MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

Number: 10/2020/TT-BYT

Hanoi, June 11, 2020

CIRCULARS

Regulations on bioequivalence testing of drugs

Pursuant to Law No. 105/2016/ QH13 dated April 6, 2016 on pharmacy;

Pursuant to Decree No. 75/2017/ ND-CP dated June 20, 2017 of the Government defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of the Director of the Department of Science, Technology and Training;

The Minister of Health promulgates a Circular on bioequivalence testing of drugs.

Article 1. Scope of regulation, subjects of application

1. This Circular prescribes the assessment of eligibility for drug bioequivalence testing establishments; instructions for bioequivalence testing of drugs and dossiers and procedures for drug bioequivalence testing.

2. This Circular applies to drug bioequivalence testing establishments and organizations and individuals involved in bioequivalence testing activities of drugs.

3. Drug bioequivalence testing establishments subject to the application of this Circular are establishments that satisfy the conditions on physical, technical and personnel facilities as prescribed at Point g, Clause 1, Article 33 of the Law. Medicines include:

a) The establishment meets the principles and standards of Good Laboratory Practice (GLP) as prescribed in the Circular No. 04/2018/TT-BYT dated February 9, 2018 of the Minister of Health on regulations on Food and Drug Administration. Good laboratory practice (hereinafter referred to as Circular 04/2018/TT-BYT) and meet the principles and standards of Good Clinical Practice (GCP) for phase 1 as prescribed in Circular No. No. 29/2018/TT-BYT dated October 29, 2018 of the Minister of Health (hereinafter referred to as Circular 29/2018/TT-BYT).

b) The facility meets GLP as prescribed in Circular 04/2018/TT-BYT, does not have an area to stay, monitor drug users for the assessment of drug interactions.

bioequivalence of the drug and has an association contract with a clinical trial facility that meets GCP for phase 1 of a clinical trial according to the provisions of Circular 29/2018/TT-BYT;

c) Establishments that meet GLP as prescribed in Circular 04/2018/TT-BYT, have an area to stay and monitor drug users in service of bioequivalence assessment of drugs that meet the standards, Principles of Good clinical trial practice are specified in the Appendix issued with this Circular and have an association contract with a GCP-compliant clinical drug testing facility as prescribed in Circular 29/2018/TT -BYT to carry out clinical research phase in bioequivalence testing of drugs.

Article 2. Dossier for assessment of eligibility for drug bioequivalence testing

1. Establishments falling into the cases specified at Point a, Clause 3, Article 1 of this Circular shall submit 01 set of dossiers as follows:

a) Dossier specified in Article 5 of Circular No. 04/2018/TT-BYT for assessment of GLP compliance and documents specified in Article 8 of Circular No. 29/2018/TT-BYT for GCP response assessment. In case an establishment has been granted a GLP Certificate or an assessment report concludes that the establishment meets GLP, the establishment shall submit an application according to the provisions of Article 8 of Circular No. 29/2018/TT-BYT to request
GCP response assessment.

b) In case the establishment has been granted a GLP, GCP or Report
The assessment report concludes that the establishment meets the GLP, GCP, the establishment only has to submit an application for the Certificate of eligibility for pharmacy business using the form specified in Clause 1, Article 32 of Decree No. 54/2017/ND- The Government's CP dated May 8, 2017 details a number of articles and measures to implement the Law on Pharmacy (for establishments providing bioequivalence testing services of drugs), clearly stating the contents already approved by the Government. issue GLP, GCP Certificate or Assessment Report concludes that the facility meets GLP, GCP. Non-commercial drug bioequivalence testing establishments only have to submit an application for bioequivalence testing of drugs using Form No. 01 issued together with this Circular.

2. Establishments falling into the cases specified at Point b, Clause 3, Article 1 of this Circular shall submit 01 set of dossiers as prescribed in Article 5 of Circular No. 04/2018/TT-BYT
(for establishments that request GLP assessment) or an application as prescribed at Point b, Clause 1 of this Article (for establishments that have been granted GLP Certificates) and the following technical documents:

a) An association contract with a medical examination and treatment facility that meets the GCP for:

phase 1 of the clinical trial;

b) A copy of the GCP Certificate for phase 1 of the affiliated establishment or
The assessment report concludes that the link facility meets GCP for phase 1.

