include form from

Documents attached to the Announcement of the Drug Division
Details of the requirements for the production of modern drug samples
for clinical research
dated 7 August 2023

** for accurate display may download fonts TH Sarabun PSK
to use in your MS Word **

Appendix 1

Form Por. 8

Receipt
No.....
date.....
Signed.....Recipient

Application for permission to produce sample drugs for drug formula registration

Written at.....

Date.....Month.....Year....

.....

I..... ..... whose name is the operator of the business ....

(name of licensee)

Permitted to produce modern drugs according to license no..... .....on pharmaceutical production facility name..... ..... Residing at number..... Alley../Alley..... ..... road..... ..... Group No..... Subdistrict / Subdistrict..... District/District..... province..... telephone..... .....

Apply for permission to produce sample drugs for registration of the drug formula named ....

Detailed list of manufactured drugs

Appearance and color of the drug .... Amount or quantity to be produced..... ..... Amount of drug constituents must be notified in metric scale in 1 unit or in percent..... .... Packing size (details of packing)..... .....

For ( ) human research studies ( ) cases other than those from human studies

(specify).....

I have attached two sets of documents/evidence as follows :

(1) drug label

(2) accompanying documents for drugs

(3) Other documents (in case of the production of drug samples for research in humans for accompanying the registration of drug formulas shall be in accordance with the announcement of the Food and Drug Administration)

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

(Signature..)..... .....Person who has duty to operate

....

Remarks: Put a tick mark ✓in the box ( ) in front of the desired message.

Appendix 2

Summary of the research project (Thai language)

(Update 7 Aug. 23)

TFDA CT no.	
date of receipt	

I hereby certify that the research project information or the research project summary (Thai language) as shown in the table below is true.

By this document

[..] For the first time , the research project data specified as of .....

[..] It is considered an update of the research project information specified on the date of .....

(with updated information display)

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.

Signed ..... Eligible person submitting request/ attorney

(..... ....) Print

Certification date..... ....

Summary of the research project (Thai language)		
1.	Thai research project name	
2.	Name of the research project in English	
3.	Program codes, i.e. those set by the sponsor, should be the same for all sites of the same protocol.	
4.	Project abbreviation or other name	[..] have , namely .... [..] none
5.	US FDA IND number	[..] have , namely .... [..] none
6.	Research registration (Clinical Trials Registry) (may be registered with a Thai or foreign registry more than one place)	*(Please specify Registry name and URL e.g. Thai Clinical Trial Registry(http://www.clinicaltrials.in.th/), ClinicalTrials.gov etc. along with registration number)*
7.	Type of trial (1-4 , as defined in ICH-E8 'General Consideration for Clinical Trials')	Phase : [..] 1 (first research on humans? [..] yes [..] no) [..] 2 [..] 3 [..] 4 [..] Bioequivalent
8.	Types of research support	[..] A research project initiated by a pharmaceutical company. [..] A research project initiated by the researcher himself.
9.	research country	[..] Only in Thailand [..] Research in many countries

Summary of the research project (Thai language)			
10.	Total number of research institutes worldwide		
11.	The total number of volunteers worldwide as planned.		
12.	Number of research institutes in Thailand as planned		
13.	Information of each research site in Thailand		
research site name		Number of subjects at each research site	Principal investigator's name, address, contact telephone number, e-mail address
(1)			Principal investigator's name address phone. Email
(2)	*Add/delete rows as appropriate.*		
14.	Research sponsors in Thailand (Thai Sponsor)	agency name address phone. Email/Website < Add more than 1 place >	
15.	Research sponsors abroad (Foreign Sponsor)	agency name address country phone. Email/Website < Add more than 1 place >	
16.	Company or agency that monitors research (Monitor)	agency name address country phone. Email/Website < Add more than 1 place >	

Summary of the research project (Thai language)		
17.	Companies or agencies that manage research projects (Project Management)	agency name address country phone. Email/Website < Add more than 1 place >
18.	Companies or departments that manage data (Data Management)	agency name address country phone. Email/Website < Add more than 1 place >
19.	laboratory All relevant (please specify whether it is used for security or effectiveness or measuring drug levels in the blood, etc.)	[ ] Use the laboratories of each research site. [ ] Use of laboratories outside of research sites in the country/abroad Including the name of the department address country phone. Email/Website < Add more than 1 place >
20.	List of drugs used in the project (List all drugs used in the project, including investigational drugs, comparator/placebo drugs, and and medicines used together regardless of whether permission is granted in this request).	

	Generic name, strength, dosage form	Trade name	another name	Medication dose and Washout Period (if any)	Choose only 1 item
(1)	*FDA Mycin 10 mg.*	-	*SOS-001*	*20 mg every 12 hrs.*	[/] research drug [..] comparative medicine [..] Medicines used together

Summary of the research project (Thai language)					
(2)	*placebo*	-	-	*2 tablets every 12 hours.*	[..] Research medicine [/] Comparative medicine [..] Medicines used together
(3)	*Paracetamol 500 mg.*	*TYLENOL*	*acetaminophen*	*500 mg. every 6 hours*	[..] Research medicine [..] comparative medicine [/] concomitant drugs
(4)	*Add/delete rows as appropriate.*				
21.	Types of main research drugs of the project	Choose 1 option [ ] Vaccines [ ] Biological drug [ ] Chemical drugs [ ] Vaccines for animals [ ] Biological drug for animals [ ] Chemical drugs for animals			
22.	Start date of research in Thailand (estimated)				
23.	End date of research in Thailand (estimated)				
24.	How to find volunteers	[..] Post an advertisement [..] invite verbally [..] Others, please explain.....			
25.	financial support	Please specify all documents showing evidence. [..] research proposal (please specify document title, version, date page clause) [..] Information sheet for volunteers (please specify document name, version, date page clause) [..] Others, please specify and attach a copy of the document.			
26.	Evidence of insurance or compensation payments in case of illness, injury, disability or death of volunteers. as a result of clinical research	Please specify all documents showing evidence. [..] insurance [..] Information sheet for volunteers (please specify document name, version, date page clause) [..] Others, please specify and attach a copy of the document.			

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

Appendix 3

Certification of Compliance with Terms and Conditions Regarding Sample Production for human research studies For applicants (Update Aug. 23)

I..... .....on behalf of .... has submitted [ ] request to expand the scope [ ] Request for permission Production of drugs upon request for a sample drug production license (Por Yor. 8) for research studies in humans.

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

.....

....

.....

research project code ....to be carried out in a research facility And under the supervision of the Human Research Ethics Committee, the Food and Drug Administration accepts the following:

at	Research site (name and address)	The name of the human research ethics committee recognized by the Food and Drug Administration. (Please provide full name)	consideration status	
			wait	approve date
1.	(Rows can be increased or decreased depending on the number of research sites.)		[.]	[.] .....
2.			[.]	[.] .....

I hereby promise that

1. Acknowledgment and will comply Drug Act B.E. 2510 and additional amendments Announcement of the Food and Drug Administration Re: Requirements for the production of modern samples of drugs for clinical research and the announcements of the related pharmaceutical divisions
2. Acknowledgment and will provide or make as well as self-checking all research documentation for compliance with Announcement of the Food and Drug Administration and the announcement of the aforementioned drug division Regardless of whether it is a document that must be submitted to the Food and Drug Administration or not. Documents must be available for research and periodic improvement as appropriate . According to the principles of the latest edition of ICH Good Clinical Practice and can support traceability at all times
3. Will revise relevant documents according to the opinions of the Food and Drug Administration and the Committee on Research Ethics in Persons that the Food and Drug Administration accepts. and submit the results of consideration by the Research Ethics Committee in accordance with the research sites listed in the table above as soon as possible in accordance with the requirements
4. In this regard, I and those involved will not initiate a clinical research process at the research facility. Until approved by the Food and Drug Administration Ethics Review Committee.

