STANDARDS FOR BIOLOGICAL RAW MATERIALS

Enacted on May 20, 2003 (MHLW Notification No. 210)
Enacted on March 30, 2004 (MHLW Notification No. 157)
Enacted on July 5, 2004 (MHLW Notification No. 262)
Enacted on March 31, 2005 (MHLW Notification No. 177)
Enacted on September 28, 2007 (MHLW Notification No. 310)
Enacted on July 1, 2009 (MHLW Notification No. 343)
Enacted on September 26, 2014 (MHLW Notification No. 375)
Enacted on February 28, 2018 (MHLW Notification No. 37)

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I. General Notices

1. These standards are intended to specify criteria for necessary measures to be taken when drug, quasi-drug, cosmetic, medical device and regenerative medical product (hereinafter, “drugs, etc.”) are manufactured with raw materials, etc. (including those that are used as additive, medium, etc. in the manufacturing process) derived from humans and other organisms (excluding plants) to ensure the quality, efficacy and safety of the drugs, etc.
2. These standards are not applied to raw materials, etc. that are used to manufacture *in vitro* diagnostics and other products that are not directly used in the human body or to microorganisms and viruses that are used to manufacture vaccines, etc.
3. The “source material” is a source of raw materials or ancillary materials that are used to manufacture drug, etc.; the “raw materials, etc.” consist of raw materials, ancillary materials, and their source materials.

4. The “source plasma” is one or a mixture of all or some of the human plasmas separated from raw materials, etc. in an appropriate manner as necessary to manufacture plasma derivatives.
5. The “donor” is a person who donates cells or tissues that are used as raw materials, etc. of drugs, etc. [excluding the body of a brain-dead person stipulated in Article 6, Paragraph 2, the Organ Transplantation Law (Law No. 104, 1997)].
6. The “donor animal” is an animal other than human that provides cells or tissues that are used as raw materials, etc. of drugs, etc.
7. The “donor screening” is to determine whether donor or donor animal is sufficiently eligible to donate cells or tissues that are used as raw materials, etc. of drugs, etc. by diagnoses based on interview, tests, etc. for donor and by tests and breeding control for donor animal
8. The “window period” is a period in the initial stage of infection during which it is impossible to detect any pathogens including bacteria, fungi, viruses, etc. or their antigens, antibodies, genes, etc.
9. The provisions of these standards are not applied to the drugs, etc. which are confirmed that the validity for the quality and safety of drugs, etc. exhibit equivalent or superior to that determined according to some provisions in these standards, and written in approval letter issued at the marketing approval, etc.
10. If drugs, etc. approved for marketing in Japan are appropriately used as raw materials, etc. of other drugs, etc., the approved drugs, etc. are regarded as raw materials, etc. conforming to the standards.

II. General Rules for Blood Products

1. General Rules for Blood Products for Transfusion

(1) A person who donates blood for blood products for transfusion (designated as “blood donor” in the General Rules for Blood Products for Transfusion below) must be considered sufficiently eligible to donate blood serving as raw materials, etc. of blood products for transfusion, and must be free from bloodborne infectious disease determined through interview, etc. Provided, however, that this provision shall not apply to cases where it is confirmed that any pathogens including bacteria, fungi, viruses, etc. spreading through blood are inactivated or removed in the manufacturing process and the details of such inactivation/removal measures are described in the approval letter issued at the marketing approval of the blood products for transfusion.

(2) When blood is collected, either of the following blood collection methods must be followed:

A. Whole blood collection
An appropriate blood preservation fluid is transferred to a blood bag, and immediately, a blood collecting needle is assembled. The bag is then sealed and autoclaved.

B. Blood component collection

Some specific blood components such as plasma and platelets are collected exclusively while others are restored, depending on either of the following:

(a) Collection of whole blood is conducted, with A applied mutatis mutandis, and thereafter, in an appropriate manner, the specific blood components are collected, while the others are restored.

(b) Using a blood component collection system, the specific blood components are collected, while blood mixed with an appropriate blood preservation fluid is circulated by extracorporeal circulation.

(3) Except for separately specified cases, any of the following collected by a blood collection method stipulated in (2) is used as raw materials, etc. of blood products for transfusion:

A. Blood collected by the whole blood collection

B. Platelet rich plasma or platelet concentrate plasma collected by the blood component collection

C. Plasma collected by the blood component collection

(4) When raw materials, etc. of blood products for transfusion are preserved, the temperature must be 1-10°C. However, if platelet preparations are manufactured or if blood components are separated, the raw materials, etc. can be kept at an ordinary temperature.

