ประกาศกองยา
เรื่อง รายละเอียดข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก

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ด้วยกองยาได้กำหนดรายละเอียดการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิกเพื่อเป็นวิธีปฏิบัติในการจัดเตรียมเอกสารให้ครบถ้วนถูกต้องและเป็นวิธีในการปฏิบัติตามเงื่อนไขในการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก ตามประกาศสำนักงานคณะกรรมการอาหารและยา เรื่อง ข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก ลงวันที่ ๑๗ กันยายน ๒๕๖๑ ข้อ ๒ ข้อ ๓ (๔) (๕) และ (๖) ข้อ ๔ (๑) และ (๒)

เพื่อเป็นการส่งเสริมการปฏิบัติตามมาตรฐานสากลที่เกี่ยวข้องกับยาวิจัยทางคลินิก กองยาเห็นควรปรับปรุงรายละเอียดข้อกำหนดเกี่ยวกับฉลากยาที่ใช้ในการวิจัยทางคลินิกให้สอดคล้องกับประกาศกระทรวงสาธารณสุข เรื่อง การกำหนดรายละเอียดเกี่ยวกับหลักเกณฑ์และวิธีการในการผลิตยาแผนปัจจุบันและแก้ไขเพิ่มเติมหลักเกณฑ์และวิธีการในการผลิตยาแผนโบราณ ตามกฎหมายว่าด้วยยา พ.ศ. ๒๕๕๙ ซึ่งระบุเกี่ยวกับฉลากยาวิจัยไว้ในภาคผนวก ๑๒ การผลิตผลิตภัณฑ์ยาวิจัย กองยาจึงออกประกาศ ดังต่อไปนี้

(๑) ให้ยกเลิกประกาศสำนักยา เรื่อง รายละเอียดข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิก ลงวันที่ ๓๑ พฤษภาคม ๒๕๖๑

(๒) กำหนดให้ใช้รายละเอียดข้อกำหนดเกี่ยวกับการนำหรือสั่งยาเข้ามาในราชอาณาจักรเพื่อการวิจัยทางคลินิกตามรายละเอียดแนบท้ายประกาศฉบับนี้แทน

ทั้งนี้ ให้ประกาศฉบับนี้มีผลบังคับใช้ตั้งแต่บัดนี้เป็นต้นไป

ประกาศ ณ วันที่ ๕ กุมภาพันธ์ พ.ศ. ๒๕๖๔

**(นายสุชาติ จองประเสริฐ)**
**ผู้อำนวยการกองยา**

# Attachment to the Announcement of the

# Drug Division Re: Details of the Requirements for Importing or Ordering

# Medicines into the Kingdom for clinical research

dated 5 February 2021

**Summary of Changes in this Issue** A.

Revised details in Section 1.5 Regulations on All Packaged Medicines B. Revised Appendix 3 Self-

Submission Check Form for Application for Import or Prescription Drugs Come into the Kingdom for research (N.M.1), only those related to

labels. to comply with Updated label requirements

c. Added Annex 21, a form for requesting a waiver of prescription drug label requirements on a specific case.

clinical research medicine

Pre-market supervision group

pile of pills

Food and Drug Administration

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**Contents**

# specification details

# about bringing or ordering drugs into the

# Kingdom For Clinical Research (Update 5 Feb. 2021)

**1. Requirements for submitting an application and attachments**

Please prepare documents and evidence accordingly. **Self-submission check form for permission request Bringing or ordering drugs into the kingdom for research (Nor Mor.Mor.1) (See Appendix** 3) and check their completeness. of the document by yourself The details are in accordance with the following requirements.

**1.1. Requirements on eligible applicants** 1.1.1. An application for permission to bring or order drugs into the Kingdom for use in the same research project **must be submitted by only one agency.** By "being the same research project" means being the same research project. (Determined by the research project code the research project initiated or the research project name the same)

1.1.2. Persons eligible to submit an application refer to the Notification of the Ministry of Public Health No. 14 (B.E. 2532 (1999)) **(Appendix** 1), namely: (1) a licensee for bringing or ordering drugs into the Kingdom; (2) a ministry or a department in duty Disease prevention or treatment (3) Thai Red Cross Society or (4) Pharmaceutical Organization **In the case of the applicant did not come to operate by myself Each request must be accompanied by a power of attorney** (see the relevant section for details).

**1.2. Requirements for the letter explaining the permission request**

1.2.1. As an example in **Appendix 4 ,** with a person signing The same as signed in the N.M.1 form and has the following key contents: (1) the name of the research project in Thai that matches the document approved by the Ethics Committee, except in the case of awaiting approval from the Ethics Committee. Related research Project name should be given. Exactly as stated in the research project summary (Thai language). However, the project name should be exactly the same in Documents of all relevant research sites (2) Research project code (3) Times requesting permission for importation of the same research project (4) Relevant research sites

(5) indicate that the submission of this application is an application “After all research sites have been approved by The research ethics committee has completed the research on the people involved” or “Parallel while waiting for the results. Considered by at least one research ethics committee involved.”

**1.3. Requirements on the Nor Mor. Mor. 1**

**form** 1.3.1. Must submit a valid Nor Mor. Mor. 1 form in accordance with the Notification of the Ministry of Public Health, Re: Criteria, Methods, and Conditions for bringing or ordering drugs into the Kingdom. without having to apply for registration of drug formulas, No. 2 (B.E. 2552) dated April 27, 2009, 2 sets **, see Appendix 2** 1.3.2. Fill out the correct and complete information in the request form by Type 1.3.3. The name of the research project in Thai corresponds to the document approved by the Ethics Committee, except in the case of pending approval from the relevant Research Ethics Committee. The project name should be correct. consistent in the documentation of all relevant research sites and match those specified in the research project summary (Thai language)

**(Appendix** 7)

1.3.4. Must be signed with the original signature of the applicant only. Both the original and the copy 1.3.5. The person who signs the application is (1) in the case of a licensee bringing or ordering drugs into the Kingdom. The signatory must be the operator of the business as specified in the license to bring or order modern drugs into the Kingdom

(2) In the case of a Ministry, Department in charge of disease prevention, the Thai Red Cross Society or the Pharmaceutical Organization, the signatories must be the top executive or the person assigned to perform the duties on behalf of related to the importation or ordering of drugs into the Kingdom, provided that a copy of the Department's order in the case of acting on behalf of the Department's Director-General, or a copy of the University's order In the case of acting on behalf of university president

**1.4. Requirements relating to the guarantee of compliance with the terms and conditions regarding the importation or prescribing of drugs. in the Kingdom for clinical research**

1.4.1. It consists of 2 documents.

(1) Certification of compliance with the terms and conditions relating to the importation or prescription of drugs into Kingdom for Clinical Research For applicants applying for NR. Mor. Mor. 1, as detailed in **Appendix 5 ,** with the signer being the same person who signed the Nor. Mor. Mor. 1 form. (2) Certification of compliance with the terms and conditions. about bringing or ordering drugs into Kingdom for Clinical Research For the Principal Investigator at a research facility in Thailand, as detailed in **Appendix 6 ,** each institute's principal investigator must sign one document per person.

**1.5. Requirements for labels for all package sizes**

1.5.1. Labels or label images of every container and packing size shall be submitted. with a pattern like a label that actually use

1.5.2. Use Thai language except drug name/drug code. and information about research project sponsors to use Thai language or can speak english and the case of drugs administered by medical personnel Please use Thai or English. can

1.5.3. **In general cases,** the labels for both the primary and secondary packaging must contain at least the following information:

(1) Drug name/drug code, dosage strength, dosage form, route of administration. unit quantity The case for a concealed treatment research The label must be labeled **"placebo or [drug name/code].**

**+ [strength scale]"**

(2) Project code or project name (3) Production version

and/or code number to identify components and containment procedures (4) Subject number or

treatment number and appointment number (If relevant) (5) Methods of medication may be referred to documents

specifically made to explain to the subject (e.g. Medication Records) or product administration personnel. to communicate whether volunteers or personnel who are How can the drug product administrator be able to properly use the drug? (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 disclosing, concealment, treatment, emergency) unless the subject is provided with an identity card showing these information and is advised to keep this document in their possession at all times (7) the statement "Used for clinical trials. only" or other words that have the same meaning in Thai language (8) Conditions of storage of drugs (9) Period of use (10) the statement "keep out of the reach of children" or any other synonyms in Thai language except

The volunteers did not bring the medication home.

1.5.4. **In the case of primary packaging always coexisting with secondary packaging (when the packaging label In addition to the details stated in clause 1.5.3) ,** the primary packaging label must contain at least the following information:

(1) Drug name/drug code, dosage strength, pharmaceutical form Route of administration (except for oral solid dosage forms) Count amount In the case of a concealed-treatment trial, the label must include the statement **"placebo or [drug name/ identification] + [dose strength]" (2)** protocol code or protocol name (3) batch and/or number. Code to identify components and

containment procedures (4) Subject or treatment number. and appointment number (if relevant)

(5) Name of research sponsor or contract research organization or researcher

1.5.5. **In the case of primary packaging in the form of blisters or small units with an area not exceeding 3 square inches (when The outer packaging label shows the details of clause 1.5.3 and the primary packaging.** The primary packaging label must contain at least the following information :

(1) drug delivery channel (Dosage route may not be specified for oral solid dosage forms.) and in the case of open-label research, specify the drug name/drug code and strength size

(2) project code or project name (3) production version and or code number to identify components and containment procedures (4) subject number or treatment number and appointment number (if applicable) (5) Name of research sponsor or contract research organization or investigator 1.5.6. Drug labeling must be carried out in accordance with standards in the proper drug manufacturing facility. and in accordance with the Notification of the Ministry of Public Health, Re: Determination of Details on Criteria and Methods in the production of modern drugs and amendments to the criteria and methods in the production of traditional drugs in accordance with the Drug Law B.E. 2559, which states about research drug labels in Annex 12, Production of research drug products, **except in the case Preparing drugs for administering drugs at the research site requires re-labeling on the packaging to be administered,** such as preparing injections. Preparing to dispense medications for immediate oral use, etc. to be able to operate at the research site by submitting a label or a label image that has the same format as the actual label with attached standard manual Standard Operating Procedures used in the preparation and labeling of drugs, provided that the labels must comply with the guidelines above. And the labeling procedure must be carried out by a pharmacist or professional personnel. other health facilities of the research site or a properly trained research supervisor Prepare operational procedures, record practices It is checked by a second person. Labeling is strictly controlled. and the operation must be consistent with the rules and procedures for modern drug production

1.5.7. If necessary Applicants may request that the Division of Drugs consider waiving the labeling requirements as listed above only in the following cases: (1) Information on drug labels for clinical drug trials conducted in multiple countries and not can change in a timely manner when applying for permission (passing the request check and receiving into the system) times first within 30 April 2021

(2) Information on the label that may refer to other documents, such as reference methods of drug administration, records of drug use, etc. by Please attach referenced documents with an explanation.

(3) Additional labeling after the drug is imported into Thailand in order to comply with the requirements for research drug labels: 1) a label or a label image with the same format as the actual label 2) the place of operation Label the place where it is licensed to produce the correct drug, or if necessary. may request a waiver Instead, carry out labeling in places that can be controlled to meet conditions. which must be carried out by

Pharmacists or other appropriately trained research site health professionals or research supervisors establish procedures. practice notes It is inspected by a second party, labeling is strictly controlled. and the operation must be consistent with the rules and procedures for Manufacture of modern medicines 1.5.8. The request for a waiver of labeling requirements in the case of clause 1.5.7 **shall use the waiver form. Drug label requirements are specific (Appendix 21) .** In all cases, the rights, safety and well-being of the volunteers must be taken into account. as well as reliable clinical research results is important.

1.5.9. For drug labels that have been submitted to the Drug Division and are permitted to bring or order drugs into the Kingdom for research The applicant may refer to the original document if no changes have been made.

1.5.10. In the case of requesting to change the information during the period of medication use Add a label indicating the new date and use of the original production version. Submit a label or a picture of the label that has the same format as the actual label. which may overlap the original date but must not close Overlaid on the original production for quality control reasons. This must be done in an authorized facility. produce the right drug or if necessary May request a waiver of labeling operations in regulated locations. to meet the conditions instead This must be labeled by a pharmacist or other health professional. of the research site or research supervisor who has been properly trained set up operating procedures practice notes It is checked by a second person. Labeling is strictly controlled and operations must comply with the guidelines and procedures for the production of modern medicines . **Specific drug label requirements (Appendix 21))** 1.5.11. Recommendations for drugs to be used as indicated in the protocol for use according to established indications. Registered in Thailand as drugs procured from the Thai market and there is no need to

pass another manufacturing process or packing process The following text should be added to the original container, but must

does not cover the original label

(1) Name of research sponsor or research organization under contract or researcher

(2) the research project

code; (3) the statement “for clinical use only” or other words that have the same meaning in Thai

**1.6. Documentation requirements (for drugs that have already been registered)**

1.6.1. In the event that the applicant submits evidence “Pharmaceutical Quality and Production Control Documents” with reference to Registration of drug formulas in Thailand Use a drug leaflet that has been approved by the Office of the Board. food and medicine

1.6.2. In the event that the applicant submits evidence “Pharmaceutical Quality and Production Control Documents” with reference to Registration of drug formulas in foreign countries Use the drug documentation of that country. If a foreign language not english to translate into Thai or English with certifying that the text in other languages matches Thai/English

1.6.3. See “Relationship Tables between Drug Quality and Manufacturing (CMC), Drug Information Sheets (i.e., PI) and Investigator (IB) and Drug Manufacturers' documentation under “Regulations on with quality control documents and drug production

**1.7. Requirements related to research documentation (Investigator's Brochure) (for drugs that have not been taken**

The researcher's

handbook is in accordance with the ICH Good Clinical Practice Guideline (http://

drug.fda.moph.go.th/zone_asean/files/ICH_GCP_Thai version.pdf) .