I will comply in all respects with the representations given. If I do not comply in any case or documents that are falsely submitted I consent to the Food and Drug Administration cancel the application/licence, and I may be denied the application for the registration of the drug formula and may be prosecuted for making false reports to officials or for other offenses under relevant laws

Therefore, the name is important to the staff.

sign .... testimonial

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

certification date .....

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

Appendix 4

Certification of Compliance with Terms and Conditions Regarding Sample Production for human research studies for the principal investigator

(Update Aug. 23)

I.. .... As the principal investigator at the research site..

.... of the research project name (Thai) ....

....

....

.....

research project code .... which the licensee.....

..... has filed

[ ] Scope Expansion Request [ ] Request for permission Production of drugs upon request for a sample drug production license (Por Yor. 8) for research studies in humans.

Related to the said research project to the Food and Drug Administration.

I hereby promise that

1. Will cooperate with the person who has the right to submit the request To comply with the terms and conditions specified in Announcement of the Food and Drug Administration Re: Requirements for the Production of Modern Sample Drugs for Clinical Research and announce the relevant drug divisions
2. To conduct clinical research in accordance with Latest edition of ICH Good Clinical Practice
3. The drug will be used only in research according to the research projects of the above research projects that have already been approved by the Secretary-General of the Food and Drug Administration.
4. Will revise documents related to the above research projects according to the opinions of the Food and Drug Administration and the Committee on Research Ethics in people accepted by the Food and Drug Administration. and deliver the results of the consideration of the Research Ethics Committee in such persons to those who have the right to submit the above request in order to be submitted to the Food and Drug Administration according to the requirements.
5. Documents related to the modified trial will be used in research only after approval by the Human Research Ethics Review Board of the Food and Drug Administration.
6. It will facilitate staff of the Food and Drug Administration in conducting research inspections (Inspection) both before the research. during the research and after the end of the research or after the termination of the research project
7. will not commence the clinical trial process of the above research project at the research site under my responsibility; Until approved by the Food and Drug Administration Ethics Review Committee. and allowed Only a sample drug is produced for human research studies .

I will comply in all respects with the representations given. If I do not comply in any case The Food and Drug Administration may issue an order suspending research or suspending use of a drug. As appropriate to the case

Therefore, the name is important to the staff.

sign .... testimonial

(..... .....) (Principal researcher)

Research site..... .....

Certification date.....

.....

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

Appendix 5

Application form for a specific waiver of drug label requirements

Please study the details of the requirements on labels for all sizes, packs and conditions for a waiver of drug label requirements in specific cases in the annex to the Drug Division Announcement on the details of the requirements for importing or ordering drugs into the Kingdom for clinical research or Subject: The latest version of the requirements for the production of modern samples of drugs for clinical research

1. general information

1.1. Information of the applicant	
Applicant's name	
on behalf of	
1.2. clinical trial data	
Research project name (Thai language)	
research project code	

2. Details for which a waiver is requested is a specific case. *(according to the terms and conditions detailed in the annex to the announcement of the Drug Division)*

2.1. Drug name as specified in the request	
2.1.1. Description of the request for a waiver	
2.1.2. necessity reason	
2.1.3. Attach documents for consideration as follows: 1. 2.	

Note: The same table may be added for each drug entry.

3. testimonial

I will consider the rights, safety and well-being of volunteers. Including reliable clinical research results are important and will supervise relevant parties to proceed in accordance with the details informed to the Food and Drug Administration.

sign .... (applicant of waiver)*

(..... .....)

position ....

date ....

* The applicant for a waiver is according to the person who has the right to apply for the relevant Nor.Mor.1 or Por.Mor.8 permits.

Appendix 6

Evidence of drug quality information

I certify that the information in the evidence shows the quality of the drug. Attached together with this document is true.

[..] for the first time , the drug information given as of .....

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

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.

Signed ..... Eligible person submitting request/ attorney

(..... ....) Print

Certification date..... ....

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

<table>
<tr><th colspan="2" rowspan="2">list of topics</th><th colspan="3">Minimum Required Topics for research phase</th></tr>
<tr><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.2.2 Description of Manufacturing Process and Process Controls (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Flow diagram of the synthetic process(es)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Narrative description of the manufacturing process(es)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.2.3 Control of Materials (name, manufacturer)</td><td>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Information on starting materials</td><td>-</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>-</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>-</td><td>✓</td></tr>
<tr><td colspan="2">S.3 Characterisation (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.3.1 Elucidation of Structure and other Characteristics (name, manufacturer)</td><td>✓</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>✓</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>✓</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>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Other characteristics</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.3.2 Impurities (name, manufacturer)</td><td>✓</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>✓</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>✓</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 research phase</th></tr>
<tr><th>1 , BE</th><th>2</th><th>3 , 4</th></tr>
<tr><td></td><td><table><tr><td></td><td></td><td></td></tr></table></td><td></td><td></td><td></td></tr>
<tr><td></td><td>List of process-related impurities (e.g., residual solvents, reagents, catalysts), including compound name and step used in synthesis</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Actual levels of impurities (e.g., drug-related and process-related) found in batches to be used in this clinical trial<table><tr><td rowspan="2">Impurity (drug-related and process-related)</td><td rowspan="2">Acceptance Criteria</td><td colspan="3">Results (include batch number and use) (e.g., clinical)</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4 Control of the Drug Substance (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.1 Specification (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Specification for the drug substance<table><tr><td>Test</td><td>Acceptance Criteria</td><td>Analytical Procedure (Type and Source)</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.2 Analytical Procedures (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the analytical procedures (e.g., suitability, key method parameters, conditions)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.3 Validation of Analytical Procedures (name, manufacturer)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.4 Batch Analyses (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the batches to be used in this clinical trial<table><tr><td>Batch Number</td><td>Batch Size</td><td>Date of Manufacture and Site of Production</td><td>Use (e.g., clinical)</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of results for the batches to be used in this clinical trial (should include tests, types of analytical procedures (e.g., HPLC, GC), and actual results)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.4.5 Justification of Specification (name, manufacturer)</td><td>-</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 research phase</th></tr>
<tr><th>1 , BE</th><th>2</th><th>3 , 4</th></tr>
<tr><td>-</td><td>Justification of the drug substance specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.6 Container Closure System (name, manufacturer)</td><td>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7 Stability (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7.1 Stability Summary and Conclusions (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Proposed storage conditions for the drug substance</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7.2 Stability Protocol and Stability Commitment (name, manufacturer)</td><td>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">S.7.3 Stability Data (name, manufacturer)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>The actual stability results (i.e., raw data) may be found in</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.S.4 (e.g., analytical procedures used only for stability studies)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">DRUG PRODUCT (NAME, DOSAGE FORM)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.1 Description and Composition of the Drug Product (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the dosage form</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Composition of the dosage form</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Composition, i.e., list of all components of the dosage form, and their amounts on a per unit basis (including overages, if any)
<table>
<tr><th rowspan="3">Component and Quality Standard (and Grade, if applicable)</th><th rowspan="3">Function</th><th colspan="4">Strength (label claim)</th></tr>
<tr><th colspan="2"></th><th colspan="2"></th></tr>
<tr><th>Quantity per unit</th><th>%</th><th>Quantity per unit</th><th>%</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of accompanying reconstitution diluent(s), if applicable</td><td>✓</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 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>✓</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>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.2 Pharmaceutical Development (name, dosage form)</td><td>✓</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>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For sterile, reconstituted products, summary of compatibility studies with diluents/containers</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3 Manufacture (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3.1 Manufacturer(s) (name, dosage form)</td><td>✓</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>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3.2 Batch Formula (name, dosage form)</td><td>✓</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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.3.3 Description of Manufacturing Process and Process Controls (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Flow diagram of the manufacturing process</td><td>✓</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>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For sterile products, details and conditions of sterilization and lyophilization</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4 Control of Excipients (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.1 Specifications (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.5 Excipients of Human or Animal Origin (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>List of excipients that are of human or animal origin (including country of origin)</td><td>✓</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 research phase</th></tr>
<tr><th>1 , BE</th><th>2</th><th>3 , 4</th></tr>
<tr><td>-</td><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.4.6 Novel Excipients (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5 Control of Drug Product (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.1 Specification(s) (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.2 Analytical Procedures (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of the analytical procedures (e.g., key method parameters, conditions, suitability)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.3 Validation of Analytical Procedures (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Tabulated summary of the validation information (e.g., system suitability testing, validation parameters and results)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.4 Batch Analyses (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><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>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.5 Characterisation of Impurities (name, dosage form)</td><td>✓</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 research phase</th></tr>
<tr><th>1 , BE</th><th>2</th><th>3 , 4</th></tr>
<tr><td>-</td><td>Information on the characterization of impurities, not previously provided in S.3.2 (e.g., summary of actual and potential degradation products)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.5.6 Justification of Specification(s) (name, dosage form)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Justification of the drug product specification (e.g., manufacturing experience, stability, historical batch analysis results, safety considerations)</td><td>-</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.7 Container Closure System (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Description of the container closure systems, including unit count or fill size,</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Materials of construction of each primary packaging component</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>For sterile products, details of washing, sterilization and depyrogenation procedures for container closures</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8 Stability (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8.1 Stability Summary and Conclusions (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of stability studies to support this clinical trial (e.g., studies conducted, protocols used, results obtained)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Description of stability study details
<table>
<tr><th>Storage Conditions (°C, % RH, light)</th><th>Strength and Batch Number</th><th>Batch Size and Date of Manufacture</th><th>Container Closure System</th><th>Completed (and Proposed) Test Intervals</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td></td><td>Summary and discussion of stability study results</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8.2 Post-approval Stability Protocol and Stability Commitment (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>If full long term stability data is not available at the time of filing, provide a summary of the stability protocol and a commitment that the stability of the clinical trial samples or representative batches will be monitored throughout the duration of the clinical trial or proposed shelf life</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td colspan="2">P.8.3 Stability Data (name, dosage form)</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>The actual stability results (ie, raw data) may be found in</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>-</td><td>Summary of analytical procedures and validation information for those procedures not previously summarized in 2.3.P.5 (eg, analytical procedures used only for stability studies)</td><td>-</td><td>✓</td><td>✓</td></tr>
</table>