(5) When blood is used as raw materials, etc. of blood products for transfusion, each blood donated by blood donor must be subjected to serological tests for *Treponema pallidum*, hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV-1 and HIV-2), and human T-cell leukemia virus type 1 (HTLV-1) at least. When the results of any of these tests indicate ineligibility, the blood must not be used as a raw material for blood products for transfusion purposes, if not corresponding to the blood stipulated in the official monographs of the Minimum Requirements for Biological Products (MHLW Notification No. 155, 2004).

(6) Blood serving as raw materials, etc. of blood products for transfusion must be subjected to nucleic acid amplification tests for hepatitis B virus DNA, hepatitis C virus RNA, and human immunodeficiency virus RNA at least. If the results of any of these tests indicate the presence of either hepatitis B virus DNA, hepatitis C virus RNA, or human immunodeficiency virus RNA, the blood must not be used as raw materials, etc. of blood products for transfusion.

(7) When blood donated by blood donors is used as raw materials, etc. of blood products for transfusion, each blood donation must be subjected to blood typing with blood type determination antibodies for ABO and Rh blood groups. In ABO blood typing, also the sera or plasmas must be tested, using already-known type A and type B red blood cells. Moreover, anti-A blood-typing antibody or dried anti-A blood-typing antibody, and anti-B blood-typing antibody or dried anti-B blood-typing antibody conforming to the Antibody Standards for Blood Type Identification (MHW Notification No. 204, 1994) must be used. In the Rh blood typing, anti-D blood-typing antibody or anti-D blood-typing mixed antibody conforming to the Antibody Standard for Blood Type Identification must be used in a given manner to

determine whether there is D (Rho) positivity or negativity. When the test results indicate negativity, anti-human globulin antibody (polyspecific antibody) conforming to the Antibody Standards for Blood Type Identification must be used as well.

(8) When blood is used as raw materials, etc. of blood products for transfusion, the following information concerning the blood are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed:

A. Site name of blood collection

B. Date of blood collection

C. Blood donor's records related to medical examinations, such as medical record

D. Results of serological test and nucleic acid amplification test

E. Working records during blood collection

F. Number to identify the blood donor who donated the blood

G. Information other than items A-F that are necessary to ensure the quality and safety of the blood products to be used for transfusion

2. General Rules for Plasma Derivatives

(1) The person who donates blood for plasma derivatives (designated as "blood donor" in the General Rules for Plasma Derivatives below) must be considered sufficiently eligible to donate blood serving as raw materials, etc. of plasma derivatives, and must be free from suspected bloodborne infectious diseases determined through interview, etc. Provided, however, that this provision shall not apply to cases where it is confirmed that any pathogens including bacteria, fungi, viruses, etc. spreading through blood are inactivated or removed in the manufacturing process and written in the approval letter issued at the marketing approval of the plasma derivatives.

(2) When blood is collected, either of the blood collection methods stipulated in (2) of 1. General Rules for Blood Products for Transfusion must be followed.

(3) Raw materials, etc. of plasma derivatives, shall be prepared from any of the following materials collected by the blood collection methods stipulated in (2), except for separately specified cases:

A. Blood collected by the whole blood collection

B. Platelet rich plasma or platelet concentrate plasma collected by the blood component collection

C. Plasma collected by the blood component collection

(4) When raw materials, etc. of plasma derivatives are preserved, the temperature must be 10°C or lower, with freezing avoided, if the raw materials, etc. correspond to A of (3), and 10°C or lower if they correspond to B or C of (3).

(5) Blood serving as raw materials, etc. of plasma derivatives must be subjected to serological tests for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV-1 and HIV-2) at least. When the results of any of these tests indicate ineligibility, the blood must not be used as the raw materials, etc., if not corresponding to the blood stipulated in the official monographs of the Minimum Requirements for Biological Products.

(6) The source plasma of plasma derivatives must be subjected to nucleic acid amplification tests for hepatitis B virus DNA, hepatitis C virus RNA, and human immunodeficiency virus RNA at least. If the results of these tests indicate the presence of either hepatitis B virus DNA, hepatitis C virus RNA, or human immunodeficiency virus RNA, the plasma must not be used as source plasma.