1.7.2. The research manual should be reviewed at least once a year and should be revised as needed.

It is necessary and may be appropriate to update more frequently as the stage of drug development and new information increases.

1.7.3. There is evidence that the research manual has been submitted to the ethics committee, except in the case of pending approval from the relevant research ethics committee. To submit the copy that is being considered

1.7.4. Contains the following information, each section should have appropriate references.

(1) Table of Contents

(2) Conclusion

(3) Introduction

(4) Physical, chemical and pharmaceutical properties including formulations

(5) Non-human animal studies

A. Pharmacology B.

Pharmacokinetics and transformation process in laboratory animals

C. Toxicology

(6) Results of a clinical study

A. Pharmacokinetics and product transformation processes used in human research

b. Safety and Effectiveness

C. Marketing experience (7) Summary of information and

recommendations for researchers

**1.8. Requirements regarding the Patient Information Sheet (Thai language)**

1.8.1. Approved by the Human Research Ethics Committee, except in pending cases.

Approved by the relevant research ethics committee. to submit the copy that is being considered

1.8.2. Volunteer guidance documents are in accordance with the ICH Good Clinical Practice Guideline.

1.8.3. There is a language suitable for the volunteers, for example, a Thai volunteer is required to submit a Thai version, a foreign volunteer must translate it into Thai with certifying that the text in other languages is the same as the Thai language 1.8.4.

provide information and explanations during the request for consent and in the consent document including other documents to be provided to volunteers The following details must be present: (1) identifying the project as a research; (2) the purpose of the research; (3) the treatment provided in the research and the likelihood that the subject will receive one of the treatments accordingly.

Methods of random selection (4) Methods of conducting research, including various procedures. with invasive (invasive) the body of volunteer (5) Volunteer responsibilities (6) Experimental part of the research project (7) Potential risks or inconveniences to the subjects. and in some cases old Infant or fetus or infant who drinks mother's milk

(8) Reasonable expected benefits In cases where the trial does not produce clinical benefit to the subject, the subject should also be informed (9) of other alternative procedures or treatments. that volunteers may receive including the benefits and the significant risk of alternative options; (10) the compensation and/or treatment the volunteers will receive; In the event of danger resulting from Research

(11) Compensation (if any) determined on a one-time basis to study subjects (12) Various expenses (if any) to study subjects (13) Text at Indicates that subjects' participation in research is voluntary and that subjects may refuse to participate or withdraw from research at any time. without guilt or Loss of benefits that the volunteers will receive. (14) The message states that the Food and Drug Administration Research supervisors, IRB/IEC research investigators and regulatory bodies will be permitted to Check the volunteer's original medical record directly to verify the correctness of the procedure. clinical research and/or other information without violating the volunteer's right to maintain confidentiality beyond to the extent permitted by law and regulation by signing the consent document Volunteers or their legal representatives allow individuals to The above has the right to examine the medical The original record of the volunteers directly.

(15) It states that records identifying the subject's personal data will be kept confidential and will not be disclosed to the public to the extent permitted by law. and/or regulation

The law allows. in the publication of research results Volunteer personal information will remain confidential.

(16) contains a statement stating that a volunteer or a legitimate representative will be notified of new information in due time This may affect the willingness of the subjects to continue participating in the research.

(17) Person to contact for additional information on the research and the subject's rights and who to be notified in the event of harm resulting from the research;

Research (19) Estimated duration of participation in the study (20) Estimated number of subjects participating in the entire project and the number of

Volunteer at each institution in Thailand

**1.9. Requirements regarding the research project**

**summary (Thai language)** are in accordance with the form in **Appendix 7 ,** complete and signed.

**1.10. The complete Study Protocol specification**

**(Thai or English)** 1.10.1.

Approved by the Human Research Ethics Committee, except pending approval from the relevant Research Ethics Committee. Submit the latest version available.

1.10.2. The research protocol is in accordance with the ICH Good

Clinical Practice Guideline 1.10.3. It must contain detailed information. on various

topics, in the following order: (1) General Information (2) Background Information (3) Trial Objectives and Purpose ) (4) 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 (9) 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 to the trial)

(13) Data Handling and Record Keeping)

(14)Financing and Insurance (if not specified In this document may be attached separate agreements.)

(15) Publication Policy

(16) Additional details (Supplements)

**1.11. Documentation requirements for quality control and drug production**

It consists of two parts of the document:

1.11.1. Form of summary of evidence of quality control documents and drug production by drug as detailed in **Appendix 8.** The manufacturer's identification of each drug confirms that the drug to be used for research will have The manufacturer actually followed that. and must match that specified in the Excel file for the Logistic system (see additional requirements in Title 1.16)

1.11.2. Evidence of quality control and drug production documents Provide evidence of one of the following four items:

(1) Information on quality of NCE (New Chemical Entity) drugs shall show information and Details of the topics mentioned in Evidence of drug quality NCE (New Chemical Entity) **Appendix 9** for various research phases As prescribed in the table , **a certificate** must be attached . **Drugmakers' Good Manufacturing Practice issued by drug regulators** to Assemble the topic " Attestation that the dosage form was manufactured under Good Manufacturing Practices (GMP) conditions" at all times.

(2) Reference to the registration of drug formulas in Thailand by informing the registration certificate number together with a copy of the document. In this case, it can be used as a reference Only if the drug to be used for research comes from the same manufacturer. with the manufacturer listed in the drug formulary registration in Thailand

(3) Certificate of Pharmaceutical Product (CPP) (See **Annex 10)/** Certificate of Free Sale (CFS) **(see Appendix 11)** together with the Good Manufacturing Practice Certificate, in which case this may be used as a reference. Only if the drug to be used for research is from the same manufacturer as the manufacturer listed with the dependency. Overseas drug formula registration and CPP/ CFS indicate that the drug is registered for sale in the market of that country too

(4) Other evidence showing registration from the drug regulatory agency, such as information that Print from the website of the Drug Regulatory Agency (NRA) of the country in which the drug is registered.

specified in the prescription or drug label that has been registered, etc., if unable to find the document

Show the manufacturer involved in such registration, attach an additional Certificate of Analysis (COA).

Yes, in this case it can be used as a reference. Only if the drug to be used for research is from the same manufacturer as the stated manufacturer.

with the registration of drug formulas in foreign countries

1.11.3. Table showing the relationship between quality control documents and drug manufacturing (CMC) documents.

Drug information (i.e. Medication Document (PI) and Investigator's Guide (IB)) and drug manufacturer

| at | Evidence Type CMC Drug Information Sheet Drug Manufacturer | | |
|---|---|---|---|
| 1 | NCE + GMP Certificate | IB | As stated in NCE |
| 2 | Registration of drug formulas in Thailand | Thai PI | as specified in the registration of drug formulas in Thailand |
| 3 | CPP/CFS | Country PI evidence | as specified in the CPP/CFS |
| 4 | register abroad (NRA web page/ No. registered in PI or label) | Country PI evidence | as specified in the web page/ PI/ label (if The manufacturer was not found in all 3 types of evidence. The applicant verifies the manufacturer with COA). |

**1.12. Requirements for research approval documents from the Research Ethics Committee in Person (IRB/ IEC) recognized by the Food and Drug Administration**

1.12.1. The applicant is responsible for obtaining research approval from the review committee.

Research ethics in people recognized by the Food and Drug Administration and get prior approval

start research in accordance with the Notification of the Food and Drug Administration on Criteria, Methods and Conditions for Acceptance of the Research Ethics Committee on Persons Considering Clinical Research Projects.

about medicine

1.12.2. A copy of the research approval document must be submitted from the Human Research Ethics Committee.

approved by the Food and Drug Administration, Thai version. The approval document must contain information

at least as follows: (1)

Name of the Board of Directors as accepted by the Food and Drug Administration

(2) Name of research project in Thai language

(3) Researcher's name

(4) Names of all approved research sites

(5) Research project documents and related documents, including specifying the version (Version) that the Board of Directors to consider the ethics of the research in the approved

persons (6) the period of approval for the research and/or expiration date

1.12.3. Cases that are pending consideration by the Research Ethics Committee who has the right to submit The request may be submitted to the Food and Drug Administration before the Ethics Committee. In-person research can authorize or endorse a research project. The person who has the right to submit an application must comply with the conditions that The Food and Drug Administration stipulates

**1.13. Documentation requirements for drug calculation**

1.13.1. Show calculations for the number of subjects at each research site considered by the committee. research ethics approved They were calculated in accordance with the doses referred to in the protocol. properly for use throughout the duration of the study drug use and as a rule, the allowance for damage is 20%, except for the bioequivalence study to allow for one repetition, up to a maximum of 2 times.

1.13.2. In case of clinical trials for which the duration of drug administration is not specified in days, months or years Of course, the calculation should

not exceed 4 years 1.13.3. The number of permitted drugs is insufficient. The drug is damaged or the drug is expired, a new license can be applied for the missing amount. damaged or expired with reasons and relevant documentary evidence

**1.14. Power of Attorney and Power of Attorney Requirements**

1.14.1. The top executive of the agency entitled to submit an application may delegate the authority to an appropriate person to proceed, submit an application, clarify, amend, and receive documents related to the request. The **attorney should be knowledgeable. Pharmacy or medical-related fields as well as having an understanding of the request for permission and related documents** 1.14.2.

Clarification and amendment of documents for permission

1.14.3. Stamp duty 30 baht

1.14.4. A copy of the identity card of the authorized person and the attorney. With signature certifying true copy

1.14.5. One set of power of attorney is used for 1 request only **1.15. Requirements for approval documents from the relevant academic committees.**

Some drug research may be subject to special supervision, such as the AIDS vaccine. and stem cells. Special supervision, such as the Academic Subcommittee on AIDS Vaccine Testing, etc. Therefore, a copy of the document for approval or approval from the said committee must also be submitted. **1.16.Excel File Requirements for Logistic Systems** See the Excel File and Fill-in Instructions Document in the relevant Citizens Manual.

**2. Amendment/submission of additional documents according to the assessment results**

If the evaluation results from the appraiser, the applicant shall revise/clarify the issues. to the applicant/assignee The authority to take corrections/clarifications based on the assessment results within the specified time by submitting a request for amendments/clarifications additionally **(Appendix 12)** together with relevant documentary evidence. to clinical research drugs Regulatory group before going to the market, Division of Medicine

**3. Submission of the results of consideration from the Human Research Ethics Committee and relevant evidence in the case of submitting an application for bringing or ordering drugs into the Kingdom for research prior to receiving approval from Human Research Ethics Committee**

person who has been granted permission The results must be submitted for consideration by the research ethics committee. The Food and Drug Administration accepted the drug division within **15 days from the date of receiving the results of the consideration. From the Human Research Ethics Committee recognized by the Food and Drug Administration at All involved** By using the letter leading to the results of the review from the Human Research Ethics Committee **(Appendix 13)** together with the Thai version of the result of the review. and related documents in Revised research project based on the opinions of the Food and Drug Administration and the Board. Consider human research ethics with revised sections.

**4. Actions after receiving permission to bring or prescribe drugs for**

**research** After being allowed to bring or prescribe drugs for research As the case may be, the person who has been granted permission must do the following:

## 4.1. Reporting on research progress

An annual research progress report is required between **1-31 October** each year until the end of the research project by using the Research Project Progress Report Form **(Appendix 15)** and the Letter of Submission **(Appendix ). 14)** From the authorized person to the Director of the Division of Drugs Office of the Food and Drug Administration, together with a power of attorney from the authorized person to file a report and clarify. Regarding the research project report specified in the power of attorney **4.2. Requesting permission for amendment from the Food and Drug Administration before proceeding** 4.2.1.