ATTACHMENTS

Attachment Number	Subject

Appendix 7 (Revised 7 Aug. 2023) _

Document self-examination form for requesting permission to produce sample drugs (Phor Yor. 8) for human research studies

check number	
date	
project code	
TFDA CT no.	TFDA-

Part 1 Summary of document inspection results (only for officers)			
Types of drug research projects [ ] Bioequivalent [ ] Not bioequivalent/ Non-BE	**Types of Research Drugs** [ ] biological medicine [ ] Animal medicine [ ] Chemical drugs [ ] Other	**Time to ask for permission of the same project** [ ]	Non-BE case : CMC used to receive permission before or not [ ] ever [ ] never

Summary of document review results [ ] Receive the request (issuing a document "Notification of the result of the request") [ ] cannot be resolved on the date of submission of the application (issuing a document " Memorandum of Defects ")	inspector ( ) dated

Part 2 Instructions and Procedures

!! Please read !!

Guidelines for using the document self-examination form

1. **Persons eligible to submit applications are licensees to produce modern drugs.**
2. Study the details of the terms and conditions in **the announcement of the Food and Drug Administration and the relevant announcement of the Division of Drugs.**
3. Read instructions and testimonials. and fill in the information in part 3 and part 4
4. Self-inspection by **answering the self-inspection results** are as follows:
   - Answer ' **Yes** ' or ' **Yes** ' or ✓means self-check and meet the requirements.
   - Answer **'N/A'** or **' not applicable '.** Upon inspection, it was found that the requirement stated that this document was not required to be submitted.
   - Reply **' Reference... '** or **'Refer ... '** Specify the receiving request number or the receipt number + receiving date Related

Part 3 Certification of Document Preparation

Eligible person/Authorized person .... On behalf of

(Company) ....

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

I hereby certify that I have studied and prepared documents according to the requirements of the FDA (such as announcements of the Food and Drug Administration and relevant announcements of the Division of Drugs) and submitting the documents according to the list. Sort by document list and check by yourself according to the table in part 4

Signed ..... (Applicant/ Attorney) Date..... ....

