Announcement of the medicine pile

Subject: Details of regulations regarding the production of modern drug samples for clinical research.

.....

The Drug Division has determined details of the production of current drug samples for clinical research. To be a practice in preparing documents completely and correctly and to comply with conditions in drug production. Samples to request registration of drug formulas for human research studies in accordance with the announcement of the Food and Drug Administration regarding regulations regarding the production of current drug samples for clinical research, dated September 17, 2018, item 2, item 3 (4) (5) and (6) Section 4 (1) and (2)

In order to promote the generic drug industry in the country and to be prepared to be able Supporting electronic facilitation, the Department of Medicine sees the need to improve the details of the regulations. Produce drug samples to request registration of drug formulas for human research studies. The Drug Division therefore issues the following announcement to cancel the Drug Division's announcement regarding details of

clause 1. regulations regarding drug production.

Example of the current plan for clinical research, dated February 5, 2021, Section 2. Provide

supporting documents for requesting permission to produce sample drugs for registration of the drug formula. For human research studies, the following are available.

1) Form Por.Yor.8

2) Summary of the research project according to the form specified

by the FDA. 3) Certification of compliance with the terms and conditions regarding the production of drug samples for use. Human research studies for applicants

4) Certification of compliance with the terms and conditions regarding the production of drug samples for Human studies for the principal investigator

5) Evidence of insurance or compensation if the volunteer is born Illness, injury, disability, or death as a result of clinical research 6) A copy of the Certificate of Good

Manufacturing Practices Standards 7) Labels for every package size 8)

Investigator's handbook (research

medicine) except for medicines used for bioequivalence studies, which must be used. Can direct medicine instead

9) Volunteer guidance document (Thai language) 10)

Complete research protocol (Thai or English language) 11) Drug quality control and

production documents 12) Research approval document

from the Human Research Ethics Committee. (IRB/ IEC) accepted by the Food and Drug Administration

๑๓) เอกสารอนุมัติจากคณะกรรมการด้านวิชาการที่เกี่ยวข้อง (ถ้ามี)

๑๔) แบบตรวจสอบเอกสารด้วยตนเอง

ข้อ ๓. กรณีการศึกษาชีวสมมูล ให้ยื่นเอกสารในข้อ ๒ เฉพาะ ๑) – ๔) เท่านั้น อย่างไรก็ตาม ผู้รับอนุญาตผลิตยายังคงมีหน้าที่รับผิดชอบจัดหาหรือจัดทำ ตลอดจนตรวจสอบเอกสารในข้ออื่น ๆ ด้วยตนเองให้เป็นไปตามข้อกำหนดในรายละเอียดแนบท้ายประกาศฉบับนี้ โดยไม่คำนึงถึงว่าจะเป็นเอกสารที่ต้องยื่นต่อสำนักงานคณะกรรมการอาหารและยาหรือไม่ก็ตาม และจะต้องมีเอกสารพร้อมสำหรับการดำเนินการวิจัยและรองรับการตรวจสอบย้อนกลับได้ตั้งแต่ก่อนเริ่มการวิจัยเป็นต้นไปและปรับปรุงตามความเหมาะสมเป็นระยะและตามหลักการของ ICH Good Clinical Practice ฉบับล่าสุดไปตลอดช่วงการดำเนินการวิจัยจนกระทั่งการวิจัยสิ้นสุดลง

ข้อ ๔. กรณีการศึกษาวิจัยในมนุษย์ที่นอกเหนือจากการศึกษาชีวสมมูลให้ยื่นเอกสารในข้อ ๒ ทั้งหมด โดยให้เป็นไปตามข้อกำหนดในรายละเอียดแนบท้ายประกาศฉบับนี้

ข้อ ๕. กรณีผู้รับอนุญาตผลิตยาเคยได้รับอนุญาตผลิตยาตัวอย่างเพื่อขอขึ้นทะเบียนตำรับยาสำหรับกรณีอื่น ๆ นอกเหนือจากการศึกษาวิจัยในมนุษย์มาก่อนหน้านี้ และต้องการขยายขอบข่ายเพื่อทำการศึกษาวิจัยในมนุษย์ให้ดำเนินการตามแนวทางในข้อ ๓ หรือข้อ ๔ แล้วแต่กรณี

ข้อ ๖. ให้ยื่นคำขอผ่านระบบอิเล็กทรอนิกส์ของกองยา แต่หากระบบอิเล็กทรอนิกส์ยังไม่พร้อมใช้งาน ให้ยื่นคำขอแบบกระดาษพร้อมด้วยเอกสารประกอบตามข้อ ๓ หรือข้อ ๔ แล้วแต่กรณี โดยเพิ่มเติมเอกสารดังต่อไปนี้

๑) หนังสือมอบอำนาจ

๒) สำเนาใบอนุญาตผลิตยาแผนปัจจุบัน

๓) ไฟล์เทมเพลต

ข้อ ๗. รายละเอียดข้อกำหนดเกี่ยวกับคำขอ เอกสารประกอบ การยื่นคำขอ และการดำเนินการหลังจากได้รับอนุญาตผลิตยาตัวอย่างสำหรับการศึกษาวิจัยในมนุษย์ ให้เป็นไปตามข้อกำหนดในรายละเอียดแนบท้ายประกาศฉบับนี้

ทั้งนี้ ให้ประกาศฉบับนี้มีผลบังคับใช้ตั้งแต่บัดนี้เป็นต้นไป

ประกาศ ณ วันที่ ๗ สิงหาคม พ.ศ. ๒๕๖๖

(นางสาววรสุดา ยูงทอง)

ผู้อำนวยการกองยา

Documents attached to the announcement

of the Drug Division regarding details of regulations regarding the production

of modern drug samples.

for clinical research, dated 7 August 2023

Summary of changes in this edition :

A. The topic “Request for production of modern drug samples for human research studies” has been omitted by improving and Specified in the announcement of the Department of Medicine and the topic "Requirements regarding those eligible to apply" because they must be The licensee is as specified by Form Por.Yor.8. Add clarifications to some documents, including Form Por.Yor.8 and a summary of the research project. will be adjusted to fill out Information through the electronic system C. Summary of the research project, add item 21, type of main research drug of the project. For use in classifying requests and adjusting the original item 25 by separating it into 2 items, items 25 and 26, which are usually in human documents. each version so that they can be referenced correctly and clearly. D. Add authorization instructions for submitting applications electronically.

E. Improve drug labeling requirements. In the case of preparing drugs for administration at the research site, it is necessary to New label with strict regulations to follow. Check it yourself and along with inspection from the authorized person, but there is no need to submit the label in this case to the Drug Division.

F. Improve the topic regarding requesting permission to make changes before proceeding and notification for acknowledgment. The changes are classified according to the appendix. “Guidelines for action when changes are made” and improve related procedures. G. Add requirements regarding changes in bioequivalence studies. H. Improve document self-check form. Certification form for the applicant and the principal investigator. I. Attach evidence of destruction or return of medicines. In notifying the conclusion of the termination/end of the research project.

New medicine group and promote drug research

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Detailed specifications

Concerning the production of modern drug samples for clinical research (updated June 2023)

1. Requirements for supporting documents for requesting the production of modern drug samples for clinical research.

1.1. Requirements regarding form Por.Yor.8

Form Por.Yor.8 **(Appendix** 1), 2 sets, is in accordance with the announcement of the Ministry of Public Health regarding specifying application forms, licenses, accounts, reports, and certifications in the production of modern medicines, dated May 18. 2559

In the case of submitting via the electronic system, information will be filled in in the system. and can create a Por.Yor.8 model by automatic

1.2. Requirements regarding a research project summary (Thai language) according to the format specified by the Drug Division.

According to the form in **Appendix 2 ,** however, in the case of filing through the electronic system, it will be Entering data into the electronic system to create research project data **1.3.**

Requirements regarding certification of compliance with the terms and conditions regarding the production of drug samples.

for human research studies for the applicant Certification of compliance with the terms and conditions regarding the production of drug samples for research in Human for the applicant As detailed in **Appendix 3 ,** signed by the licensee. **1.4. Requirements regarding**

certification of compliance with the terms and conditions regarding sample drug production. For human research studies for

the principal investigator. Certification of compliance with the terms and conditions regarding the production of drug samples for research in Human for the Principal Investigator As detailed in **Appendix 4** by the Principal Investigator at every research institute. In connection with this permission, one document must be signed by each person. **1.5. Requirements regarding evidence showing insurance or**

compensation in the event that a volunteer is sick, injured, disabled, or dies. As a result of clinical research Evidence of insurance or compensation If a volunteer becomes sick, injured, disabled, or dies As a result of clinical research It may be a document issued by an insurance company. or an agreement document specifying who is responsible and their responsibilities Including the payment of various compensation. **1.6. Requirements regarding a copy of the certificate of good standards for drug production.** Certificate of standards for good methods for producing modern medicines which shows certification in the category of drugs that will request permission to produce sample drugs and maintain certification status during the period of production of drug samples for human research studies To show that the drug production facility meets the standards and good methods for producing research drugs. of the announcement of the Ministry of Public Health regarding the criteria, methods and conditions for the production of modern medicines

In the case that it does not yet exist and is in the process of receiving certification of good manufacturing methods standards. modern medicine Evidence of application for certification of such standards must be submitted. **1.7.**

Requirements regarding drug labels of all package sizes.

1.7.1. Submit labels or images of labels of every container and every size. with a label-like format

Actually use it

1.7.2. Use Thai language except for drug names/drug codes. and research project sponsor information Can you use Thai? Able to speak English and the case of drugs administered by medical personnel. Please use Thai or English.
can

1.7.3. **In general cases,** labels for both primary and secondary packaging must contain at least the following information: (1) Drug name/drug code, size, strength, pharmaceutical form, route of drug administration. Unit quantity In the case of a blinded treatment study The label must include the statement **"Placebo or [drug name/drug code].**

+ [strength size]"

(2) Research project code or name of the

research project. (3) Production lot and/or code number to identify components and packaging procedures. (4) Subject number or treatment number. and appointment number (If relevant) (5) Medication methods may be based on documents specifically designed to explain to volunteers (such as dosing records) or personnel who manage medicinal products. To communicate that volunteers or personnel are How can pharmaceutical product

administrators use drugs correctly? (6) Name, address, and telephone number of the research sponsor or contract research organization or investigator (main point of contact for product information). clinical research and disclosure of concealment, treatment in emergencies) unless the subject is provided with identification showing this information and is instructed to keep this

document in their possession at all times. (7) Statement "For use in clinical research. only" or other words with the same meaning in

Thai (8) Conditions of storage of medicines (9) Period of use (Specify use within the date, expiration date, or retest date as appropriate) in months/years and in a

manner that avoids ambiguity. (10) The statement "keep out of the reach of children" or other words with the same meani Volunteers did not take medicine home.

1.7.4. **In the case where the primary packaging is always together with the secondary packaging. (When the packaging label is In addition to showing the details in Section 1.7.3),** the primary packaging label must contain at least the following information:

(1) Drug name/drug code, strength, pharmaceutical form Route of administration (except solid dosage form given orally) Quantity unit In the case of a blinded research study, the label must state **"placebo or [drug name/drug code] + [dose and strength]"** (2) Research project code or name of the research project.