(7) When source plasma is preserved, the temperature must be at 6°C or lower.

(8) When blood and source plasma are used as raw materials, etc. of plasma derivatives, the following information concerning the blood and source plasma are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed:

A. Site name where the raw materials, etc. were collected

B. Date of the raw materials, etc. collection

C. Records related to medical examinations, such as medical record, of the blood donor who donated the blood for source plasma

D. Records of serological and nucleic acid amplification assays

E. Working records during blood collection of the raw materials, etc. and production of the source plasma

F. Manufacturing number to identify the raw materials, etc. and source plasma

G. Number(s) to identify the blood donor who donated the blood used for source plasma

H. Information other than items A-G that are necessary to ensure quality and safety of the plasma derivatives

III. General Rules for Human-Derived Raw Materials

1. Standards for Human Cell/Tissue-based Raw Materials

(1) The human-derived cell or tissue serving as raw materials, etc. constituting drugs, etc. (excluding blood products) (hereinafter, “human cell/tissue-based raw materials, etc.”) must be collected in facilities with sufficient personnel and equipment for necessary sanitation management.

(2) For collection of human cell/tissue-based raw materials, etc., the following measures must be taken:

A. Necessary measures must be taken to prevent contamination with microbial pathogen and other pathogenic agents when collection of human cell/tissue-based raw materials, etc.

B. The collected human cell/tissue-based raw materials, etc. shall be confirmed to be free from contamination with microbial pathogen and other pathogenic agents by appropriate examinations in light of the latest knowledge about infections, if it necessary.

(3) The donor must meet all the following conditions and be sufficiently eligible to donate human cell/tissue-based raw materials, etc. In the case where the donor is the same as the recipient of the drugs, etc., the donor screening may not be always required.

A. Infection of the donor with any pathogens including bacteria, fungi, viruses, etc. is denied by interview, medical examinations, tests, etc. before the human cell/tissue-based raw materials, etc. are collected, according to their intended uses.

B. The test items and test methods used at A. should be appropriate in light of the latest knowledge about infection, etc.

C. The tests or management shall be performed in consideration of the window period: for example, based on the test items and test methods, etc. used at A, re-tests are performed in appropriate timing.

D. In addition to the conditions A-C, the donor eligibility must be determined by conducting interview, medical examinations, tests, etc. for important diseases, and the consideration of experience of blood transfusion or transplantation therapy, etc.

(4) The personnel engaged in collecting human cell/tissue-based raw materials, etc. must confirm that the human cell/tissue-based raw materials, etc. meet the requirements below, and can be appropriately used in drugs, etc.

A. If the human cell/tissue-based raw materials, etc. are collected from a deceased person, the person in charge of the collection should keep appreciation in mind and shall appropriately explain to his/her bereaved family about intended use of the human cell/tissue-based raw materials, etc. and other necessary information on the collection in written form using as easy expressions as possible, and the informed written consent of the family is subsequently obtained.

B. Before the donation of the human cell/tissue-based raw materials, etc., the following matters are appropriately explained to the donor in written form with as easy expressions as possible, and the written consent is obtained from him/her:

(a) Intended use of the human cell/tissue-based raw materials, etc.

(b) Expected risks and disadvantages associated with the donation of the human cell/tissue-based raw materials, etc.

(c) The Donor's actions are voluntary

(d) Matters related to withdrawal of the consent

(e) The donor does not suffer any disadvantage, even if stopping donating the human cell/tissue-based raw materials, etc. or withdrawing the consent to donate them.

(f) Matters on expenses for the donation of the human cell/tissue-based raw materials, etc.

(g) Matters on compensation for health hazards due to the donation of the human cell/tissue-based raw materials, etc.

(h) Matters on protection of the donor's personal information

(i) Matters on ownership of patent rights, copyright, and other property rights or economic benefits of drugs, etc. manufactured with the human cell/tissue-based raw materials, etc.

(j) Other important matters depending on details of drugs, etc. manufactured with the human cell/tissue-based raw materials, etc.

C. When another person serves as proxy for the person donating the human cell/tissue-based raw materials, etc., the following matters are appropriately explained to the proxy in written form with as easy expressions as possible, and the written consent is obtained from the proxy prior to donation concerning:

(a) Intended use of the human cell/tissue-based raw materials, etc.

(b) Expected risks and disadvantages associated with the donation of the human cell/tissue-based raw materials, etc.

(c) The proxy's actions are voluntary.