3. Establishments falling into the case specified at Point c, Clause 3, Article 1 of this Circular shall submit 01 set of dossiers as prescribed in Article 5 of Circular No. 04/2018/TT-BYT (for establishments that request GLP assessment) or an application as prescribed at Point b, Clause 1 of this Article (for establishments that have been granted GLP Certificates) and the following technical documents:

a) List of physical, technical and emergency facilities of the facility;
bioequivalence testing facility of drugs;

b) An association contract with a medical examination and treatment facility that meets GCP;

c) A copy of the affiliate's GCP certificate or assessment report
price conclusion link base meets GCP.

Article 3. Process and procedures for assessment of eligibility for drug bioequivalence testing

1. The drug bioequivalence testing establishment shall submit 01 set of dossier corresponding to the eligible cases as prescribed in Article 2 of this Circular, together with the appraisal fee as prescribed, to the Drug Administration of Vietnam. Ministry of Health.

2. Establishments falling into the case specified at Point a, Clause 3, Article 1 of Circular this:

a) The Drug Administration of Vietnam cooperates with the Department of Science, Technology and Training conduct simultaneous assessment of GLP and GCP compliance according to the process and procedures specified in Circular No. 04/2018/TT-BYT and/or Circular No. 29/2018/TT
A FLAT.

b) In case the bioequivalence testing establishment has obtained the GLP Certificate or the evaluation report concludes that the facility meets the GLP, the Drug Administration of Vietnam shall coordinate with the Department of Science, Technology and Training to conduct an assessment. GCP prices according to the process and procedures specified in Circular No. 29/2018/TT-BYT.

c) In case the bioequivalence test establishment has obtained the GLP or GCP Certificate or the report on assessment concludes that the facility meets GLP or GCP: the Drug Administration of Vietnam shall coordinate with the Department of Science, Technology and Training. create, receive and evaluate on the application's dossier.

3. Establishments falling into the cases specified at Point b, Clause 3, Article 1 of Circular this:

a) For establishments that do not have the GLP Certificate or the final assessment report,

Thesis on GLP compliance: The Drug Administration of Vietnam cooperates with the Department of Science, Technology and Training to assess GLP compliance according to the process and procedures specified in Circular No. 04/2018/TT-BYT.

b) For establishments that have been granted GLP Certificates or assessment reports that conclude that establishments meet GLP: Drug Administration of Vietnam shall coordinate with the Department of Science, Technology and Training to receive and evaluate the dossiers of the establishments. suggested basis.

4. Establishments falling into the cases specified at Point c, Clause 3, Article 1 of this

Circular: a) For establishments that do not have GLP Certificates or report on assessment of GLP satisfaction: the Drug Administration of Vietnam coordinates with the Department of Science, Technology and Training to assess GLP compliance and accommodation areas, monitor drug users for bioequivalence testing according to the procedures specified in Circular No. 04/2018/TT-BYT.

b) For establishments that have been granted a GLP Certificate or an assessment report that concludes the establishment meets GLP: The Drug Administration of Vietnam shall coordinate with the Department of Science, Technology and Training to conduct an assessment of the accommodation area, monitor drug users for bioequivalence testing of drugs and emergency equipment at the facility within 15 days from the date of receipt of complete and valid dossiers.

Article 4. Processing results of assessment of eligibility for drug bioequivalence testing

1. Establishments falling into the cases specified at Point a, Clause 3, Article 1 of this Circular this:

a) The handling of assessment results and issuance of a Certificate of eligibility for pharmacy business with the scope of drug bioequivalence testing (for drug bioequivalence testing service providers), a Receiving GLP, GCP or failing to issue these certificates to establishments that are eligible for drug bioequivalence testing comply with the provisions of Article 8 of Circular No. 04/2018/ TT-BYT or Article 11 of Circular No. 04/2018/TT-BYT. 29/2018/TT-BYT.

b) For establishments testing bioequivalence of drugs that are not eligible for the Certificate of eligibility for pharmacy business, the Certificate or report on assessment of GLP and GCP satisfaction is a certification document for the establishment to implement. bioequivalence activity of the drug.

c) In case the bioequivalence test establishment has obtained the GLP or GCP Certificate or the evaluation report concludes that the establishment meets GLP and GCP: After examining and evaluating the dossier, the Drug Administration of Vietnam , the Ministry of Health shall submit to the Minister of Health for a Certificate of eligibility for pharmacy business with the scope of bioequivalence testing of the drug (for bioequivalence testing service providers).

of the drug) or issue a written notice that the establishment satisfies the conditions for conducting bioequivalence testing of the drug using Form No. 02 issued together with this Circular within 15 days from the date of receipt of a complete and valid dossier. .