(3) Production lot and/or code number to indicate components and packaging process. (4)
Subject number or treatment number. and appointment number (if relevant) (5) Name of the research
sponsor or contract research organization or researcher 1.7.5. **In the case that the**
primary packaging is in the form of a blister or small unit with an area not exceeding 3 square inches (when the outer packaging label shows the details in accordance with 1.7.3 and the primary packaging is Always together with secondary packaging) Primary packaging labels must include at least the following information:

(1) Drug administration route (The route of administration may not be specified for oral solid dosage forms.) Quantity
Unit Count And in the case of research that reveals treatment, specify the drug name/drug code and
strength size

(2) Research project code or name of the research
project. (3) Production lot and/or code number to indicate ingredients and packaging
process. (4) Subject number or treatment number. and appointment number (if relevant) (5) Name of
research sponsor Organizations that undertake contract research or researchers

1.7.6. Labeling of medicines must be carried out according to standards in places licensed to produce the correct medicines. and in accordance with the announcement of the Ministry of Public Health regarding the determination of details regarding the criteria and Methods for producing modern drugs and amending the criteria and methods for producing traditional drugs according to the Drug Law 2016, which specifies the labeling of research drugs in Appendix 12, Production of research drug products 1.7. 7. **In the case of preparing drugs for administration at the research site, new labels must be attached to the packaging that will be used for administration,** such as preparing or mixing injection drugs. Preparing to dispense medication for immediate use, etc. The applicant must
ensure that the principal investigator or designated person (1) prepares a label with appropriate
and accurate information for the purpose of the research project; (2) prepares Standard Operating Procedure Manual
or method that is Standards for drug preparation and drug labeling are consistent with the principles and
methods for producing modern medicine.
(3) Carry out the manual by a pharmacist or other health professional at the approved research site.
appropriate training
(4) There is evidence to record the practice. It is inspected by at least a second person under supervision.
Strictly control labeling
(5) Preserve evidence and record various related documents to support inspection by those involved.
Power or medicine
However, the applicant does not have to submit a label in this case along with the application. But it must be ensured that the main researcher or person who receives It is tasked with carrying out these requirements and is always available for review or review of research.

1.7.8. If there is a necessary reason The applicant may request the Drug Division to consider waiving the labeling requirements as mentioned above only in the following cases:

(1) Information on the label that may refer to other documents, such as methods for giving medicine, references to medication records, etc. by Attach reference documents with explanations.

(2) Adding labels after producing drug samples to request drug formula registration in order to comply with Requirements regarding the labeling of investigational drugs: 1) Labels or images of labels that have the same format as actual labels are used. 2) The place where labeling is carried out is a place that has permission to produce the correct medicine or, if necessary, may request. Relaxation of labeling operations in controlled locations instead, which must be carried out by pharmacists or other health professionals at the research site or by research supervisors. Properly trained Create work procedures Practice record It is inspected by a second party. Labeling is strictly controlled. and operations must be consistent with the criteria and methods for producing modern medicine 1.7.9. Requesting a waiver of labeling requirements in the case in Section 1.7.7, **use the waiver request form. Drug labeling requirements are case-specific (Appendix 5) .** In all cases, the rights, safety and well-being of the volunteer must be taken into account. As well as reliable clinical research results are important.

1.7.10. For drug labels that have been submitted to the Drug Division and have been permitted to produce modern drug samples for Research studies have been done on humans. The applicant may refer to the original document if it has not been changed.

1.7.11. In the case of requesting to change information about the period of use of medicine Apply additional labels that indicate the new date and use the same production lot. Submit labels or images of labels that are formatted like the actual labels. The original date may be hidden. But must not close over the original production model for quality control reasons. This must be done in an authorized location. Produce the correct medicine or if necessary May request a waiver of labeling operations in controlled locations. Instead, follow the conditions. This must be labeled by a pharmacist or other health professional. of the research facility or an appropriately trained research supervisor. Create work procedures Practice record There is a second party inspection. Labeling is strictly controlled and operations must be consistent with the rules and methods for producing modern medicine (submit a **waiver request form Drug labeling requirements are case-specific (Appendix 5)**

1.7.12. Recommendations for drugs to be used according to the protocol for use according to the established indications. Registered in Thailand as drugs sourced from the market in Thailand and there is no need to pass Another production process or packaging process The following information should be added to the original container, but must Does not cover the original label

(1) Name of the research sponsor or organization that undertakes research under contract or the researcher.

(2) Research project code (3) Statement “Used for clinical research only” or other words with the same meaning in Thai.

1.8. Requirements regarding drug packaging documents (drugs for bioequivalence studies) or investigator documentation (drugs research)

1.8.1. In the case of drugs for bioequivalence studies Prepare a draft drug package document for medical personnel. It should be consistent with the announcement of the Food and Drug Administration on guidelines for preparation.

Medicine documentation

1.8.2. In the case of investigational drugs, which includes new drugs, biological drugs, including biosimilar drugs. To prepare documents Investigator's handbook that adheres to the current version of the ICH Good Clinical Practice Guidelines.

(1) The investigator manual should be reviewed at least once a year and should be revised as necessary, and it may be appropriate to update it more often depending on the stage of drug development and new information.

(2) There is evidence that the researcher's handbook has been presented to the ethics committee, except in the case of waiting for approval from the relevant research ethics committee. Submit the version that is between that consideration

(3) Contains the following information, each section should be accompanied by appropriate reference documents: -

Table of contents

- Summary -

Introduction

- Physical, chemical and pharmaceutical properties including the formula - Studies not conducted on humans (Animal Study) A. Pharmacology B. Pharmacokinetics and change processes in laboratory animals

C. Toxicology

Results of human studies (Clinical Study)

A. Pharmacokinetics and the process of changing products used in human research.

B. Safety and effectiveness

C. Marketing experience

Summary of information and recommendations for researchers **1.9. Requirements regarding the volunteer information sheet (Patient Information Sheet) (Thai language)**

1.9.1. This topic covers the volunteer information sheet and the consent letter. 1.9.2. Received. Approval from the Human Research Ethics Committee, except in cases where approval is pending. from the relevant research ethics review committee Submit the version that is under consideration.

1.9.3. Volunteer guidance documents and informed consent are in accordance with ICH Good Clinical. Current version of the Practice Guideline

1.9.4. Have appropriate language for volunteers, for example, Thai volunteers must submit the Thai version, foreign volunteers must translate into Thai and certify that the text in other languages matches Thai. 1.9.5. Documents

recommending volunteers for Provide information and explanations during the consent request and in the consent document Including other documents that will be given to volunteers. The following details

must be included: (1) that the project is

research; (2) the aim of the

research; (3) the treatment provided in the research and the opportunity for volunteers to receive one of these treatments. Random selection

method (4) Research method including various procedures. that is invasive (invasive) of the body Volunteer

(5) Volunteers' responsibilities (6) Experimental

parts of the research project (7) Risks or

inconveniences that may occur to volunteers. and in some cases to the embryo or a fetus or infant who drinks mother's milk

(8) Benefits that are reasonably expected to be received. In the case where the research does not bring clinical benefit to Volunteers should inform volunteers as well.

(9) Alternative procedures or treatments. that volunteers may receive Including the benefits and The major risks of the alternatives are: (10) the compensation and/or

treatment the volunteer will receive; In the event of danger resulting from

Research (11) Payment of compensation (if any) determined on a monthly basis to volunteers

participating in research. (12) Various expenses (if any) for

volunteers participating in research. (13) Specified message. that a volunteer's participation in research is voluntary and that a volunteer may refuse to participate or withdraw from the research at any time; Without any guilt? Loss of

benefits that volunteers should receive. (14) Statement stating that the Food and Drug Administration Research supervisors, investigators, IRB/IEC and regulatory agencies are permitted to inspect medicine. The original records of direct subjects to verify the correctness of clinical research methods. and/or other information without violating the volunteer's right to maintain confidentiality beyond the limits of the law. and legal regulations allow this by signing the consent form Volunteers or representatives by The righteousness of volunteers allows individuals to The above have the right to inspect the original medical records of Volunteer directly

(15) A statement stating that records identifying the personal information of volunteers will be kept confidential and will not be disclosed to the public beyond the limits of law. and/or regulations

The law allows. in publishing research results Volunteers' personal information will remain confidential.

(16) Contain a statement specifying that the volunteer or legal representative will be notified of new information in reasonable time, which may affect the volunteer's willingness to continue participating in the research

(17) Persons to contact for additional information about the research and the rights of human subjects. and the person who will Receive notification in case of danger resulting from research.

(18) Circumstances and/or reasons for withdrawing subjects from the research. (19) The expected duration of the subjects' participation in the research. (20) The estimated number of subjects participating in the entire project. and the number of volunteers and institutions in Thailand

1.10.Complete research proposal requirements (Thai or English)

1.10.1. Receive approval from the human research ethics review committee, except in the case of waiting for approval from the relevant research ethics review committee. Submit the latest version available.

1.10.2. The research protocol follows the current version of the ICH Good Clinical Practice Guidelines. 1.10.3. Must contain detailed information. on various topics completely, in the following order:

(1) General Information (2) Background Information (3) Objectives and aims of the research (Trial Objectives and Purpose))

(4) Setting up the research design (Trial Design) (5) Selection and Withdrawal of volunteers (Selection and Withdrawal of Subjects)

(6) Treatment of Subjects (7) Assessment of Efficacy (8) Assessment of Safety (Assessment of Safety)

(9) Statistics (Statistics)

(10)Direct Access to Source Data/Documents)

(11)Quality control and quality assurance of research (Quality Control and Quality Assurance)

(12)Description of ethical considerations relating to research the trial)

(13)Data Handling and Record Keeping (14)Financing and Insurance (if not specified in Separate agreements may be attached to this document.)

(15)Publication Policy (Publication Policy) (16)Additional details

(Supplements)

1.11.Requirements regarding quality control documents and drug production

1.11.1. In the case of a bioequivalence study Please prepare the following documents.

(1) Batch Formula

(2) Manufacturing Process

(3) Finished Product Specification

(4) Certificate of Analysis

1.11.2. In the case of human research studies other than bioequivalence studies Provide quality information of medicines by displaying information and details according to the topics specified in evidence showing information on the quality of medicines according to Topics given for the various phases of research are listed in **Appendix 6.**

1.12.Requirements regarding approval documents for research from the Human Research Ethics Committee (IRB/ IEC) accepted by the Food and Drug Administration. 1.12.1. The applicant is

responsible for requesting approval. Conduct research from the review committee Ethics for human research accepted by the Food and Drug Administration and received prior approval Start conducting research This is in accordance with the announcement of the Food and Drug Administration on criteria, methods, and conditions for acceptance of human research ethics committees considering clinical research projects regarding drugs. 1.12.2. A copy of the approval document to conduct

research must be submitted from the committee. Human Research Ethics Committee The Thai language version has been accepted by the Food and Drug Administration. The approval document must contain at least the following information: (1) Name of the

committee. As accepted by the Food and Drug Administration (2) Name of the research

project in Thai (3) Name of the

researcher (4)

Names of all approved research facilities (5)

Research project documents and related documents, including specifying the version that the committee Consider the ethics of human research approval. (6)

The time period for which research is approved. and/or expiration date

1.12.3. The case is pending consideration by the Research Ethics Committee. Person eligible to submit Requests may be submitted to the Food and Drug Administration before the Ethics Review Committee. Human research can give approval or accreditation to a research project. The person eligible to submit the request must comply with the conditions set forth. The Food and Drug Administration determines and see how to submit the results for consideration by the committee Consider the ethics of human research and related documents and evidence in **Section 3.**

1.13.Requirements regarding documents approved by the relevant academic committee.

Some types of drug research may have special supervision, such as the AIDS vaccine, etc. The Ministry of Public Health may set up a committee or academic subcommittee related to supervised research drugs. to take special care, such as the Academic Subcommittee on AIDS Vaccine Trials, etc. Therefore, when submitting a request for permission, a copy of the approval or approval document from the said committee must also be submitted. **1.14.Requirements regarding authorization and power of attorney**

1.14.1. The business operator may authorize a person with appropriate qualifications to submit a request, clarify, amend, and receive documents related to the request. However, the **power of attorney should be a person with knowledge in pharmacy or a field that medically related as well as understanding the request for permission and various documents related**

1.14.2. The scope and responsibilities of the attorney must be specified to cover the filing of

Clarifies and corrects permission request documents

1.14.3. Stamp duty 30 baht

1.14.4. Copy of ID card of the grantor and the attorney-in-fact. Complete with signature to certify that the copy is correct.

1.14.5. One set of power of attorney is used for 1 request only. 1.14.6. In the case of granting power of attorney for submitting requests electronically. Contact the system development group.

1.15. Template file requirements In the case of submitting a paper form

To submit a paper application Must fill out a template file for importing data into the information system in order to Initial information for entrepreneurs to process electronically and benefits in supervision Continue to oversee clinical research. Please use the template file on the Division of Medicine website or ask the staff.

2. Correcting/submitting additional documents according to the evaluation results.

If the result of consideration by the evaluator allows the applicant to correct/clarify various issues. to the applicant/recipient Power to make corrections/clarifications based on the evaluation results within the specified time by submitting an additional correction/ clarification request form **(Appendix 8)** along with related documents and evidence. for clinical drug research work New drug groups and

Promote drug research, Drug Division

In the case of submitting through the electronic system, follow the steps of the system.