(d) Matters related to withdrawal of the proxy's consent

(e) The proxy does not suffer any disadvantage, even if stopping or withdrawing his/her consent.

(f) Matters on expenses for the donation of the human cell/tissue-based raw materials, etc.

(g) Matters on compensation for health hazards due to the donation of the human cell/tissue-based raw materials, etc.

(h) Matters on protection of the donor's and proxy's personal information

(i) Matters on ownership of patent, copyright, and other property rights or economic benefits of drugs, etc. manufactured with the human cell/tissue-based raw materials, etc.

(j) Other important matters depending on details of drugs, etc. manufactured with the human cell/tissue-based raw materials, etc.

D. In case where human cell/tissue-based raw materials, etc. are donated under consent of a proxy, records should be prepared to document the proxy's consent and the relation between the proxy and the person donating the human cell/tissue-based raw materials, etc.

E. Even if the donor consents to the use of the human cell/tissue-based raw materials, etc. in manufacture of drugs, etc., he/she can have the chance to withdraw the consent until the human cell/tissue-based raw materials, etc. undergo process such as culture.

F. If the human fertilized embryo is donated as human cell/tissue-based raw materials, etc., the donor can have the chance to withdraw the consent to the donation for at least 30 days after the consent, during which the human cell/tissue-based raw materials, etc. are held at the medical institution, not used to establish human embryonic stem cell.

G. The human fertilized embryo can be donated, if the following requirements are met:

(a) The human fertilized embryo was prepared for use with assisted reproductive technology but is not currently being used for this purpose and the donor's intension regarding destruction of the fertilized embryo has also been confirmed.

(b) Cryopreserved.

(c) Within 14 days after fertilization, except for the cryopreservation period.

(d) Necessary procedures are followed to establish human embryonic stem cell appropriately.

H. The human cell/tissue-based raw materials, etc. are donated without compensation. Provided, however, that this shall not apply to cases where actual expenses occur, such as the cost of transportation for the donation of the human cell/tissue-based raw materials, etc.

I. Collection of the human cell/tissue-based raw materials, etc. is not preferentially conducted after change of policies for medical treatment, surgery, and other therapeutics.

(5) The following information concerning the human cell/tissue-based raw materials, etc. are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed:

A. Site name where the human cell/tissue-based raw materials, etc. were collected

B. Date when the human cell/tissue-based raw materials, etc. were collected

C. Results and status of diagnosis based on interview, medical examinations, tests, etc. for donor screening

D. Working records during collection of the human cell/tissue-based raw materials, etc.

E. Results of discussion by the ethics committee, etc.

F. Written consent explanation and consent

G. Donor identification number

H. Information other than items A-G that are necessary to ensure quality and safety of the drugs, etc.

2. Standards for Human-Urine-Derived Raw Materials

(1) When urine of a person (urine of a specific donor, the same below) or pooled urine (mixture of urines given by many donors, the same below) (hereinafter, human urine) is used as raw materials, etc. of drugs, etc., the provision H of (4) under Standards on Human Cell/Tissue-based Raw Materials is applied mutatis mutandis.

(2) The human urine must be tested for infection at an appropriate stage to confirm that the urine is not contaminated with pathogenic microorganism, etc. Provided, however, that this shall not apply to cases where it is confirmed that pathogenic microorganism, etc. are inactivated or removed in the manufacturing process, and written in the approval letter issued at the marketing approval of the products.

(3) The pooled urine must be subjected at an appropriate stage to nucleic acid amplification tests for hepatitis B virus DNA, hepatitis C virus RNA, and human immunodeficiency virus RNA at least. Provided, however, that this shall not apply to cases where appropriate nucleic acid amplification tests confirm that neither hepatitis B virus DNA, hepatitis C virus RNA, nor human immunodeficiency virus RNA is detected in the urine serving as raw materials, etc.

(4) Human urine must be confirmed that any pathogens including bacteria, fungi, viruses, etc. are inactivated or removed in the manufacturing process. Provided, however, that this shall not apply to cases where there is a reasonable reason this treatment is not conducted, and also that the effect is written in the approval letter issued at the marketing approval.

