animals with the approval of the study director for remedial treatment, as necessary, unless it may interfere with the study. In that case, record reasons for the need of remedial treatment, approval to such remedial treatment, and methods of, drugs used for, and date and results of, such remedial treatment, and other relevant matters, and retain those records. ○ (3) Acclimate animals to the study environment for an appropriate period before the initiation of the study. ○ (4) Properly identify animals to be used for the study, as necessary, by a tattoo mark, ear punching, ear tag, color code or other means.	Compliant Others	SOP (Exists/Not exists)	II 5.2-1 Part of II 5.2-2, modified Part of II 5.2-2, modified II 5.2-4 Part of II 5.2-5, modified

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (5) For the animals used for the study, information to identify those animals in the rooms should be indicated on the exteriors of the cages, crates or racks, as necessary, in order to avoid any error in accommodation.			Part of II 5.2-5, modified
○ (6) Different species of animals should be accommodated, in principle, in separate breeding rooms.			No corresponding paragraphs/items
○ (7) If the same species of animals accommodated in the same breeding room are used for different studies, space should be put between them for appropriate separation and identification.			No corresponding paragraphs/items
2. Check the methods of receipt, inspection, quarantine (acclimatization) or characteristic inspection and isolation, etc. of biological test systems.	Compliant Others	(Appendix 1)	
(Article 20) (Test Systems) (Biological) Systems used for the generation for biological data should comply with each of the following:			
○ (2) House biological test systems newly accepted externally in a facility or container that can prevent contamination or infection of other biological test systems, and observe and record whether or not there is any unusualness;			Part of II 5.2-2, modified
○ (3) In the immediately preceding item, do not use a lot in studies, and when appropriate, humanely destroy the lot if any unusual mortality or morbidity or pathological conditions that might adversely affect the whole lot is recognized;			Part of II 5.2-2
○ (4) At the experimental starting date of a study, biological test systems for the relevant study are free of any disease or pathological condition that might interfere with the purpose or conduct of the study;			Part of II 5.2-2
○ (5) Isolate and remedy, if necessary to maintain the integrity of the study, biological test systems that become diseased or injured during the course of a study. Record any diagnosis and treatment of any disease or pathological condition before or during a study.			Part of II 5.2-2
○ (7) Acclimatize biological test systems to the test environment for an adequate period before the first administration or application of the test substances or reference substances;			II 5.2-4
○ For Article 5 (3) of Annex 4, refer to [5] 1.			II 5.2-4
3. Check how biological test systems suffering any disease or in pathological condition that might interfere with the purpose or conduct of the study should be treated.	Compliant Others	(Appendix 2)	
○ For Article 20, (4) (Test Systems) (Biological), refer to [5] 2.			Part of II 5.2-2
○ For Article 20, (5) (Test Systems) (Biological), refer to [5] 2.			Part of II 5.2-2
○ For Article 5(2) of Annex 4, refer to [5] 1.			Part of II 5.2-2, modified
4. Check individual identification of biological test systems, and methods of labeling on their cages, containers, etc.	Compliant Others	SOP (Exists/Not exists)	
○ (Article 20, (8)) (Test Systems) (Biological) Display all information needed to properly identify the biological test systems on their housing or containers. Give appropriate identification to individual test systems that are to be removed from their housing or containers during the conduct of the study.			II 5.2-5
○ For Article 5 (4) of Annex 4, refer to [5] 1.			Part of II 5.2-5, modified

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
5. Check that biological test systems are separately housed by species. ○ For Article 20 (Test Systems) (Biological) (1), refer to [5] 1. ○ For Article 5 (5) of Annex 4, refer to [5] 1. ○ For Article 5 (6) of Annex 4, refer to [5] 1.	Compliant Others		II 5.2-1 Part of II 5.2-5 modified No corresponding paragraphs/items
6. Check, if different studies are conducted in the same area, that area is appropriately separated and identified. ○ For Article 20, (8) (Test Systems) (Biological), refer to [5] 4. ○ For Article 5 (5) of Annex 4, refer to [5] 1. ○ For Article 5 (7) of Annex 4, refer to [5] 1.	Compliant Others	SOP (Exists/Not exists)	II 5.2-5 Part of II 5.2-5 modified No corresponding paragraphs/items
7. Check the methods of hygienic management of animal breeding facilities or cultivation rooms, or animal or other goods. ○ (Article 20, (9)) (Test Systems) (Biological) During use, clean and sanitize housing or containers for biological test systems at appropriate intervals. Any material that comes into contact with the biological test systems should be free of contaminants at levels that would interfere with the study. Change bedding for animals when appropriate. Document the use of pest control agents.	Compliant Others	SOP (Exists/Not exists)	II 5.2-6
8. Check the way of storage and management of animal goods (mainly feed) or other culture media. ○ For Article 18 (Equipment, Apparatus, Materials, and Reagents) (Materials), refer to [4] 7.	Compliant Others	(Appendix 3)	II 4-3
9. Check the methods of hygienic disposal of waste. ○ For Article 15 (Facilities) (Waste Disposal Facilities), refer to [3] 5.	Compliant Others	SOP (Exists/Not exists)	II 3.5
10. With respect to completed studies, check by the relevant records that the following operations were conducted in accordance with the study plan or the standard operating procedures.			
(1) Placement of orders, receipt, species, strains, sources of supply, sex, number, age,	Compliant		

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
characteristics, etc. of biological test systems. ○ (Article 20, (6)) (Test Systems) (Biological) Maintain records of source of supply, date of arrival, and arrival condition of biological test systems; Studies chosen for inspection ( ) study ( ) study	Others		II 5.2-3
(2) Acceptance inspection, quarantine (acclimatization) or characteristic inspection, etc. of biological test systems. ○ For Article 20, (2) (Test Systems) (Biological), refer to [5] 2. ○ For Article 20, (7) (Test Systems) (Biological), refer to [5] 2. Studies chosen for inspection ( ) study ( ) study	Compliant Others		Part of II 5.2-2, modified II 5.2-4
(3) Handling of sickness or morbidity of biological test systems before, or during the conduct of, the study (diagnosis, isolation or treatment, etc.) and handling of dead biological test systems (when applicable). ○ For Article 20, (3) (Test Systems) (Biological), refer to [5] 2. ○ For Article 20, (4) (Test Systems) (Biological), refer to [5] 2. ○ For Article 20, (5) (Test Systems) (Biological), refer to [5] 2. Studies chosen for inspection ( ) study ( ) study	Compliant Others		Part of II 5.2-2 Part of II 5.2-2 Part of II 5.2-2
(4) Environmental conditions of biological test systems (frequency of changes, temperature, humidity, etc. of cages, containers and beddings). ○ For Article 20, (1) (Test Systems) (Biological), refer to [5] 1. ○ For Article 20, (9) (Test Systems) (Biological), refer to [5] 7. ○ For Article 2(1) and (2) of Annex 4, refer to [4].3. Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 5.2-1 II 5.2-6 Part of II 5.2-6, modified