2. Establishments falling into the cases specified at Point b, Clause 3, Article 1 of this Circular this:

a) For an establishment that does not have a GLP Certificate or an assessment report that concludes the establishment meets GLP: The processing of assessment results and issuance of a Certificate of eligibility for pharmacy business with a testing scope equivalent to biological of drugs (for establishments providing bioequivalence testing services of drugs), GLP certificates, or failing to issue these certificates to establishments eligible for bioequivalence testing of drugs complying with regulations of law. prescribed in Article 8 of Circular No. 04/2018/TT-BYT.

For establishments testing bioequivalence of drugs that are not eligible for the Certificate of eligibility for pharmacy business, when granting the GLP Certificate, the Drug Administration of Vietnam and the Ministry of Health must simultaneously notify the establishment in writing. response conditions for conducting bioequivalence testing of drugs according to Form No. 02 promulgated together with this Circular. b) For establishments that have been granted the GLP Certificate or the

evaluation report that concludes the establishment meets GLP: After examining and evaluating the dossier, the Drug Administration of Vietnam, the Ministry of Health shall submit it to the Minister of Health. issue a Certificate of eligibility for pharmacy business with the scope of bioequivalence testing of drugs (for drug bioequivalence testing service providers) or issue a written notification that the establishment satisfies the actual conditions for drug bioequivalence testing. Currently testing bioequivalence of drugs according to Form No. 02
promulgated together with this Circular within 15 days from the date of receipt of complete and valid dossiers.

3. Establishments falling into the cases specified at Point c, Clause 3, Article 1 of Circular this:

a) For establishments that do not have a GLP Certificate or an assessment report that concludes the establishment meets GLP: the handling of assessment results shall comply with the provisions of Point a, Clause 2 of this Article.

b) For an establishment that has been granted a GLP Certificate or an assessment report that concludes that the establishment meets GLP: - In case the report on assessment of the satisfaction of

conditions of the establishment testing the bioequivalence of the drug concludes a bioequivalence testing facility that meets the requirements of an area for accommodation and monitoring of drug users in service of bioequivalence testing of the drug, accompanied by first aid facilities as prescribed in the Appendix No.

promulgated together with this Circular, the Drug Administration of Vietnam, the Ministry of Health shall submit to the Minister of Health for granting a Certificate of eligibility for pharmacy business with the scope of bioequivalence testing of the drug (for medical service establishments). bioequivalence testing) or send a written notification that the establishment meets the conditions for conducting bioequivalence testing of the drug, made according to Form No. 02 issued together with this Circular.
within 10 days from the date of signing the assessment minutes.

- In the case of an assessment report on the satisfaction of the conditions of a similar testing facility, Bioequivalence of the drug concludes that the bioequivalence test establishment needs to be corrected or repaired: within 5 working days from the date of completion of the actual assessment at the bioequivalence testing facility and signs a written report. In the evaluation report, the Drug Administration of Vietnam shall send a written request to the bioequivalence testing establishment to remedy and correct the deficiencies recorded in the evaluation report.

After completing the remedial and repair work, the bioequivalence testing establishment must submit a written report together with proofs (documents, photos, videos, certificates) that the remediation has been completed. restore and repair existing problems recorded in the evaluation report;

Within 20 days from the date of receipt of the written remedial report, the Drug Administration of Vietnam shall coordinate with the Department of Science, Technology and Training to evaluate the remedial results of the bioequivalence testing establishment and draw conclusions. on the satisfaction status of bioequivalence testing establishments.