(5) The following information concerning the human urine are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed:

A. Institution name where the human urine was prepared

B. Date when the human urine was prepared

C. Results from tests of the human urine

D. Working records to prepare the human urine

E. Lot no.(s) of human urine

F. Information other than items A-E that are necessary to ensure quality and safety of the drug, etc.

3. Standards for Human-Derived Raw Materials

(1) When raw materials or ancillary materials derived from humans (excluding human cell/tissue-based raw materials, etc., human urine, and those considered to be known publicly in the scientific field to have no risk of bacterial or viral infection; hereinafter, "human-derived raw materials, etc.") are used as raw materials, etc. of drugs, etc. (excluding blood preparation), the cells or tissues that are origins of the human-derived raw materials, etc. (including cell strains and cells after the termination of their culture, if the products are manufactured through cell culture using a cell bank as the starting material) must be subjected to a virus test at an appropriate stage. If in this test, an adventitious virus is detected, the human-derived raw materials, etc. must not be used to manufacture drugs, etc., in principle. Provided, that this shall not apply to cases where the raw materials, etc. consist of cell banks derived from humans, and really assembled when these standards are applied, and also it is confirmed, in terms of guarantee of quality and safety, that the use as raw materials, etc. has the validity equivalent or superior to that confirmed in this test and written in the approval letter issued at the marketing approval.

(2) The person who donates human-derived raw materials, etc. derived from human blood must be considered sufficiently eligible to donate blood serving as the human-derived raw materials, etc., and must be free from suspected bloodborne infectious diseases determined through interview, etc.

(3) The human-derived raw materials, etc. must be treated to inactivate or remove any pathogens including bacteria, fungi, viruses, etc. in the manufacturing process. Provided, however, that this shall not apply, if there is a reasonable reason this treatment is not conducted, and also that the effect is written in the approval letter issued at the marketing approval.

(4) The following information concerning the human-derived raw materials, etc. are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed:

A. Institution name where the human-derived raw materials, etc. were prepared.

B. Date when the human-derived raw materials, etc. were prepared.

C. Results of test, etc. of the human-derived raw materials, etc.

D. Lot no.(s) of the human-derived raw materials, etc.

E. Information other than items A-D that are necessary to ensure quality and safety of the products.

IV. General Rules for Animal-Derived Raw Materials

1. Standards for Ruminant-Derived Raw Materials

(1) When raw materials, etc. derived from ruminant animals (excluding raw materials, etc. produced by heating and alkali treatment, etc. produced by other appropriate treatments; hereinafter, “ruminant-derived raw materials, etc.”) are used as raw materials, etc. of drugs, etc., the following parts of the ruminant animals must not be used:

A. Pituitary gland

B. Thymus

C. Dura mater

D. Trigeminal ganglion

E. Pineal body

F. Spinal cord

G. Backbone

H. Placenta (excluding bovine origin)

I. Skull

J. Intestine

K. Brain

L. Cerebrospinal fluid

M. Dorsal root ganglion

N. Spleen (excluding bovine origin)

O. Adrenal gland

P. Tonsil

Q. Eye

R. Lymph node

(2) The ruminant-derived raw materials, etc. must be native to the countries in which the risk of BSE pathogen propagation is considered negligible by the World Organisation for Animal Health, and those listed below. Provided, however, that this shall not apply to cases where gelatin (including collagen) derived from wool, milk, bone, and skin (hereinafter, “low-risk raw materials, etc.”) and ruminant-derived raw materials, etc. native to Canada (hereinafter, “Canadian raw materials”) are used to manufacture injection through cell culture (Canadian raw materials are used in cell banks only), and other equivalent; cases where Canadian raw materials are used to manufacture vaccine (oral vaccine only); cases where Canadian raw materials are used to manufacture injection by microbial culture (Canadian raw materials are

only used in the seed culture) or oral preparation, and other equivalent; or cases where Canadian raw materials are used to manufacture external preparation.

A. El Salvador

B. Kenya

C. Costa Rica

D. Swaziland

E. Nigeria

F. Namibia

G. Nicaragua

H. New Caledonia

I. Pakistan

J. Vanuatu

K. Botswana

L. Mauritius

(3) The following information concerning the ruminant-derived raw materials, etc. (excluding low-risk raw materials, etc.) are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed:

A. Origin country

B. Date of preparation of the ruminant-derived raw materials, etc.

C. Breeding or slaughter conditions of the ruminant animals from which the ruminant-derived raw materials, etc. are derived

D. Working records of treatment and other measures to prevent the spread of transmissible spongiform encephalopathy of the ruminant-derived raw materials, etc.