Cases that require permission from the Food and Drug Administration Before proceeding as follows:

(1) Changes in licenses to bring or order drugs into the Kingdom for research (Form Nor Mor. Mor. 1), except information on licensees, list of drugs and quantities; (2) any changes related to quality. and safety of research drugs, such as changes in

- Expiration date or request to extend the shelf life of the drug To submit additional relevant documents such as the results of the proficiency test.

stabilized (real-time or accelerated) with reference guideline attached or the results of the test

relevant

- Text on the label Submit a label or a picture of the label with a description of the changed part. If not,

Labeling in a GMP certified facility must be accompanied by an operating procedure document of mounting.

A replacement label for the original label, which must detail the record of the operation, inspection and

Strictly controlled with the exception of non-substantial text editing and labeling operations.

GMP certified places, let us know.

- Research Drug Manufacturing Facility Provide additional relevant documentation such as a copy of the GMP

certification or a copy of the CPP document covering the GMP standard, updating manufacturer information in the NCE.

Improve the information that has been used to refer to drug production sources and Certificate of Analysis, etc.

(3) Changes in drug use across research institutions This can only be done in the event of necessity. The details

must be clearly stated, such as relevant licenses, number of research sites, reasons for necessity. preparation of drug

accounts, etc., as well as certifying that evidence will be kept and that the accounts are complete, correct and

can check

4.2.2. Preparation and inspection of documents

(1) Requesting permission to make changes Please prepare documents and evidence accordingly. **Filing check Manual Documents for Requests to Amend Items Regarding Permission Form Nor.Mor.1 / Por.Dor.8 for Human Research Studies (Appendix 16)**

(2) Submit a **request for amendment to the list of permissions under Form Nor. Mor. Mor. 1 / Por Por 8 for human research studies (Appendix 17)** 1 set.

(3) Attach relevant documents showing in the revised section and attach one power of attorney.

every time

(4) Please note that for one request, only one main issue can be amended, e.g. (This changes the quality and

results in the re-labeling of the expiration date) to be filed in 1 request, etc.

**4.3. Notifying the Food and Drug Administration for acknowledgment**

4.3.1. Cases that must be notified to the Food and Drug Administration are as follows:

(1) Update the details of the research protocol and related documents such as data sheets

For the volunteers, consent form, researcher handbook, etc., upon approval/certification from the committee.

Research ethics considered

(2) Changes in information that do not affect the quality and safety of medicines, such as

Change research sponsors Contract research company Upon approval from the review committee

research ethics

(3) Changes in the management of the research project or the conduct of the research once approved by the Research Ethics Committee, such as changing the principal investigator. Temporary cessation of accepting volunteers, etc. (4) Inspection of research by foreign regulators sending officers to inspect the site.

Research in Thailand

(5) In the case of termination or termination of the research project before the specified time However, the notice must be made within 30 days from the date of the order to terminate the project prematurely. and prepare reports accordingly termination/termination summary notification form carry out the research project **Annex 19** within 60 days from the date of termination of research at the research site where the last research was conducted in Thailand

4.3.2.Method

Notifying the Food and Drug Administration Must submit a letter of clarification and refer to the license. to bring or order medicines into the kingdom for research previously received along with attaching relevant documents by showing in the section edit or something that needs to be notified to know as detailed in **Annex 18. 4.4. Termination or termination of the research project.** Must notify the termination/termination summary of the research project. along with drug details left to destroy or return as detailed in **Annex 19 ,** within 60 days from the closing date of the research project at the last research site in Thailand.

**4.5. Reporting adverse drug reactions from the research drug**

shall be in accordance with the criteria and method for reporting adverse drug reactions from the clinical trial as detailed in **Annex 20.**

**4.6. Facilitating the staff to inspect the research (Inspection)**

The Food and Drug Administration has measures to monitor research that is permitted to be taken or ordered. Medicines entered the kingdom for research. This may be done in the pre-research period. during the research or after the end of the research or after the termination of the research project before and with a written notice of the official schedule at least 7 days in advance, except in the case that the office The Food and Drug Administration has issued a special order to monitor the research immediately, with a short notice or without prior notice.

Those who are permitted to bring or order drugs into the Kingdom for research will cooperate and facilitate. convenience for inspectors Here's an example: - Notify relevant people, such as the Principal Investigator and staff. Ethics Committee related research, etc.

- Assign a coordinator to be a representative contact with the inspector before the research review

- Send information to the inspector team in advance according to the items stated in the notification of the research inspection clinic

- Prepare various equipment and locations. 1) the following

Conference rooms for open and close meetings, surveillance, research. which will be used on the first day and day The final review of the research, respectively.

2) Room for inspectors to be able to inspect documents can during patrol

3) A computer that can be connected to the recording/reporting system of the volunteers in This research project includes both the source data and the Case Report Form. electronic-based

4) a place used for conducting each stage of a research project for monitoring, such as examination rooms, laboratory laboratories. drug storage facility, etc.

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

- Provide safe and clean lunch and drinking water in sufficient quantity and value

Appendix 1

# (copy)

## Notification of the Ministry of Public Health No. 14 (B.E. 2532) Re: Rules, Procedures and Conditions for Importing or Ordering Medicines into the Kingdom without having to register the recipe

---

By virtue of Section 79 bis (4) of the Drug Act B.E. 2510 as amended by Drug Act (No. 5), B.E. 2530, Minister of Public Health With the approval of the Drugs Committee, the announcement is issued as follows: Clause 1 In this Notification, “Drug” means modern drug. or traditional medicine “Drug manufacturing licensee” means a licensee to produce modern drugs or a licensee to produce traditional drugs. “A licensee to bring or order drugs into the Kingdom” means a person licensed to bring in or order modern drugs into the Kingdom. come into the kingdom or a person licensed to bring or order traditional drugs into the kingdom. Article 2 Bringing or ordering drugs into the kingdom that is exempted from the need to register a drug formula must be an import for research. analysis of exhibitions or charitable donations

Article 3 Bringing or ordering drugs into the Kingdom for research or analysis shall be in accordance with The requirements are as follows:

(1) The importer must be a licensed drug manufacturer. A licensee to bring or order drugs into the Kingdom

Ministries, bureaus, departments in charge of disease prevention, the Thai Red Cross Society or the Pharmaceutical Organization

(2) An importer must submit an application in the form of Nor. Mor. Mor. 1 or Nor Mor. Mor. 2 annexed to this notification. together with the evidence as specified in the Form Nor. Mor. Mor. 1 and Nor Mor. Mor. 2, as the case may be.

Clause 4 Bringing or ordering drugs into the Kingdom for the purpose of organizing an exhibition shall be in accordance with the following requirements: (1) the importer must be a production licensee. Licensee to bring or order drugs into the Kingdom, ministries, bureaus, departments in charge of prevention and treatment, the Thai Red Cross Society, the Government Pharmaceutical Organization. Associations or foundations that are juristic persons or foreign trade representatives

(2) An importer must submit an application in the form of Nor. Mor. Mor. 3 attached to this notification. with evidence as specified in the form Nov. 3

(3) The importer must bring or return all such drugs. along with sending a letter showing the introduction or delivery return to the Ministry of Public Health for acknowledgment or give it to the Ministry of Public Health within 1 month from the date of the performance The exhibition ends Article 5 Bringing or ordering drugs into the Kingdom to donate to charity in accordance with the following requirements:

(1) The importer must be a licensee to produce drugs. A licensee to bring or order drugs into the Kingdom

Ministries, Ta-buangs, Departments in charge of disease prevention, Thai Red Cross Society, Pharmaceutical Organization the Red Cross of a foreign country or

Association or foundation that is a juristic person

(2) An importer must submit an application in the form of Nor Mor. Mor. 4 attached to this notification. with evidence as specified in the form

Nov. 4

(3) Donations must be donated to ministries, bureaus, departments in charge of prevention and treatment, the Red Cross Society.

Thailand or a private hospital approved by the Ministry of Public Health

(4) The importer must submit evidence of receipt of such drug donation to the Ministry of Public Health for acknowledgment within

1 month from the date of import

Clause 6 A licensee to produce drugs or a licensee to bring or order drugs into the Kingdom shall apply for a license.

can import modern or traditional drugs for the purposes under Clause 2, only modern or traditional drugs that they

obtaining a license, as the case may be

Clause 7. An application under this Notification shall be submitted at the Drug Control Division, the Food and Drug Administration.

Ministry of Health

Clause 8 Permission. The licensor may show permission in the application for permission or may issue a license. and will be permitted with

conditions or condition of time or have both terms and conditions

Announced on May 28, 1989

(Signed) Chuan Leekpai

(Mr. Chuan Leekpai)

Minister of Health

Form N.M. 1

Receipt No.....

date.....

Signed .....Recipient of request

Type ÿ Modern medicine

ÿ traditional medicine

1. I (Mr./Mrs./Miss) .....

position .....

On behalf of ÿ Ministry ..... bureau ..... Department .....

ÿ Thai Red Cross Society ÿ Government Pharmaceutical Organization

ÿ Drug manufacturing licensee ..... license number .....

Name ÿ Licensee to bring or order medicines at a place named ..... license number .....

located at ..... alley / alley ..... road .....

No. Village ..... sub-district/sub-district ..... District/District .....

province ..... telephone ..... fax .....

wishing to apply for permission to bring or order drugs into the Kingdom for research

2. Name of research project

(English) .....

.....

(Thai language) (if any) .....

.....

3. Research project code (if any) .....

4. Research site .....

.....

5. Drug name

(1) Drug name or drug code ..... dosage form, ..... quantity ..... Details of all packing sizes .....

(2) Drug name or drug code ..... dosage form, ..... quantity ..... Details of all packing sizes .....

(3) Drug name or drug code ..... dosage form, ..... quantity ..... Details of all packing sizes .....

(4) Drug name or drug code ..... dosage form ..... quantity ..... Details of all packing sizes .....

*(In case of more details Please attach additional documents of the same format. which has a number of.....pages)*



**Application for permission to bring or order drugs into the Kingdom for research purposes** Appendix 2

6. Attached with the following evidences:

(1) Drug labels of all sizes *(Thai or English)*

(2) drug documentation (for drugs that have already been registered with the drug formula)

(3) Researcher's handbook (Investigator's Brochure) (for unregistered drugs)

(4) Volunteer recommendation document (Patient Information Sheet) (Thai language)

(5) Summary of the research project (Thai language)

(6) *Details of the research project, complete version (Thai or English).*

(7) *Documents for quality control and drug production*

(8) *Documents for research approval from the Human Research Ethics Committee (Institutional Review Board: IRB or Independent Ethics Committee: IEC) at the Board of Directors. food and drug* accepted

7. Description of the drug

| No. | Drug name or drug code | Active Ingredients | quantity per unit |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |

*(In case of more details Please attach additional documents of the same format. which has a number of.....pages)*

(signature) ---------- applicant

( ---------- )

Note: Put a checkmark ÿ in the ÿ box in front of the desired message.

Appendix 3 (Update 5 Feb. 21)

**Self-Submission Check Form for requesting**

**permission to bring or order drugs into the Kingdom for research purposes**

**(Form N.M.1)**

| | |
|---|---|
| **check number** | |
| **date** | |
| **project code** | |
| **TFDA CT no.** | |

**Part 1 Summary of Document Inspection Results (Only officials)**

| | | | |
|---|---|---|---|
| **Types of Research Drugs**<br>[ ] Biological drugs, veterinary drugs Phase 1 research drug [ ] other | **when asking for permission of the same project**<br>[ ] | **Quality data type**<br>[ ] CMC (at least one drug) [ ] Reference registration (all) | **In the case of CMC had received**<br>Has **the permission been granted before?** [ ] ever [ ] never |

| | |
|---|---|
| **Summary of document inspection results** [ ] Accepting the request (Issuing the document "Results of Application Consideration") [ ] cannot be amended on the date of submission of the application (Issuing the document "Defects Memorandum") | **request inspector**<br>)<br>dated |

**Part 2 Instructions and Procedures**

**!! Please read!!**

**Instructions for using the self-filing check form** 1. Study the details of terms and conditions in the **Notification of the Food and Drug Administration and the relevant announcement of the Drug Division.** 2. Prepare a signed Nor.Mor.1 form. 2 sets of actual documents, 1 set of other documents according to the requirements and the same files recorded on a CD

1 sheet, complete with all items Sort by document list

3. Arrange the documents according to the sequence number corresponding to the form .

- Answer **'Yes'** or **'Yes'** or ÿ means self-examined to meet the requirements - Answer **'N/A'** or **'Not applicable'** upon review and found that the requirement states that this document is not required - Reply **'Refer...'** or **'Refer...'** specify the request number or the receipt number + date of receipt. related

**Part 3 Certification of Document Preparation**

**Authorized person/authorized person ..... ..... On behalf of (organization) ..... .....**

**Call ……Fax……E-mail: … ……**

***I certify that I have studied and prepared documents in accordance with the requirements of the FDA (such as the Notification of the Food and Drug Administration and the Notification of the Drug Division), along with submitting 2 sets of the Nor Mor. Mor. 1 form and 1 other document. and the same file saved in 1 CD, complete with all items. Sort by document list and have checked by yourself according to the table in section 4.***