In case the bioequivalence test facility's remedy has met the requirements: The Drug Administration of Vietnam, the Ministry of Health shall submit to the Minister of Health for a Certificate of eligibility for pharmaceutical business with the scope of bioequivalence testing. of the drug (for drug bioequivalence testing service providers) or a written notification that the establishment meets the conditions for conducting bioequivalence testing of the drug, Form No. 02 issued together with this Circular. this;

In case the bioequivalence testing establishment's remedial work has not met the requirements, the Drug Administration of Vietnam shall issue a written reply, clearly stating the reasons for sending the request to the establishment.

Within 6 months from the date on which the Drug Administration of Vietnam issues a written request for amendment and supplementation, the bioequivalence testing establishment must submit a revised and supplemented dossier as required. After the above time limit, if the bioequivalence testing establishment does not amend or supplement, or after 12 months from the date of submitting the application for the first time, if the additional dossier fails to satisfy the requirements, the submitted dossier will no longer be valid. value.

- In case the assessment report of the satisfaction of the conditions of the drug bioequivalence testing establishment concludes that the bioequivalence testing establishment does not satisfy

Requirements on areas for accommodation and monitoring of drug users in service of bioequivalence testing of drugs, together with first aid facilities as prescribed in the Appendix issued together with this Circular: within 5 days , from the date of completion of the actual assessment at the bioequivalence testing facility and signing the evaluation minutes, the Drug Administration of Vietnam shall issue a written notice of the non-fulfillment of the conditions enclosed with the report on assessment of the satisfaction of the conditions. satisfy the conditions of the bioequivalence testing facility of the drug sent to the establishment.

4. Within 05 working days from the date of issuance of the Certificate of eligibility for pharmaceutical business with the scope of bioequivalence testing of the drug or the GLP Certificate, the GCP Certificate, the written notice of the establishment. If the facility meets the conditions for conducting bioequivalence testing of the drug, the Drug Administration of Vietnam shall publish on the Portal of the Ministry of Health and the Website of the Drug Administration the following information:

a) Name and address of the bioequivalence testing facility of the drug;

b) Full name of person in charge of pharmacy expertise, number of pharmacy practice certificate;

c) Number of Certificate of eligibility for pharmacy business and number of Certificate of GLP, GCP (if any);

d) Expiration time of the assessment of satisfaction of bioequivalence test conditions of the drug and the date of the next periodic assessment;

d) Scope of operation of bioequivalence testing establishments of drugs.

Article 5. Evaluation of maintenance of satisfaction of conditions for drug bioequivalence testing establishments.

Periodic assessment and processing of results of periodical assessment, change control and unexpected assessment of the maintenance of satisfaction of bioequivalence test conditions of drugs comply with the provisions of Chapter IV of Circular No. 04. /2018/TT-BYT and Chapter V of Circular No. 29/2018/TT-BYT.

Article 6. Guidelines for drug bioequivalence testing

The implementation of bioequivalence trial studies of drugs must comply with the instructions specified in Appendix 1 of Circular 32/2018/TT-BYT dated November 12, 2018 on registration of circulation of drugs and raw materials. medicine, Circular 08/2010/TT-BYT dated April 26, 2010 of the Minister of Health guiding the reporting of bioavailability/bioequivalence research data in drug registration and the list of control drugs issued by the Minister of Health.

Article 7. Bioequivalence testing dossiers of drugs

Dossier for bioequivalence testing of a drug means a technical dossier including a dossier of registration for a drug's bioequivalence trial; Dossier of application for approval of a drug bioequivalence trial study; Dossier of application for approval of bioequivalence test results of drugs, specifically specified as follows:

1. An application for registration of a drug's bioequivalence trial includes:

a) An application form to conduct a bioequivalence trial study of the drug according to Form No. 03 issued together with this Circular;

b) Records of information on bioequivalent reagents: drug name, name of active ingredient, ingredients, concentration/content, dosage form and other relevant information (if any).