Section 4 Checklist of documents

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
* 1	**About submitting this request (please fill in information)**				
	the time.....of the permission of the same project				
	☐ filed after all ECs have been approved , or ☐ Parallel waiting for EC results				
* 2	**Recording device (** in case of filing a paper form **)**				
	2 .1 Copy of all submitted documents (PDF file)				
* 3	**Form Phor.Yor.8** ☐ Paper ☐ e-sub				
	3.1 In the case of e-sub, it will create a request in the system.				
	3.2 In case of submitting a paper form Submit 2 copies of original with original signature + complete information				
* 4	**Summary of the research project (Thai language) according to the form prescribed by the Drug Division** (in case of submitting through the system will be filling information through the system)				
	* As for the testimonial, complete and sign.				
	1) Thai research project name				
	2) Name of the research project in English				
	3) Project code (should be the same code used across all sites of the same protocol)				
	4) Project abbreviation or other name				
	5) US FDA IND number				
	6) Clinical Trials Registry				
	7) type of research project				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
	8) Types of research support				
	9) research country				
	10) Total number of research institutes worldwide				
	11) The total number of volunteers worldwide as planned.				
	12) Number of research institutes in Thailand as planned				
	13) Information of each research site in Thailand				
	14) research sponsors in Thailand				
	15) Overseas Research Sponsor				
	16) Company or agency that monitors research (Monitor)				
	17) Companies or agencies that manage research projects (Project Management)				
	18) Companies or departments that manage data (Data Management)				
	19) clinical laboratory				
	20) List of drugs used in the project (both according to Nor.Yor.1 and domestic procurement)				
	21) Types of main research drugs of the project				
	22) Start date of research in Thailand (estimated)				
	23) End date of research in Thailand (estimated)				
	24) How to find volunteers				
	25) financial support + with attached documents				
	26) Evidence of insurance or compensation payments in case of illness, injury, disability or death of volunteers. as a result of clinical research + with attached documents				
* 5	**Certification of compliance with the terms and conditions for the applicant**				
	Signed by the entrepreneur who signed the Por.Por.8 form				
	1) Issue 7 Aug. 23				
	2) The research protocol code corresponds to the research protocol.				
	3) EC name matches those recognized by the FDA.				
	4) complete information				
	5) The content is as specified.				
* 6	**Certificate of Compliance for Principal Investigators**				
	1) Issue 7 Aug. 23				
	2) The research protocol code corresponds to the research protocol.				
	3) complete information				
	4) The content is as specified.				
	5) The principal investigator provided full assurance at all sites.				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
* 7	**Evidence of insurance or compensation in the event of harm.**				
* 8	**Power of Attorney** (Only in the case of submitting paper)				
	1) Power of Attorney (submit request, clarify, amend, receive document)				
	2) Copy of the attorney's ID card/passport				
	3) Copy of ID card of the attorney				
	4) Stamp duty 30 baht per 1 attorney				
* 9	**A copy of the license to produce modern drugs** (In case of submitting paper)				
	1) A copy of the current and unexpired edition.				
	2) If there is none and it is still waiting to be examined submit supporting evidence				
1 0	**Copy of GMP Certificate**				
	1) The place where the drug is produced matches the model. Nov. 8				
	2) The category of drugs that are allowed to produce corresponds to the category of drugs that have been certified.				
11	**Drug labels for every package size** (**Thai or English) namely** 1) Drug label ..... Drug label				
	11.1 Complete with all containers and sizes that have the same format as the actual label.				
	11 .2 Use Thai language, **except** drug names / drug codes and research sponsor information. Able to use Thai or English language and in the case of drugs administered by healthcare professionals Able to speak Thai or English				
	11 .3 Secondary label consisting of (at least)				
	Drug name/drug code, strength, form dosing channel unit quantity In the case of concealing treatment, specify : “placebo or [drug name/drug code] + [strength dose] ”				
	Research Project Code or Research Project Name				
	Model number and/or code number to identify components and packaging.				
	Volunteer number or treatment number and appointment number (if applicable)				
	Dosing instructions may be based on documentation that is specifically created to explain to volunteers (such as medication records) or personnel handling the drug product.				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
	Name, address and telephone number of the Sponsor/CRO/ Investigator, unless the subject has been provided with an identification card showing these (with supporting documents).				
	Message “ For Clinical Research Use Only”				
	Drug storage conditions				
	Specify use by date/expiration date/retest date (month/year)				
	The message "Keep out of the reach of children" in Thai, except that the volunteer did not take the medicine home.				
	11. 4 Primary label, in general case, include (at least)				
	Drug name/drug code, strength, form dosing channel unit quantity In the case of concealing treatment, specify : “placebo or [drug name/drug code] + [strength dose] ”				
	Research Project Code or Research Project Name				
	Model number and/or code number to identify components and packaging.				
	Volunteer number or treatment number and appointment number (if applicable)				
	Dosing instructions may be based on documentation that is specifically created to explain to volunteers (such as medication records) or personnel handling the drug product.				
	Name, address and telephone number of the Sponsor/CRO/ Investigator, unless the subject has been provided with an identification card showing these (with supporting documents).				
	Message “ For Clinical Research Use Only”				
	Drug storage conditions				
	Specify use by date/expiration date/retest date (month/year)				
	The message "Keep out of the reach of children" in Thai, except that the volunteer did not take the medicine home.				
	11.5 Primary label Where primary packaging always co-exists with secondary packaging, it contains (at least)				
	Drug name/drug code, strength, form Dosing channel (except oral solids) Unit dose In the case of concealing treatment, specify : “placebo or [drug name/drug code] + [strength dose] ”				
	Research Project Code or Research Project Name				
	Model number and/or code number to identify components and packaging.				
	Volunteer number or treatment number and appointment number (if applicable)				
	Name of Sponsor/CRO/ Investigator				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
	11. 6 Primary Label If the primary packaging is in blister or small unit form not exceeding 3 square inches and always co-locating with the secondary packaging, it contains (at least)				
	Dosing channel (except oral solids) Unit dose In case of disclosure of treatment, specify : drug name / drug code and strength				
	Research Project Code or Research Project Name				
	Model number and/or code number to identify components and packaging.				
	Volunteer number or treatment number and appointment number (if applicable)				
	Name of Sponsor/CRO/ Investigator				
	11. 7 In the case of drug preparation for drug administration at the research site, the label must be re-labeled on the packaging that will be used for drug administration. drug (To be followed, but not required to be submitted with the request)				
	The label is appropriate, correct, according to the purpose.				
	There is a SOP or a standard method that complies with GMP.				
	Operated by qualified and trained personnel				
	There is evidence of practice records. and inspection by at least a second party. under strict control				
	Keep evidence and record documents to support audits.				
	11. 8 If necessary Exemptions may be granted <u>in specific cases.</u> following				
	☐ Relax information on labels that may refer to other documents, such as medication instructions, reference medication records, etc. - Application form for a specific waiver of drug label requirements **Referenced documents include ....**				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
	☐ Additional labeling after sample drug production for registration of drug formula to **meet the requirements** **-** Application form for a specific waiver of drug label requirements **-** Labels or label images that look like actual labels **-** The labeling facility is a licensed place to produce the correct drug, name .... License to produce modern drugs number..... .... **- or** in case of necessity Request for a waiver of labeling in a place that can be controlled in accordance with the conditions instead by 1) State **the reason** and **Attach SOP [Appropriate personnel trained Procedures, records, second-party audits are in place. Strictly controlled and comply with GMP]**				
12	**Drug leaflet (for drugs for bioequivalence studies)**				
1 3	**Investigator 's Brochure (for research drugs)**				
	There is evidence that an up-to-date Investigator Handbook document has been submitted to the Ethics Review Committee. (except parallel filing)				
	Table of Contents Summary Introduction				
	Physical, chemical, pharmaceutical properties and formulations				
	Non-Human Study Results (Animal Studies)				
	1. Pharmacology				
	2. pharmacokinetics and transformation in laboratory animals				
	3. toxicology				
	Results of human studies (Clinical Study)				
	1. pharmacokinetics and product conversion processes				
	2. safety and effectiveness				
	3. marketing experience				
	Data summaries and recommendations for investigators.				
1 4	**Volunteer introduction document (Thai)**				
	1) Have a language that is appropriate for the volunteer*				
	2) EC approved (except parallel filing)				
	3) Estimated number of subjects participating in the entire project and the number of volunteers in each institution in Thailand (page.....)				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
	4) Stated that the FDA supervises research Research reviewers, IRB/IEC and regulatory bodies law It will be allowed to directly verify the subject's original medical record. (page.....)				
	5) Marked as research				
	6) Aim of the research				
	7) The treatment given and the chance to be randomly selected.				
	8) How to conduct research and invasive (invasive) bodies				
	9) Volunteer Responsibilities				
	10) part of the experimental research project				
	11) potential risks or inconveniences to subjects; or to the embryo or fetus or those who drink the mother's milk.				
	12) Expected Benefits In the event that there is none, the volunteer must be notified.				
	13) Procedures or alternative treatments				
	14) Compensation and / or treatment to be received by volunteers				
	15) Remuneration (if any) which is determined on a case-by-case basis				
	16) Various expenses (if any)				
	17) State that the subject's participation in the research is voluntary. and may refuse to participate or withdraw from the research at any time. Without fault or loss of benefits that the volunteer should receive.				
	18) Specify that personal information of volunteers will be kept confidential. and will not disclose this information to the public beyond the scope of the law. Although the research results are published				
	19) Specify that volunteers or their legal representatives will be informed of new information in due course. This may affect the subjects' willingness to continue participating in the research.				
	20) Who to contact for more information about the research and subject rights? and the person who will be notified in case of harm resulting from the research				
	21) Circumstances / reasons that may subject the subject to withdraw from the study				
	22) The length of time the subject is expected to participate in the research.				
1 5	**Details of the research project, complete version (Thai or English)**				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
	1) EC approved (except parallel filing)				
	2) general information				
	3) Research background information				
	4) Objectives and aims of the research				
	5) research modeling				
	6) Volunteer recruitment and volunteer withdrawal				
	7) volunteer care				
	8) evaluation of effectiveness				
	9) safety assessment				
	10) statistics				
	11) Direct access to original data and original documents				
	12) Quality control and quality assurance of research				
	13) ethics related to research				
	14) Data management and record keeping				
	15) Financial support and insurance (if not specified in this document Agreement made separately may be attached) *				
	16) Research Publication Policy				
	17) more details				
16	**quality control and pharmaceutical production documentation**				
	1 7. 1 case of bioequivalence studies				
	1) Batch Formula				
	2) Manufacturing Process				
	3) Finished Product Specification				
	4) Certificate of Analysis				
	1 7 .2 In addition to bioequivalence studies				
	1) NCE for Phase				
	- As for certification, complete and sign.				
	- Drug Substance contains complete information according to the specified sub-topics.				
	- Drug Product contains complete information according to the subheadings specified.				