**…… (Eligible Person/Authorized Person) Date..... sign**

# Part 4 Checklist of Documents

| | | results check too myself | examination results by officer # 1 | # 2 | note |
|---|---|---|---|---|---|
| * | certify or certified true copy | | | | |
| ** | The same research project Someone has applied for permission to be my agency Only one agency in Thailand only (Only new projects from 1 Oct 16) | | | | |
| *** | list of imported drugs **There is at least one drug classified as a biologic drug. Animal, Phase 1 research drug?** ☐ Yes, including items in the order of ..... ☐ do not have | | | | |
| 1 | **CD recorder** | | | | |
| | 1.1 Copy of all documents submitted (MS word 1.2 Excel file for PDF file) | | | | |
| | Logistic system | | | | |
| | 1.3 Producer in the file directly to the manufacturer stated in form 11.1 | | | | |
| **2 2.1 Letter explaining the request for permission** | | | | | |
| | 1) Name of the company/organization that is eligible | | | | |
| | 2) The name of the Thai research project corresponds to EC approval or in the case of parallel submission to match the summary of the research project (Thai language) | | | | |
| | 3) Research project code (same code worldwide) | | | | |
| | 4) the time of requesting the import of the same project | | | | |
| | 5) research site | | | | |
| | 6) Specify whether to file after all ECs are approved or parallel pending EC results. | | | | |
| | 7) signed by authorized person | | | | |
| | **2.2** Order of assigning a representative to act In the event that the top executive of a ministry, department in charge of prevention and treatment, the Thai Red Cross Society or the Pharmaceutical Organization are assigned to perform duties on behalf of relating to bringing or ordering drugs into the Kingdom | | | | |
| **3 forms NM. 1 (only for this item, submit 2 sets with real signatures)** | | | | | |
| | 1) Same as the prototype form as announced by the Ministry of Public Health. | | | | |
| | 2) The name of the Thai research project corresponds to EC approval or in the case of parallel submission to match the summary of the research project (Thai language) | | | | |
| | 3) Filling out the information by typing 4) Signed | | | | |
| | by the authorized person with 2 real signatures | | | | |
| | 5) The drug list is consistent with Logistics. | | | | |
| **4 4.1 Certification of Compliance with Terms and Conditions for Applicants** **Nov. 1** | | | | | |
| | 1) The signatory is the same person who signed the Nor Mor. Mor.1 form. | | | | |
| | 2) The research project code corresponds to the research protocol. | | | | |
| | 3) Complete information | | | | |
| | 4) Content is as prescribed. | | | | |



verse **document list**

| | | results check too myself | The results of the examination by the staff | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | **4.2 Terms and Conditions Compliance Statement for researchers Principles of research sites in Thailand** | | | | |
| | 1) The research project code is consistent with the research | | | | |
| | project 2) Complete information 3) Content as specified 4) | | | | |
| | Principal investigator gave a complete endorsement at every | | | | |
| | research site **5 drug labels for all dosage sizes (Thai or** | | | | |
| | **English)** as follows:<br>1) Drug label……..…<br>2) Drug label……..… | | | | |
| | 5.1 All containers and all packing sizes with the same format as the label used.<br>TRUE | | | | |
| | 5.2 Use Thai language **except** drug name/drug code. and information of research project sponsors in Thai or English and the case of the drug Drug administration by medical personnel Can be used in Thai or English. **5.3 Secondary** | | | | |
| | **label contains (at least)** (1) drug name/code, strength, form, route of administration, | | | | |
| | dose, unit count. In case of concealment of treatment, specify: “placebo or [drug name/ code]. Medicine] + [Strength size]” | | | | |
| | (2) research project code or research project name (3) | | | | |
| | production version and or code number to identify components and packaging | | | | |
| | (4) Volunteer number or treatment number and appointment number (if relevant). to volunteers (eg medication records) or personnel who are Drug product | | | | |
| | administrator (6) Name, address and telephone number of Sponsor/CRO/Researcher unless Volunteers were issued an identity card showing these information (with attached | | | | |
| | document) | | | | |
| | (7) Statement “for clinical use only” (8) Conditions for storage | | | | |
| | of the drug (9) Specify use within date/expiration/retest date | | | | |
| | (month/year) (10) Statement “Keep out of hand children" in Thai, except for | | | | |
| | volunteers<br>did not bring the medicine home | | | | |
| | **5.4 Primary label, generic case, consisting of (at least)** (1) drug | | | | |
| | name/drug code, strength, form, route of administration, dose, unit count, in case of concealed treatment stating: “placebo or [drug name/drug code] + [Strength size]” | | | | |
| | (2) Project code or project name (3) Production version | | | | |
| | and/or code number to identify components and packaging (4) Subject number or | | | | |
| | treatment number and the appointment number (if relevant). | | | | |



verse

**document list**

| | | results check too myself | The results of the examination by the staff | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | (5) The method of use of the drug may refer to documents specifically made to describe it. to volunteers (eg medication records) or personnel who are Drug product administrator (6) Name, address and telephone number of Sponsor/CRO/Researcher unless Volunteers | | | | |
| | were issued an identity card showing these information (with attached document) | | | | |
| | (7) Statement "for clinical use only" (8) Conditions for storage of the drug | | | | |
| | (9) Specify use within date/expiration/retest date (month/year) (10) | | | | |
| | Statement "Keep out of hand children" in Thai, except for volunteers | | | | |
| | did not bring the medicine home | | | | |
| | **5.5 Primary label, in case the primary package is always co-existed with the secondary packaging, consists of (at least)** (1) drug name/code, strength, form, route of administration (except | | | | |
| | edible solids) quantity, unit count In the case of concealed treatment, specify: "placebo or [drug name/drug code] + [strength dosage]" (2) protocol code or trial name (3) batch and/or code | | | | |
| | number to identify ingredients and packaging. (4) Volunteer number or treatment number and Appointment | | | | |
| | number (if applicable). (5) Name Sponsor/CRO/Investigator **5.6 Primary label in case the primary** | | | | |
| | **package is in blister format. or a small unit with an area not exceeding 3 square inches and coexisting with Secondary packaging always contains (at least)** (1) dosing channels (except | | | | |
| | oral solids). In case of treatment disclosure, specify: drug name/drug code and dosage strength (2) | | | | |
| | research project code or research project name (3) production version and or code number to identify ingredients and packaging. | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | (4) Volunteer number or treatment number and Appointment Number (if applicable) (5) Name Sponsor/ CRO/Investigator **5.7 In the case of drug preparation for administration at the research** | | | | |
| | **site, re-labeling is required on the drug administration package** (1) Label or label image. with the | | | | |
| | same format as the actual label (2) SOP [appropriate personnel trained There are procedures, there are records, there is a second party audit. are strictly controlled and comply with GMP] **5.8 If necessary** | | | | |
| | **may be waived only in the following cases** | | | | |
| | | | | | |
| | | | | | |
| | ☐ The information on the MRCT label is waived and cannot be changed immediately upon submission. For the first time, pass the examination and get into the system within 30 April 64 - A request form for a waiver of prescription drug label requirements on a specific case | | | | |



verse

**document list**

| | | results check too myself | The results of the examination by the staff | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | ☐ Relax label information that may refer to other documents, such as instructions for giving medicine. Referring to medication records, etc.<br>- Form to request a waiver of prescription drug labeling for specific cases<br>- Reference documents are ..... ..... | | | | |
| | ☐ Additional labeling after the drug is brought into Thailand in order to comply with the regulations **[in the case of labeling in a manufacturing facility where Licensed to produce the correct drug]**<br>- A request form for a waiver of prescription drug label requirements on a specific case<br>- a label or a picture of a label that has the same format as the actual label - The place of labeling is a place that is licensed to produce the correct drug. Specify the name ..... ..... ..... modern drug production license number..... ..... - **or** in case of necessity Request a waiver of labeling operations in A place that can be controlled to satisfy conditions instead by<br>1) **State the reasons** and<br>2) Attach the **SOP** [Trained appropriate personnel, have procedures, have records, have second-party audits, are strictly controlled. and comply with GMP] **drug documentation (for drugs that have already been registered in the** | | | | |
| 6 | **drug formula)** are:<br>6.1 Drug documentation .....<br>6.2 Drug documentation ..... It | | | | |
| | belongs to the recipe register referred to in Article 11* if | | | | |
| | it is in another language. To translate into Thai / English with certifying that the text language Others correspond to Thai/English* **Researcher's handbook Investigator's** | | | | |
| 7 | **Brochure (for unregistered drugs)** Evidence that an up-to-date Investigator's Brochure has been submitted to the Board. consider ethics (except parallel filing) Table of contents | | | | |
| | Conclusion Introduction Physical, chemical, pharmaceutical properties and formulations Results of a study not conducted in humans (Animal Study) 1. Pharmacology. | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | 2. Pharmacokinetics and transformation processes in experimental animals | | | | |
| | 3. Toxicology | | | | |
| | Results of a human study (Clinical Study) 1. | | | | |
| | Pharmacokinetics and product transformation processes. | | | | |
| | 2. Safety and effectiveness | | | | |
| | 3. Marketing experience | | | | |
| | Summary of Information and Recommendations for | | | | |
| 8 | Researchers **Volunteer Information Sheet (Thai)** | | | | |



verse **document list**

| | | results check too myself | The results of the examination by the staff | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | 1) Language appropriate for subjects* 2) EC | | | | |
| | approval (except parallel submissions) 3) Estimated | | | | |
| | number of subjects participating in the entire project. and the number of volunteers in each institution in Thailand (Page.....) 4) It states that the FDA is supervising | | | | |
| | the research. Research investigators, IRB/IEC and regulatory bodies will be permitted to Check the volunteer's original medical record directly. (page.....) | | | | |
| | 5) Identified as a research 6) | | | | |
| | Research objectives 7) Treatment | | | | |
| | provided and chances of being randomly selected 8) Research | | | | |
| | methodology and invasive body 9) Responsibilities of subjects 10) Part | | | | |
| | of an Experimental Research Project 11) Possible risks or | | | | |
| | inconveniences to the subjects. or to the embryo or fetus or breast | | | | |
| | milk drinker. 12) Expected benefit. If not, notify the volunteer. 13) Alternative methods or treatments. 14) Compensation and/or treatment that the volunteer | | | | |
| | will receive. 15) Compensation (if any), which is determined on an individual basis. | | | | |
| | Time 16) Costs (if any) 17) Indicates that volunteer participation in the research is | | | | |
| | voluntary. and may refuse to participate or withdraw from the research at any time. | | | | |
| | 18) states that the subject's personal information will be kept confidential and will | | | | |
| | not disclose this information to the public beyond the extent permitted by law. | | | | |
| | Publication of research findings 19) indicates that the subjects or their legal representatives will be notified. new information in a reasonable time which may affect the willingness of 20) Persons to contact for additional information about the | | | | |
| | research and the subject's rights and who to be notified in the event of a potential hazard. | | | | |
| | | | | | |
| | research results | | | | |
| | 21) Circumstances/reasons for which subjects may be withdrawn from the study; | | | | |
| | 22) Estimated duration of participation in the study. **Summary of the research** | | | | |
| 9 | **project (Thai language) in accordance with the form prescribed by the FDA** * | | | | |
| | Part of the certification, complete information and sign 1) Name of research project | | | | |
| | in Thai 2) Name of research project in English 3) Project code (should be the | | | | |
| | same code) in all research sites of the same research framework) 4) the | | | | |
| | abbreviation of the project or another name | | | | |
| | | | | | |
| | 5) US FDA IND number | | | | |



verse **document list**

| | | results check too myself | The results of the examination by the staff | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | 6) Clinical Trials Registry 7) Type of research project | | | | |
| | | | | | |
| | 8) Type of research support 9) Country | | | | |
| | of research 10) Total number of research | | | | |
| | institutions worldwide 11) Total number of | | | | |
| | subjects worldwide according to the Plan 12) | | | | |
| | Number of research institutions in Thailand as planned | | | | |
| | 13) Information of each site Research sponsors in | | | | |
| | Thailand 14) Research sponsors in Thailand 15) | | | | |
| | Research sponsors abroad 16) Research regulatory | | | | |
| | companies (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.O.M. | | | | |
| | 1 and procurement in the country) | | | | |
| | | | | | |
| | 21) Did you use a | | | | |
| | placebo? 22) Thailand trial start date (estimated) 23) | | | | |
| | Thailand trial end date (approximate) | | | | |
| | 24) How to find volunteers | | | | |
| | 25) Financial Support and Assurance **10** | | | | |
| **Research Project Details Complete (Thai or English)** 1) EC approved | | | | | |
| | (except parallel filings) 2) General information 3) Research | | | | |
| | background 4) Objectives and aims of the research; 5) Research | | | | |
| | modeling; 6) Selection of subjects and withdrawing of subjects. | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | 7) caring for volunteers | | | | |
| | 8) efficacy evaluation | | | | |
| | 9) Safety Assessment | | | | |
| | 10) Statistics | | | | |
| | 11) Direct access to manuscript data and manuscripts 12) | | | | |
| | Quality control and quality assurance of research 13) Research- | | | | |
| | related ethics 14) Data management and record keeping 15) | | | | |
| | Financial support and assurance (If not specified in this | | | | |
| | document, a separate agreement may be attached.)* | | | | |
| | 16) Research results publication | | | | |
| | policy 17) Additional details **11** | | | | |
| **Quality control and drug production documents** | | | | | |