3. Submission of the results of consideration by the Human Research Ethics Committee and related documents in the case of submitting a request to produce drug samples for research in humans before receiving approval from the Human Research Ethics Committee Human Research Ethics Committee

The licensee must submit the results for consideration by the Human Research Ethics Committee. The Food and Drug Administration accepts it for the Drug Division within **15 days from the date of receipt of the consideration results. From the Human Research Ethics Committee accepted by the Food and Drug Administration.** Attached to the announcement of the Drug Division regarding details of requirements regarding the production of modern drug samples for clinical research, dated 7 Aug. 2023.

All involved. By using the letter submitting the consideration results from the Human Research Ethics Committee **(Appendix** 9) with the Thai version of the consideration results attached. and related documents and evidence The research project has been revised according to the opinions of the Food and Drug Administration and the committee. Consider the ethics of human research and show the edited portion. Requests that already

have information in the electronic system Submit documents according to the system's procedures.

4. Actions after receiving permission to produce drug samples for human research studies

After receiving permission to produce drug samples for registration of drug formulas (Phor.Yor.8) for research studies in humans, the licensee must take the following actions:

4.1.Reporting progress of research operations

The research progress report is required to be submitted annually between **1-31 October** of every year until the end of the research project using the research project progress report form **(Appendix 11)** and the submission letter **(Appendix 10)** From the authorized person to the Director of the Drug Division Requests that already have

information in the electronic system Submit documents according to the system's procedures.

4.2. Actions when there are changes

4.2.1. Various changes must be considered according to the guidelines for operations when changes are made **(Appendix 12)** by dividing changes into 3 groups: 1) Changes that must be notified 2) Changes that require an amendment request. changes before implementation and 3) changes that must be submitted Request permission to produce again.

4.2.2. Changes in P.Y.8

for bioequivalence studies. If it does not qualify as “Changes that A new application for production permission must be submitted.” The licensee can submit changes to the notification form without having to request permission before proceeding. However, the licensee must keep records of various documents and evidence to support inspection by the Drug Division or authorized persons. examine And still has duties to carry out various actions to the committee to consider research ethics in human subjects that the FDA accepts as before.

4.3. Methods for requesting permission to make changes that must be approved

before proceeding. When it is considered that the change or situation is in accordance with the guidelines specified above, proceed with submitting a change request by

(1) Prepare documents and evidence according to **Document self-check form for correction requests Change the items regarding permission according to form N.Y.M.1 / P.Yor.8 for human research studies (Appendix 13)** (2) Submit

a **request to change the items regarding permission. According to the form N.Y.M.1 / P.Y.8 for human research studies (Appendix 14) ,** 1 set

(3) Attach relevant documents by showing in the revised section and attach 1 set of power of attorney every time. (4)

Please note that 1 request can request amendments to only 1 main issue, such as in the case of requesting to extend the validity of medicines. (This is a change in quality and results in a new expiration date label.) Filed in 1 request etc.

(5) Requests that already have information in the electronic system Submit documents according to the system's procedures.

4.4.Methods for changes that must be notified When it is considered that the change or situation complies with the guidelines specified above, proceed to notify the Drug Division. By submitting a letter of explanation and referring to the license to produce sample medicines for Research studies on humans who have received Along with attaching related documents showing the revised or updated parts or things that need to be informed. As detailed in **Appendix 15 ,** requests that already have information in the electronic system Submit documents according to the system's procedures. **4.5. Termination or termination of the research project.** Must notify the form summarizing the termination/end of the research project. along with drug details remaining to destroy and evidence supporting the destruction or return of drugs As detailed in **Appendix 16** within 60 days from the closing date of the research project at the final research location in Thailand. Requests that already have information in the electronic system Submit documents according to the system's procedures.

4.6. Reporting of adverse reactions from drugs used in research

must be in accordance with the criteria and methods for reporting adverse reactions from drugs used in clinical research, as follows:

Details in **Appendix 17.**

4.7. Facilitating officials in inspecting research (Inspection)

The Food and Drug Administration has measures to monitor research that has been approved for drug production. Example for requesting registration of a drug formula (Form P.Yor.8) for research studies on humans It may be carried out During the pre-research period During research or after the research ends or after the termination of the research project.

Generally, a designated official will contact the licensee to make an appointment to know the inspection schedule. before and have an official notice of the schedule at least 7 days in advance, except in cases where the office The Food and Drug Administration has special orders to conduct research inspections immediately. This may be given in a short period of time or without prior notice.

The licensee to produce drug samples for human research will cooperate and facilitate. Convenient for inspectors As in the following example: - Inform relevant people such as the principal investigator and staff. hospital director or Management of that research facility, relevant research ethics committee, etc. - Assign a coordinator to be the representative to contact the inspector before inspecting the research. Attached to the announcement of the

- Send information to the inspection team in advance According to the list stated in the notification of inspection of medical research clinic

- Prepare various equipment and locations: 1) as follows

Conference room for opening and closing research inspection meetings. which will be used on the first day and day The last step of the research inspection is in order.

2) A room for inspectors to be able to inspect various documents. during patrol

3) Computers that can connect to the volunteer data recording/reporting system. This research project Both the original data and the patient record form in the case of storage electronic data as well as all electronic systems used in Conduct research

4) Internet network system

5) Places used to carry out each step of the research project for surveillance, such as examination rooms, operating rooms. Place to store medicine, etc.

- Prepare various documents as appropriate to the current research project status (refer to ICH GCP Section 8 Essential documents for the conduct of a clinical trial [8. Essential documents for the conduct of a clinical trial]) and related licenses from the Food and Drug Administration at the research sites listed above.

- Prepare lunch and clean drinking water in sufficient quantity and value.

Appendix 1

Format P.Yor.8

Receiving number.....

date.....

Signed.....Recipient of

request **Request for permission to produce sample medicine for registration of drug formula**

Written at.....……...

Date.....Month.....…….....B.E.... ……..

I..... ..... which has a business operator named..... ..... **(name of licensee)** is permitted

to produce modern medicine according to license number..... .....on Drug production site

name..... ..... Located at number..... Alley../alley..... .....

road..... ..…... Group..... Subdistrict / Subdistrict..…..…..……..

District / District..... province..... telephone.....…….....

Requesting permission to produce a sample drug for registration of a drug formula named…….....……. ..

Detailed list of manufactured drugs

Appearance and color of medicine……...……

…….. Number or quantity to be

produced……..…… ÿ Unit or percentage…… ..... Quantity of drug ingredients Must be reported in

……..……..

Packaging size (packaging details)..…….....…… ……..... For ( ) human

research studies ( ) Cases other than those from human research studies

(specify)……...

I have attached 2 sets of documents/evidence:

(1) Drug label

(2) medicine package document

(3) other documents (in the case of producing drug samples for human research studies For registration of recipes Medicines shall be as prescribed by the Food and Drug Administration)

(Signature..)..... .....Licensee

(Signature..)..... .....Person with operational duties

……

Note: Put a check mark ÿ. in the box ( ) in front of the desired text.

Appendix 2

Summary of research project (Thai language)

TFDA CT no.	
Date of receipt	

We hereby certify that the information about the research project or the summary of the research project (in Thai) as shown in the table below is true. This

document [..] is the first time that information on the research project specified as of ... .

[..] It is considered an update of research project information specified as of ..... (with updated information displayed)

If there is a change in the information provided I will update the document and submit it to the Food and Drug Administration.

as soon as possible

sign …… Person entitled to submit the request/attorney

(……..……) Handsome

Date of certification.....

Summary of research project (Thai language)		
1. Name of research project in Thai		
2. Research project name English		
3. Project code, including the code set by the research sponsor (sponsor), should be The code is the same for all research sites of the same protocol.		
4. Project abbreviation or other name	[..] Includes:	[..] do not have
5. IND number of US FDA	[..] Includes:	[..] do not have
6. Clinical Trials Registration Registry) (May register with Thai or foreign Registry. More One place is fine.)	*(Please specify the Registry name and URL such as Thai Clinical Trial Registry(http:// www.clinicaltrials.in.th/), ClinicalTrials.gov, etc. along with the registration number)*	
7. Type of research project (1-4 definitions According to ICH-E8' General Consideration for Clinical Trials')	Distance: [..] 1 (Did the first research on people? [..] Yes [..] No) [..] 2 [..] 3 [..] 4 [..] Bioequivalent	
8. Types of research support	[..] Research projects initiated by pharmaceutical companies. [..] Research projects initiated by the researchers themselves.	
9. Countries conducting research 10.	[..] Only in Thailand [..] Research in many countries	
Total number of institutions participating in research around the world.		
11. Total number of volunteers worldwide according to plan.		
12. Number of institutions participating in research in Thailand according to the plan.		
13. Information about each research location in Thailand		

Summary of research project (Thai language)		
Name of research facility	Number of volunteers Each research location	Name of principal investigator, address, contact telephone number, email.
(1)		Name of Principal Investigator Address phone. Email
(2) *Add/decrease rows as appropriate* 14. Research		
sponsors in Thailand (Thai Sponsor)	Organization name, address, telephone. Email/Website <You can add more than 1 location>	
15. Research sponsors abroad (Foreign Sponsor)	Organization name, address country phone. Email/Website <You can add more than 1 location>	
16. Companies or agencies that supervise research (Monitor)	Organization name, address country phone. Email/Website <You can add more than 1 location>	
17. Companies or administrative agencies Manage research projects (Project Management)	Organization name, address country phone. Email/Website <You can add more than 1 location>	
18. Companies or administrative agencies Manage data (Data Management)	Organization name, address country phone. Email/Website <You can add more than 1 location>	

Summary of research project (Thai language)

19. Related laboratories All (please specify completely Whether it is used for safety or effectiveness or level measurement drugs in the blood, etc.)	[ ] Use the laboratories of each research site. [ ] Use a laboratory outside of a research facility in the country/abroad, including the name Agency address country phone. Email/Website <You can add more than 1 location>

20. List of drugs used in the project (Specify all drugs used in the project, including investigational drugs, comparator drugs/placebos and medicines used together regardless of whether permission is requested in this request or not)

Generic name, strength, dosage form	Trade name	Another name	The amount of medicine given and Washout Period(if have)	Choose only 1 item
(1) *FDAmycin 10 mg.*		*SOS-001*	*20 mg every 12 hrs.*	[/] Research medicine [..] comparative medicine [..] Medicines used together
(2) *placebo*			*2 tablets every 12 hours.*	[..] Research medicine [/] comparative medicine [..] Medicines used together
(3) *Paracetamol 500 mg.*	*TYLENOL acetaminoph in*		*500 mg every 6 hrs.*	[..] Research medicine [..] comparative medicine [/] Combined medicines
(4) *Add/decrease rows as needed.* *appropriate*				

21. Types of main investigational drugs of the project	You can choose 1 item.	
	[ ] Vaccines [ ]	[ ] Vaccines for animals
	Biological drugs [ ]	[ ] Biological medicines for animals
	Chemical drugs	[ ] Chemical drugs for animals

22. Research start date in Thailand (approximate)	
23. End date of research in Thailand (approximate)	

24. How to Find Volunteers	[..] Post an advertisement. [..] verbal invitation [..] Others, please explain..... ....

		Summary of research project (Thai
25.	Financial support	**language)** Please specify all documents showing evidence [..] Research outline (Please specify document name, version, date, page, section) [..] Information document for volunteers (Please specify document name version Date Page Item) [..] Others, please specify and
26.	Evidence of Insurance or Payment of compensation if volunteers become sick, injured, disabled, or die as a result of	attach a copy of the document. Please specify all documents showing evidence of [..] insurance. [..] Information document for volunteers (please specify document name, version, date, page, item) [..] Others, please specify and attach a copy of the document.

clinical research. Note: Please check ÿ in [ ] or fill in the text that matches the facts.

Appendix 3

Certification of compliance with the terms and conditions regarding the production of sample medicines

for human research studies For applicants (revised Aug. 2023)

I..... .....On behalf of…….. .....…….has submitted [ ] request to expand the scope [ ]

request for permission to produce drugs according to the request for permission to produce sample drugs (Pho. 8) for research in humans.