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
(5) Analysis of contaminants of feed, culture media, water, beddings (when applicable). ○ For Article 20, (1) (Test Systems) (Biological), refer to [5] 1. ○ For Article 20, (9) (Test Systems) (Biological), refer to [5] 7. ○ For Article 2(1) and (2) of Annex 4, refer to [5] 10.(4). ○ For Article 2 (3) of Annex 4, refer to [4] 3. Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 5.2-1 II 5.2-6 Part of II 5.2-6, modified Related to II 5.2-6
(6) Fact of use of cleansers or pesticides that may interfere with the study (when applicable). ○ For Article 20, (1) (Test Systems) (Biological), refer to [5] 1. ○ For Article 20, (9) (Test Systems) (Biological), refer to [5] 7. ○ For Article 2 (4) of Annex 4, refer to [4] 3. Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 5.2-1 II 5.2-6 Part of II 5.2-6, modified
[6] Test substances and reference substances (Chapter 7) Purpose: To examine the procedures for assuring that the test and other substances designated in the study plan are administered to the test systems in the designated dosage of administration.	(Comprehensive assessment of [6])		II **6. Test and Reference Items**
1. Check whether the procedures for distribution, receipt, storage, handling, labeling, return, etc. of the test and other substances have been established. ○ (Article 21, 2.) (Test Substances and Reference Substances) (Receipt, handling, sampling and storage) Procedures on handling, sampling and storage should be specified respectively in order that the homogeneity and stability are assured to the degree possible, and that contamination or mix-up are precluded. ○ (Annex 4: Article 3) (Handling of Test Substances and Reference Substances) For the methods of handling test substances and reference substances in a test facility, the following should be complied with: (2) to add necessary labelings through the process of distribution.	Compliant Others	SOP (Exists/Not exists)	II 6.1-2 Related to II 6.2-1
2. To check whether the procedures for handling, labeling, storage, distribution, disposal, etc. of mixtures of test substances etc. and vehicle (such as feed) have been	Compliant Others	SOP (Exists/Not exists)	

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
established. ○ For Article 21, 2. (Test Substances and Reference Substances) (Receipt, Handling, Sampling and Storage), refer to [6] 1. ○ (Article 21, 3.) (Test Substances and Reference Substances) (Receipt, Handling, Sampling and Storage) Storage container(s) should carry identification code, expiry date, and specific storage conditions. ○ (Annex 4: Article 4, 3.) (Mix-up in a Vehicle) If there is an expiry date for any ingredients in the mixture of the test substances or reference substances and the vehicle, the test facility must indicate that date on the storage container. In that case, if there are expiry dates for two or more ingredients, the earlier date should be indicated.			II 6.1-2 II 6.1-3 No corresponding paragraphs/items
3. Check whether the procedures have been established for preventing contamination and quality deterioration of test and other substances. ○ For Article 21, 2. (Test Substances and Reference Substances) (Receipt, Handling, Sampling and Storage), refer to [6] 1. ○ (Annex 4: Article 3) (Handling of Test Substances and Reference Substances) For the methods of handling test substances and reference substances in a test facility, the following should be complied with: (1) to distribute test substances and reference substances in such a method that is unlikely to cause contamination or quality deterioration.	Compliant Others	SOP (Exists/Not exists)	II 6.1-2 Related to II 6.1-2
4. Check the following matters with respect to completed studies.			
(1) Records on name of test and other substances, lot numbers, and characterization defining those substances (such as identification, purity or content, composition, concentration and potency). ○ (Article 22, 1.) (Test Substances and Reference Substances) (Characterization) Each test substance and reference substance should be appropriately identified by identification code, Chemical Abstracts Service Registry (CAS) number, name or other biological parameters. ○ (Article 22, 2.) (Test Substances and Reference Substances) (Characterization) Confirm, for each study, the lot number, purity, composition, concentration, or other characteristics to define the test substance or reference substance. Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 6.2-1 II 6.2-2
(2) Consistencies of the records of receipt, use and return or disposal of test and other substances. ○ (Article 21, 1.) (Test Substances and Reference Substances) (Receipt, Handling, Sampling and Storage)	Compliant Others		II 6.1-1

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
Maintain the records including characterization, date of receipt, expiry date, quantities received, quantities used in studies of test substances and reference substances. ○ (Annex 4: Article 3) (Handling of Test Substances and Reference Substances) For the methods of handling test substances and reference substances in a test facility, the following should be complied with: (3) to record dates and amounts of distribution and return for each lot. Studies chosen for inspection ( ) study ( ) study			No corresponding paragraphs/items
(3) Records on the stability of test and other substances. ○ (Article 22, 4.) (Test Substances and Reference Substances) (Characterization) Specify the stability of test substances and reference substances under storage and test conditions for all studies. Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 6.2-4
(4) If the test and other substances are mixed with a vehicle (such as feed) and used, records on the measurement of stability of those test and other substances in the mixture, and records on the measurement of the accuracy of mixing and the homogeneity of the mixture. ○ (Article 22, 5.) (Test Substances and Reference Substances) (Characterization) If the test substance is administered or applied after mixing with a vehicle, the homogeneity, concentration and stability of the test substance in that mixture should be determined. ○ (Annex 4: Article 4, 1.) (Mixing with a Vehicle) When a test facility uses test substances or reference substances after mixing them with a vehicle, the test facility should measure the stability of test substances or reference substances after the mixing, in principle, before the initiation of the study. If there are any circumstances in which the test facility cannot measure the stability before the initiation of the study, the test facility should establish the standard operating procedures on the measurement of the stability and make periodical measurement in accordance with those standard operating procedures. ○ (Annex 4: Article 4, 2.) (Mixing with a Vehicle) If the vehicle is a feed, the test facility should measure the homogeneity of the test substances or reference substances when they are prepared by mixing with the feed, and periodically measure the concentration of the test substances and reference substances in the mixture. Studies chosen for inspection ( ) study ( ) study	Compliant Others		Part of II 6.2-5 Part of II 6.2-5, modified Part of II 6.2-5, modified
(5) Check whether analytical samples have been stored for each batch of test and other substances for studies except short-term studies. ○ (Article 22, 6.) (Test Substances and Reference Substances) (Characterization) Retain sample for	Compliant Others		II 6.2-6

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
analysis from each batch of test substance for studies other than short-term studies. Studies chosen for inspection ( ) study ( ) study			
(6) If a test substance is supplied by the sponsor, check whether a cooperation mechanism to verify the identity of that test substance used for the study has been developed between the sponsor and the test facility. ○ (Article 22, 3.) (Test Substances and Reference Substances) (Characterization) In cases where the test substance is supplied by the sponsor, develop a mechanism in cooperation between the sponsor and the test facility, to verify the identity of the test substance used for the study. Studies chosen for inspection ( ) study ( ) study			II 6.2-3
[7] Standard Operating Procedures (Chapter 8) Purpose: To check whether the test facility has standard operating procedures related to studies conducted.	(Comprehensive assessment of [7])		II **7. Standard Operating Procedures**
1. Check for each room or area of the test facility, that the standard operating procedures for the activities to be performed therein are made available. Also check whether a study plan and its amendments are made available to the study personnel. ○ (Article 23, 4.) (Standard Operating Procedures) (General) Each separate test facility room or area should have immediately available current standard operating procedures relevant to the activities being performed therein. Publications, published articles, and other manuals of analytical methods may be used as supplements to these standard operating procedures. ○ For Article 6, (3) (Organization and Personnel) (Study Director's responsibilities), refer to [1] 6.	Compliant Others		II 7.2 II 1.2-2 c)
2. Check whether the standard operating procedures have been established with respect to the following issues:			
(1) Receipt, identification, labeling, handling, sampling, storage of test substances and reference substances, and mixing with a vehicle and sampling	Compliant Others	SOP (Exists/Not exists)	