verse

**document list**

| | | results check too myself | The results of the examination by the staff | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | **11.1 Form of summary of evidence of drug quality and production control documents classified by drug list** | | | | |
| | - Confirmation section, fill out and sign completely - Complete | | | | |
| | information All items of drugs that will be requested for L.O.M. 1 11.2 | | | | |
| | Attached evidence of quality control documents and drug production 1) **NCE** | | | | |
| | **for Phase .....** Drugs..... ..... - Certification part, complete | | | | |
| | information and sign - The manufacturer in the evidence is the same as the | | | | |
| | manufacturer stated in Form 11.1 - GMP certificate by the government agency | | | | |
| | and has not expired - Drug Substance has complete information as specified in | | | | |
| | the sub-headings - Drug Product contains complete information in accordance | | | | |
| | with the specified sub-sections. 2) **Refer to the registration of drug formulas** | | | | |
| | **in Thailand.** (certificate number Registration .....) for medicines ..... Along with attaching a copy - the manufacturer in the evidence is the same as the manufacturer | | | | |
| | stated in Form 11.1 3) **Registration of drug formulas abroad** (CPP / CFS / evidence | | | | |
| | showing registration from the drug regulatory agency) of the drug.. ..... - Not expired - The source of production in the evidence matches the drug to be researched - In case of | | | | |
| | showing evidence showing registration from the agency website Drug supervision But the | | | | |
| | manufacturer was not identified on the website/medicine leaflet/label, attach the COA **12** | | | | |
| | **additional documents approved for research from the Human Research Ethics Committee accepted by the Food and Drug Administration (of all agencies according to the regulations) ) 12.1 Name of organization……** | | | | |
| | **12.2 Name of organization…… …. (except parallel filings, may not have or are incomplete)** 1) Thai version* 2) Name of the IRB/IEC according to the FDA's announcement 3) Name of research project 4) Name of researcher 5) Name of place All research approved. 6) Research project documents. and related documents, including specifying the version (Version) approved by the Human Research Ethics Committee. and/or expiration date **13 Documents calculating the amount of medication** | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | 1) Refer to the number of subjects as requested by the EC | | | | |
| | 2) Calculate the dosage for the entire planned program period 3) If the duration of the | | | | |
| | drug is not determined in the number of days, months, or years Of course, calculate not more than 4 years. | | | | |
| | **14 Power of Attorney** | | | | |
| | 1) Power of Attorney (Submitting an application, clarification, amendment, | | | | |

receiving documents) Attached to the Announcement of the Drug Division Re: Details of the Requirements for Importing or Ordering Drugs into the Kingdom for Clinical Research, February 5, 64, page 31

verse

**document list**

| | | results check too myself | examination results by officer | | note |
|---|---|---|---|---|---|
| | | | # 1 | # 2 | |
| | 2) Copy of the identity card of the authorized person/passport | | | | |
| | 3) A copy of the identification card of the attorney | | | | |
| | 4) Stamp duty of 30 baht per 1 attorney. | | | | |
| **15 Other (if any)** | - Documents approved by the committee or the academic sub-committee that associated with specially supervised research drugs, such as the AIDS vaccine and stem cells, etc. ..... | | | | |



verse **document list**

Appendix 4

# Notice of permission

Company / department header

date..... ...

**Subject :** Permission to bring or order drugs into the Kingdom for research purposes according to the form N.Yor.M.1

**Attention:** Secretary-General of the Food and Drug Administration

**Refer to ..... ..... .....**

**Enclosures (amount of 1 set, except for the No. Mor. Mor. 1 form, there are 2 sets) as follows:**

Document number 1 ...(specify in the list).... Document

number 2 ...(specify according to the list)....

...

Document number *N* ...(specify according to the list)....

with (name of company/agency) ..... ..... wish to request

Permission to bring or order drugs into the Kingdom for research purposes In a research project called

.....

.....

Research project code..... ..... and TFDA CT no. ..... (if any). This time is the

request for import no.....of the aforementioned research project for use at research sites ..... of ( including 1)……. 2)……..

and … ). The submission of this application is a request [ ] after all research sites have been approved by the committee. Review the

ethics of the research in the relevant person or [ ] parallel while waiting for the results of the committee. Consider research ethics in at

least one relevant person (may add further clarifications). as appropriate)

Therefore, please be informed accordingly.

Best regards

.....

(.....)

position ..... .....

Note: Please tick ÿ in [ ] or fill in the statement that matches the facts.

Appendix 5

**Certification of compliance with the terms and conditions regarding the importation or ordering of drugs into the Kingdom for clinical research For applicants who apply for N.M. 1**

I..... ..... ..... .....

On behalf of ..... has submitted an application for permission to bring or order drugs for research (Form.

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

.....

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

The Committee on Ethics for Research in Persons recognized by the Food and Drug Administration as follows:

| at | Research site (name and address) | Name of the Board of Directors<br>Research ethics in person at the office<br>Food and Drug Administration<br>Accept (Please provide full name) | the status of the consideration | |
|---|---|---|---|---|
| | | | wait | approve date |
| 1. | (Increase or decrease rows according to the number of research sites) | | [.] | [.] ..... |
| 2. | | | [.] | [.] ..... |
| 3. | | | [.] | [.] ..... |

I promise that

1. Acknowledge and will abide by the terms and conditions stated in Announcement of the Food and Drug Administration Subject Requirements for bringing or ordering drugs into the Kingdom for clinical research and announced the relevant drug division

2. Will comply with the Drug Act B.E. 2510 and related regulations

3. Will amend the relevant documents according to the opinions of the Food and Drug Administration and the Board. Consider research ethics in people recognized by the Food and Drug Administration. and bring the results of the committee's consideration

Consider the research ethics of such individuals consistent with the research sites listed in the table above as soon as possible. with attached documents

All revised to the Food and Drug Administration will display a mark on the revised or clarified statement.

Updated to be clear and detailed.

4. However, I and those involved will not begin the clinical trials process at such research sites. until approved From the Research Ethics Committee recognized by the Food and Drug Administration.

I will comply with all the assurances given. If I do not comply under any circumstances or the documents submitted are false I hereby authorize the Food and Drug Administration to revoke my aforementioned application/license, and I may be prosecute for reporting a false report to an official or for other offenses under relevant law

therefore signed as important to the staff

sign ..... ..... certifier

(..... .....) (Applicant)

Operator or the highest executive of the Thai Red Cross Society / Provincial Police / Ministry, Department in the duty of prevention and treatment

Certification date .....

Note: Please tick ý in [ ] or fill in the statement that matches the facts.

Appendix 6

**Certification of compliance with the terms and conditions regarding the importation or ordering of drugs into the Kingdom for clinical research For Principal Investigators at research sites in Thailand**

I..... ..... As the principal investigator at the research site..... ..... of the research project name (Thai language) ..... ..... ..... .. ..... research project code ..... ..... which those who have the right to apply for permission to bring or order drugs For research (Form NR.M.1) on behalf of ..... ..... ..... has submitted an application in connection with the said research project. the Food and Drug Administration

I hereby promise that 1.

I will cooperate with the person who is eligible to submit the application in compliance with the terms and conditions specified in office announcement Food and Drug Administration Re: Requirements on Importing or Prescribing Drugs into the Kingdom for Clinical Research and Announcements of Related Drug Divisions. 2. To conduct clinical research in accordance with the guidelines of good clinical research practice. (GCP) 3. Drugs shall be used only in research in accordance with the protocol of the aforementioned research program authorized by the committee secretary. 4. To amend documents related to the above research project according to the opinion of the Food and Drug Administration. and the Research Ethics Committee recognized by the Food and Drug Administration. and bring the results for consideration of the Human Research Ethics Committee to those eligible to submit the above application for filing with the Office. Food and Drug Administration Compliance

5. Documents relating to the revised research project will be used in the conduct of research only if approved by the Research Ethics Committee recognized by the Food and Drug Administration.

6. To facilitate the staff of the Food and Drug Administration to inspect the research (Inspection) both before the research. during research and after the end of the trial or after the termination of the trial;

It has been approved by the Food and Drug Administration (FDA) Ethics Review Committee. and is allowed to bring or order drugs into the kingdom for research purposes only I will comply with all the assurances given. If I do not comply under any circumstances Food and Drug Administration Drugs may order to suspend research or suspend use of the drug. as appropriate

therefore signed as important to the staff

sign ..... ..... certifier

(..... .....) (principal researcher) Research site..... .....

Date of certifying ..... .....

Note: Please tick ÿ in [ ] or fill in the statement that matches the facts.

Appendix 7

**Summary of the research project (Thai language)**

| **TFDA CT no.** | |
|---|---|
| **pick up date** | |

I hereby certify that the information about the research project or research summary (Thai language) as shown in the table below is true. This document [..] is the first time providing information on a research project specified as at ... .....

[..] counts as an update of the research project information specified as at ..... (with updated information)

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

**as soon as possible**

sign …… Applicant/Authorized Person

(……) Print

Date of certifying .....

| **Summary of the research project (Thai language)** | | |
|---|---|---|
| 1. | research project name Thai language | |
| 2. | research project name English | |
| 3. The project code, i.e. the code set by the sponsor, should be The codes used are the same across all research sites of the same protocol. | | |
| 4. Abbreviated name of the project or other names [..] are ..... ..... [..] [..] do not have | | |
| 5. US FDA IND number | have ..... ..... [..] do not have | |
| 6. Clinical Trials Registration Registry) (may be registered with Thai or foreign Registry more one of them) | *(Please specify Registry name and URL such as Thai Clinical Trial Registry(http:// www.clinicaltrials.in.th/), ClinicalTrials.gov, etc. along with registration number)* | |
| 7. Types of research projects (1-4 definitions According to ICH-E8 'General Consideration for Clinical Trials') | Phase: [..] 1 (doing the first research in person? [..] yes [..] no) [..] 2 [..] 3 [..] 4 [..] bioequivalence | |
| 8. Types of Research Support | [..] a research project initiated by a pharmaceutical company [..] a research project initiated by the researcher himself | |
| 9. Research countries 10. Total | [..] Only in Thailand [..] Research in many countries | |
| number of research institutions around the world | | |
| 11. Planned total number of volunteers worldwide | | |
| 12. Number of institutions participating in research in Thailand according to the plan | | |
| 13. Information of each research site in Thailand | | |

| **Summary of the research project (Thai language)** | | |
|---|---|---|
| research site name | number of volunteers each research site | Principal researcher's name, address, contact phone number, email |
| (1) | | Principal researcher's name, address phone. Email |
| (2) *Add/ reduce rows as appropriate* 14. Thai | | |
| Sponsor | Name of organization, address, tel. Email/Website | |
| 15. Supporting research abroad (Foreign Sponsor) | Name of organization, address, tel. Email/Website | |
| 16. Companies or agencies that monitor research (Monitor) | [ ] is the applicant [ ] is not the applicant, name of organization, address, tel. Email/Website [ ] | |
| 17. Company or administrative agency Manage research projects (Project Management) | is the applicant [ ] is not the applicant name of organization address phone. Email/Website | |
| 18. Company or administrative agency Manage data (Data Management) | [ ] is the applicant [ ] is not the applicant, name of organization, address phone. Email/Website | |

| Summary of the research project (Thai language) | |
|---|---|
| 19. Clinical Laboratory (Clinical Laboratory) | [ ] Use the clinical laboratories of each research site.<br>[ ] Use a clinical laboratory outside the research site in the country/outside the country, including:<br>1. Name of organization<br>address<br>phone.<br>Email/Website<br>2. Name of organization<br>address<br>phone.<br>Email/Website |

20. List of drugs used in the project (specify all drugs used in the project, including research drugs, comparator/placebo, and drugs used together regardless of whether or not to request permission in this request)

| Common name, strength, form drug | trade name | another name | and Washout Period (if any) | Choose only 1 item |
|---|---|---|---|---|
| (1) *FDA Amycin 10 mg.* | | *SOS-001* | *20 mg every 12 hours* | [/] research medicine<br>[..] Comparative medicine<br>[..] combination drug |
| (2) *Placebo* | | | *2 tablets every 12 hours* | [..] research medicine<br>[/] Comparative drugs<br>[..] combination drug |
| (3) *Paracetamol 500 mg* | *TYLENOL acetaminophen 500 mg every 6 hours.* | | | [..] research medicine<br>[..] Comparative medicine<br>[/] Combined drugs |
| (4) *increase/decrease rows as needed appropriate* | | | | |

| | |
|---|---|
| 21. Use a placebo? | [..] use [..] do not use |
| 22. Date of commencement of research in Thailand (approximately) | |
| 23. End date of research in Thailand (approximately) | |
| 24. How to find volunteers [..] Post an advertisement<br>[..] verbal invitation<br>[..] Others, please explain..... ..... ..... | |

| Summary of the research project (Thai language) | | |
|---|---|---|
| 25. Way Support | finance and guarantee (Financing and Insurance) | Specified in the documents approved or approved by the Ethics Committee: [..]<br>Research protocol (please specify document name, version, date, page, item) [..]<br>Information sheet for volunteers (please specify document name, version, date, page) Clause)<br>[..] other than the above, including (please specify document name, version, date, page, item) with attachment copy of documents<br>[..] if not specified in the document approved or certified by the Ethics Committee to the applicant There is a statement with evidence attached, such as an insurance policy. Related agreement documents, etc. Note: |

Please tick ÿ in [ ] or fill in the statement that corresponds to the facts.