2. An application for approval of a drug bioequivalence trial study includes:

a) An application form for approval of bioequivalence testing of drugs from a drug bioequivalence testing facility to the grassroots level Ethics Council in biomedical research, made according to Form No. 04 attached to this Circular. this.

b) Profile of information on bioequivalent reagents, including research documents on the drug: formula ingredients, origin of raw materials, summary production scheme/process, drug quality standards, test sheet drug (manufacturer's test sheet meets Good Manufacturing Practice (GMP) or
of a GLP-compliant drug testing facility), pharmacological development documents/records of bioequivalence reagents;

c) Legal documents of bioequivalent reagents include:

- The instruction sheet which has been licensed for circulation of the control drug used in research and bioequivalence reagents (if any);

- A contract for cooperation in research on bioequivalence testing of drugs between an establishment having bioequivalence reagents and an establishment testing bioequivalence of drugs; a cooperation contract between an organization or individual having reagents and a research support organization (if any).

d) Outline of bioequivalence trial of the drug, including: - Explanation of the outline of bioequivalence trial of the drug;

- Research information collection form or Research medical record (Case Report Form - CRF);

dd) Scientific curriculum vitae and a copy of the certificate of completion of the course Good clinical practice, safety reporting practice of the main investigator, issued by the Ministry of Health or by other functional institutions. about GCP grant;

e) A copy of the research information supply and the volunteer's form to participate in the study of the participant in the bioequivalence trial of the drug;

g) Reagent labels include information: drug name, active ingredient name, concentration/ content, dosage form, batch number, expiry date, name and address of the manufacturer. In case the drug has been granted a circulation registration license, drug labels according to the provisions of the Circular No. 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health on regulations on labeling of drugs and ingredients medicine.

3. An application for approval of bioequivalence test results of a drug includes:

a) An application form for approval of bioequivalence test results of the drug, made according to Form No. 05 issued together with this Circular;

b) Report on the results of bioequivalence trial of the drug.

Article 8. Bioequivalence testing process of drugs

The bioequivalence testing process of the drug is carried out according to regulations in Article 100, Article 101 of the Law on Pharmacy, specifically as follows:

1. Registration of a drug bioequivalence trial study:

a) An establishment that has drugs to be tested for bioequivalence shall send 01 application for registration of bioequivalence testing of the drug according to the provisions of Clause 1, Article 7. This Circular reaches the bioequivalence testing facility of the drug.

b) The drug bioequivalence testing facility considers and approves the request for bioequivalence testing of the drug and signs a contract to test the drug's bioequivalence with the establishment having the drug to be tested for bioequivalence.

2. Approving bioequivalence trial studies of drugs:

a) The drug bioequivalence testing establishment prepares 01 set of documents as prescribed in Clause 2, Article 7 of this Circular and sends it to the grassroots Ethics Council in biomedical research.

b) The grassroots level Ethical Council in biomedical research shall hold a meeting to appraise the bioequivalence trial protocol of the drug within 10 days from the date of receipt of a complete and valid dossier with a valid written record. bioequivalence trial protocol evaluation of the drug.

c) Within 05 days from the date of receipt of the appraisal report of the Ethics Council in biomedical research at grassroots level, the person responsible for professional

The subject of the drug bioequivalence testing facility shall decide to approve the drug bioequivalence trial protocol if the drug bioequivalence trial protocol meets the requirements.
d) In case the drug bioequivalence trial protocol needs correction, the drug bioequivalence

testing establishment is responsible for completing the dossier within a maximum of 20 days from the date of receipt of the minutes of evaluation. The decision of the Ethics Council in biomedical research at grassroots level proposes corrections and supplements. Past this time limit, the research protocol approval procedure must start from the beginning.

dd) Within 05 days from the date of receipt of the completed research protocol, the person in charge of expertise of the bioequivalence testing establishment shall approve the bioequivalence trial protocol of the drug.

3. Organize bioequivalence testing of drugs

Drug bioequivalence testing establishments carry out stages of bioequivalence studies at bioequivalence testing establishments or related units in accordance with approved research protocols.

4. Acceptance and approval of bioequivalence test results of drugs.

a) The lead researcher responsible for research shall directly send 01 application for acceptance of bioequivalence test results of the drug as prescribed in Clause 3, Article 7 of this Circular to the Ethics Council in research. basic biomedical research.

b) Within 10 days from the date of receipt of complete and valid dossiers, the grassroots level Ethics Council in biomedical research shall hold a meeting and issue a record of acceptance of bioequivalence research results of the applicant. drugs in which there must be satisfactory conclusions; satisfactory but need to be corrected, supplemented or not met the requirements.

c) Within 05 days from the day on which the acceptance record of meeting safety and effectiveness requirements is issued by the grassroots-level Ethical Council in biomedical research, the person in charge of expertise of the testing establishment shall bioequivalence of drugs approval of the bioequivalence study report of the drug. d) In case the test

record is passed but needs to be corrected or supplemented, the bioequivalence testing establishment shall complete the dossier within 25 days from the date of receipt of the written notice. Past this time limit, the procedure for approving bioequivalence test results of the drug must be repeated from the beginning.

dd) Within 05 days from the date of receipt of the completed dossier according to the written notification, the person in charge of expertise of the bioequivalence testing establishment shall decide to approve the drug bioequivalence study report.

drug bioequivalence.