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (1) (Test Substances and Reference Substances) Receipt, identification, labeling, handling, sampling, storage, and mixing with a vehicle.			II 7.4-1 modified
(2) Operation, inspection, cleaning, maintenance, and calibration of equipment and apparatus	Compliant Others	SOP (Exists/Not exists)	
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (2) (Equipment and Apparatus) Operation, inspection, cleaning, maintenance, and calibration.			II 7.4-2 a)
(3) Validation, operation, maintenance and inspection, securement of security, upgrade management, backing up, etc. of computerized systems	Compliant Others	SOP (Exists/Not exists)	
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (3) (Computerized systems) Validation, operation, inspection, maintenance, security measures, change control, and backup.			II 7.4-2 b)
(4) Preparation, storage, labeling, etc. of reagents etc.	Compliant Others	SOP (Exists/Not exists)	
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (4) (Reagents) Preparation, storage, labeling, etc.			II 7.4-2 c) modified
(5) Record keeping, reporting, storage, and search (identification coding, data collection, preparation of reports, search systems, and handling of data (including the use of computerized systems))	Compliant Others	SOP (Exists/Not exists)	
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (5) (Record keeping, reporting, storage, and retrieval) Identification coding, data collection, preparation of reports, search systems, and handling of data (including the use of computerized systems).			II 7.4-3
(6) Physical layouts and maintenance of animal breeding facility or cultivation rooms,	Compliant	SOP (Exists/Not exists)	

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
management of animal breeding or cultivation, and environmental conditions	Others		II 7.4-4 a) modified
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (6) Test systems (when applicable) 1) Room or area housing the test system, and environmental conditions			II 7.4-4 a) modified
○ (Annex 4: Article 6) (Matters Specified in Standard Operating Procedures) For the toxicity or other test, the standard operating procedures should be specified by additionally including each of the following: (1) Maintenance of animal breeding facilities, and breeding and management of animals;			
(7) Methods of receipt, housing, proper placement and transfer, characterization, identification, grouping, and management of biological test systems (animals, bacteria strains or cells).	Compliant Others	SOP (Exists/Not exists)	
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (6) Test systems (when applicable) 2) Receipt, transfer, proper placement, characterization, identification and care of the test system.			II 7.4-4 b)
○ (Annex 4: Article 6) (Matters Specified in Standard Operating Procedures) For the toxicity or other test, the standard operating procedures should be prepared with each of the following included additionally: (2) Identification, accommodation, placement and transfer of test animals			Part of II 7.4-4 b), modified
(8) Preparation, observation and examinations of the biological test system, before, during and at the conclusion of the study.	Compliant Others	SOP (Exists/Not exists)	
○ For Article 24 (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) (6) 2), refer to [7]2. (7).			II 7.4-4 b)
○ (Related, Annex 4: Article 6) (Matters Specified in Standard Operating Procedures) For the toxicity or other test, the standard operating procedures should be prepared with each of the following included additionally: (3) Observation of general and other symptoms of test animals;			Part of II 7.4-4 c)
(9) Handling of test system individuals found moribund or dead during the study.	Compliant Others	SOP (Exists/Not exists)	
○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (6) Test systems (when applicable) 4) Handling of test system individuals found moribund or dead during the study.			II 7.4-4 d)
○ (Annex 4: Article 6) (Matters Specified in Standard Operating Procedures) For the toxicity or other			II 7.4-4 d)

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
test, the standard operating procedures should be specified by additionally including each of the following: (4) Handling of moribund or dead animals			
(10) Necropsy or postmortem anatomy of animals ○ (Article 24) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Standard operating procedures should, at a minimum, set forth the following categories of test facility activities: (6) Test systems (when applicable) 5) Collection, identification and handling of specimens (including necropsy and histopathology). ○ (Annex 4: Article 6(5)) Necropsy or postmortem anatomy of animals	Compliant Others	SOP (Exists/Not exists)	II 7.4-4 e) Part of II 7.4-4 e)
(11) Collection and identification of specimens ○ For Article 24, (6) 5) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures), refer to [7]2. (10). ○ (Annex 4: Article 6) (Matters Specified in Standard Operating Procedures) For the toxicity or other test, the standard operating procedures should be specified by additionally including each of the following: (6) Collection and identification of specimens	Compliant Others		II 7.4-4 e) Part of II 7.4-4 e)
(12) Histopathological examination ○ For Article 24, (6) 5) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures), refer to [7]2. (10). ○ (Annex 4: Article 6) (Matters Specified in Standard Operating Procedures) For the toxicity or other test, the standard operating procedures should be prepared with each of the following included additionally: (7) Histopathological examination	Compliant Others		II 7.4-4 e) Part of II 7.4-4 e)
(13) Activities of the quality assurance unit in each phase of the study and the final report, and planning, scheduling, performing, documenting and reporting audit or inspections into the test facility (including the preparation of a quality assurance or other report). ○ (Article 24, (7)) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Activities of the quality assurance unit in planning, scheduling, performing, documenting and reporting audit or inspections.	Compliant Others	SOP (Exists/Not exists)	II 7.4-5
(14) Matters relating to the health management of the study personnel from the viewpoint	Compliant	SOP (Exists/Not exists)	

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
of the quality assurance of the study. ○ (Article 24, (8)) (Standard Operating Procedures) (Matters Specified in Standard Operating Procedures) Prevention for safety and hygiene.	Others		No corresponding paragraphs/items
(15) Other necessary matters	Compliant Others	SOP (Exists/Not exists)	No corresponding paragraphs/items
3. Check whether creation of or revisions to the standard operating procedures are approved together with the date of its creation or revisions and reason(s) for revisions, and are properly maintained. ○ (Article 23, 1.) (Standard Operating Procedures) (General) 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. ○ (Article 23, 2.) (Standard Operating Procedures) (General) Revisions to standard operating procedures should be approved in writing by test facility management. ○ (Article 23, 3.) (Standard Operating Procedures) (General) Each creation of or revisions to the standard operating procedures should be dated, justified (in the case of revisions) and maintained. ○ (Article 9, 5.) (Quality Assurance Unit) (General) Whenever the standard operating procedures referred to in the immediately preceding paragraph are created and revised, the standard operating procedures should be maintained together with the date of its creation or revisions and reason(s) for revisions.	Compliant Others		Part of II 7.1, modified Part of II 7.1 modified Related to II 10.1-f Related to II 2.2-1a
[8] Performance of the Study (Chapter 9) Purpose: To check whether the study plan and the conduct of the study are in accordance with the GLP for Chemical Substances.	(Comprehensive assessment of [8])		II **8. Performance of the Study**
1. Check how the study plan was prepared, approved and validated, and was revised. ○ For Article 25 (Performance of the Study) (Study Plan), refer to [2] 7. ○ For Article 26, 1 (Performance of the Study) (Content of the Study Plan), refer to [2] 7. ○ For Article 6, (1) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.	Compliant Others		Part of II 8.1-1, modified II 8.1-2 a) II 1.2-2 a)
2. Check the following matters with respect to the completed studies. (1) that the study plan was prepared, and approved by the study director, prior to the conduct of the study.	Compliant Others		