For the research project name (Thai language) ....

……

Research project code ....to be carried out in a research facility and under the supervision of

The Committee for Ethical Consideration of Research on Human Subjects has been accepted by the Food and Drug Administration as follows:

at	Research location (name and address)	Name of the review committee Ethics of research on human subjects at the office Food and Drug Administration testifies Accept (please provide full name)	Consideration Result Status	
			wait	Approved date
1.	(You can increase or decrease rows according to the number of research locations)		[.]	[.] …….
2.			[.]	[.] …….

I promise that

1. Acknowledge and will comply with the Drug Act B.E. 2510 and its amendments. Announcement of the Office of the Commission

Food and Drug Administration: Requirements regarding the production of modern drug samples for clinical research and announcement of related drug divisions

2. Acknowledge and will procure or prepare as well as manually checking all research documents according to the requirements to ensure they are in accordance

According to the announcement of the Food and Drug Administration and the announcement of the said medicine division. Regardless of whether it is a document that must be submitted

Food and Drug Administration or not. And there must be documents ready for research and improvement accordingly.

Appropriate periodically and according to the latest ICH Good Clinical Practice principles and supports traceability.

at any time

3. Relevant documents will be revised according to the opinions of the Food and Drug Administration and the committee.

Consider the ethics of human research accepted by the Food and Drug Administration. and submit the results of the committee's consideration.

Consider the ethics of research on such human subjects consistent with the research sites listed in the table above as soon as possible in accordance with the regulations.

4. However, I and those involved will not begin the clinical research process at the said research site. until approved

From the Human Research Ethics Committee accepted by the Food and Drug Administration.

I will abide by the assurances given in every respect. If I do not comply in any case or the documents submitted are false. I agree that the Food and Drug Administration will cancel

the request/license. and my application for registration may be rejected

medicine formula and may be prosecuted for making false reports to officials or other offenses according to relevant laws.

Therefore, sign your name as important to the officials.

sign .... certifying person

(..... ...) (Licensee/Chief Executive)

Date of certification .....

Note: Please check ÿ in [ ] or fill in the text that matches the facts.

Appendix 4

Certification of compliance with the terms and conditions regarding the production of

sample medicines for human research studies For

the main researcher

(revised Aug. 2023) I..... ..... As the main investigator at the research site..... ..... of the research project name (Thai language) ....

Research project code .... which the licensee..... .....has submitted [ ] request to expand the scope [ ] request for permission to produce drugs according to the request for permission. Produce drug samples (Ph.Yor.8) for research in humans. related to the said research project to the Food and Drug Administration;

I hereby promise that 1. I will cooperate with those who have the right to submit an application. In complying with the terms and conditions specified in Office Announcement Food and Drug Administration: Requirements regarding the production of modern drug samples for clinical research and related drug division announcements.

2. Clinical research will be conducted in accordance with the latest version of ICH Good Clinical Practice.

3. Medicines will be used only in research according to the research project of the above research project that has been authorized by the Secretary-General of the Committee. Food and Drug Administration only. 4. Documents related to the above research project will be revised according to the opinions of the Food and Drug Administration. and the Human Research Ethics Committee accepted by the Food and Drug Administration. and submit the results for consideration of the Human Research Ethics Committee to those eligible to submit the above request for submission to the office. Food and Drug Administration according to regulations

5. Documents related to the revised research project will be used in the research process only if they have been certified by The Human Research Ethics Committee has been accepted by the Food and Drug Administration.

6. It will facilitate officials of the Food and Drug Administration in inspecting research.

(Inspection) both before research During research and after the research ends or after the termination of the research project.

7. The clinical research process of the above research project will not be started at the research site under my responsibility until It has been approved by the Human Research Ethics Committee at the Food and Drug Administration. and has received permission to produce drug samples for research studies in humans only I will abide by the assurances given in every respect. If I do not comply in any case Food and Drug Administration Office and Medicine may issue an order to suspend research or suspend use of medicine. As appropriate to the case

Therefore, sign your name as important to the officials.

sign .... certifying person

(..... .....) (Principal Investigator)

Research location..... .....

Date of certification..... .....

Note: Please check ÿ in [ ] or fill in the text that matches the facts.

Appendix 5

Form requesting relaxation of drug labeling requirements for specific cases

Please study the details of the label requirements for every package size and the conditions for requesting a waiver of label requirements. Medicines are a specific case in the document attached to the announcement of the Drug Division regarding details of regulations regarding the importation or ordering of drugs into Kingdom for clinical research or details of regulations regarding the production of modern drug samples for Latest clinical research

1. General information 1.1.

Information on those eligible to submit an	
application Name of	
the applicant on behalf of	
1.2. Clinical research project information Research	
project name (Thai language)	
Research project code	

2. Details of the request for relief in specific cases *(According to the terms and conditions detailed in the document attached to the Department of Drug Administration's announcement)*

2.1. Name of the drug as specified in the	
request. 2.1.1. Description of the request for waiver.	
2.1.2. Necessary reasons	
2.1.3. Attach supporting documents for consideration as follows: 1. 2.	

~~*Note: A similar*~~ *table may be added for each drug entry.*

3. Testimonials

I will consider the rights, safety and well-being of my volunteers. as well as research results Trustworthy clinics are important and will direct relevant people to carry out the details that have been reported to the Food Administration Office.

and medicine

sign .... (Person applying for a waiver)*

(.....)

position ....

date ....

* Applicants requesting a waiver are according to those eligible to apply for permission from N.Y.M.1 or Por.Yor.8.

Appendix 6

Evidence of drug quality information

We certify that the information in the evidence shows information about the quality of the drug. Attached together is the truth of this document.

[..] This is the first time that drug information is provided as of .....

[..] It is considered an update of the drug information specified as of ..... (with updated information displayed)

If there is a change in the information provided I will update the document and submit it to the Food and Drug Administration.

as soon as possible

sign …….. Person entitled to submit the request/attorney

(…….....……) Handsome

Date of certification.....

Topic list	Minimum required topics For research term		
	1, BE	2	3, 4
DRUG SUBSTANCE (NAME, MANUFACTURER)	ÿ ÿ ÿ		
S.1 General Information (name manufacturer)	ÿ ÿ ÿ		
S.1.1 Nomenclature (name, manufacturer)	ÿ ÿ ÿ		
- Recommended International Non-proprietary name (INN)	ÿ ÿ ÿ		
Compendial name, if relevant	- ÿ ÿ		
Chemical name(s)	- ÿ ÿ		
- Company or laboratory code	ÿ ÿ ÿ		
Other non-proprietary name(s) (e.g., national name, USAN, BAN)	- ÿ ÿ		
Chemical Abstracts Service (CAS) registry number	- ÿ ÿ		
S.1.2 Structure (name, manufacturer)	ÿ ÿ ÿ		
- Structural formula, including relative and absolute stereochemistry	ÿ ÿ ÿ		
- Molecular formula	ÿ ÿ ÿ		
- Molecular mass	ÿ ÿ ÿ		
S.1.3 General Properties (name, manufacturer)	ÿ ÿ ÿ		
Physical description (e.g., appearance, colour, physical state)	ÿ ÿ ÿ		
Physical form (e.g., preferred polymorphic form, solvate, hydrate)		- ÿ	
Solubilities (eg. solubility profile, tabular format, reporting in (mg/mL)	ÿ ÿ ÿ		
- pH and pKa values	ÿ ÿ ÿ		
- Other relevant information	ÿ ÿ ÿ		
S.2 Manufacture (name, manufacturer)	ÿ ÿ ÿ		
S.2.1 Manufacturer(s) (name, manufacturer)	ÿ ÿ ÿ		

<table>
<tr><th rowspan="2">Topic list</th><th colspan="3">Minimum required topics For research term</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>- Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer) ý ÿ ÿ</td></tr>
<tr><td>- Flow diagram of the synthetic process(es)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Narrative description of the manufacturing process(es)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.2.3 Control of Materials (name, manufacturer)</td></tr>
<tr><td>- For drug substances or drug substance manufactured with reagents obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Information on starting materials</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)</td></tr>
<tr><td>- Summary of the controls performed at critical steps of the manufacturing process and on intermediates</td><td></td><td>- ÿ</td><td></td></tr>
<tr><td colspan="4">S.3 Characterisation (name, manufacturer)</td></tr>
<tr><td colspan="4">S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)</td></tr>
<tr><td>List of studies performed (e.g., IR, UV, NMR, MS, elemental analysis) and summary of the interpretation of evidence of structure</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Discussion on the potential for isomerism and identification of stereochemistry (e.g., geometric isomerism, number of chiral centres and configurations)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of studies performed to identify potential polymorphic forms (including solvates), if available</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of studies performed to identify the particle size distribution of the drug substance, if available</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Other characteristics</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.3.2 Impurities (name, manufacturer)</td></tr>
<tr><td>Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>List of drug-related impurities (e.g., starting materials, by-products, intermediates, chiral impurities, degradation products, metabolites), including chemical name and origin
<table>
<tr><th>Drug-related Impurity (chemical name or descriptor)</th><th>Structure</th><th>Origin</th></tr>
<tr><td></td><td></td><td></td></tr>
</table>
</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="4">Topic list</th><th>Minimum required topics For research term
1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td colspan="3"><table><tr><td></td><td></td><td></td></tr></table></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="3">List of process-related impurities (e.g., residual solvents, reagents, catalysts), including compound name and step used in synthesis</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">- Actual levels of impurities (e.g., drug-related and process-related) found in batches to be used in this clinical trial<table><tr><td rowspan="2">Impurity (drug-related and process-related)</td><td rowspan="2">Acceptance Criteria</td><td colspan="3">Results (include batch number and use) (e.g., clinical)</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.4 Control of the Drug Substance (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.4.1 Specification (name, manufacturer)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td colspan="3">Specification for the drug substance<table><tr><td>Test</td><td>Acceptance Criteria</td><td>Analytical Procedure (Type and Source)</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.4.2 Analytical Procedures (name, manufacturer)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">- Summary of the analytical procedures (e.g., suitability, key method parameters, conditions)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.4.3 Validation of Analytical Procedures (name, manufacturer)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td colspan="3">Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.4.4 Batch Analyses (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td colspan="3">Description of the batches to be used in this clinical trial<table><tr><td>Batch Number</td><td>Batch Size</td><td>Date of Manufacture and Site of Production</td><td>Use (e.g., clinical)</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td colspan="3">Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (e.g., HPLC, GC), and actual results)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="4">S.4.5 Justification of Specification (name, manufacturer)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="2" rowspan="2">Topic list</th><th colspan="3">Minimum required topics For research term</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td>Justification of the drug substance specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.6 Container Closure System (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of the container closure system(s) for the storage and shipment of the drug substance</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7 Stability (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7.1 Stability Summary and Conclusions (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Proposed storage conditions for the drug substance</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7.2 Stability Protocol and Stability Commitment (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment for the continued monitoring of the drug substance stability according to the protocol</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.7.3 Stability Data (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- The actual stability results (i.e., raw data) may be found in</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.S.4 (e.g., analytical procedures used only for stability studies)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">DRUG PRODUCT (NAME, DOSAGE FORM)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.1 Description and Composition of the Drug Product (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of the dosage form</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Composition of the dosage form</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Composition, i.e., list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any)
<table>
<tr><th rowspan="3">Component and Quality Standard (and Grade, if applicable)</th><th rowspan="3">Function</th><th colspan="4">Strength (label claim)</th></tr>
<tr><th></th><th></th><th></th><th></th></tr>
<tr><th>Quantity per unit</th><th>%</th><th>Quantity per unit</th><th>%</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Composition of all components that are mixtures (e.g., colorants, coatings, capsule shells, imprinting inks)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of accompanying reconstitution diluent(s), if applicable</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="2" rowspan="2">Topic list</th><th colspan="3">Minimum required topics For research term</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td>Type of container closure system used for accompanying reconstitution diluent(s), if applicable</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Qualitative list of the components of the placebo samples to be used in this clinical trial, if different from the components listed in 2.3.P.1(b)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.2 Pharmaceutical Development (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Discussion on the development of the dosage form, the formulation, manufacturing process, etc</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>For sterile, reconstituted products, summary of compatibility studies with diluents/containers</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.3 Manufacture (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.3.1 Manufacturer(s) (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in the manufacturing of the batches to be used in this clinical trial</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.3.2 Batch Formula (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>List of all components of the dosage form to be used in the manufacturing process, and their amounts on a per batch basis (including overages, if any)
<table>
<tr><td>Strength (label claim)</td><td></td></tr>
<tr><td>Batch Size(s) (number of dosage units)</td><td></td></tr>
<tr><td>Component and Quality Standard
(and Grade, if applicable)</td><td>Quantity per batch</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Total</td><td></td></tr>
</table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="5">P.3.3 Description of Manufacturing Process and Process Controls (name, dosage form) ÿ ÿ ÿ</td></tr>
<tr><td></td><td>Flow diagram of the manufacturing process</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Detailed narrative description of the manufacturing process, including equipment type and working capacity, process parameters</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>For sterile products, details and conditions of sterilization and lyophilization</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.4 Control of Excipients (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.4.1 Specifications (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.4.5 Excipients of Human or Animal Origin (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>List of excipients that are of human or animal origin (including country of origin) ÿ ÿ ÿ</td><td colspan="3"></td></tr>
</table>