Article 9. Amendments and supplements to Appendix I of Circular No. 29/2018/TT-BYT

Amendments and supplements to Appendix I on Good clinical practice in clinical trials of Circular No. 29/2018/TT-BYT in the Appendix issued together with this Circular.

Article 10. Effect

This Circular takes effect from August 10, 2020.

Annul the Annex I on Good Clinical Practice (GCP) promulgated attached to Circular No. 29/2018/TT-BYT, from the effective date of this Circular.

Article 11. Terms of Reference

In case the documents cited in this Circular are replaced, amended or supplemented, the replaced document or the revised and supplemented document shall apply.
sung.

Article 12. Responsibilities for implementation

1. Department of Science, Technology and Training:

a) Coordinate with the Drug Administration of Vietnam and relevant ministries guide and organize the implementation of this Circular;

b) Participate in the assessment of satisfaction of conditions for drug bioequivalence testing establishments;

c) Publish updated GCP documents for bioequivalence testing of drugs on the website of the Ministry of Health and the website of the Department of Science, Technology and Training;

d) Coordinate with the Inspectorate of the Ministry of Health and relevant units of the Ministry of Health in inspecting and inspecting the compliance with GCP requirements for bioequivalence testing establishments of drugs, handling violations according to its competence or propose competent agencies to handle;

dd) Coordinate with the Drug Administration of Vietnam to announce updates on administrative procedures integrated in current procedures to ensure convenience for agencies, organizations and individuals to carry out administrative procedures.

2. Drug Administration of Vietnam:

a) Coordinate with the Department of Science, Technology and Training in providing guidance implementation of this Circular.

b) Coordinating with the Department of Science, Technology and Training in receiving application dossiers, conducting assessment for drug bioequivalence testing establishments according to the provisions of this Circular.

3. Bioequivalence testing facilities of drugs:

a) Thực hiện hoạt động thử tương đương sinh học của thuốc theo đúng phạm vi được cấp phép trên cơ sở tuân thủ các quy định của pháp luật;

b) Tuân thủ việc đánh giá đáp ứng đủ điều kiện thử tương đương sinh học của thuốc theo quy định tại Thông tư này;

c) Thực hiện hoạt động thử tương đương sinh học của thuốc theo đúng hồ sơ, quy trình quy định tại Thông tư này;

d) Chuẩn bị các hồ sơ bảo đảm theo đúng quy định tại Thông tư này trình Hội đồng đạo đức trong nghiên cứu y sinh học cấp cơ sở xem xét, thẩm định; lưu trữ hồ sơ theo quy định của pháp luật.

đ) Chịu sự thanh tra, kiểm tra, đánh giá đột xuất việc duy trì đáp ứng GCP của cơ quan Nhà nước có thẩm quyền theo quy định của pháp luật.

Trong quá trình thực hiện nếu có khó khăn vướng mắc, các cơ quan, tổ chức, cá nhân phản ánh kịp thời về Bộ Y tế (Cục Quản lý Dược hoặc Cục Khoa học công nghệ và Đào tạo) để xem xét, giải quyết./.

Nơi nhận:
- Uỷ ban Về các vấn đề xã hội của Quốc hội (để giám sát);
- Văn phòng Chính phủ (Công báo, Cổng TTĐTCP);
- Phó Thủ tướng Vũ Đức Đam (để báo cáo);
- Bộ trưởng Bộ Y tế (để báo cáo);
- Các Thứ trưởng Bộ Y tế;
- Các Bộ, Cơ quan ngang Bộ, Cơ quan thuộc CP;
- Bộ Tư pháp (Cục Kiểm tra văn bản QPPL);
- Ủy ban nhân dân các tỉnh, thành phố trực thuộc Trung ương;
- Sở Y tế các tỉnh, thành phố trực thuộc TƯ;
- Y tế các Bộ, Ngành;
- Các đơn vị thuộc, trực thuộc Bộ Y tế;
- Tổng công ty dược Việt Nam - Công ty cổ phần;
- Hiệp hội Doanh nghiệp dược Việt Nam;
- Hội Dược học Việt Nam;
- Cổng Thông tin điện tử Bộ Y tế;
- Trang thông tin điện tử Cục KHCN&ĐT;
- Lưu: VT, PC, K2ĐT (05).