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
			Part of II 8.1-1, modified
○ For Article 25 (Performance of the Study) (Study Plan), refer to [2] 7. ○ For Article 6, (1) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.			II 1.2-2 a)
Studies chosen for inspection ( ) study ( ) study			
(2) that the study plan includes the items presented in Article 27 of the chemical substance GLP and the items presented in Article 7 of Annex 4 to the chemical substance GLP.	Compliant Others		
(Article 27) (Performance of the Study) (Content of the Study Plan) The study plan should contain, at a minimum, the following information:			
(1) Identification of the study, and test substances and reference substances;			
○ 1) A descriptive title;			II 8.2-1 a)
○ 2) Types and purpose of the study;			II 8.2-1 b) modified
○ 3) Name, abbreviation or identification code of the test substances and reference substances;			II 8.2-1 c) modified, and d)
(2) Information on the test facility, the sponsor, etc.			
○ 1) Name and address of the test facility, the sponsor, etc.;			II 8.2-2 a), b)
○ 2) Name and organization of the study director;			II 8.2-2 c) modified
○ 3) Name and organization of the principal investigators (only if appointed), and phase(s) of the study delegated by the study director and performed under the responsibility of the principal investigator(s).			II 8.2-2 d) modified
(3) Dates			
○ 1) The date of approval of the study plan by signature or seal of the study director;			II 8.2-3 a)
○ 2) The proposed experimental starting and completion dates.			II 8.2-3 b)
(4) Test methods			
○ Test methods to be adopted and the test method guidelines to be referred to.			II 8.2-4
(5) Other issues (where applicable)			
○ 1) The justification for selection of the test system;			II 8.2-5 a)
○ 2) Characterization of the test system (species, strain, substrain, source of supply, number, body weight range, sex, age, and other necessary information);			II 8.2-5 b) II 8.2-5 c)
○ 3) The method of administration and the reason for its choice;			II 8.2-5 d)
○ 4) The dose levels and/or concentration(s), frequency, and duration of administration/application;			II 8.2-5 e)
○ 5) Other detailed information on the study (including a description of the chronological procedure of the study, type, frequency and method of analysis, measurements, observations and examinations to be performed, and statistical testing methods to be used for data analysis).			
(6) Records			
○ A list of records, and reagents and materials to be retained			II 8.2-6 modified
(Annex 4: Article 7) For the toxicity or other test, the study plan should be prepared with each of the following included additionally:			
○ (1) Justification for selection of the test system;			II 8.2-5 a)
○ (2) Species, strain, number, age, sex, body weight range and sources of supply of test systems;			II 8.2-5 b) modified
			No corresponding paragraphs/items

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (3) Methods of identification of test systems;			No corresponding paragraphs/items
○ (4) Experimental planning methodology that will minimize bias;			No corresponding paragraphs/items
○ (5) Feed (including, if the presence of a contaminant that may be mixed in excess of a specified concentration is likely to interfere with the purpose or performance of the study, the setting of permitted concentration of such contaminant) and other vehicles;			II 8.2-5 c)
○ (6) Routes of administration of test substances and reference substances, and justification for selection thereof;			II 8.2-5 d) modified
○ (7) Amount, method, frequency and duration of administration of test substances and reference substances, as well as justification for selection thereof;			No corresponding paragraphs/items
○ (8) If necessary to achieve the purpose of the study, methods of measuring the absorption rates of test substances and reference substances in the test systems;			No corresponding paragraphs/items
○ (9) Other necessary matters.			II 1.2-2 d)
○ For Article 6, (10) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.			
Studies chosen for inspection			
( ) study			
( ) study			
(3) that amendments to the study plan were documented, and were approved by the study director.	Compliant Others		
○ (Article 26, 1.) (Performance of the Study Plan) (Amendments to the Study Plan) Amendments to the study plan should be documented and justified, approved by dated signature or seal of the study director, and maintained with the unamended study plan.			II 8.1-2 a)
○ For Article 6, (1) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.			II 1.2-2 a)
Studies chosen for inspection			
( ) study			
( ) study			
(4) that the study are conducted under instructions, supervision and control of the study director and in accordance with the study plan and the standard operating procedures.	Compliant Others		
○ (Article 28, (1)) (Performance of the Study) (Performance of the Study) The study should be conducted under instructions, supervision and control of the study director and in accordance with the study plan and the standard operating procedures.			II 8.3-2 modified
Studies chosen for inspection			
( ) study			
( ) study			

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
(5) that deviations from the study plan and the standard operating procedures, if reported from the study personnel, are documented with reason(s) and acknowledged by the study director and principal investigator(s) (if appointed) without delay. ○ (Article 23, 5.) (Standard Operating Procedures) (General) 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) (if appointed). ○ (Article 26, 2.) (Performance of the Study Plan) (Amendments to the Study Plan) Deviations from the study plan should be documented with reason(s), acknowledged by dated signature or seal of the study director or the principal investigator(s), (if appointed), without delay, and maintained with the raw data of the study. ○ For Article 6 (Organization and Personnel) (Study Director's Responsibilities) (4), refer to [1] 6. ○ (Article 8) (Organization and Personnel) (Study Personnel's Responsibilities) Study personnel's responsibilities are as follows: (2) to comply with the standard operating procedures applicable to the study plan and their functions in the relevant study. Any deviation from these standard operating procedures should be documented and communicated directly to the study director or, if appointed, the principal investigator(s). Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 7.3 II 8.1-2 b) modified II 1.2-2 e) Part of II 1.4-2
(6) that all data directed in the study plan are recorded. (Article 28) (Performance of the Study) (Performance of the Study) In conducting the study, the following should be complied with:] ○ (1) Refer to [8]2.(4). ○ (3) Entries of data should be recorded, directly, promptly, accurately, legibly, and in a manner that cannot be easily erased, and be dated, and signed or sealed, by the individual entering the data, except in cases where data are entered directly into the computer. ○ For Article 6, (5) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6. ○ (Article 8(3)) (Organization and Personnel) (Study Personnel's Responsibilities) Study personnel's responsibilities are as follows: to be responsible for recording raw data promptly and accurately, and be responsible for the quality of the data so recorded; Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 8.3-2 modified II 8.3-3 modified II 1.2-2 f) II 1.4-3
(7) that recording of raw data and their change (including the case where data generated as a direct input into a computer) are made in accordance with the GLP for Chemical Substances.	Compliant Others		