E. Lot no.(s) of the ruminant-derived raw materials, etc.

(4) In the cases where ruminant-derived raw materials, etc. non-conforming to (1) and/or (2) are unavoidably used to manufacture drug, quasi-drug, medical device, and regenerative medicine because their therapeutic benefit exceeds the risk of the use of the ruminant-derived raw materials, etc. or because they are necessary, the validity of their use is written in the approval letter issued at the marketing approval.

(5) Concerning cosmetics, ruminant-derived raw materials, etc. nonconforming to (2) can be unavoidably used, only if meeting necessary conditions specified by the director of the Pharmaceutical and Food Safety Bureau, MHLW.

2. Standards for Animal Cell/Tissue-based Raw Materials

(1) The animal-derived cell and tissue serving as raw materials, etc. constituting drugs, etc. (hereinafter, “animal cell/tissue-based raw materials, etc.”) must be collected in facilities with sufficient personnel and equipment for necessary sanitation management.

(2) Necessary measures must be taken to prevent contamination with microbial pathogen and other pathogenic agents when collection of animal cell/tissue-based raw materials, etc.

(3) The donor animal for animal cell/tissue-based raw materials, etc. must be considered sufficiently eligible to donate them. However, the material does not include sources of ancillary materials for drugs, etc. that were manufactured through cell culture using a characterized cell bank as the starting material, and past uses.

(4) When animal cell/tissue-based raw materials, etc. are used, it must be confirmed that they have been subjected to verify for viral infection risk and other tests required.

(5) The information concerning the animal cell/tissue-based raw materials, etc. below are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed. However, the raw materials, etc. does not include sources of ancillary materials for drugs, etc. that were manufactured through cell culture using a characterized cell bank as the starting material, and past uses.

A. Facility name where the animal cell/tissue-based raw materials, etc. were collected.

B. Date when the animal cell/tissue-based raw materials, etc. were collected.

C. Statuses of acceptance, test, and breeding control of donor animals

D. Working records during collection of the animal cell/tissue-based raw materials, etc.

E. Lot no.(s) of the animal cell/tissue-based raw materials, etc.

F. Information other than items A-E that are necessary to ensure quality and safety of the products

3. Standards for Animal-Derived Raw Materials

(1) When raw materials, etc. derived from animals (excluding animal cell/tissue-based raw materials, etc. and those considered to be known publicly in the scientific field to have no risk of infection with any pathogens including bacteria, fungi, viruses, etc.; hereinafter, “animal-derived raw materials, etc.”) are used as raw materials, etc. of drugs, etc., it must be confirmed, unless derived from a healthy animal, that the animal-derived raw materials, etc. are aseptic, and have been subjected to test for viral infection risk and other tests required.

(2) If a characterized animal-derived cell bank is used as the starting material to manufacture products through cell culture, a virus test must be conducted at an appropriate stage. If in this test, an adventitious virus is detected, the cell bank must not be used to manufacture drugs, etc., in principle. Provided that this shall not apply to cases where the raw materials, etc. consist of cell banks, and really assembled when these standards are applied, and also it is

confirmed, in terms of guarantee of quality and safety, that the use as raw materials, etc. has the validity equivalent or superior to that confirmed in this test and written in the approval letter issued at the marketing approval.

(3) If the whole of a living animal is used as the starting material to manufacture products, the provisions of (2) and Standards on Animal Cell/Tissue-based Raw Materials (3) are applied.

(4) The animal-derived raw materials, etc. must be treated to inactivate or remove any pathogens including bacteria, fungi, viruses, etc. in the manufacturing process. Provided, however, that this provision shall not apply to cases where there is a reasonable reason this treatment is not conducted, and also that the effect is written in the approval letter issued at the marketing approval.

(5) Information concerning animal-derived raw materials, etc. below are necessary to ensure quality and safety, and must be recorded and stored so that the information can be confirmed. However, raw materials, etc. do not include sources of ancillary materials for drugs, etc. that were manufactured through cell culture using a characterized cell bank as the starting material and then used.

A. Institution name where the animal-derived raw materials, etc. were prepared.

B. Date when the animal-derived raw materials, etc. were prepared.

C. Results of tests, etc. of the animal-derived raw materials, etc.

D. Lot no.(s) of the animal-derived raw materials, etc.

(6) The provisions of (2) to (4) are applied to the drugs, quasi-drugs, cosmetics, and medical devices that are designated as biologically derived products.