<table>
<tr><th rowspan="2">Topic list</th><th colspan="3">Minimum required topics For research term</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td>- Summary of the information (e.g., sources, specifications, description of the testing performed, viral safety data) regarding adventitious agents for excipients of human or animal origin</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), provide an attestation (with supporting documentation, if applicable) confirming that the material is free of BSE/TSE agents</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.4.6 Novel Excipients (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of the details on the manufacture, characterization, and controls, with cross references to supporting safety data (nonclinical and/or clinical) on novel excipients</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5 Control of Drug Product (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.1 Specification(s) (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Specification(s) for the drug product<table><tr><th>Test</th><th>Acceptance Criteria</th><th>Analytical Procedure (Type and Source)</th></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.2 Analytical Procedures (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of the analytical procedures (e.g., key method parameters, conditions, suitability)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.3 Validation of Analytical Procedures (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.4 Batch Analyses (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>Description of the batches to be used in this clinical trial (or representative batches)<table><tr><th>Strength and Batch Number</th><th>Batch Size</th><th>Date of Manufacture and Site of Production</th><th>Input Drug Substance Batch</th><th>Use (e.g., clinical)</th></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of results for the batches to be used in this clinical trial or representative batches (should include tests, types of analytical procedures (type and source), and actual results)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>P.5.5 Characterisation of Impurities (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
</table>

<table>
<tr><th colspan="2" rowspan="2">Topic list</th><th colspan="3">Minimum required topics For research term</th></tr>
<tr><th>1, BE</th><th>2</th><th>3, 4</th></tr>
<tr><td></td><td>Information on the characterization of impurities, not previously provided in S.3.2 (e.g., summary of actual and potential degradation products)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.5.6 Justification of Specification(s) (name, dosage form)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Justification of the drug product specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.7 Container Closure System (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of the container closure systems, including unit count or fill size,</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Materials of construction of each primary packaging component container size or volume</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>For sterile products, details of washing, sterilization and depyrogenation procedures for container closures</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8 Stability (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8.1 Stability Summary and Conclusions (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Description of stability study details
<table>
<tr><th>Storage Conditions (°C, % RH, light)</th><th>Strength and Batch Number</th><th>Batch Size and Date of Manufacture</th><th>Container Closure System</th><th>Completed (and Proposed) Test Intervals</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Summary and discussion of stability study results</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment that the stability of the clinical trial samples or representative batches will be monitored throughout the duration of the clinical trial or proposed shelf life</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">P.8.3 Stability Data (name, dosage form)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- The actual stability results (i.e., raw data) may be found in</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">- Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.P.5 (e.g., analytical procedures used only for stability studies)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
</table>

ATTACHMENTS

Attachment Number	Subject

Appendix 7 (revised 7 Aug. 2023) Document self-check form for

Request for permission to produce drug samples (Ph.Yor.8) for research in humans

Check number	
date	
Project ID	
TFDA CT no. TFDA-	

Part 1 summarizes the results of document inspection. (Officers only)

Types of drug research projects	**Types of research drugs**	**The time of requesting permission of the same project**	In the case of Non-BE: Has CMC ever received permission before?
[ ] Bioequivalent [ ] Non-bioequivalent/Non-BE	[ ] Biological drugs [ ] Veterinary drugs Chemical drugs [ ] Other [ ]	[ ]	[ ] ever [ ] never

Summary of the results of document inspection	Request Inspector
[ ] Accepting the request (Issuing the document "Results Notification of Request Consideration") [ ] Unable to make corrections on the date of submitting the request (Issuing the document "Record of Defects").	( ) dated

Part 2: Instructions and steps

!! Please read!!

Instructions for using the document self-check form

1. Those eligible to submit an application include those licensed to produce modern medicine . 2. Study the details of the various terms and conditions in **the announcement of the Food and Drug Administration and the announcement of the Drug Division. relevant**

3. Read instructions and testimonials. And fill in information in Part 3 and Part 4. 4. Check yourself by **answering the results of the self-check** as follows.

- Answer **'Yes'** or **'Yes'** or ÿ means you have checked yourself and it meets the requirements. - Answer **'N/A'** or **'Not applicable'.** When you check and find that the requirements state that you do not need to submit this document - Answer. **'Reference...'** or **'Refer...'** specify the request receipt number or request receipt number + receipt date. related

Part 3 Certification of document preparation

Authorized person/attorney .... On behalf of (company) ....

Call ……..……..……Fax……..……..……E-mail: … ……..……..

We certify that we have studied and prepared documents according to FDA regulations (including announcements from the Food and Drug Administration and announcements of the relevant Drug Division) and have submitted documents as listed. Sort by document list and checked by myself According to the table in section 4

sign …… (Applicant/attorney) Date.....

Part 4 Document check table

clause	Document list	Results Also check. myself	Results of inspection by officials # 1	# 2	note
*1	**About submitting this request (please fill in**				
	information) The time of requesting permission for the same				
	☐ project, submitted after all EC approvals or in parallel, waiting for				
EC results	***2 Data recording device** (In case of paper				
	submission) 2.1 File copies of all submitted documents (PDF file)				
***3 Form Por.Yor.8**	☐ e-sub paper ☐				
	3.1 In the case of e-sub, the request will be created in the				
	system. 3.2 In the case of paper **submission.** Submit 2 copies with the actual signature + fill out the				
information completely	***4 Brief summary of the research project (Thai language) according to the** **format specified by the Drug Division** (in the case of				
	submitting through the system, information will be filled in through				
	the system) * As for the certification, fill				
	in the information and post. Complete name:				
	1) Name of research project in Thai 2) Name of research project in English 3) Project code (should be the same code used at				
	all research sites of same research outline) 4) Abbreviated name of the project or other name				
	5) IND number of US FDA				
	6) Clinical Trials Registry 7) Type of research project 8) Type of				
	research support 9) Country of				
	study 10) Total number of participating				
	institutions worldwide 11)				
	Total number of subjects worldwide according to				
	Plan 12) Number of institutions participating in research				
	in Thailand according to plan 13) Information of each research				
	location in Thailand 14) Research sponsors in Thailand				
	15) Research sponsors abroad 16) Companies				
	or agencies that oversee research. (Monitor)				
	17) Companies or agencies that manage research projects (Project Management)				
	18) Companies or agencies that manage data (Data Management) 19) Clinical				
	laboratories 20) List of drugs				
	used in the project (both according to N.Y.M.1 and procured domestically) 21) Types				
	of main research drugs of the project 22) Start date				
	of research in Thailand (estimated) 23) End date of research				
	in Thailand (estimate) 24) How to find volunteers 25) Financial				
	support + with attached				
	documents _____				

clause	Document list	Results Also check. myself	Results of inspection by officials # 1	# 2	note
	26) Evidence of insurance or compensation if Volunteers become sick, injured, disabled, or die as a result of clinical research + along with attached documents				
***5 Certification of compliance with terms and conditions for the applicant.** Signed by the					
	business operator who signed the Por.Yor.8 form.				
	1) Issue 7 Aug. 2023				
	2) The research project code corresponds to the research protocol. 3)				
	The EC name corresponds to that accepted by the FDA. 4)				
	The information is completely				
	filled in. 5) The content is as specified.				
***6 Certification of compliance with the terms and conditions for the researcher. main**					
	1) Issue 7 Aug. 2023				
	2) The research project code corresponds to the research outline.				
	3) Complete information. 4)				
	Content is as specified. 5) The main				
	investigator provides complete certification at all research sites. ***8**				
Evidence of insurance or compensation in the event of dangerous					
***9 power of attorney** (Only in the case of submitting paper)					
	1) Power of attorney (submit a request, clarify, amend, receive documents) 2)				
	A copy of the power of attorney's ID card/passport 3) A copy of the power of				
	attorney's ID card 4) Stamp duty 30 baht per 1 power of				
	attorney ***10 copies of a license to produce modern medicine.** (In				
the case of submitting paper) 1) A copy of the current version and not yet expired. 2) In					
	the case where it is not yet available and is awaiting inspection.				
	Submit evidence assemble				
11 Copies of GMP certificate					
	1) The drug production location matches the				
	Por.Yor.8 form. 2) The drug category requested for production matches the				
approved drug category. **12 Drug labels for every package size. (Thai or English) including:** 1) Medicine label……..… Medicine label……..					
	12.1 All containers and all sizes must have the same format as the actual labels. 12.2 Use Thai language,				
	except for drug names/drug codes. and information on sponsors of research projects can be used in Thai or English. and the case of drugs Medication is administered by medical personnel. Can use Thai or English. **12.3 Secondary labels include (at least)**				

clause	Document list	Results Also check. myself	Results of inspection by officer		note
			# 1	# 2	
	Drug name/drug code, strength, form, route of administration Unit quantity In case of treatment concealment, specify: “placebo or [drug name/drug code] + [dose strength]”				
	research project code or research project name				
	Production model and or code number to indicate components and packaging.				
	Volunteer number or treatment number and appointment number Meaning (if relevant)				
	How to use the medicine may be based on the documentation specifically designed to explain it to you. volunteers (e.g. medication records) or administrative personnel Pharmaceutical products				
	Name, address and telephone of Sponsor/CRO/Researcher Except in the case where Volunteers receive an identification card showing this information (with attached document)				
	Statement “For clinical research use only”				
	Drug storage conditions				
	Specify use by date/expiration date/retest date (month/year)				
	The message "Keep out of the reach of children" in Thai, except that volunteers do not bring medicine to take home				
	12.4 Primary label, general case, consists of (at least)				
	Drug name/drug code, strength, form, route of administration Unit quantity In case of treatment concealment, specify: “placebo or [drug name/drug code] + [dose strength]”				
	Research project code or research project name				
	Production model and or code number to indicate components and packaging.				
	Volunteer number or treatment number and appointment number Meaning (if relevant)				
	How to use the medicine may be based on the documentation specifically designed to explain it to you. volunteers (e.g. medication records) or administrative personnel Pharmaceutical products				
	Name, address and telephone of Sponsor/CRO/Researcher Except in the case where Volunteers receive an identification card showing this information (with attached document)				
	Statement "For clinical research use only" Medicine storage				
	conditions				
	Specify use within date/expiration date/retest date (month/year). Text: "Keep				
	out of reach of children" in Thai, unless volunteers do not bring. medicine to take home				
	12.5 Primary label in the case where the primary packaging is together with the packaging. Secondary always consists of (at least)				
	Drug name/drug code, strength, form, route of administration (except solid eat) quantity, unit count In the case of treatment concealment, specify: “placebo or [drug name/drug code] + [dose strength]”				