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
(Article 28) (Performance of the Study) (Performance of the Study) In conducting the study, the following should be complied with: ○ (1) Refer to [8] 2.(4). ○ (3) Refer to [8] 2.(6). ○ (4) Any change in the data should be made so as not to obscure the previous entry, should indicate the reason for the change and should be dated, and signed or sealed by the individual making the change, except for any change in the data that are entered directly into the computer. ○ (5) Accuracies of the data generated as a direct computer input should be verified at the time of data input by the individual(s) responsible for direct data entries, and the dates of data entries, the name of the individual(s) responsible for data entries and others should be recorded. ○ (6) Any change in the data generated as a direct input should indicate the reason for, and date of, change, as well as the name of the individual(s) making the change, and should enable traceability, if possible, by separately making entries thereof. Studies chosen for inspection ( ) study ( ) study			II 8.3-2, modified II 8.3-3, modified II 8.3-4 Part of II 8.3-5, modified Part of II 8.3-5, modified
(8) that records, specimens and others relating to the study carry unique identification codes given to each study. Specimens can be identified to confirm their origin by appropriately indicating the type of study, identification code of test systems, date of collection, and other relevant information thereon. ○ (Article 28, (2)) (Performance of the Study) (Performance of the Study) A unique identification code should be given to each study, and all records, specimens and others concerning the study should carry this identification code. Specimens can be identified to confirm their origin. ○ (Annex 4: Article 8, 1.) (Performance of the Study) Kind of the test, and identification number and collection date of the test systems should be indicated in a specimen in an appropriate manner. ○ (Annex 4: Article 8, 2.) (Performance of the Study) When a histopathologic retrieval of tissue specimen is conducted, macroscopic observation records at the time of necropsy of that specimen should be made available to the person(s) in charge of such retrieval. Studies chosen for inspection ( ) study ( ) study	Compliant Others		Part of II 8.3-1 II 8.3-1 modified Related to II 7.4-4 e)
(9) that any unusual or unforeseen phenomenon that has occurred during the study, and measures or other actions taken are recorded. ○ For Article 26, 2. (Performance of the Study) (Amendments to the Study Plan), refer to [8] 2.(5). ○ For Article 6 (4) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6. ○ For Article 8 (2) (Organization and Personnel) (Study Personnel's Responsibilities), refer to [8] 2.(5). Studies chosen for inspection ( ) study ( ) study	Compliant Others		II 8.1-2 b) modified II 1.2-2 e) Part of II 1.4-2

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
[9] Reporting of Study Results (Chapter 10) Purpose: To examine that the final report is prepared in accordance with the GLP for Chemical Substances, and records and other specimens are properly maintained.	(Comprehensive assessment of [9])		II **9. Reporting of Study Results**
1. Check how the final report is prepared, and the validity of the study results are assured.	Compliant Others		
(Article 29) (Reporting of Study Results) (General) In reporting the study results, each of the following should be complied with:			
○ (1) A final report should be prepared for each study.			Part of II 9.1-1
○ (2) The final report should be dated and signed or sealed by the study director to indicate acceptance of responsibility for the validity of the study results and add a statement that the study is in compliance with these Principles.			II 9.1-3 modified
○ (3) When a report on the study prepared by the principal investigator(s) (only if appointed) or other scientist(s) involved with the study is attached to the final report, that relevant report should specify the date of preparation and should be signed or sealed by the individual(s) preparing it.			II 9.1-2 modified
○ (4) Corrections and additions to a final report should be made in the form of amendments so as not to obscure the previous entry. Amendments should clearly specify the reason for the corrections or additions and should be dated and signed or sealed by the study director. Those corrections and additions should also be notified to the quality assurance unit.			II 9.1-4 modified
2.Check the following matters with respect to the completed study.			
(1) that the final report was prepared, and signed or sealed by the study director. When a report relating on the study, prepared by the principal investigator(s) (if appointed) or other scientists involved with the study is attached to the final report, that relevant report carries the date of its preparation and the signature or seal impression of the individual who prepared it.	Compliant Others		
○ For Article 29, (2) (Reporting of Study Results) (General), refer to [9] 1.			II 9.1-3 modified
○ For Article 29, (3) (Reporting of Study Results) (General), refer to [9] 1.			II 9.1-2 modified
○ For Article 6, (7) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.			II 1.2-2 h)
Studies chosen for inspection ( ) study ( ) study			

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
(2) that the final report includes the items presented in Article 31 of the GLP for Chemical Substances and the items presented in Article 9 of Annex 4 to the GLP for Chemical Substances.	Compliant Others		
(Article 31) (Reporting of Study Results) (Content of the Final Report) The final report should include, at a minimum, the following information:			
(1) Identification of the study, and test substances and reference substances;			II 9.2-1 a) modified
○ 1) A descriptive title and purpose of the study;			II 9.2-1 b) modified,
○ 2) Name, abbreviation or identification code of the test substances and reference substances;			c) modified
○ 3) Characterization of test substances (including information on purity, stability and homogeneity).			II 9.2-1 d)
(2) Information on the test facility, the sponsor, etc.			
○ 1) Name and address of the test facility, the sponsor and others;			II 9.2-2 a), b)
○ 2) Name and organization of the study director;			II 9.2-2 c) modified
○ 3) Name and organization of the principal investigator(s) (only if appointed), and phase(s) of the study delegated;			II 9.2-2 d) modified
○ 4) Name and job description of the study personnel;			No corresponding paragraphs/items
○ 5) Name and organization of scientists having contributed reports to the final report.			II 9.2-2 e) modified
(3) Dates			
○ 1) Study initiation date;			No corresponding paragraphs/items
○ 2) Experimental starting date and experimental completion date.			II 9.2-3
(4) Description of Materials and Test Methods			
○ 1) Materials used;			II 9.2-5 a)
○ 2) Test methods adopted and test method guidelines referred to.			II 9.2-5 b)
○ (5) Environmental factors that would have affected the quality of the study results			No corresponding paragraphs/items
(6) Study results			
○ 1) A summary of results;			II 9.2-6 a)
○ 2) All information and data required by the study plan;			II 9.2-6 b)
○ 3) A presentation of the study results (including results of statistical testing);			II 9.2-6 c) modified
○ 4) An evaluation and discussion based on the study results, and conclusions.			II 9.2-6 d)
(7) Storage			
○ The location(s) where the study plan, samples of test substances and reference substances, specimens, raw data and the final report are to be stored.			II 9.2-7
(Annex 4: Article 9) (Matters to Be Described in the Final Report) For the toxicity or other test, the final report should be prepared by additionally including each of the following matters:			
○ (1) The stability of test and reference substances under the administration conditions;			II 9.2-1 d) modified
○ (2) Kind, strain, number, age, sex, body weight range, sources of supply, date of obtaining and breeding conditions of the test systems;			No corresponding paragraphs/items
○ (3) Route, amount, method, frequency and duration of administration of test substances or reference substances;			No corresponding paragraphs/items
○ (4) Justification for the setting of the amount of administration of test substances or reference substances;			No corresponding paragraphs/items
○ (5) Other necessary matters.			No corresponding paragraphs/items
○ For Article 6, (10) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.			II 1.2-2 d)