Clause	list of documents	self-examination results	Examination results by staff		note
			# 1	# 2	
17	**Research Approval Document from the Human Research Ethics Review Committee at the Food and Drug Administration accept (of all departments) according to the requirements)** **18.1 Organization name .....** **18.2 Organization name .....** **(except parallel filing may not be available or not complete)**				
	1) Thai version*				
	2) The name of the IRB/IEC is as approved by the FDA.				
	3) research project name				
	4) Researcher's name				
	5) Names of all approved research sites.				
	6) Research Project Documents and related documents, along with identifying the version (Version) approved by the Human Research Ethics Committee.				
	7) Time period approved for research and/or expiration date				
18	**Other (if applicable)** - Approvals from academic committees or subcommittees related to specially regulated research drugs, such as AIDS vaccines. -				

Appendix 8

Amendment/Additional Clarification Request Form

for Applicant/ Attorney **:** I (name-surname)..... .... On behalf of..... ..... who is the applicant/ attorney for [ ] Application for expanding the scope of drug production according to the request for permission to produce a sample drug (Por Yor. 8) for human research studies [ ] Application for permission to produce drug samples (Por Yor. 8) for human research studies Receiving number at ..... Receiving date ..... and being informed to correct / clarify within the date ..... Please clarify the issues by submitting the following documents :	**Clinical Research Medicine Received date..... recipient..... .....**

number document	list of documents (Please prepare, certify and inspect the documents yourself.)	**for <u>the applicant</u> check it yourself** (Answer ✓means checked, blank = not checked, will return)
*	Sign the certification or certify true copies on every copy of the document.	
1	data recording device 1.1 [ ] Copies of all submitted documents (MS word , PDF file)	
	1.2 [ ] Excel file for Logistic system	
2	clarification book	
	(add a list of documents as appropriate ready to check by yourself)	

I certify that I have clarified on various issues. according to the opinion of the appraisers along with submitting complete documents for all items that have been notified for clarification/correction

Signed ..... **(Applicant/ Attorney)** dated.....

(..... .....)

<u>Note</u> : Please check mark.✓ in [ ] or fill in the text that matches the facts.

Appendix 9

Letter of submission of results of review from the Ethics Review Committee on Human Research

company header

date..... ...

Subject Requesting the results of consideration from the Human Research Ethics Review Committee (after parallel filing)

learn director of pharmaceutical division

Refer to the license to produce sample drugs (Por Yor. 8) for human research studies, receipt number ... .

Attachments* (amount 1 set) as follows:

1. A copy of the license to produce sample drugs (Por Yor. 8) for human research studies, receipt number .....
2. Human research ethics committee.....(Name)..... namely

No. 2.1 Approval or results from the ethics review committee on research in human subjects.....(name).....

No. 2.2 Volunteer recommendation document..... (revised edition)

No. 2.3 ..... (revised edition)

3. Human research ethics committee.....(Name)..... namely

No. 3.1 .....

.... Devices to record file data that are the same as all documents submitted this time.

According to the Food and Drug Administration allowed..... < Licensee > .....Producing drug samples (Por. Yor. 8) for research studies in humans, receipt number .... Date received..... For a research project in Thai name ....

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

I have now received the results of all human research ethics review committees. Therefore, the review results and all related evidence, revised in accordance with the opinions of the Food and Drug Administration and the Human Research Ethics Review Committee, are hereby attached.

In this regard, I would like to inform that

[ ] All research sites specified in the license have been approved .

[ ] Some research sites listed in the license are not approved: 1) ..... and 2) ..... I would like to inform the cancellation of the research facility. And certify that the drug will not be used in the canceled research facility.

Please be informed accordingly.

Yours sincerely

....

(..... .....)

position .....

Note : Signed by authorized persons according to the requirements in item 1.1 and marked ✓related text page and fill in the correct statement according to the facts

Appendix 10

Example of a progress report submission letter

company header

date..... ...

Subject Request for submitting a research project progress report form ..... For the year .....

learn director of pharmaceutical division

Refer to the license to produce sample drugs (Phor Yor. 8) for research studies in humans, receipt number at ...*< complete all requests >*...

Attachments* (amount 1 set) as follows:

No. 1, research project progress report form

No. 2 .....

No. 3 Recording devices, files that are the same as all documents submitted this time.

According to the Food and Drug Administration allowed..... < Name of company/organization > .....Manufacturing drug samples (Por Yor. 8) for human research studies Receipt No. .... Date received..... For a research project named..... < Name in Thai > .... Research project code..... TFDA CT no. ..... (if any) as detailed in the attachment No. 1

Now, I would like to submit the research project progress report as specified in the relevant Notification of the Food and Drug Administration and attached herewith.

Please be informed accordingly.

Yours sincerely

....

(..... .....)

position .....

Note : Signed by the authorized person according to the requirements in item 1.1 and fill in the facts that are correct.

Appendix 11

research project progress report form

<table>
<tr><td colspan="3">research project progress report form
Permitted to [ ] import drugs for research (Nor. Yor. 1) [ ] produce drug samples (Por. Yor. 8) for research studies in humans.</td><td>Research Project Code
....
TFDA CT no. .....</td><td>Page ..... of .....
data between dates
..... to .....</td></tr>
<tr><td colspan="5">Refer to the request [ ] No. Yor.M.1, receiving number at .....< Complete all requests >..... ..... [ ] Nov. 8, receiving number at .....< complete all requests >..... .....</td></tr>
<tr><td colspan="3">authorized person ....
(Please specify the name of the organization / company)</td><td colspan="2">Overall/global status of research projects
[ ] In progress . [ ] closed on schedule . [ ] close early</td></tr>
<tr><td colspan="5">Thai research project
name ....
....
.....</td></tr>
<tr><td>Research sponsor in Thailand
Name ....
.....
address ....
.....
Phone/E-mail ....</td><td>Overseas research sponsor
Name ....
.....
address ....
.....
Phone/E-mail ....</td><td>Contract Research Company (CRO)
name ....
.....
address ....
.....
Phone/E-mail ....</td><td colspan="2">Research supervisor (Monitor)
Name-
surname ....
affiliation ....
.
Phone/E-mail ....</td></tr>
<tr><td></td><td></td><td>Number of volunteers (people)</td><td></td><td></td><td></td></tr>
</table>

research project progress report form

Permitted to [ ] import drugs for research (Nor. Yor. 1) [ ] produce drug samples (Por. Yor. 8) for research studies in humans.

Research Project Code ....

Page ..... of .....

TFDA CT no. .....

data between dates ..... to .....

list of research sites	Principal Investigator's name	according to the goal	who actually participated	in the trial period	within follow-up	leaving research ahead of	who participated in the	Closing date for accepting volunteers to participate in the project (or approximately) [a]	The date of the last appointment of the last study subject. (or approximately) [a]	Status of research conduct at each research site [b]
1.										
2.										
3.										
N										

* Are there any changes? That falls under the scope of "4.3 in the event that the Food and Drug Administration is required to be informed" which has not been notified to the FDA or not?
[ ] no . [ ] Yes (attach the clarification letter with supporting documents)

** Are there any deviations from the research outline during this reporting period?
[ ] no . [ ] Yes (attach the clarification letter with supporting documents)

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

Additional explanation

I certify that all information is true.