clause	Document list	Results Also check. myself	Results of inspection by officials # 1	# 2	note
	Research project code or research project name,				
	production version, and/or code number to indicate components and packaging.				
	Volunteer number or treatment number and appointment number (if relevant). Name of				
	Sponsor/CRO/Researcher.				
	12.6 Primary label, in case the primary packaging is in blister form. or a small unit with an area not exceeding 3 square inches and co-located with Secondary packaging always includes				
	(at least) the route of administration (except oral solids), the quantity of the unit. In the case of disclosing treatment, specify: drug name/				
	drug code and strength, protocol code or				
	research project name, production version, and/or code number. To indicate ingredients and packaging				
	Volunteer number or treatment number and appointment number (if relevant), name of the Sponsor/				
	CRO/investigator **12.7 In the**				
	case of preparing drugs for administration at the research site, it is necessary to put new labels on the packaging that will be used for drug administration				
	(must be done but does not need to be				
	submitted along with request) the label is				
	appropriate, correct for its purpose, has SOP or standard methods				
	consistent with GMP, and is carried out by qualified and trained personnel. There is evidence of practice records. and the				
	inspection by the second party is at least under strict control.				
	Collect evidence and record documents to support inspections. **12.8 If necessary Relaxation may be granted only in the following cases.**				
	☐ Relaxation of information on the label that may refer to other documents, such as how to administer the drug. Refer to medication records, etc. - Form requesting relaxation of drug labeling requirements in specific cases **Referenced documents include:.....**				

clause	Document list	Results Also check. myself	Results of inspection by officials # 1	# 2	note
	☐ Adding labeling after producing drug samples to request drug formula registration In order to comply with the requirements **[In the case of labeling in place Manufactured in a place that has permission to produce the correct medicine]** - Form requesting relaxation of drug labeling requirements in specific cases - Label or image of a label that has the same format as the actual label. - The place where labeling is performed is a place that has permission to produce the correct medicine. Specify the name .... Modern drug production license number..... ..... - **or** in case of necessity Request for a waiver of labeling operations in Places that can be controlled to comply with conditions instead by 1) **Specify the reason** and **Attach SOP [Appropriate personnel trained There are procedures, records, and verification by a second person. It is strictly controlled. and complies with GMP] 13 drug accompanying documents (For**				
drugs for bioequivalence studies) 14 Investigator's handbook Investigator's					
Brochure (for investigational drugs) Evidence that an up-to-date Investigator's Brochure has been					
	submitted to the Committee. Consider ethics (except for parallel submission) Table of contents, summary, introduction, physical, chemical,				
	pharmaceutical properties and				
	formulations. Results of studies not conducted on humans (Animal Study)				
	1. Pharmacology 2.				
	Pharmacokinetics and transformation processes in laboratory animals 3. Toxicology				
	Results of human studies (Clinical Study) 1.				
	Pharmacokinetics and product change processes				
	2. Safety and effectiveness				
	3. Marketing experience				
	Summary of information and recommendations for researchers				
15 Volunteer Recommendation Documents (Thai)					
	1) contains appropriate language for the subjects*				
	2) has been approved by the EC (except for parallel submissions)				
	3) the estimated number of subjects participating in the entire project and the number of volunteers at each institution in Thailand (Page.....) 4) Indicates that the FDA is				
	supervising the research. Research auditors, IRB/IEC and regulatory agencies are permitted to Directly inspect the subjects' original medical records. (page.....)				
	5) State that it is research; 6)				
	Aim of the research; 7) Treatment				
	provided and opportunity to be randomly assigned.				

clause	Document list	Results Also check. myself	Results of inspection by officials # 1	# 2	note
	8) Research methods and invasiveness. 9) Volunteers' responsibilities.				
	10) Experimental parts of the research project.				
	11) Risks or discomfort that may occur to volunteers.				
	or to the embryo or fetus or those drinking mother's milk. 12) Benefits expected to be received In the event that there is none, the volunteer must be				
	informed. 13) Other alternative procedures or treatments. 14) Compensation				
	and/or treatment that the volunteer will receive. 15) Compensation				
	payment (if any) which is determined on a case-by-case basis. 16)				
	Various expenses (if any) 17) Indicate that the volunteer's				
	participation in the research is				
	voluntary. and may refuse to participate or withdraw from the research at any time. without offense or loss of benefits that volunteers should receive. 18) State that the personal information of volunteers will be kept secret and will not disclose				
	this information to the public beyond the limits of the law, even if there is Publication of research results 19) Specify that the subject or legal representative will be informed. new information in a timely manner which may affect				
	the willingness of Volunteers who will continue to participate in the research. 20) Persons to contact for additional information about the research and the rights of volunteers, and persons to be notified in				
	the event of danger. Results from research				
	21) Circumstances/reasons that may withdraw a subject from the research. 22) The				
	expected duration of the subject's participation in the research.				
16 Complete research project details (Thai or English)	1) Approved by the EC				
	(except for parallel submission) 2) General information 3)				
	Background				
	information on the research 4) Objectives				
	and aims of the research 5) Setting up the research				
	design 6) Selection of volunteers				
	and withdrawal of volunteers				
	7) Volunteer care 8)				
	Effectiveness evaluation				
	9) Safety assessment				
	10) Statistics				
	11) Direct access to original data and documents 12) Quality control				
	and quality assurance of research 13) Ethics related to research 14) Data				
	management and record keeping 15)				
	Financial support and insurance (If not specified in this document,				
	a separate agreement may be attached.)*				
	16) Policy on publishing research results				

clause	Document list	Results Also check. myself	Results of inspection by officer		note
			# 1	# 2	
	17) More details				
17 Quality control and drug production documents					
	17.1 Case: Bioequivalence study				
	1) Batch Formula				
	2) Manufacturing Process				
	3) Finished Product Specification				
	4) Certificate of Analysis				
	17.2 Cases other than bioequivalence studies				
	1) NCE for Phase.....				
	- As for the certification, fill out the information and sign completely.				
	- Drug Substance has complete information according to the specified subtopics.				
	- Drug Product has complete information according to the specified subtopics.				
18 Approval documents for research from the Ethics Review Committee	**Research in humans accepted by the Food and Drug Administration (of all agencies according to regulations)** **18.1 Name of organization……..** **18.2 Name of organization……..** **(Except for parallel submissions, they may not be available or may be incomplete.)**				
	1) Thai version*				
	2) The name of the IRB/IEC corresponds to what the FDA has announced.				
	3) Name of research project				
	4) Name of researcher				
	5) Names of all approved research facilities.				
	6) Research project documents and related documents, including the version (version) approved by the Human Research Ethics Committee. 7) The period				
	of time for which the research was approved. and/or expiration date				
19 Other (if relevant)	- Approval document from the committee or academic subcommittee that Relates to specially regulated investigational medicines, such as AIDS vaccines. etc.				

Appendix 8

Form for requesting corrections/additional clarifications

For the applicant/attorney: I (name- surname)..... .... On behalf of..... .....who is the applicant/attorney for [ ] request to expand the scope of drug production in accordance with the request for permission to produce sample drugs (Ph. Phor.8) to conduct research studies in humans [ ] Request for permission to produce sample medicine (Por.Yor.8) to conduct research studies in humans Receipt number……...Receipt date…..…….. and have been informed to correct/clarify Within date…… Please clarify various issues by submitting the following documents:	**Clinical drug research work Date of receipt..... recipient.....** **For the applicant** **Check it yourself** (Answer ÿ means Checked the exceptions. Free = not checked, will be returned)

document number	Document list (Please prepare, certify, and check the documents yourself.)	
*	Sign an affidavit or certify that every copy of the document is correct. Data recording	
1	equipment 1.1 [ ] Copy files of all submitted documents (MS word 1.2 [ ] Excel files for . PDF file)	
	the logistics system, explanation letter (Add a list of	
2	documents as	
	appropriate Ready to check by yourself)	

I certify that I have clarified various issues. According to the evaluator's opinion

along with submitting all complete documents that were notified for clarification/ correction

sign…… **(Applicant/attorney)** dated.....

(.....)

Note: Please check ÿ in [ ] or fill in the text that matches the facts.

Appendix 9

Letter of submission of results for consideration by the Human Research Ethics Committee

Company header

date..... ...

Subject: Requesting results of consideration from the Human Research Ethics Committee (After parallel submission) **Dear** Director

of the Drug Division, **referring to** the license to produce sample medicine (Por.Yor.8) for research in humans. Receipt number.....

Attachments* (1 set) as follows: 1. Copy of sample drug production license (Phor.8) for research in humans. Receipt number..... 2. Human Research Ethics Committee.....(insert name)..... Including number 2.1 approval letter or result of consideration from the human research ethics committee.....(specify name).....

Number 2.2 Volunteer recommendation document..... (Correction version)

No. 2.3 ..... (edited version) 3. Human Research Ethics Committee.....(specify name)..... namely

Number 3.1 .....

.... File data recording equipment that is the same as all documents

submitted this time. As the Food and Drug Administration allows.....<Licensee>.....to produce drug samples (Ph.Y.8) for research in humans. Receive number no. ..... Date of receipt.....

For the Thai name research project..... ....

Research project code..... TFDA CT no. ..... (if any) as detailed in attachment number 1

Now, I have received all the results of the consideration from the Human Research Ethics Committee. I would like to submit the results of the consideration and all relevant documents and evidence that have been revised according to the opinions of the committee. The Food and Drug Administration and the Human Research Ethics Committee have come together. In this connection, I would like to inform

you that [ ] all research sites specified in the license Approved [ ] Some research locations specified in the license Not approved include: 1)..... and 2)..... I would like to notify you of the cancellation of the said research location. and certify that the medicine will not be used at the canceled research site

Therefore, I would like to inform you.

Best regards

.....

(.....)

position .....

Note: Signed by the authorized person according to the requirements in Section 1.1 and marked ÿ Related message page and fill in the correct statements according to the facts

Appendix 10

Sample letter for submitting a progress report

Company header

date..... ...

Subject : Request to submit a progress report of a research project. ..... For the year .....

Dear Director of the Drug

Division, **referring to** the license to produce sample medicines (Por.Yor.8) for research in humans, receipt number…

<specify all requests>… **Attached items* (1 set) as follows:**

Number 1 Research project progress report form

Number 2 .....

Number 3: File recording device that is the same as all documents submitted this time.

As the Food and Drug Administration allows.....<company name/agency>.....to produce sample medicine (Pho. 8) for research in humans. ..... Date of receipt..... For the research project named.....<Thai name>..... .... Research project code..... TFDA CT no. ..... (if any) as detailed in attachment number 1

Now, I would like to submit a report on the progress of the research project in accordance with the requirements in the announcement.

The Food and Drug Administration is involved and is attached herewith.

Therefore, I would like to study for your consideration.

Best regards

.....

(.....)

position .....

Note: Signed by the authorized person according to the requirements in Section 1.1 and fill in the correct information according to the facts.

Appendix 11

Research project progress report form

Research Project Progress Report Form [ ] that has permission to [ ] import drugs for research purposes (N.Y.M.1) Production of drug samples (Ph.Yor.8) for research in humans.	Research project code …….....	Page ..... of .....
	TFDA CT no.	Intraday data ..... to .....
Refer to request [ ] N.Y.M.1, receipt number…….<specify all requests>……..... [ ] Por.Yor.8 Receive number…….<Specify all requests>……..... Authorized		
person .... (Please specify the name of the organization/company)	Overall/global status of research projects [ ] In progress . [ ] Closed as scheduled. [ ] Closed ahead of schedule.	
Name of research project in Thai		

Research sponsor in Thailand	Overseas research sponsor	Contract research company (CRO)	Research Supervisor (Monitor) Name-
name .... address .... Telephone/ Email	name .... address .... Telephone/ Email	name .... address .... Telephone/ Email	Surname .... Affiliation .... Telephone/Email ....

List of research locations	Name of primary investigator	Number of volunteers (people)						Closing date Volunteer in Join the project (or approximately) *a*	The date of the volunteer's last appointment. Participate in research people Finally (or approximately) *a*	status of Conduct research at each research location *b*
		According to the goal	that actually participated	that is in the trial period	within the follow-up distance time	who left the research before the deadline	that participated in the research completely according to			
1.										
2.										
3.										

Research project progress report form	Research project code …….....	Page ..... of .....
that has permission to [ ] import drugs for research purposes (N.Y.M.1) [ ] Produce drug samples (Ph.Yor.8) for research in humans.	TFDA CT no.	Intraday data ..... to .....

N										

* Are there any changes? that falls under Section “4.3 Cases that must be notified Food and Drug Administration for information” which has not yet been notified. FDA or not? [ ] None . [ ] Yes (attach the clarification letter with supporting documents)	** Were there any deviations from the research protocol during this reporting period? [ ] do not have . [ ] Yes (attach the clarification letter with supporting documents)	*** If in doubt or there is an urgent/necessary reason regarding the research project Please contact .... Responsibilities in the project are ..... Tel.....Fax..... .....Email.....