Appendix 8

**Summary form of documented evidence of quality control and production of drugs by drug.**

We hereby certify that the information in the Summary Form of Documentation of Drug Quality and Manufacturing Segregation by Drug As the table below is true by this document.

[..] This is the first time to provide information on the specified drug as

of ..... [..] This is the update of the drug information that Specify as at ..... (with updated information)

**If there is a change of information provided I will update the document and submit it to the Food and Drug Administration. as soon as possible**

sign …….. Applicant/Authorized Person

(……)

Print, date of certifying..... .....

| **[ ] Research drug** Item ..... **[ ] Comparative drug** Item ..... **[ ] Combination drug** Item ..... | |
|---|---|
| 1. Trade name of Drug Product 2. | |
| Generic name of Drug Substance or other name (eg code) | |
| 3. Dosage Form and Strength | |
| 4. Treatment group | |
| 5. Type of medication<br>[ ] **Category 1** new research drug that has not previously been clinically researched [ ] **Category 2** new research drug with Phase 1, 2 or 3 clinical trials [ ] **Category 3** registered drug formulation drug (Thai or foreign) but is undergoing clinical research to study the indications.<br>New, new drug administration methods. or a form of a new drug, etc.<br>[ ] **Category 4** drug that has been registered as a drug formula (Thai or foreign), but used in this research project as a drug, research, comparative medicine or concomitant medications In the indications, the method of drug administration or the form of the drug that has been registered 6. | |
| Manufacturer of the drug to be imported (name, address, country) | |
| 7. Sponsor (name, address, country) 8. | |
| What country is the production version of the drug to be imported | |
| from? 9. Status of drug formulation registration in the country under Article 8 | |
| 10. Evidence of documented quality control and production of the drug attach<br>***Choose one of the four options that have the same manufacturer as confirmed in Section 6 and also match the EXCEL file for the Logistic System.** | [] NCE<br>[ ] Reference to the registration of drug formulas in Thailand (Registration Certificate No..... .....)<br>[ ] CPP / CFS with GMP certification and confirmation of sell<br>[ ] Other evidence showing registration from the agency Drug supervision Note 1) Add the same table for each drug 2) Please tick ÿ in [ ] 3) Fill in the factual statement. |

Appendix 9

# Evidence of drug quality data NCE (New Chemical Entity)

I hereby certify that the information in the accompanying qualitative evidence of NCE (New Chemical Entity) is The truth by this document

[..] This is the ~~first time giv~~en information on the specified drug as of .....

[..] counts as an ~~update on~~ the specified drug information as of ..... (with updated information)

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

**as soon as possible**

sign …… Applicant/Authorized Person

(……) Print

Date of certifying .....

| list of topics | Minimum required topics for the research phase | | |
|---|---|---|---|
| | 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 colspan="2">list of topics</th><th colspan="3">Minimum required topics for the research phase</th></tr>
<tr><th></th><th></th><th>1, BE</th><th>2</th><th>3, 4</th></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 colspan="5">S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer) ÿ ÿ ÿ</td></tr>
<tr><td></td><td>- Flow diagram of the synthetic process(es)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><td>Narrative description of the manufacturing process(es)</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.2.3 Control of Materials (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><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></td><td>Information on starting materials</td><td>- ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.2.4 Controls of Critical Steps and Intermediates (name, manufacturer)</td><td></td><td>- ÿ</td><td></td></tr>
<tr><td></td><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="2">S.3 Characterisation (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><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></td><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></td><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></td><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></td><td>- Other characteristics</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td colspan="2">S.3.2 Impurities (name, manufacturer)</td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td></td><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></td><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>

| list of topics | Minimum required topics for the research phase | | |
|---|---|---|---|
| | 1, BE | 2 | 3, 4 |
| | | | |
| List of process-related impurities (e.g., residual solvents, reagents, catalysts), including compound name and step used in synthesis | ÿ ÿ ÿ | | |
| - Actual levels of impurities (e.g., drug-related and process-related) found in batches to be used in this clinical trial | ÿ ÿ ÿ | | |
| S.4 Control of the Drug Substance (name, manufacturer) | ÿ ÿ ÿ | | |
| S.4.1 Specification (name, manufacturer) | - ÿ ÿ | | |
| Specification for the drug substance | - ÿ ÿ | | |
| S.4.2 Analytical Procedures (name, manufacturer) | - ÿ ÿ | | |
| - Summary of the analytical procedures (e.g., suitability, key method parameters, conditions) | - ÿ ÿ | | |
| S.4.3 Validation of Analytical Procedures (name, manufacturer) | - ÿ ÿ | | |
| Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results) | - ÿ ÿ | | |
| S.4.4 Batch Analyses (name, manufacturer) | ÿ ÿ ÿ | | |
| Description of the batches to be used in this clinical trial | ÿ ÿ ÿ | | |
| 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) | ÿ ÿ ÿ | | |
| S.4.5 Justification of Specification (name, manufacturer) | - ÿ ÿ | | |

| Impurity (drug-related and process-related) | Acceptance Criteria | Results (include batch number and use) (e.g., clinical) | | |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| Test | Acceptance Criteria | Analytical Procedure (Type and Source) |
|---|---|---|
| | | |
| | | |
| | | |

| Batch Number | Batch Size | Date of Manufacture and Site of Production | Use (e.g., clinical) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

<table>
<tr><th colspan="2">list of topics</th><th colspan="3">Minimum required topics for the research phase</th></tr>
<tr><th colspan="2"></th><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>- Summary of stability studies to support this clinical trial (e.g., studies conducted,</td><td>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>- The actual stability results (i.e., raw data) may be found in</td><td></td><td>ÿ ÿ ÿ</td><td></td><td></td></tr>
<tr><td>- Summary of analytical procedures and validation information for those</td><td>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><td></td><td></td><td></td><td></td></tr>
<tr><td>Quantity per unit</td><td>%</td><td>Quantity per unit</td><td>%</td></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">list of topics</th><th colspan="3">Minimum required topics for the research phase</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>list of topics</th><th>Minimum required topics for the research phase</th><th></th><th></th></tr>
<tr><th></th><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>

| list of topics | Minimum required topics for the research phase | | |
|---|---|---|---|
| | 1, BE | 2 | 3, 4 |
| Information on the characterization of impurities, not previously provided in S.3.2 (e.g., summary of actual and potential degradation products) | ÿ ÿ ÿ | | |
| P.5.6 Justification of Specification(s) (name, dosage form) | - ÿ ÿ | | |
| Justification of the drug product specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations) | - ÿ ÿ | | |
| P.7 Container Closure System (name, dosage form) | ÿ ÿ ÿ | | |
| Description of the container closure systems, including unit count or fill size, container size or volume | ÿ ÿ ÿ | | |
| Materials of construction of each primary packaging component | ÿ ÿ ÿ | | |
| For sterile products, details of washing, sterilization and depyrogenation procedures for container closures | ÿ ÿ ÿ | | |
| P.8 Stability (name, dosage form) | ÿ ÿ ÿ | | |
| P.8.1 Stability Summary and Conclusions (name, dosage form) | ÿ ÿ ÿ | | |
| - Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained) | ÿ ÿ ÿ | | |
| Description of stability study details | ÿ ÿ ÿ | | |

| Storage Conditions (°C, % RH, light) | Strength and Batch Number | Batch Size and Date of Manufacture | Container Closure System | Completed (and Proposed) Test Intervals |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

| | | | |
|---|---|---|---|
| Summary and discussion of stability study results | ÿ ÿ ÿ | | |
| Proposed storage conditions and shelf life (and in-use storage conditions and in use period, if applicable) | ÿ ÿ ÿ | | |
| P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form) ÿ ÿ ÿ | | | |
| 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 | ÿ ÿ ÿ | | |
| P.8.3 Stability Data (name, dosage form) | ÿ ÿ ÿ | | |
| - The actual stability results (i.e., raw data) may be found in | ÿ ÿ ÿ | | |
| - 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) | - ÿ ÿ | | |

ATTACHMENTS

| Attachment Number | Subject |
|---|---|
| | |

| | |
|---|---|
| | |

Appendix 10

# Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical ProductP1P

This certificate conforms to the format recommended by the World Health Organization

*(general instructions and explanatory notes attached).*

Certificate No: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredient(s)P 2 P and amount(s)P 3 P per unit dose:

_____

_____

For complete composition including excipients, see attached.P4

1.2 Is this product licensed to be placed on the market for use in the exporting country?P 5

oYes o No

1.3 Is this product actually on the market in the exporting country?

o Yes o No o unknown

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.P 6

2A.1 Number of product licenseP7 Pand date of issue :

_____

2A.2 Product-license holder (name and address):

Name: _____

Address: _____

2A.3 Status of product-license holder:P 8

of ob o c

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are : P 9

Name: _____

Address: _____

2A.4 Is Summary Basis of Approval appended?P10 P

o Yes o No

2A.5 Is the attached, officially approved product information complete and consonant with the license? P 11

(yes/no/not provided)

o Yes o No o Not provided

2A.6 Applicant for certificate, if different from license holder (name and address) :P12

Name: _____

Address: _____

2B.1 Applicant for certificate (name and address) :

Name: _____

Address: _____

2B.2 Status of applicant :P8

of ob o c

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are :P

Name: _____

Address: _____

2B.3 Why is marketing authorization lacking?

o not required o under consideration

o not requested o refused

2B.4 Remarks :P13

_____

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?P14P

o Yes o No o N/A

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years) : _____

3.2 Has the manufacture of this type of dosage form been inspected?

o Yes o No

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?P 15

o Yes o No o N/A

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?P16

If no explain: _____

Address of certifying authority:

_____

Telephone number: _____

Fax number: _____

Name of authorized person:

_____

Signature of authorized person:

_____

Stamp and date:

_____

**Explanatory notes**

1 This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2 Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

3 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4 Details of quantitative composition are preferred, but their provision is subject to the agreement of the product license holder.

5 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.

6 Sections 2A and 2B are mutually exclusive.

7 Indicate, when applicable, if the license is provisional, or the product has not yet been approved.

8 Specify whether the person responsible for placing the product on the market :

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

9 This information can be provided only with the consent of the product-license holder or, in the case of non registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

10 This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11 This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

12 In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

13 Please indicate the reason that the applicant has provided for not requesting registration :

(a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the country of export;

(b) the product has been reformulated with a view to improving its stability under tropical conditions;

(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;

(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;

(e) any other reason, please specify.

14 Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15 The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to

biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16 This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Appendix 11

**Requirements on Certificate of Free Sale** 1. CFS letter must be issued by the country of manufacture or the country of sale certified by the Food and Drug Administration. The CFS letter issued by the country of sale at the Food and Drug Administration. guarantee These are the following cases: 1.1 The product is owned by the country of purchase and has hired the country of production to be the manufacturer instead. 1.2 the country of production does not sell the product because there is no case to use the product or 1.3 other cases as The Food and Drug Administration deems appropriate. Additional documents must be attached as follows: 2.1 Certificate of origin from the country of manufacture 2.2 For pharmaceutical and food products, the following documents shall be attached: 2.2.1 Certificate from the country of manufacture that specifies the quality certificate of production according to

international standard

2.2.2 Certificate of product standard stating that it is of the same quality as the products sold in Country issuing CFS

Letters 3. CFS pursuant to Article 1 and affidavits pursuant to Article 2.1 and Article 2.2.1 must be issued or certified by a government agency that It is responsible for the supervision of that kind of health product. or a government-certified private agency. 4. The CFS letter must include the following details: 4.1 Product name 4.2 Manufacturer name and location 4.3 Meaningful statement certifying that "Available in the country of issue" 4.4 Other statements as required by each product division, such as - medicinal products, specify the active ingredient and quantity as well - medical devices, specify the model or individual products as well. CFS if in another language in addition to English, to be translated into Thai or English with

Trusted agency certifying

6. In case of using a copy of the CFS instead of the original, the statement must be certified by a government agency or private agency 7. In case of multiple products using the same CFS, the original CFS must be filed together.