....

<table>
<tr><td colspan="2">research project progress report form
Permitted to [ ] import drugs for research (Nor. Yor. 1) [ ] produce drug samples (Por. Yor. 8) for research studies in humans.</td><td>Research Project Code
....
TFDA CT no. .....</td><td>Page ..... of .....
data between dates
..... to .....</td></tr>
<tr><td colspan="2">*a* In the event that there are reasons that have not yet been identified or the last volunteer is not yet closed State "Unable to determine".
b e.g. " Cancelled due to lack of volunteers ", " In progress ", " Volunteers completed ", " Early closed due to..... " etc.
c Signed by the authorized person in accordance with clause 1.1.
Please select a tick ✓ in [ ] and fill in the correct information according to the facts.</td><td colspan="2">(..... .....)
position..... .....
As the operator / chief executive of agency [c]</td></tr>
</table>

Appendix 12

Guidelines for action when making changes

After obtaining permission to produce drug samples for human research studies or bringing or ordering drugs into the Kingdom for research purposes Changes may occur with regard to the drug or with respect to authorized clinical trials. The Division of Medicine has therefore prepared a guideline for changes to be used as a practical guideline. by dividing the changes into 3 groups

1.	**Noticeable changes** namely	for	
		Nov. 1	**Nov. 8**
1.1.	Any information in the research project summary (except adding research sites), some of which require approval/approval from the EC that has been accepted by the FDA, along with attached evidence, such as the name of the research project in Thai or English research project code Project abbreviation or other designation, principal investigator, or item that may result from changes to the research protocol.	✓	✓
1.2.	Abolish or reduce research facilities	✓	✓
1.3.	Investigator Handbook or Volunteer Instruction Sheet or Volunteer Drug Administration Documentation or Insurance Documentation Once approved/approved by the EC that is accepted by the FDA	✓	✓
1.4.	Permitted drug labels 1) In the event that the format has been changed but the text is still complete according to the requirements in all respects or 2) In case of correction of the name, address and telephone number of the research sponsor or contract research organization or researcher; or 3) In case of spelling mistakes In both cases, the licensee must personally verify and certify that the requirements are still met. and labeling is carried out in a GMP certified facility.	✓	✓
1.5.	Documentation In the event that academic information is updated according to the pharmacopoeia register previously referenced	✓	✓
1.6.	Change the manufacturer of Drug S ubstance of chemical pharmaceuticals in quality control and pharmaceutical production	✓	✓

1.	**Noticeable changes** namely	for	
		Nov. 1	**Nov. 8**
	documentation . The licensee must verify and certify themselves that this change does not reduce the quality of the drug.		
1.7.	Extending shelf life of an investigational drug or placebo - where stability studies have been conducted according to the stability protocol. and the analytical results are consistent with the stability specification. It is in accordance with the latest permission, Nov. 1/ Nov. 8. The licensee must verify and certify himself. whether it is in accordance with such conditions	✓	✓
1.8.	Notification of oversight of clinical trials conducted in Thailand by foreign pharmaceutical regulatory agencies (Whether arriving in person or online) must be notified as soon as known.	✓	✓
1.9.	Notify the termination or termination of the research project before the specified time. according to the plan of the research project ready to inform the cause	✓	✓
1.10.	Serious violations of the Guidelines for Good Clinical Practice (ICH GCP) or the protocol. or legal requirements This may affect the safety or well-being of volunteers. or the scientific value of clinical research. Corrective and preventive measures (CAPA) must also be declared.	✓	✓

2.	**Changes that require a change request and get permission before proceeding** namely	for	
		Nov. 1	**P.Y.8**
2.1.	Add a research site without increasing the amount of medication requested to be imported or produced	✓	✓
2.2.	Add or edit drug labels that are not subject to notification for acknowledgment.	✓	✓
2.3.	quality control and pharmaceutical production documentation (1) DS and DP producers of biological drug or (2) DP manufacturer of chemical drugs	✓	N/A
2.4.	Extending the shelf life of a research drug or placebo - The drug stability studies **did not** follow the stability protocol. The latest that was allowed Nov. 1 / Nov. 8	✓	✓
2.5.	Taking a drug from one research site quota from one license to another research site that is not covered by the same license. Even though it's the same study. Can apply for permission to change only	✓	N/A

2.	**Changes that require a change request and get permission before proceeding** namely	for	
		Nov. 1	**P.Y.8**
	in case of necessity. as well as certifying that evidence will be kept and accounts can be traced back.		
2.6.	Other changes that do not apply "Changes that must be notified " or " Changes that require a new request for approval Nov.Mor.1/Por.8 "	✓	✓

3.	**Changes that must be submitted for a new approval Nov.Mor.1/ Nov.8** namely	for	
		Nov. 1	**Nov. 8**
3.1.	Change the applicant company for the project (must cancel the original license)	✓	N/A
3.2.	Add a list of drugs or the number of drugs requested to be imported.	✓	N/A
3.3.	Change of drug formulation or product specification	✓	✓
3.4.	Increase research facilities and increase the number of drugs requested for import or production.	✓	✓
3.5.	want to produce a new original research drug for use in the original research project	N/A	✓
3.6.	Use of previously licensed drugs for use in new clinical trials	N/A	✓

* *Note* : Changes from Por.Yor.8 for bioequivalence studies. If it does not fall within the scope of " Changes that require a new production permit application", the licensee shall submit pattern change Notify for information. No need to ask for permission before proceeding. However, the licensee will Records, documents and evidence must be kept to support inspection by the Drug Division or authorized person. And still have the duty to carry out various actions to the ethics review committee for research in people that the FDA has accepted as before

Appendix 13

self-examination form

For the request to amend the details regarding permission according to Form Nor Yor. 1 / Por Yor. 8 for research studies in humans.

Request for amendment about [ ] Nov. 1 [ ] Nov. 8 (research)	
project code	
check number	
date	

Part 1 Summary of document inspection results (only for officers)	
Type of research drug (main body) [ ] biological medicine [ ] Animal drugs [ ] Chemical drugs [ ] Others	
Summary of document review results [ ] Receive the request (issuing a document “Notification of the result of the request”) [ ] cannot be resolved on the date of submission of the application (issuing a document “ Memorandum of Defects ”)	inspector ( ) dated

Part 2 Recommendations and Testimonials

Guidelines for using the document self-examination form

1. Study the requirements in the announcement of the relevant drug division.
2. Prepare documents in accordance with the requirements in the announcement. complete all items Sort by document list
3. Any changes made should be clearly visible in the document. or have good communication for the assessors to easily understand
4. Sort the documents in the order number corresponding to the form.
5. **Responses to self-check results** are as follows:
   - Answer ' **Yes** ' or ' **Yes** ' or ✓means self-check and meet the requirements.
   - Answer **'N/A'** or **' not applicable '.** Upon inspection, it was found that the requirement stated that this document was not required to be submitted.
   - Reply **' Reference... '** or **'Refer ... '** Specify the receiving request number or the receiving number + receiving date Related

Note ** Leaving blank because the applicant did not check by himself The officer will return the request, so if there is any doubt about the requirements or the preparation of documents Please ask staff **

Applicant/Attorney (name-surname) ....

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

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

We certify that we have studied and prepared documents according to the FDA regulations and have prepared every document completely. Sort by list of documents and check yourself according to the table below.

Signed ..... (Applicant/ Attorney) Date..... ....