Additional explanation

a In the case that there is a reason that it cannot yet be determined or that the last volunteer has not yet been closed, specify "Unable to determine".

b such as "Cancelled due to lack of volunteers", "In progress", "Full follow-up of volunteers", "Closed first Determined because....." etc.

c Signed by an authorized person according to the requirements in Section 1.1. Please check ÿ in [ ] and fill in the correct information according to the facts.

We certify that all information is true.

……

(……)

position..... .....

As the operator/chief executive of the agencyc

Appendix 12

Guidelines for action when there is a change

After receiving permission to produce drug samples for human research or to import or order drugs
Came to the kingdom for research Changes may occur with respect to medicines or clinical trials.

With permission, the Drug Division has prepared guidelines for action when there are changes to be used as guidelines, divided into
Changed into 3 groups

1.	**Changes that must be notified** include:	for	
		N.Y.M.1	**P.Y.8***
1.1.	Any information in the research project summary (except adding research locations) by some items It needs to be approved/approved by the EC that has been accepted by the FDA and attached. Evidence such as the name of the research project in Thai or English Research project code, abbreviation Research project or other names, principal investigator, or items that may result from Change research outline	ÿ	ÿ
1.2.	Document detailing research outline Once approved/approved by the EC accepted by the FDA, unless there are special conditions.	ÿ	ÿ
1.3.	Cancel or reduce research facilities	ÿ	ÿ
1.4.	Researcher's manual document or volunteer guidance document or document regarding Administer medicines given to volunteers or insurance documents. Upon approval/ Approved by the EC which has been accepted by the FDA.	ÿ	ÿ
1.5.	Drug labels that were previously allowed 1) In the case of changing the format but still having complete text according to all requirements or 2) In the case of editing the name, address, and telephone number of the research sponsor, or Contract research organization or researcher or 3) In the case of correcting spelling errors In both cases, the licensee must personally inspect and certify that it is still in compliance. requirements and perform labeling in a GMP certified facility.	ÿ	ÿ
1.6.	Medicine documentation In the case where there is an update of academic information according to the previous drug registration refer	ÿ	ÿ
1.7.	Change the manufacturer of Drug Substance ~~of chemic~~al drugs in the quality control documents and To produce medicine, the licensee must inspect and certify himself that this change Does not reduce the quality of the medicine	ÿ	ÿ

1.	**Changes that must be notified** include:	for	
		N.Y.M.1	**P.Y.8***
1.8.	Extending the shelf life of investigational drugs or placebos - in the case of stability studies which have Carry out according to stability protocol and have analysis results consistent with stability specifications. It is in accordance with the latest permission granted by N.Y.M.1~~/P.Y.~~8. ~~Licensees must verify and certify themselves that they meet these conditions.~~	ÿ	ÿ
1.9.	Notification of inspection of clinical research operations in Thailand by regulatory agencies Taking care of medicine from abroad (whether traveling in person or online) by This must be notified as soon as possible.	ÿ	ÿ
1.10.	Notification of termination or termination of the research project before the time specified according to the research project plan Ready to report the cause	ÿ	ÿ
1.11.	Serious violation of Good Clinical Research Practice (ICH GCP) guidelines or research outline or legal requirements which may affect safety or the well-being of volunteers or the scientific value of scientific research Clinic, which must also notify corrective and preventive measures (CAPA).	ÿ	ÿ

2.	**Changes that require a change request to be submitted and is allowed Before proceeding** include:	for	
		N.Y.M.1	**P.Y.8***
2.1.	Add a research study location without increasing the number of drugs requested to be imported or produced	ÿ	ÿ
2.2.	Add or edit drug labels that are not eligible for notification.	ÿ	ÿ
2.3.	Drug quality control and production documents (1) In the case of amending the manufacturer's DS and DP of a biological drug, or (2) Correct the DP manufacturer of chemical drugs.	ÿ	N/A
2.4.	Extending the shelf life of an investigational drug or placebo - a case where drug stability studies are not possible. Complies with the latest stability protocol ever permitted. N.Y.M.1/P.Y.8	ÿ	ÿ
2.5.	Taking drugs from one research site's quota from one license and using them at a research site. another location which is not specified in the same license Although it is a research study The same can be applied for permission to change only in cases of necessity. As well as ensuring that evidence will be collected and accounts prepared for inspection. Can go back	ÿ	N/A
2.6.	Other changes that do not qualify “Changes that must be notified” or “Changes that require a new application for permission to be submitted to N.Y.M.1/P.Yor.8”	ÿ	ÿ

3.	**Changes that require submitting a new application for permission from N.Y.M.1/P.Yor.8** namely	**for**	
		N.Y.M.1	**P.Y.8***
3.1.	Change the applicant company for the project (must cancel original license)	ÿ	N/A

3.	**Changes that require submitting a new application for permission from N.Y.M.1/P.Yor.8** namely	**for**	
		N.Y.M.1	**P.Y.8***
3.2.	Add a list of drugs or the number of drugs requested to be	ÿ	N/A
3.3.	imported, change the drug formula or product specification. Increase	ÿ	ÿ
3.4.	research facilities and increase the number of drugs requested to be imported or produced.	ÿ	ÿ
3.5.	Want to produce new research drugs for use in original research projects	N/A	ÿ
3.6.	Use previously licensed drugs in new clinical research projects.	N/A	ÿ

* Note the change of P.Yor.8 for bioequivalence studies. If it does not qualify as "Changes that must

Submit a new application for a production license" allowing the licensee to submit changes to the notification form. No need to ask for permission.

Before taking action, however, the licensee must maintain records of various documents and evidence to support the action.

Check from the Drug Division or someone with inspection authority. and still has duties to carry out various actions before the consideration committee

Research ethics on human subjects is accepted by the FDA as before.

Appendix 13

Document self-check form

For requests to change the items regarding permission

according to the form N.Y.M.1 / P.Y.8 for human research studies.

Request for change regarding	
[ ] N.Y.M.1 **[ ] P.Y.8 (Research)**	
Project ID	
Check number	
date	

Part 1 summarizes the results of document inspection. (Officers only)

Types of research drugs (main ones)

[ ] Biological drugs [ ] Animal medicine [ ] Chemical medicine [ ] other

Summary of the results of document inspection [ ] Accepting the request (Issuing the document "Results Notification of Request Consideration") [ ] Unable to make corrections on the date of submitting the request (Issuing the document "Record of Defects").	Request Inspector ( ) dated

Part 2: Advice and Testimonials

Instructions for using the document self-check form: 1. Study the requirements in the announcement of the relevant Division of Medicine. 2. Prepare documents in accordance with the requirements in the announcement. All items complete Arrange in order according to the document list. 3. Changes that have occurred should be clearly displayed in the document. Or there is good communication so that the evaluator can easily understand. 4. Arrange the documents according to the sequential number that corresponds to the form. 5. **Responses to the self-inspection results** are as follows: - Answer **'Yes'** or **'Yes'** or ÿ Meaning, check yourself and meet the requirements - answer **'N/A'** or **'not applicable'.** When you check, you will find that the requirements indicate that you do not need to submit this document - answer **'Reference...'** or **'Refer.. .'** Specify the request receipt number or request receipt ~~number + re~~ceipt date. Related Note** Leaving blank Because the applicant did not check it himself. Staff will return the request, so if in doubt about the requirements or preparing documents Please ask the staff **

Applicant/attorney (First name-Last name) .... On behalf of (company/ agency) ....

Call ……..……..……Fax:……..……..……..…… ……E-mail: ……..

We certify that we have studied and prepared the documents according to the regulations. The FDA is ready to prepare all documents completely.

Items are sorted by document list and manually checked according to the table below.

sign …… (Applicant/attorney) Date.....

Part 3 Document check table

clause	checklist	Results examine by yourself	Results of inspection by Officer 1st time	2nd time	note
*	Acknowledge that you cannot apply for changes to the licensee, drug list, or quantity. Instead, you must cancel the original license and apply. New permission				
**	Acknowledged that 1 request may only request changes to 1 main issue, such as in the case of requesting to extend the expiration of medicines (this is changes in quality and results in a new expiration date label) to be submitted in 1 request, etc.				
*** All documents that are photocopies must be certified as true copies.					
1	**Data recording device** (In the case of submitting a paper form)				
	1.1 Copy of all submitted documents (PDF file)				
	1.2 Excel files for logistics systems				
2	**2.1 Request to change the items regarding permission according to the form N.Y.M.1 / P.Y.8 (Research)** ☐ e-sub paper ☐				
	1) The information of those eligible to submit an application matches those of those granted permission.				
	2) Express your wishes				
	3) Research project information (name, code TFDA (permission date from Oct. 2016, except for expanding the scope of BE, the director will not know)				
	4) Specify the main points that need to be revised from, to, and why.				
	5) Are there any other changes related to the main issue? If so, specify from, to, and why.				
	6) Specify documentary evidence				
	7) Risk prevention measures and assurances, such as in the case of changes that may pose a risk to research or volunteers or in the case of requesting Changes due to errors In the case of requesting to use drugs across research institutions, it must be Ensure that evidence is stored Make a complete account and can be verified or in the case of changes that may cause risks to the research or Volunteers etc.				
	8) Signed by the authorized person - the business operator - the highest executive at the department level and above.				
	2.2 Orders for assigning government officials In the case where the highest executive of a ministry or department in charge of disease prevention and treatment, the Thai Red Cross Society or an organization Pharmacy is assigned to perform duties on behalf of Bringing or ordering drugs into the Kingdom				
3 power of attorney (In the case of submitting a paper form)					
	1) Power of attorney (submit request, clarification, correction, receive document)				
	2) Copy of the identity card of the grantor/passport				
	3) Copy of the identification card of the attorney-in-fact.				

clause	checklist	Results examine by yourself	Results of inspection by Officer		note
			1st time	2nd time	
	4) Stamp duty 30 baht per 1 attorney.				
4	**Copy of relevant license** 1) Complete as				
	specified in the request for amendment.				
	(Add a list of documents as appropriate Ready to check by yourself)				
5					
6					
7					
8					
9					
10					

Appendix 14

Request to amend items regarding permission

According to the form N.Y.M.1 / P.Y.8 for human research studies

Receiving number.....
date.....
Recipient.....

1. I ----------

position ----------

on behalf of

[ ] Ministry ---------- [ ] Department ----------

[ ] Thai Red Cross Society [ ] Government Pharmaceutical Organization

[ ] Licensee to produce drugs, ---------- License number ----------

name [ ] Licensee to bring or order drugs at the place named ---------- License number ----------

2. Intend to request to amend the details regarding permission according to Form [ ] N.Y.M.1, receipt

number [ ] Phor.8 for ----------

human research studies, receipt number 3. for the ----------

project. Name research (Thai language) ----------

Research project code ---------- and TFDA CT no. ----------

4. Items requested to be changed (Choose 1 main item)

[ ] Information in the license **except** licensee information, drug list, and quantity

[ ] Medicine label

[ ] Medicine package document

[ ] Researcher's manual document

[ ] Volunteer guidance document

[ ] Summary of the research project

[ ] Research project details

[ ] Documents for quality control and drug production

[ ] Other (specify) ----------

from ----------

is ----------

because ----------

and [ ] does not have [ ] there are changes related to the main points above, including ----------

from ----------

is ----------

due to ----------

5. Document evidence

[ ] Copy of license according to form N.Y.M.1 / P.Yor.8 for research studies on human subjects.

[ ] Medicine label

[ ] Medicine package document

[ ] Researcher's manual document

[ ] Volunteer guidance document

[ ] Summary of the research project

[ ] Research project details

[ ] Evidence of approval from the Human Research Ethics Committee accepted by the FDA.

[ ] Others include ----------

---

6. Risk prevention measures and guarantees (if relevant) ----------

---

sign .... Applicant

(.....)

Appendix 15

Sample notification letter

Company / department header

date..... ...