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
Studies chosen for inspection ( ) study ( ) study			
(3) that the quality assurance statement including the items presented in Article 30 of the chemical substance GLP is attached to the final report.	Compliant Others		
○ (Article 30) (Reporting of Study Results) (Attachment of a Quality Assurance Statement) A quality assurance statement signed or sealed by the quality assurance personnel listing the following items should be attached to the final report. This quality assurance statement would also serve to confirm that the final report reflects the raw data. (1) Type and date of conduct of audit or inspections; (2) Phase of the study audited or inspected; (3) The date on which results of audit or inspections were reported to the test facility management, the study director, and principal investigator(s) (if appointed).			II 9.2-4
Studies chosen for inspection ( ) study ( ) study			
(4) that any corrections and additions to the final report are made in the form of amendments so as not to obscure the previous entry; that amendments clearly specify the reason for the corrections or additions and are dated and signed or sealed by the study director; and that those corrections and additions are notified to the quality assurance unit.	Compliant Others		
○ For Article 29, (4) (Reporting of Study Results) (General), refer to [9] 1.			II 9.1-4 modified
Studies chosen for inspection ( ) study ( ) study			
(5) that the final report accurately reflects the raw data.	Compliant Others		
Studies chosen for inspection ( ) study ( ) study			

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
(6) that unpredictable circumstances that are suspected to adversely affect the quality of the study, and deviations from the study plan are described in the final report. ○ (Article 31) (Content of the Final Report) The final report should include, at a minimum, the following information: (5) Environmental factors that would have affected the quality of the study results ○ For Article 6 (Organization and Personnel) (Study Director's Responsibilities) (4), refer to [1] 6. ○ For Article 8 (Organization and Personnel) (Study Personnel's Responsibilities) (2), refer to [8] 2.(5). Studies chosen for inspection ( ) study ( ) study	Compliant Others		No corresponding paragraph/items II 1.2-2 e) II 1.4-2
[10] Storage and Retention of Records and Materials (Chapter 11) Purpose: To examine that records and materials are properly stored and retained.	(Comprehensive assessment of [10])		II **10. Storage and Retention of Records and Materials**
1. Check the name, job titles, CV, etc. and other relevant information of the person responsible for the storage of archives. ○ (Article 33) (Storage and Retention of Records and Materials) (Methods of Storage and Retention) In retaining records and materials, each of the following should be complied with: (2) An individual responsible for the management of archives has been designated by the test facility management. The standard operating procedures for storage and retention have been created.	Compliant Others		Related to II 1.1-2 l), Related to II 7.4-3
2. To check the physical layouts of the archive facilities. ○ (Article 33) (Storage and Retention of Records and Materials) (Methods of Storage and Retention) In retaining records and materials, each of the following should be complied with: (1) Records and materials should be indexed so as to facilitate orderly storage and retrieval.	Compliant Others		II 10.2

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
3. Check the methods of controlling access to the archive facilities.	Compliant Others	SOP (Exists/Not exists)	
○ (Article 33) (Storage and Retention of Records and Materials) (Methods of Storage and Retention) In retaining records and materials, each of the following should be complied with: (3) Only the individual responsible for the management of archives, or personnel authorized by the test facility management beforehand should have access to the archive facilities. Entries into the archive facilities and movement of materials in and out of the archive facilities should be properly recorded.			II 10.3 modified
4. Check the methods of managing archives (carrying in and out, retrieval techniques, measures against deterioration, disposal, transfer, retention period, etc.).	Compliant Others	SOP (Exists/Not exists)	
○ For Article 33(2) (Storage and Retention of Records and Materials) (Methods of Storage and Retention), refer to [10] 1.			Related to II 7.4-3
5. If a test method or an archive contracting facility goes out of business and has no legal successor, check whether the records and materials in this archive facility are transferred to the archive facility of the relevant sponsor.	Compliant Others		
○ (Article 34) (Storage and Retention of Records and Materials) (Transfer of Materials) If a test facility or an archive contracting facility goes out of business and has no legal successor, the records and materials in this archive facility should be transferred to the archive facilities of the sponsor(s) of the study(s).			II 10. 4
6. Check the following matters with respect to completed studies.			
That the materials presented in Article 32 of the GLP for Chemical Substances, such as the master schedule, study plan, raw data, final report, records of audit or inspection by the quality assurance unit, standard operating procedures, recorded documents, test, reference and other substances, and specimens, are properly stored and retained.	Compliant Others		
○ For Article 6(8) (Organization and Personnel) (Study Director's Responsibilities), refer to [1] 6.			II 1.2-2 i)
(Article 32) (Storage and Retention of Records and Materials) (Retention Period of Time) Records and materials should be stored and retained for the period specified for each of the following items:			
○ (1) The master schedule;			Part of II 10.1 b)
○ (2) Study plan, raw data and the final report of each study;			Part of II 10.1 a)
○ (3) Records of audit or inspections performed by the quality assurance unit;			Part of II 10.1 b)
○ (4) Records of qualifications, training, experience and job descriptions of personnel;			II 10.1 c)
○ (5) Records and reports of the maintenance, inspection and calibration of apparatus;			II 10.1 d)
○ (6) Validation documentation for computerized systems;			II 10.1 e)
○ (7) The chronological file of all standard operating procedures;			II 10.1 f)

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
○ (8) Environmental monitoring records. The retention period of those items mentioned in (1) through (8) should be ten years after the receipt of notice under the provisions of Article 4, paragraph (1) or (2), Article 5, paragraph (2), (3) or (8), Article 10, paragraph (3) or Article 14, paragraph (2) of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Act No. 117 of 1973; hereinafter referred to as the "Act").			II 10.1 g)
○ (9) Test substances, reference substances, and other reagents;			Part of II 10.1 a)
○ (10) Specimens. The retention period of those items mentioned in (9) and (10) should be ten years after the receipt of notice under the provisions of Article 4, paragraph (1) or (2), Article 5, paragraph (2), (3) or (8), Article 10, paragraph (3) or Article 14, paragraph (2) of the Act or the duration or the period during which those items can be retained stably with no deterioration in quality, which is shorter.			Part of II 10.1 a)
○ (Not applicable) If any sample test or reference substances or specimens were destroyed for any reason prior to the expiry date of the retention period required, whether such destruction is justified and documented.			Part of II 10.1
○ (Annex 4: Article 10) (Storage) During the period of storage and retention of documents or specimens, consideration should be given to minimize damage to, or quality deterioration of those documents or specimens.			No corresponding paragraphs/items
○ (Annex 4: Article 11) (Retention Period of Specimens) For the retention period of wet specimens and specially prepared specimens of whose quality would substantially change during the retention period, such as tissue chemistry specimens, electron microscope specimens, blood specimens, and teratogenicity test specimens, the period during which quality can withstand evaluation should be considered to be the period during which those specimens can be stably preserved as set forth in these Principles.			Part of II 10.1
Studies chosen for inspection ( ) study ( ) study			
[11] Outsourcing of the study (when applicable) Purpose: If the study is outsourced, to examine whether the outsourcing procedures and other relevant matters are taken in accordance with the GLP for Chemical Substances.	(Comprehensive assessment of [11])		
1. Check the procedures for outsourcing the study and other relevant matters.	Compliant Others	SOP (Exists/Not exists)	
○ (Article 35) (Others) (Confirmation with the Sponsor of the Study) If the test facility accepts a request for a study, the test facility should confirm with the sponsor of the study beforehand whether the study should be conducted in accordance with these Principles.			No corresponding paragraphs/items