Part 3 Checklist of documents

Clause	checklist	self-examination results	Examination results by staff		note
			1st time	2nd time	
*	Acknowledge that you cannot submit an application to change the licensee, drug list or quantity, but cancel the original license and apply for a new license.				
**	Acknowledgment that 1 request can request to change only 1 main issue, such as in the case of requesting to extend the shelf life of a drug (It is a change in quality and results in a new expiration date labeling) to be submitted in 1 request, etc.				
***	All copies of documents must be certified as true copies.				
1	**Recording device (** in case of filing a paper form **)**				
	1.1 Copies of all submitted documents (PDF file)				
	1.2 Excel file for Logistic system				
2	**2.1 Request for amendment of items related to permission according to Form Nor.Mor.1 / Por.Yor.8 (Research)** ☐ Paper ☐ e-sub				
	1) The information of the authorized person submitting the request is the same as that of the authorized person.				
	2) Express your wish				
	3) Research project information (name, code, TFDA (date of approval since Oct. 2016, except for expanding the scope of BE , the PorPorPhor. will not know)				
	4) Specify the main items to be corrected, from, to, and why.				
	5) Are there any changes related to the main issues? If so, specify from, is and why.				
	6) Identify documentary evidence				

Clause	checklist	self-examination results	Examination results by staff		note
			1st time	2nd time	
	7) Hedge measures and representations, such as cases of changes that may pose a risk to the researcher or subject. or in the case of requesting a change due to a mistake In the case of requesting drug use across research institutes must ensure that evidence is kept complete accounting and can be checked or the case of changes that may pose a risk to the researcher or subjects, for example.				
	8) Signed by authorized persons - business operators - top executives at department level and above.				
	2.2 Order of assignment of officials In the event that the top executives of the ministries, departments in charge of preventing and treating diseases, the Thai Red Cross Society or the Pharmaceutical Organization There is an assignment to perform duties on behalf of the duties related to importing or ordering drugs into the Kingdom.				
3	**Power of attorney (** in case of submitting a paper form **)**				
	1) Power of attorney (submit request, clarify, amend, receive documents)				
	2) A copy of the attorney's ID card/passport				
	3) A copy of the authorized person's ID card				
	4) stamp duty 30 baht per 1 attorney				
4	**Copies of relevant licenses**				
	1) complete as specified in the request for amendment				
	(add a list of documents as appropriate ready to check by yourself)				
5					
6					
7					
8					
9					
10					

Appendix 14

Request to amend the items regarding permission according to the form N.Y.M.1 / P.Y.8 for human research studies

Receipt
No.....
date.....
Request
recipient.....

1. I.....

   position .....

   on behalf of

   [ ] Ministry .....[ ] Department.....

   .....

   [ ] Thai Red Cross Society [ ] Government Pharmaceutical Organization

   [ ] Drug manufacturing licensee Name .....License No.....

   .....

   [ ] Licensee to bring or order drugs at the place of name, ...license number .....

2. would like to request Modify the list of permissions according to the form.

   [ ] Nov. M. 1 Receipt No.....

   .....

   [ ] Por.Por.8 for research studies in humans. Receipt No.....

   .....

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

   .....

   Research Project Code .....and TFDA CT no.....

   .....

4. Items to be amended (choose 1 main item)

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

   [ ] drug label

   [ ] Documentation

   [ ] Researcher handbook

   [ ] Volunteer introduction document

   [ ] Summary of the research project

   [ ] research project details

   [ ] quality control and pharmaceutical production documentation

[ ] other (specify).....

.....

from.....

is.....

due to.....

and [ ] None [ ] There are changes related to the above main items, including.....

.....

from.....

is .....

due to.....

5. evidence document

[ ] A copy of the license according to the Nor Yor Mor 1 / Por Yor 8 form for human research studies.

[ ] drug label

[ ] Documentation

[ ] Researcher handbook

[ ] Volunteer introduction document

[ ] Summary of the research project

[ ] research project details

[ ] Evidence of approval from the Ethics Review Committee on human subjects accepted by the FDA

[ ] Others include.....

.....

.....

6. Hedge Measures and Testimonials (if applicable).....

.....

sign .... Applicant

(..... .....)

Appendix 15

Example of a notice for acknowledgment

Company / department header

date..... ...

Subject: To notify about Produce drug samples for human research studies.

learn director of pharmaceutical division

Refer to the license to produce sample drugs (Phor Yor. 8) for research studies in humans, receipt number at ...*< complete all requests >*...

What's included (1 set) as follows:

No. 1 copy of license Production of drug samples for human research studies, receipt number at .....

Number 2 ...(approval document/certification of change from the Ethics Committee accepted by the FDA) ...

Number... ...(Specify) ....

Number... The file recording device that is the same as all documents submitted this time.

As the Food and Drug Administration allows... ..... _ _ _ _ _ _ _ _ _ ..... Date received..... For a research project named..... < Name in Thai > ....Research project code..... .. TFDA CT no. ..... (if any) that

I would like to notify the Food and Drug Administration of changes made to Approved/certified by the Research Ethics Review Committee that the Food and Drug Administration has accepted. (Attachments....) with the following items:

1. . < Specify what was changed, what was the original, what was changed, reasons, and measures to prevent risks >

2. . < Specify what was changed, what was the original, what was changed, reasons, and measures to prevent risks >

Please be informed accordingly.

Yours sincerely

....

(..... .....)

position ....

Note : *Signed by the authorized person in accordance with clause 1.1 and filled in factually correct statement.*

Appendix 16

Form to notify summary of termination / termination of the research project

Company / department header

date..... ...

Subject : Summary of the termination / termination of the research project

learn director of pharmaceutical division

Refer to the license to produce sample drugs (Por Yor. 8) for research studies in humans, receipt number .....

Attachments* (amount 1 set) as follows:

No. 1 Copy of license to produce sample drugs (Por Yor. 8) for human research studies Receipt No. .....

Number... Evidence of the return or destruction of the medication.

Number... The file recording device that is the same as all documents submitted this time.

with (name of company/organization) ....

Licensee to Production of drug samples (Por Yor. 8) for research studies in humans, receipt number ..... Date received..... For a research project named .... Research project code..... TFDA CT no. ..... (if any) has now terminated / terminated the research project due to * ....

The information is summarized as follows:

(1) Project commencement date ... . Termination date / project termination ... Total duration .....

(2) all research sites in Thailand..... Including .....

(3) Volunteers who received the drug number ..... people

(4) Number of subjects separated by research sites as shown in the table below.

list of research sites	Number of volunteers (person)				
	according to the goal	screening	who actually participated	who participated in the research as specified	leaving research ahead of time
1.					
2.					
3.					

N					

(5) Procedures for Volunteer Tracking In case of termination of the research project due to the safety of research drugs as detailed in the enclosed number.....

(6) There is a deviation from the research protocol that has not been notified in the research project progress report. as detailed in the enclosed number.....

(7) There is an application for permission. Produce drug samples (Por Yor. 8) for research studies in humans. For the above mentioned research projects ..... times, details are as follows:

Nov. 8 pick-up number	drug list	amount of medication		Actual number of drugs at the research institute		
		allowed	actually produced	get into account	pay for volunteers	remaining

(8) Procedures for remaining or expired research drugs with attached evidence

....

....

Please be informed accordingly.

Yours sincerely

....**

(..... .....)

position ....

.