Subject : Notification about the production of drug samples for research studies in humans. **To** the Director of the Drug Division, **referring to** the license to produce drug samples (P.Yor. 8) for research studies in humans. *Receiving number…<specify all requests>…*

Attachments (1 set) are as follows: No. 1 Copy of license to produce drug samples for research in humans, receipt number……. No. 2 ...(approval document/certification of change from the Ethics Review Committee that the FDA accepts)...

number... ...(specify).... Number... File recording device that is the same as all documents submitted this time. As permitted by the Food and Drug Administration.....<Company/Agency Name>.....

Produce drug samples for research in humans. Receipt number ..... Date of receipt.....

For the research project named.....<Thai name>..... ....

Research project code..... TFDA CT no. ..... (if any)

I would like to notify the Food and Drug Administration of the changes that have been made.

Approved/certified by the Research Ethics Committee accepted by the Food and Drug Administration (attachment....) with the following items:

1. <Specify what was changed, what it was, what the change was, reasons, and preventive measures. Risk>

2. <Specify what was changed, what it was, what the change was, reasons, and preventive measures. Risk>

So I studied to know.

Best regards

.....

(.....)

position ....

note: *Signed by the authorized person according to the requirements in Section 1.1 and filled in with correct, factual information.*

Appendix 16

Form for notification of termination/end of research project

Company / department header

date..... ...

Subject : Notification of summary of termination/end of research project, **to**

the Director of the Drug Division,

referring to the license to produce sample drugs (Por.Yor.8) for conducting research studies on humans. Receive number…….

Attached items* (1 set) are as follows: No. 1 Copy of

sample drug production license (Pho.8) for research in humans. Receipt number…… Number... Evidence of returning or destroying medicine

Number... File recording device that is the same as all documents

submitted this time.

With (name of company/unit) .... Licensee to produce

Sample medicine (Ph.Yor.8) to conduct research studies in humans. ..... Date of receipt..... For the research project

named..... .... Research project code..... TFDA CT no. .....

(If any) Now the research project has been terminated/terminated. due to*…….. Summary information is as follows: (1) Project start date. ……..Date of

termination/end of the project...Total

duration …….. (2) All

research locations in Thailand (3) Volunteers who received the drug, number of……people (4) Number of

volunteers separated by research location as shown in this table. Places include……..

List of research locations	Number of volunteers (people)				
	follow target	screening	participating TRUE	Completely participating in research On schedule	who left the office Research first time
1.					
2.					
3.					
N					

(5) Procedures for tracking volunteers In the event that the research project is terminated Due to the safety of research drugs According to the details in the

attachment. number.....

(6) There is a deviation from the research outline that has not been notified in the research project progress report according to

Details in the attachment number.....

(7) There is an application for permission. Produce drug samples (Ph.Yor.8) for research in humans. For such research projects

The above ..... times have the following details.

P.Y.8 Receipt number	medicine list	Number of medicines		Actual number of drugs at the research institute		
		that received permission	for actual production	Received into account, paid to volunteers, remaining balance		

(8) Processing of remaining or expired investigational drugs. Ready to attach evidence

.....

.....

So I studied to know.

Best regards

..... **

(.....)

position ....

note: * *Please specify the reason for terminating/ending the research.*

** *Signed by the business operator*

Appendix 17

Criteria and methods for reporting adverse reactions from drugs used in clinical trials.

ÿ. Definition of words

Definition of terms other than this list Refer to the ICH Good Clinical Practice book. Guideline Thai version published by the Food and Drug Administration.

ÿ.ÿ Adverse drug reaction (ADR) means

ÿ.ÿ.ÿ Adverse reactions from new investigational drugs or investigational drugs refer to all dangerous and adverse reactions resulting from any dose of a drug. The term "drug-induced" means that it is at least reasonably possible to explain that the adverse reaction is due to the drug. studied, that is, it cannot be ruled out that there is no relationship.

1.1.2 Adverse reactions from drugs already on the market mean any symptoms that are dangerous. or

To change the physiological functions of the body

1.2 Unexpected Adverse Drug Reaction means an adverse reaction whose nature or severity is not in accordance with the relevant product information (e.g. information in the investigator's handbook for investigational drugs that have not yet been registered as a drug formula Medicine documentation or summary Information on drugs that have been registered in the drug formula)

1.3 Serious Adverse Event (SAE) or adverse reaction

Serious Adverse Drug Reaction means any adverse medical event that occurs when taking any dose of drug and causes

(1) died

(2) is dangerous and life-threatening;

(3) Must be admitted to the hospital or have to stay in the hospital for a longer period of time

(4) permanent significant disability/disability or

(5) Birth defect/abnormality.

1.4 Annual Safety Data Cut-off Date means

The annual due date of the safety data used to prepare the annual safety report.

ÿ. Reporting Adverse Reactions Occurring During Expedited Clinical Studies

Reporting)

Persons permitted to import or order drugs into the Kingdom for research purposes/ Persons permitted to produce drugs Example for requesting registration of a drug formula (Form P.Yor.8) for research studies on humans Is responsible for watching over Be aware of safety concerns regarding investigational drugs. and report to the Food and Drug Administration with the following requirements: 2.1

Things that must be reported urgently include:

2.1.1 Serious adverse drug reactions that were not previously expected. found in Thailand which was born from research drugs or that has been reported by other regulatory agencies or publications. 2.1.2

Other safety includes safety information that changes the evaluation of benefits. Risks of investigational drugs Change the method of giving the medicine or change overall research operations, such as

(1) unexpected serious adverse reactions that has an increased incidence or severity and is considered to be of clinical importance; (2) the occurrence of significant harm

to subjects, such as the ineffectiveness of drugs that used to treat life-threatening diseases; (3) important new information regarding safety from

animal testing, such as

cancer

2.2 **Reporting deadline** 2.2.1

Serious adverse drug reactions that were not previously expected to cause death or harm. life threatening Must report within 7 days after the authorized person first receives the information. and submit additional reports within the next 8 days. Reports must be submitted periodically if additional information is available. 2.2.2 Serious adverse

reactions from drugs that were unexpected but not fatal or dangerous. life threatening The report must be submitted within 15 days after the authorized person receives the information for the first time. The report must be submitted periodically if additional information is available. 2.2.3 Adverse

reactions that occur after the subject leaves the research or Research has ended. The report must be submitted within 15 days after the authorized person receives the information for the first time. The report must be submitted in period if there is additional information

2.3 **Urgent reporting method**

2.3.1 Individual reporting must be submitted through the information system of the Security Surveillance Center. Safe health products **(http://thaihpvc.fda.moph.go.th)** Except in cases where the system is not available or has a malfunction, the report must be submitted as a document to the New Drugs and Drug Research Promotion Group, Drug Division, Office of the Commission. food and medicine

2.3.2 Other reporting Make a book with information, including a summary of the issues. Evaluation

Risks and related details Send new drug groups and promote drug research, Drug Division, Food Administration

and medicine

2.3.3 Individual reporting information Must contain at least the following information:

(1) Information that can identify volunteers, such as volunteer ID.

(2) drugs used in research

(3) adverse symptoms or Results suspected to be related to medication which can indicate that it is

Serious and unexpected events

(4) Trackable source of the report.

(5) Research project code or name of the research project.

(6) Reporting number, such as the report number assigned by the research sponsor.

2.3.4 Reporting research cases in which treatment is concealed

Submit a report that reveals the subject's treatment code. In the case where the code cannot yet be revealed

treatment of that volunteer Submit a report that has not disclosed the treatment code and submit a report that has disclosed the treatment code.

of volunteers later, unless the Office of the Committee sees fit to open the treatment code immediately. Those who receive

The authorized person must disclose the treatment code to the Food and Drug Administration as soon as possible.

3. Annual Safety Report and End of

Study Safety Report)

Persons permitted to import or order drugs into the Kingdom for research purposes/ Persons permitted to produce drug samples

To request registration of a drug formula (Form P.Yor.8) for research studies in humans. is responsible for surveillance

Safety regarding investigational drugs and report safety data annually and when research ends by

Gather information both domestically and internationally. Send new drug groups and promote drug research, Drug Division, Office

Food and Drug Administration with the following requirements:

ÿ.ÿ **Reporting must be made according to the** following

forms: 3.1.1 Letter explaining the safety of volunteers in the research project annually or at the end of the research.

3.1.2 List of serious adverse drug reactions (Serious) Adverse Drug Reaction)

For each volunteer

3.1.3 Table summarizing the number of reports including serious adverse drug reactions (Serious Adverse)

Drug Reaction) separated by terminology (symptoms and diagnosis)

3.2 **Reporting schedule and reporting methods**

3.2.1 Safety report when research ends. The report must be made within 6 months after the date the research ends. The report must be submitted as a document to the New Drugs and Drug Research Promotion Group, Drug Division, Office of the Commission. food and medicine

3.2.2 Annual safety report Must report within 3 months from the date of intersection. Annual Safety Data Cut-off Date must be reported as a document to the drug group. New and promoting drug research, Drug Division, Food and Drug Administration

Annual safety report book or when research ends

Write at (name of agency/company, address, telephone number)

date ----------

Subject: Clarifying the safety of volunteers in annual research projects/when research ends

Dear Head of the New Drugs and Drug Research Promotion Group

Attachment 1. List of serious adverse drug reactions for each volunteer.

2. Table summarizing the total number of reports of serious adverse drug reactions separated by terminology.

According to the agency/ ----------

company As a person who has permission to [ ] import or order drugs for research (N.Y.M.1) [ ] produce drug samples (P.Yor.8) for

human research studies

Research project name ----------

Research project code ---------- TFDA CT no. ---------- (if any)

There is a list of N.Y.M.1 students who are permitted as follows:

1. Number dated ---------- ----------
2. ----------

have collected and analyze safety data and report adverse drug reactions of such research [ ] annually or [ ] when the research ends. which

includes information between Therefore, I would like to clarify and summarize important issues. ----------

To date ---------- as the following topic

1. Safety analysis (emphasis on newly discovered issues)

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2. Benefit-risk assessment (emphasis on assessment of impact on volunteers/volunteers)

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3. Risk management measures

I'm here to inform you. If you have any questions or suggestions, (Agency/Company) ----------

Happy to cooperate fully.

Signed ----------

List of serious adverse drug reactions that occurred for each volunteer.

(Line Listing of All Suspected Serious Adverse Drug Reactions)

Reporting Period		Research project name (Protocol Name)
[ ] Annual (Annual)	together with Intraday data	----------
[ ] Research end (End of Study)	---------- to ----------	----------
Number of Adverse Reactions Reported (Numbers of Reports) ----------		---------- Research project code (Protocol Code No.) .... TFDA CT no. .....(if any)

code Volunteer (Subject Identification)	Reference number (Case Reference No.)	country (Country)	age (Age)	sex (Sex)	Daily dose (Daily Dose)	birth date Symptoms (Date of Onset)	Date the medicine was received (Dates of Treatment)	Unpleasant symptoms Desire (Adverse) Reaction)	Continued results Volunteer (Patient's Outcome)	Meaning Cause(Comments)	Code opening results Treatment information (Unblinding Results)

Table summarizing the number of reports including serious adverse drug reactions by terminology (symptoms and diagnosis).

(Aggregate Summary Tabulation of All Serious Adverse Drug Reactions)

Reporting Period		Research project name (Protocol Name)
[ ] Annual (Annual)	together with Intraday data	----------
[ ] Research ends (End of Study)	---------- to	----------
Number of adverse reactions reported (Numbers of Reports) ----------		Research project code (Protocol Code No.) .... TFDA CT no. .....(if any)

Number of reports by terms (signs, symptoms and diagnoses) for the clinical research trial

Body systems/vocabulary of adverse symptoms wish (Body system / ADR term)	***Investigational drug 1 (Study Drug 1)***	***Investigational drug 2 (Study Drug 2)***	***Research drug ... (Study Drug ...)***	***Investigational drug N (Study Drug N)***	**Placebo (Placebo)**	**Medicine that masks treatment (Blinded)**
CNS						
*Hallucinations**	*2*	*2*	*2*	*2*	*2*	*0*
*Confusion**	*1*	*1*	*1*	*1*	*1*	*0*
.....	.....	.....	.....	.....	.....	.....
Sub-total	*3*	*3*	*3*	*3*	*3*	*0*
CV						
.....						
Sub-total						

** Indicates an example of a serious adverse drug reaction.*