	Compliance Status	Comments	Corresponding Paragraphs/Items of OECD GLP
2. Check the following matters with respect to the completed study. ○ For Article 35 (Other) (Confirmation with the Sponsor of the Study), as mentioned earlier. Refer to [11] 1. Studies chosen for inspection ( ) study ( ) study	Compliant Others		No corresponding paragraphs/items

(Note) The word “Part of” in the column “Corresponding Paragraphs/Items of OECD GLP” indicates that a part of OECD GLP Principle specified by the article number is cited. The word “modified” indicates that OECD GLP Principle specified by the article number is cited with modification. The word “Related to” indicates that the check item is not made based on OECD GLP Principles but that the check item has some association with the Principle.

Appendix 1

(1) Information concerning received animals
(1. In-house production; 2. Commissioned production; 3. Producer; 4. Distributor; 5. Other)
(1. Conventional animals 2. Specific pathogen-free (SPF) animals; 3. Germ-free animals; 4. Other)
1. Microbe monitoring results obtainment (Obtained/Not obtained)
2. Transport information (Obtained/Not obtained)
3. Records (Exists/Not exists)

(2) Methods of receiving animals
1. Receiving room/Quarantine room/Breeding room
2. Quarantine room/Breeding room
3. Breeding room

1. Checked the number of received animals (Done/Not done) 2. Checked the sex of received animals (Done/Not done)
3. Measured weight (Done/Not done) 4. Checked abnormal appearance (Done/Not done)
5. Records (Exists/Not exists)

(3) Quarantine (acceptance inspection)
1. Quarantine period: days
2. Microbiological quarantine findings (protozoan, parasitic worm, bacteria, virus)

3. Clinical examination to obtain findings (Done/Not done)
4. Person responsible for assessment of health condition (qualification)

5. Records (breeding and management records)
Microbiological quarantine findings (Exists/Not exists)
General symptom observation findings (Exists/Not exists)
Weight measurement records (Exists/Not exists)
Feeding and watering records (Exists/Not exists)

(4) Feeding management method
1. Ordinary animal housing facility (conventional system)
2. Closed animal breeding facility
A Barrier system
B Isolation rack
C Vinyl isolator
D Other

Appendix 2

For the handling of sickness or morbidity in real cases, the following examinations should be conducted:

1) Handling of sick or morbid animals
1. Method of detecting sickness or morbidity
2. Date on which the sickness or morbidity was detected
3. Number of sick or morbid animals detected
4. Sickness or morbidity records (Exists/Not exists)
5. Reporting to the study director (Done/Not done)
6. Instructions from the study director (Done/Not done)
7. Methods of isolation (isolation room, killing, other)

2) Measures in case of a killing
1. Approval of the study director (Exists/Not exists)
2. Justification for killing
3. Method of killing
4. Gathering of a specimen (Exists/Not exists)
5. Records (Exists/Not exists)

3) Procedures in case of a remedial treatment given
1. Approval of the study director (Exists/Not exists)
2. Justification for requiring remedial treatment
3. Method of remedial treatment
4. Period of remedial treatment from [date]
to [date]
(days)
5. Name of medicine used for remedial treatment
6. Person in charge of remedial treatment
7. Records on the progress of remedial treatment (Exists/Not exists)
8. Records on the remedial treatment results (Exists/Not exists)
9. Handling of animals after remedial treatment

Appendix 3

Management of Feed, Water and Animal Breeding Equipment, and Cleansers and Other Items

1. Permitted feeding and watering levels (Set/Not set)

2. Feed
1) Feed manufacturer
2) Type of feed (for each species of animal)
3) Form of feed
4) Analysis location
5) Feed storage conditions
a) Normal environment
b) Refrigerating system (Exists/Not exists)
c) Storage period

3. Water
1) Tap water under the Water Supply Act (Used/Not used)
2) Privately pumped up water (Used/Not used)
3) Water receiving tank (Exists/Not exists)
4) Harmful metal removing equipment (Exists/Not exists), its type
5) Disinfection or sterilization equipment (Exists/Not exists), its type
6) Microbiological monitoring of water bottles (Done/Not done)
7) Frequency of replacement of water supply equipment using water bottles or other items
8) Analysis location
9) Records (Exists/Not exists)

4. Animal breeding instruments/equipment

1) Hygienic treatment of animal breeding instruments/equipment
(a) Cleansing facility (Exists/Not exists)
(b) Disinfection treatment (Done/Not done)
(c) Sterilization facility (Exists/Not exists)
(d) Other

2) Storage of breeding instruments/equipment
(a) Classification between untreated and treated instruments/equipment (Done/Not done)
(b) Storage area or storage place/room (Exists/Not exists)
(c) Method of storage

5. Whether cleansers/pesticides that would interfere with the study have been used, and whether the cleansers/pesticides used have been recorded. For the real cases, the following examinations should be conducted:

1) Cleansers

(i) Instructions of the study director (Exists/Not exists)
(ii) Justification for the use of cleansers
(iii) Type of cleansers
(iv) Scope of the use of cleansers (in the breeding room)
(v) Method of use
(vi) Method of the amount used
(vii) Records (Exists/Not exists)

2) Pesticides

(i) Instructions of the study director (Given/Not given)
(ii) Justification for the use of pesticides
(iii) Type of pesticides
(iv) Scope of the use of pesticides
(v) Method of use
(vi) Records (Exists/Not exists)

(Annex 2)

Check items for computer validation

1. Introduction (change) of computer system
   (1) The standard operating procedures for system introduction (change) are established.
   (2) System introduction (change) is conducted according to the above standard operating procedures.
   (3) The purpose of system introduction (change) and the user requirements specification that are definitely specified.
   (4) Computer system is validated to comply with the user requirements specification and the record of validation is preserved.
   (5) Measures for problems in the above validation are appropriately taken.
   (6) Activities of introduction (change) are reviewed and a Test Facility Manager confirms that reliability of the system was validated and approves the introduction (change).