Note : * *State the reason for terminating / terminating the research.*

** *signed by operator*

Appendix 17

Criteria and Method for Reporting Adverse Reactions from Drugs Investigated in Clinical Research

๑. definition of term

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

๑.๑ Adverse Drug Reaction (ADR) means

๑.๑.๑ Adverse Reactions to New Investigational Drugs or Investigational Drugs for New Indications mean All dangerous and undesirable symptoms at any dose. research The term " caused by drugs " means It is at least reasonably likely to explain that the adverse reaction is a result of the study drug. that is cannot be ruled out that there is no relationship

๑.๑.๒ Adverse reactions from drugs already on the market mean any symptoms Whatever the dangers and unwanted arising from the use of the drug in normal doses, both for prevention. diagnosis or disease treatment or to modify the physiological functions of the body

๑.๒ Unexpected Adverse Drug Reaction means an adverse reaction whose nature or severity is not consistent with the relevant product information (e.g. information in the investigator's leaflet for a drug). In research that has not yet been registered with a medicinal formula Documentation or a summary of drug information that has been registered for the drug formula)

๑.๓ Serious Adverse Event (SAE) or Serious Adverse Drug Reaction means any adverse event. Clinically occurring when taking any dose of the drug and causing

(๑) Died

(๒) life threatening

(๓) having to stay in hospital or have to stay in the hospital longer

(๔) significant permanent disability / disability; or

(๕) Birth defects / congenital abnormalities

๑.๔ Annual Safety Data Cut -off Date means The annual due date of the security data used for the annual security report.

๒. Expedited Reporting of Adverse Reactions During Clinical Trials

Persons allowed to import or order drugs into the Kingdom for research purposes / Persons permitted to produce sample drugs for registration of drug formulations (Form Por Yor. 8) for research studies in humans Responsible for safety surveillance of research drugs. and report to the Food and Drug Administration. with the following requirements

๒.๑ **Things that need to be reported urgently** include:

๒.๑.๑ Unexpected Serious Adverse Drug Reactions found in Thailand caused by research drugs or that has been reported by other regulators or publications

๒.๑.๒ Other safety features include safety data that altered the benefit-risk assessment of the investigational drug. change the way the drug is administered or change the overall research such as

(๑) Anticipated Serious Adverse Reactions with increased incidence or violence and considered clinically important.

(๒) Significant harm to subjects, such as the ineffectiveness of drugs used to treat life-threatening diseases.

(๓) Important new safety information from animal studies such as carcinogenicity.

๒.๒ **Reporting deadline**

๒.๒.๑ Serious, unexpected adverse drug reactions that are fatal or life-threatening. Must report within 7 days after the authorized person first receives the information. and submit additional reports within 8 days. However, reports will be sent periodically if there is additional information.

๒.๒.๒ Serious adverse drug reactions that were unexpected but not fatal or life threatening. The report must be submitted within 15 days after the authorized person first receives the information.

๒.๒.๓ Adverse reactions occurring after the subject has left the study or the study has ended. The report must be submitted within 15 days after the authorized person first receives the information.

๒.๓ **How to report urgently**

๒.๓.๑ Individual reports must be submitted via the information system of the Health Product Safety Surveillance Center **(http://thaihpvc.fda.moph.go.th)** , except in the event

that the system is unavailable or crashes. Submit a document report to the New Drug and Drug Research Promotion Division, Drug Division, Office of the Food and Drug Administration.

๒.๓.๒ other reporting Make a book with information such as a summary of the problem. risk assessment And related details Submit New Drugs and Drug Research Promotion, Drug Division, Food and Drug Administration

๒.๓.๓ individual reporting information It must contain at least the following information:

(๑) Information that identifies the volunteer, such as a volunteer ID.

(๒) Research drugs

(๓) Adverse symptoms or Results suspected to be related to medication This can indicate a serious and unexpected event.

(๔) Trackable report sources

(๕) Research project code or name of the research project

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

๒.๓.๔ Reporting research cases where treatment is concealed

Submit a report that reveals the subject's treatment code. In the event that the subject's treatment code has not yet been disclosed Submit a report in which the treatment code has not been disclosed, and a report revealing the subject's treatment code shall be submitted thereafter, unless the Board deems it appropriate to immediately release the treatment code. The authorized person must disclose the treatment code to the Food and Drug Administration as soon as possible.

๓. Annual Safety Report and End of Study Safety Report

Persons allowed to import or order drugs into the Kingdom for research purposes / Persons permitted to produce sample drugs for registration of drug formulations (Form Por Yor. 8) for research studies in humans Responsible for safety surveillance of research drugs. And the annual safety data report and when the research ends by collecting data from both domestic and foreign countries, sending new drug groups and promoting drug research, Drug Division, Food and Drug Administration with the following requirements

๓.๑ **The report shall be made in the** following form:

๓.๑.๑ Statement of subject safety during the annual trial or at the end of the trial.

๓.๑.๒ List of serious adverse drug reactions (Serious Adverse Drug Reaction) for each subject.

๓.๑.๓ Reaction Summary Table by Terminology (Symptoms and Diagnosis)

๓.๒ **report schedule and how to report**

๓.๒.๑ safety report at the end of the study Must report within 6 months after the end of the study Submit a document report to the New Drug and Drug Research Promotion Division, Drug Division, Office of the Food and Drug Administration.

๓.๒.๒ Annual safety report Must report within 3 Months from the date of the cut-off date of the annual safety data (Annual Safety Data Cut-off Date), submit a document report to the New Drug and Drug Research Promotion Division, Drug Division, Food and Drug Administration.

annual safety report book or at the end of the research

Written at (name of department/company, address, telephone number)

date .....

Subject: Clarification of the safety of subjects in the annual trial/at the end of the trial

Dear Head of New Drug and Drug Research Promotion Group

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

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

According to the agency/company .....As a person authorized to [ ] bring or order drugs for research (Nor. Yor. 1) [ ] produce sample drugs (Por. Yor. 8) for research studies in humans.

research project name.....

.....

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

There is a list of No. Yor. Mor. 1 permitted as follows:

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

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

.....

To date, ...I would like to clarify and summarize important issues. as the following topics

1. **security analysis (Emphasis on newly discovered issues)**

   .....

   .....

2. **Benefit-Risk Assessment (emphasis on impact assessment on volunteers/volunteers)**

   .....

   .....

3. **risk management measures**

.....

.....

Please be informed accordingly. If you have any questions or suggestions (Departments/Company) are willing to cooperate fully.

sign.....

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

(Line Listing of All Suspected Serious Adverse Drug Reactions)

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

Volunteer ID (Subject Identification)	Case Reference No.	Country (Country)	Age _	Sex _	Daily Dose	Date of Onset	the date the drug was received (Dates of Treatment)	Adverse Reactions	Outcomes Per Volunteer (Patient's Outcome)	Notes _	Unblinding Results)

The table summarizes the total number of serious adverse drug reactions reported by terminology (symptoms and diagnosis).

(Aggregate Summary Tabulation of All Serious Adverse Drug Reactions)

Reporting Period		Research project name (Protocol Name)
[ ] Annual _	together with data between dates ..... to	.....
[ ] end of research (End of Study)		.....
Number of reported adverse reactions (Numbers of Reports).....		Research Project Code (Protocol Code No.) ..... TFDA CT no. ....(if any)

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

Body System / Terminology of Adverse Reactions (Body system / ADR term)	*research drug 1* *(Study Drug 1)*	*research drug 2* *(Study Drug 2)*	*Research drug ...* *(Study Drug ...)*	*Research drug N* *(Study Drug N)*	placebo (Placebo)	Medicine that conceals healing (Blinded)
CNS						
*Hallucinations**	*2*	*2*	*2*	*2*	*2*	*0*
*Confusion**	*1*	*1*	*1*	*1*	*1*	*0*
.....	.....	.....	.....	.....	.....	.....
Sub-total	*3*	*3*	*3*	*3*	*3*	*0*
CV						
.....						
Sub-total						

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