A copy shall be verified by an inspector to certify the copy.

8. The CFS shall be valid within the period specified in the CFS, and in the case where the validity period is not specified, the CFS shall be filed within 2 years from the date of issuance of the CFS.

Notes according to the order of the office No. 398/2544 dated October 4, 2001, amended by the Office of Order No. 122/2548 dated February 25, 2005. and amendments according to the order of the Office No. 477/2549 dated 29 September 2549

| | |
|---|---|
| **For** the applicant/ attorney: I (name-<br>surname)..... ..... ..... On behalf<br>of ..... ..... .....<br>which is the applicant/ attorney for the request Nor Mor. Mor. 1 Receipt number at…….date of<br>receipt…….…… and was informed to amend/clarify within the date …… Please clarify<br>the issues by submitting the following documents: | **clinical research medicine**<br>**Receipt date.....**<br>**recipient..... For**<br>**the applicant Check by**<br>**yourself** (Answer ÿ means<br>Checked, omissions<br>empty = not checked, will be returned) |

| document number | document list (Please prepare, certify and verify documents by yourself) | |
|---|---|---|
| * | Sign the affidavit or certify true copy in every copy of the document. Record CD 1.1 [ ] | |
| 1 | Copy of all documents submitted (MS word 1.2 [ ] Excel file for logistic system, notice<br>(Add a list of documents as appropriate ready to check by yourself), PDF file) | |
| | | |
| 2 | | |
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*I certify that I have clarified on various issues. according to the opinion of the assessor along with submitting 1 set of documents (except the Nor Mor. Mor. 1 form, which must have 2 sets) and the same file recorded on a CD of 1 disc, complete with all items that have been notified for clarification/ correction*

sign……. **(Applicant/Authorized Person)** dated.....

**(.....)**

Note: Please tick ÿ in [ ] or fill in the statement that matches the facts.

Appendix 13

## The result of the review from the Human Research Ethics Committee

Company / department header

date..... ...

**Subject:** Request for results of consideration from the Human Research Ethics Committee (After parallel filing) **Attention:**
Secretary-General of the Food and Drug Administration

**Refer to** a license to bring or order drugs into the Kingdom for research purposes. Receipt number
at……. . **Enclosure* (amount 1 set) as follows:**

1. A copy of the license to bring or order drugs into the kingdom for research, receipt number……
Including number 2.1, the approval certificate or the result of consideration from the Human
Research Ethics Committee.....(specify name).....

No. 2.2 Volunteer recommendation document..... (Revised edition) No.
2.3 ..... (Revised version) 3. Human Research Ethics Committee.....
(Name)..... namely
No. 3.1 .....
.... CD save the files like all documents filed this time.

As permitted by the Food and Drug Administration.....<name of company/agency>.....bring Or ordering drugs into the kingdom for research (Form N.Yor.M.1) Receiving number at ..... Date of receipt..... For the research project, Thai name..... ..... ..... Research project code..... TFDA CT no. ..... (if any) as detailed in the Enclosure No. 1

Now that I have received the results of the review from the Human Research Ethics Committee, I hereby request the results of the review and all relevant documentary evidence that has been revised in my opinion. The Food and Drug Administration and the Human Research Ethics Committee are here together. has been approved [ ] some research sites specified in the license Not approved include 1)..... and

2)..... Therefore, I would like to inform the cancellation of the research facility. and certify that the drug will not be imported for use in a research facility that cancel

Please be informed accordingly.

Best regards

.....

(.....)

position .....

Note: Signed by an authorized person pursuant to clause 1.1 and marked ÿ Related text pages and fill in the correct statement according to the facts

Appendix 14

**Progress report submission letter**

Company / department header

date..... ...

**Subject:** Request to submit a research project progress report form ..... Year of the year .....

**Dear** Secretary-General of the Food and Drug Administration

**Refer to** a license to bring or order drugs into the Kingdom for research purposes. *Receipt number at…<Enter all requests>…* **Enclosures* (1 set) are as follows:**

No. 1 Research Project Progress Report Form

number 2 .....

No. 3 CD record the same file as the documents filed this time.

As permitted by the Food and Drug Administration.....<Name of company/agency>..... Bringing or ordering drugs into the Kingdom for research (Form N.Yor.M.1) Receiving number at ..... Date of receipt.....

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

.....

Research project code..... TFDA CT no. ..... (if any) as detailed in the Enclosure No. 1

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

Food and Drug Administration concerned and attached herewith

Therefore, please be informed accordingly.

Best regards

.....

(.....)

position .....

Note: Signed by the authorized person pursuant to clause 1.1 and filled in factually correct statement.

Appendix 15

**research project progress report form**

| **research project progress report form**<br><br>that is permitted to bring or order drugs into the Kingdom without having to register a formula for research | research project code ..... | Page ..... from ..... |
|---|---|---|
| | TFDA CT no. ..... | data between date<br>..... to ..... |

Refer to Form Nor. Mor. Mor. 1, receipt number at……<specify all

requests>……. authorized person ..... ..... ..... .....

(Please specify the name of the organization/company) [ ] in progress . Research project name in Thai

Overall/Global Status of Research Projects

[ ] Close as scheduled . [ ] Close early

language ..... ..... ..... ..... ..... .....

.....

| Research sponsor in Thailand<br>Name ..... .....<br>address ..... .....<br>Phone/Email ..... ..... | Research sponsor in foreign countries<br>Name ..... .....<br>address ..... .....<br>Phone/Email ..... ..... | Contract Research Company (CRO)<br>Name ..... .....<br>address ..... .....<br>Phone/Email ..... ..... | Research supervisor (Monitor) name-<br>surname ..... .....<br>Affiliated ..... ..... Phone/<br>Email ..... ..... |
|---|---|---|---|

| | | Number of volunteers (person) | | | | | | Closing date Volunteer participation (or approximate) *a* | Date of the last study subject (or approximate) *a* | status of Conduct research at each research site *b* . |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

[redacted]

# research project progress report form

that is permitted to bring or order drugs into the Kingdom without having to register a formula for research

research project code .....

Page ..... from .....

TFDA CT no. .....

data between date
..... to .....

| *N* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|

* Are there any changes? that fall within the scope of Article 4.3 in case of notification
Food and Drug Administration for acknowledgment", which has not yet been notified.
FDA or not

[ ] N/A . [ ] Yes (Attach a statement with supporting documents)

** Was there any deviation from the protocol during this reporting period?

[ ] do not have . [ ] Yes (Attach a statement with supporting documents)

*** If in doubt or there is a necessity/urgency concerning the research project
Please contact ..... .....
Responsibilities in the project are .....
Call.....Fax..... .....E-mail.....

***Additional explanation***

***a*** If there is an unidentified cause or the last volunteer has not yet been closed, state "unavailable".

***b*** e.g. "Cancelled due to lack of volunteers", "Proceeding", "Complete follow-up", "Close early.
Determined because of....." etc.

**c** Signed by an authorized person pursuant to clause 1.1 ,

please tick ÿ in [ ] and fill in factually correct statements.

**I hereby certify that all information is true.**

.....

(.....)

position..... .....

As the operator/top executive of the unitc

Appendix 16

## Document submission check form

## For requests to modify the list of permissions

## According to the form N.M.1/D.8 for human research studies.

| request for amendment regarding | |
|---|---|
| [ ] Nov. 1 [ ] Nov. 8 (Research) | |
| project code | |
| check number | |
| date | |

### Part 1 Guidance and Testimonials

**Instructions for using the self-submission check form**

1. Study the requirements in the announcement of the relevant drug division.

2. Prepare 1 set of documents according to the requirements of the announcement and the same files are recorded on a CD of 1 sheet.

complete all items Sort by document list

3. Changes that occur should be clearly displayed in the document. or have good communication for the assessors to understand easily

4. Arrange the documents in the sequence number corresponding to the form.

5. **The self-examination results** are as follows:

- Answer **'Yes'** or **'Yes'** or ÿ means self-examine and meet the requirements.

- Answer **'N/A'** or **'Not applicable' ,** upon inspection the requirement states that this document is not required.

- To answer **'Refer...'** or **'Refer...' ,** specify the request number or the receipt number + date of receipt. related

Note** Leaving it blank because the applicant did not check by himself The staff will return the request.

requirements or document preparation Please ask the staff **

Applicant/ Attorney (Name-Last Name) ..... ..... .....

On behalf of (company/organization) ..... ..... ..... .....

Tel ……..……..……Fax:……..…… ……E-mail: ……..……..……..

***I certify that I have studied and prepared the documents according to the requirements of The FDA has prepared 1 set of documents for every item and the same files are recorded on a CD of 1 sheet, complete with all items. Sort by document list and Have checked by yourself according to the table below.***

**sign ……. (Applicant/Authorized Person) Date.....**

### Part 2 Checklist of Documents

| verse | checklist | results examine by myself | examination results by Officer 1st time | 2nd time | note |
|---|---|---|---|---|---|
| * | Acknowledged that an application for amendment of the licensee, list of drugs, or amount cannot be submitted, but the former license shall be revoked and applied. new authorization | | | | |

| verse | checklist | results examine by myself | examination results by Officer 1st time | 2nd time | note |
|---|---|---|---|---|---|
| ** | Acknowledgment that a request can only be amended for one main issue, for example, in the case of requesting an extension of the drug shelf life (it is quality changes and result in the re-labeling of the expiration date) to be filed in 1 request, etc. | | | | |
| *** All copies of documents must be certified as true copies. | | | | | |
| 1 | **CD recorder** | | | | |
| | 1.1 Copy of all documents submitted (MS word 1.2 Excel . PDF file) | | | | |
| | file for Logistic system | | | | |
| 2 | **2.1 Request for amendments to the list of permissions under the Form Nor. Mor. Mor. 1 / Por Por 8 (Research)** | | | | |
| | 1) The information of the person who has the right to submit the request is the same as the person who is authorized. | | | | |
| | 2) express a will | | | | |
| | 3) Research project information (name, code, TFDA (authorization date from Oct. 2016, except for the extension of BE scope, the director will not know) | | | | |
| | 4) Identify the main clauses that need to be modified from, to, and why. | | | | |
| | 5) Are there any changes related to the main points? If so, must specify from, to, and why? | | | | |
| | 6) Identify documentary evidence | | | | |
| | 7) Hedging measures and assurances such as in the event of change That could pose a risk to research or subjects. or in the case of requesting change due to error In the case of requesting a drug across a research institute, it must Ensure that evidence is kept complete the account and can check or cases of changes that may pose a risk to research or volunteers, etc. | | | | |
| | 8) Signed by authorized person - operator - top executive at department level and above | | | | |
| | **2.2** Order of assigning a representative to act In the event that the top executive of a ministry, department in charge of disease prevention, 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** | | | | | |
| | 1) Power of Attorney (Submit an application, clarify, amend, receive documents) | | | | |
| | 2) Copy of the identity card of the authorized person/passport | | | | |
| | 3) A copy of the identification card of the attorney | | | | |
| | 4) Stamp duty of 30 baht per 1 attorney. | | | | |
| 4 | **Copy of relevant licenses** 1) | | | | |
| | Complete as specified in the amendment request letter | | | | |
| | ***(Add a list of documents as appropriate ready to check by yourself)*** | | | | |

| verse | checklist | results examine by myself | examination results by Officer | | note |
|---|---|---|---|---|---|
| | | | 1st time | 2nd time | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |

**Part 3 Summary of Document Inspection Results**

**Summary of document inspection results by staff**

[ ] Accepting the request (Issuing the document “Notification of the results of the request for medicinal products)

[ ] cannot be amended on the date of submission of the application, issuing the document “Defects memorandum and additional documents to be submitted”

**Signed** ..... **the inspector accepts the request**

(.....)

date.....

Appendix 17

**Request to modify the list of permissions**

**According to the form N.M.1/D.8 for human research studies.**

Receipt No.....

date.....

Applicant .....

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

position ----------

on behalf of

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

[ ] Thai Red Cross Society [ ] Pharmaceutical Organization

[ ] Drug manufacturing licensee [ ] ---------- license number ----------

Licensee to bring or order medicines at a place named ---------- license number ----------

2. Wish to request to amend the list of permissions according to Form [ ] Nor. Mor. Mor. 1, Receipt No. [ ] Por Por 8 for human research studies, Acceptance No. 3. For the project Name ----------

research (Thai language) ----------

---------- ----------

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

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

[ ] information in the license, **except** for the licensee, the list of drugs and the amount

[ ] drug label

[ ] drug documentation

[ ] Researcher's Manual

[ ] Volunteer recommendation document

[ ] Summary of the research project

[ ] Research project details

[ ] Documents for quality control and drug production

[ ] other (specify) ----------

from ----------

It is ----------

because ----------

and [ ] does not have [ ] there are amendments related to the above main clauses, namely: ----------

from ----------

is ----------

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

5. Documentation

evidence [ ] A copy of the license in the form of Nor. Mor. Mor. 1 / Por Mor. 8 for research studies in humans.