2. Operation control of computer system
   (1) The standard operating procedures for the following issues are established and utilized appropriately.
      1) Definition of raw data
      2) Operation procedures of system
      3) Control system and maintenance procedures for system
      4) Procedures for changing and controlling system
      5) Procedures for abolishing system
      6) Procedures for other necessary items
   (2) The procedures for record and change comply with the GLP for Chemical Substances when electromagnetic record is raw data.
      1) Sampling of raw data should be done to check the conditions of raw data meet the conditions specified in the GLP for Chemical Substances or not. The conditions of raw data mean that data have the following records.
         a) Identification of individual studies, types of test operation
         b) Test substance, dose group, male/female, animal, organ, etc.
         c) Person in charge of data entry, entry date, and entry time (when necessary)
         d) Equipment (equipment for gathering data)
      2) Checking the record of changing raw data meets the conditions of change specified in the GLP for Chemical Substances. The conditions of change mean that data have the following records.
         a) Data before change (data and information specified in the above 1) a) to d))
         b) Reason of data change, date and a person who changed the data

c) Equipment (terminal for changing)

(3) The following items, related to measures for errors that occurred after operation started and measures for program change, are investigated.

a) Problems that occurred after system operation started and measures for the problems

b) Approval of Test Facility Manager for important system change

c) Validation test that was conducted when system was changed

(4) The following items related to assurance of system security are investigated.

a) Backup of raw data

b) Measures for preventing system abuse

c) The procedures for operation control of the room when the system is set in a dedicated computer room

(5) The implementation status and record of system maintenance are investigated.

(6) The following items about the procedures for data archive are investigated.

a) Handling of raw data after the completion of a test

b) Archive conditions

c) Measures for data loss due to deterioration of electromagnetic media, etc.

3. Abolishment of computer system

(1) Reliability after data transfer is guaranteed where raw data in abolishment of computer system are transferred.

4. Investigation of computer system by Quality Assurance Unit

(1) The standard operating procedures for investigation of computer system by Quality Assurance Unit are established.

(2) Computer system has function to enable investigation of computer system by Quality Assurance Unit.

(3) Quality Assurance Unit investigates computer system throughout life cycle of computer system.

5. Other investigations

(1) Host computer is set under appropriate conditions.

a) Building site and structure, etc.

b) Layout, structure and equipment of host computer room, etc.

c) Air conditioning equipment

(2) Where a computer system processed data of a test to be inspected already stopped due to renewal, reliability of raw data is guaranteed based on archived documents and records on the stopped computer system.

(3) Where the existing computer system did not comply with the "1. Introduction (change) of computer system" at its introduction, items in Section 1 and 2 are evaluated using data and records of system introduction (change) and operation. Additional measures or alternative

procedures are taken to secure validity of the computer system based on evaluation results.

(Annex 3)

Classification of and actions in response to indication etc. during chemical substance-related GLP inspection (human health effect)

The classification and actions for the items specified in (4) of 2) under 5 of the Appendix to the Inspection Implementation Guidelines Notification are as follows.

(1) Serious deviation

A serious deviation from the Principles of GLP is recognized that impairs the reliability of studies conducted at the test facility.

As a result of deliberation in the GLP Review Council, in case where it falls into "Serious deviation" due to totally or partly incompliant with chemical substance-related GLP, the inspector, taking into account of justification by the testing facility which is an object of the inspection, after conducting additional inspection where necessary, gets the case deliberated again by the GLP Review Council.

(A) In case where the GLP Review Council accepts the justification, a chance shall be given to the testing facility which is an object of the inspection to report the state of improvement according to the prescription in 3) under 7 of the Appendix to the Inspection Implementation Guidelines Notification. Taking its content into consideration, after conducting an additional inspection where necessary, either one of the following measures shall be implemented.

(a) In case the inspector judges it as equivalent to non-compliant, give the testing facility a chance of justification, taking its results into consideration, gets it deliberated by the GLP Review Council and as the result of the final evaluation,

(i) In case the justification was not accepted and judged as "failure", the serious deviation concerned shall be presented as an attachment to a notification of the judgement result, which is prescribed in 2) under 8 of the Appendix to the Inspection Implementation Guidelines Notification.

(ii) In case the justification was accepted and judged as "pass", a notification, which is prescribed in 2) under 8 of the Appendix to the Inspection Implementation Guidelines Notification shall be issued.

(b) In case the inspector confirmed an improvement, a notification, which is prescribed in 2) under 8 of the Appendix to the Inspection Implementation Guidelines Notification shall be issued.

(B) In case the GLP Review Council does not accept the justification, the serious deviation concerned shall be presented as an attachment to a notification of the judgement result, which is prescribed in 2) under 8 of the Appendix to the Inspection Implementation Guidelines Notification.

(2) Minor deviation

A minor deviation from the Principles of GLP is recognized that requires correction to ensure the reliability of future studies conducted at the test facility (including cases where the reliability of only a specific and limited range of studies is affected).

The Pharmaceutical Evaluation Division notifies the testing facility by writing and requests for a report on a remediation measure, including a remediation plan. The report on remediation measure shall be submitted, within 30 days from the date of notification mentioned above, to the Office of Chemical Safety, Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare. Besides, a notification, which is prescribed in 8 of the Appendix to the Inspection Implementation Guidelines Notification shall not be issued until a report concerned on remediation measure is submitted. After submission of a report on remediation measure, a similar measure shall be implemented as (1) (A) (a) or (b). And an implementation status of the remediation measure concerned shall be confirmed at the time of the next inspection.

(3) Non-deviation finding(s)

Cases where corrective action would help to improve the reliability of future studies.

The Pharmaceutical Evaluation Division notifies the testing facility by writing but does not request for a report on remediation measures. Besides, remediation measures in response to non-deviation findings shall be confirmed at the time of the next inspection.

(4) Non-deviation slight finding(s)

Minor points where corrective action would be beneficial but is not essential for the reliability of future studies.

Awareness shall be raised orally at the time of the inspection concerned, and remediation measures shall be confirmed at the time of the next inspection.

(Annex 4)

The correspondence table of test fields of the GLP for Chemical Substances to the GLP for Pharmaceuticals

The correspondence table of test fields of the GLP for Chemical Substances to the GLP for Pharmaceuticals is specified as follows.

GLP for Chemical Substances	GLP for Pharmaceuticals
28-day repeated dose toxicity study in mammals 90-day repeated dose toxicity study in mammals	Repeated dose toxicity study (subacute) or Repeated dose toxicity study (chronic)
Chronic toxicity study	Repeated dose toxicity study (chronic)
Studies of reproductive potential and the influence on later generation Teratogenicity study	Reproductive and developmental toxicity study
Combined Repeated dose toxicity with the reproduction/ developmental toxicity study in mammals	Repeated dose toxicity study (subacute) or Repeated dose toxicity study (chronic) and Reproductive and developmental toxicity study
Mutagenicity study (reverse mutation test in bacteria, chromosomal aberration test in mammalian cultured cells, mouse lymphoma TK assay, and micronucleus assay in rodents)	Genotoxicity study
Carcinogenicity study	Carcinogenicity study
Study for metabolic fate Pharmacological study	Please consult with the Office of Chemical Safety as required.