[ ] drug label

[ ] drug documentation

[ ] Researcher's Manual

[ ] Volunteer recommendation document

[ ] Summary of the research project

[ ] Research project details

[ ] Evidence of approval from the research ethics committee approved by the FDA

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

---

6. Risk Prevention Measures and Testimonials (if relevant) ----------

---

sign ..... ..... applicant

(.....)

Annex 18

## Sample letter of notification

Company / department header

date..... ...

**Subject:** Notifying about the importation or ordering of drugs into the Kingdom for research purposes

**Dear** Secretary General, Food and Drug Administration

**Refer to** a license to bring or order drugs into the Kingdom for research purposes. Receipt number at

…… **Enclosure (1 set) as follows:** No. 1 A copy of the license to bring or order drugs into the

kingdom for research. Receipt number at……. No. 2 ...(specify)....

...

No.... CD record files identical to all documents filed this time.

As permitted by the Food and Drug Administration.....<name of company/agency>.....bring Or ordering drugs into the kingdom for research (Form N.Yor.M.1) Receiving number at ..... Date of receipt..... For the research project, name .....<Thai name>..... ..... .....

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

I would like to inform the Food and Drug Administration of the changes that have been approved.

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

1. <Indicate what has changed, what was original, what has changed, reasons and preventive measures. Risk (if any)>

2. <Indicate what has changed, what is original, what has changed, reasons and preventive measures. Risk (if any)>

therefore learned to know

Best regards

.....

(.....)

position ..... .....

**note:** *signed by an authorized person pursuant to the provisions of Article 1.1 and fill in factually correct statements*

Appendix 19

**Form for summary notification of termination/termination of the research project**

Company / department header

date..... ...

**Subject:** Notification of the conclusion of the termination / termination of the research project

**Dear** Secretary General, Food and Drug Administration

**Refer to** a license to bring or order drugs into the Kingdom for research purposes. Receipt number

at …… **Enclosure* (1 set) as follows:** No. 1 License to bring or order drugs into the

Kingdom for research Receipt number …… (original)

...

No.... CD record files identical to all documents filed this time.

with (name of company/agency) ..... ..... licensee to bring or ordering drugs into the kingdom for research In the research project name..... .....

Research project code..... TFDA CT no. ..... (if any) The research project has now been terminated/terminated. due to*…….. The information is summarized as follows: (1) Project start date ……..Date of termination/end of the project…total period …… (2) All research sites in Thailand are …….. (3) The number of subjects receiving the drug ……. person (4) Number of subjects classified by research site as shown in the table below.

---

| list of research sites | Number of volunteers (person) | | | | |
|---|---|---|---|---|---|
| | follow target | screened | participating TRUE | who complete the research as scheduled | who left the research ahead of time |
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |
| *N* | | | | | |

(5) Actions for Volunteer Tracking In case of termination of the research project Due to the safety of research drugs according to the details in the enclosed number..... (6) There is a deviation from the research protocol that has not been reported in the research progress report form. as detailed in the accompanying number.....

(7) There is a request for permission According to the form N.M.1 For the above research project _____ times, the details are as follows.

• Pick up number _____ Date of receipt ..... Number of requests to import

_____

Research Drug Names _____ Actual amount imported

_____

• Pick up number _____ pick up date _____ Number of requests to import

_____

(may attach additional documents if multiple)

Including a list of all drugs, the list is as follows:

Research drug name 2. Research drug name Total amount (8) Total amount 1. _____ remaining _____

Actions for remaining or expired research drug therefore learned to _____ remaining _____

Best regards

.....**

(.....)

position ..... .....

**note:** ** State the reason for termination/termination of research.*

*** Signed by the person entitled to the terms in the clause 1.1 and fill in the correct statement according to the facts*

Appendix 20

**Criteria and method for reporting adverse drug reactions in clinical trials.**

ÿ. **term definition**

Definitions of terms other than this list Refer to 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 to new research drugs or new indications are all dangerous and undesirable symptoms caused by any dose. In studies, the term “drug-caused” means that there is at least a reasonable probability that an adverse reaction is a result of a drug that that study, that is, cannot be ruled out that there is no correlation.

1.1.2 Adverse drug reaction that is commercially available means any symptom that is dangerous.

or

to modify the physiological functions of the body

1.2 Unexpected Adverse Drug Reaction means an adverse reaction whose nature or severity does not correspond to the relevant product data (eg, In the investigator's handbook for research drugs that have not yet been registered as a formulation Medication document or summary Drug information that has been registered with the drug formula)

1.3 Serious Adverse Event (SAE) or Adverse Reactions Serious Adverse Drug Reaction means any medical adverse event that occurs when taking any dose and causing

(1) death

(2) is life-threatening

(3) having to stay in the hospital or have to stay in the hospital for a longer time;

(4) causing a permanent disability/important disability; or

(5) having a congenital disability/abnormality.

1.4 Date at the intersection of the annual safety data (Annual Safety Data Cut-off Date) means The due date of the security data used to make the annual security report.

ÿ. **Reporting of Adverse Reactions Occurring During Expedited Clinical Trials**

## Reporting)

Persons who are permitted to bring or order drugs into the kingdom for research/people who are licensed to produce drugs Sample request for drug formula registration (Form Por Por 8) for human research studies Responsible for monitoring Be aware of safety concerns about researched drugs. and report to the Food and Drug Administration with the following requirements: 2.1 Requirements **to be reported urgently :** 2.1.1 Unexpected serious adverse drug reactions found in Thailand, which was born from research drugs or that have been reported by other regulatory agencies or publications.

Research Drug Risks change the way the medication is administered or change the overall research operation, for example:

(1) Foreshadowed serious adverse reactions that have an increased incidence or severity and are considered clinically important; used to treat life-threatening diseases. (3) Important new information on the safety of animal studies such as

cancer

2.2 **Deadline for reporting** 2.2.1

Unexpected serious, fatal or dangerous drug adverse reactions. life threatening Must report within 7 days after the authorized person first received the information. An additional report should be submitted within the next 8 days. Periodic reports are to be made if additional information is available. 2.2.2 Unexpected serious adverse drug reactions but not fatal or dangerous life threatening Reports must be submitted within 15 days after the subject is first informed of the information. Periodic reports are to be submitted if further information is available. research is over The report must be submitted within 15 days after the authorized person receives the information for the first time. period if there is more information

## 2.3 Urgent reporting methods

2.3.1 For individual reporting, the report must be submitted via the information system of the surveillance center. Safe for health products **(http://thaihpvc.fda.moph.go.th)** Except in the case where the system is not ready for use or is disrupted, a report must be submitted in a document to the Pre-Marketing Drug Regulatory Group, Drug Division, Office of the Commission. food and medicine

2.3.2 Other reporting Make a book with information such as a summary of the issues. Risk assessment and related details Submit to the Pre-Marketing Drug Regulatory Division, Division of Medicine, Food Commission and medicine

2.3.3 Individual reporting data It must include at least the following information: (1) identifiable information such as volunteer code.

(2) drugs used in research

(3) adverse reactions or Results suspected to be related to drug which can be indicated as

Serious and unexpected events

(4) traceable source of the report.

(5) research project code or research project name

(6) a reporting number such as a report number assigned by a research sponsor.

2.3.4 Reporting research cases with concealed treatment

Submit a report that reveals the volunteer's treatment code. In the event that the code cannot be disclosed

treatment of that volunteer Submit a report that does not disclose the treatment code and submit a report that reveals the treatment code.

of the volunteers at a later time, unless the Commission deems it necessary to open the treatment code immediately.

Licensees 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 who are permitted to bring or order drugs into the kingdom for research / who are permitted to produce drug samples

To apply for drug formula registration (Form Por Por 8) for human research studies responsible for surveillance

Research Drug Safety and an annual safety data report and at the end of the research by

Gather information both domestically and internationally. Submit the drug supervision work group before going on the market, Medicine Division, Office

Food and Drug Administration with the following requirements

ÿ.ÿ Reports shall be made in the following forms: 3.1.1

Safety statement of subjects in the annual trial or at the end of the trial; 3.1.2 List of serious drug-related adverse reactions. Adverse Drug Reaction)

for each volunteer

3.1.3 Summary table of the total number of reports of serious adverse drug reactions (Serious Adverse)

Drug Reaction) by terminology (symptoms and diagnosis)

## 3.2 Reporting schedule and how to report

3.2.1 Safety report at the end of the research Reports must be made within 6 months after the research date.

Finally, the report must be submitted in a document to the Pre-Marketing Drug Regulatory Division, Drug Division, Food Commission.

and medicine

3.2.2 Annual Safety Report Must be reported within 3 months from the date of the intersection of

Annual Safety Data Cut-off Date: Submit a documented report to the group.

Drug supervision before market, Division of Medicine, Food and Drug Administration

# Annual safety report book or when the research is over.

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

date ----------

Subject: Clarification of the safety of volunteers in the annual research project/when the research ends

Attention: Pre-Marketing Drug Regulatory Division

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

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

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

company As a person who has been granted permission to [ ] bring or order drugs for research (PM1) [ ] produce sample drugs (Por. Mor.8) for human research studies

research project name ----------

---

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

There is a list of approved N.O.M. 1 as follows:

1. No. dated ---------- ----------
2. ----------

have collected and analyze the safety data and report adverse drug reactions of such trials [ ] annually or [ ] at the end of the trial.

Which consists of information between the date and the date. Therefore, would like to ~~clarify and summarize the im~~portant issues. as the following topics ----------

1. **Security Analysis (Emphasis on newly discovered issues)**

---

---

2. **Benefit-Risk Assessment (Emphasis on Volunteer Impact Assessment)**

---

---

3. **Risk Management Measures**

---

---

Please be informed accordingly. If you have any questions or suggestions (organization/company) ----------

willing to cooperate fully

sign ----------

# List of serious adverse drug reactions that occurred in each volunteer.

(Line Listing of All Suspected Serious Adverse Drug Reactions)

| The reporting period consists of | | Research Project Name (Protocol Name) |
|---|---|---|
| [ ] annual (Annual) | data between date ---------- | ---------- |
| [ ] End of research Study) | to ---------- | ---------- |
| Number of Reported Adverse Reactions (Numbers of Reports) Reference---------- | | Research project code (Protocol Code No.) ..... ..... TFDA CT no. .....(if any) |

| code volunteer (Subject Identification) | number (Case Reference No.) | country (Country) | age (Age) | sex (Sex) | daily dose (Daily Dose) | birth date Symptoms (Date of Onset) | date of receiving the drug (Dates of Treatment) | unpleasant symptoms will (Adverse Reaction) | results continue volunteer (Patient's Outcome) | Meaning cause (Comments) | open code result treatment information (Unblinding Results) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

## Summary table of total reports of serious adverse drug reactions by term (symptoms and diagnosis).

(Aggregate Summary Tabulation of All Serious Adverse Drug Reactions)

| Reporting Period | | Research Project Name (Protocol Name) |
|---|---|---|
| [ ] annual (Annual) | Contains data between dates ---------- to ---------- | ---------- |
| [ ] End of research (End of Study) | | |
| 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 trial

| **body system/adverse symptom terminology (Body system / ADR term)** | ***Research Drugs 1 (Study Drug 1)*** | ***Research Drugs 2 (Study Drug 2)*** | ***Research drugs ... (Study Drug ...)*** | ***Research Drugs N (Study Drug N)*** | **placebo (Placebo)** | **Drugs that conceal 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** | | | | | | |

** Refers to an example of a serious drug-related adverse reaction.*

Appendix 21

**Application form for waiver of prescription drug label requirements on a case-by-case basis**

*Please consult the details of label requirements for all package sizes and conditions for waiver of label requirements. Medicine is a specific case in the attachment to the announcement of the Drug Division regarding details of the requirements for importing or prescribing drugs into Kingdom for clinical research Clinical Research, Latest Issue*

**1. General information**

| | |
|---|---|
| 1.1. Information of eligible applicants | |
| Applicant's name | |
| on behalf of | |
| 1.2. Information on clinical research projects | |
| Research project name (Thai anguage)<br>Research project code | |
| | |

**2. Details requesting a waiver is a specific case** *(According to the terms and conditions in the details in the attachment to the announcement of the Drug Division)*

| | |
|---|---|
| **2.1. Name of the drug as specified in** | |
| **the request 2.1.1. Description of the request for a waiver** | |
| **2.1.2. Reason for necessity** | |
| **2.1.3. Attach the following documents for consideration:**<br>1.<br>2. | |

*Note the same schedule may be added for each drug listing.*

**3. Testimonials**

I will consider the rights, safety and well-being of volunteers. as well as research results A reliable clinic is important and will direct those involved to proceed according to the details that have been notified to the Food Commission.

and medicine

sign ..... ..... (Applicant for waiver)*

(.....)

position ..... ..

date ..... .....

* Applicants for waivers are subject to those who have the right to apply for permission Nor Mor. Mor. 1 or Mor. Mor. 8 concerned.