KT. BỘ TRƯỞNG
THỨ TRƯỞNG

Nguyễn Trường Sơn

TEXT FORM

(Attached to Circular No. 10/2020/ TT-BYT dated June 11, 2020 of the Minister of Health)

Form No. 01 Application for bioequivalence testing of drugs

Form No. 02 Written notice of eligibility for equivalent testing Medicine's biology

Form No. 03 Application for conducting bioequivalence trial of medicine

Form No. 04 Application for approval of bioequivalence trial of medicine

Form No. 05 Application for approval of bioequivalence test results of drugs

Form No. 01 - Application for bioequivalence testing of drugs

NAME OF MANAGER UNIT
FACILITY NAME
Number: ……../……

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness
……, *date … month… year 20…*

PROPOSAL
IMPLEMENTATION OF DRUG BIOequivalence

To: Drug Administration - Ministry of Health

Name of establishment: ……

Address: ……

Phone/fax/email: ……

Contact person: …… Title: ……

Phone/fax/email: ……

Has been granted a GLP Certificate or a baseline conclusion assessment report meets GLP No. day month Year…..

GCP certificate or baseline assessment report has been issued meet GCP number day month Year…..

Implement Circular No. /2020/TT-BYT dated ... month ... 2020 of the Ministry Health regulations on bioequivalence testing of drugs, we kindly request the Ministry of Health (Drug Administration) to notify in writing the satisfaction of the conditions for conducting bioequivalence testing of drugs to our facility.

We pledge to fully comply with the provisions of relevant laws and strictly abide by the direction of the competent management agency.

Head of the facility
(Signature, full name, stamp)

Form 02 - Written notification that the establishment is eligible to conduct bioequivalence testing of drugs

MINISTRY OF HEALTH
DRUG ADMINISTRATION
Number /

SOCIALIST REPUBLIC OF VIETNAM
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Hanoi Day Month Year ...

Notice of eligibility
perform biotechnological testing of the drug

Dear: [name of Drug Bioequivalence Testing Facility]

The Drug Administration of Vietnam has received the application file of [name of drug bioequivalence testing facility] requesting to perform bioequivalence testing of the drug.
Based on records and/or results of assessment of response to good clinical practice for bioequivalence testing of drugs, the Drug Administration of Vietnam has an opinion.
as follows:

[Name of drug bioequivalence testing facility] meets the conditions for drug bioequivalence testing as prescribed in the Health Minister's Circular No. on bioequivalence testing of drugs. The assessment of response to good practice in clinical trials to bioequivalence testing of drugs of [name of drug bioequivalence testing facility] is performed every 3 years from the date of the most recent assessment. according to current regulations.

The Drug Administration of Vietnam shall notify so that [name of drug bioequivalence testing facility] can be known and implemented./.

Head of Department

Recipients:
- As above;
- TT in charge (for reporting);
- Department of Science, Technology and Investment;
- Biochemical testing facility of the drug (for implementation);
- Save: VT (02 copies).

Form No. 03 – Application for conducting bioequivalence testing of drugs

SOCIALIST REPUBLIC OF VIETNAM

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APPLICATION FOR RESEARCH BIODIVERSITY CARD

Dear: [Name of drug bioequivalence testing facility]

Organizations and individuals having bioequivalent reagents:

Address: Phone,

Fax, Email:

Suggest ***[Name of drug bioequivalence testing facility]*** to conduct trial research bioequivalence with the following contents:

- Drug name
- Concentration, content
- Dosage form, route of use
- Name of the manufacturer of the drug

Day month Year……

Organizations and individuals that have drugs

bioequivalence test

Form No. 04 – Application for approval of drug bioequivalence trial study

SOCIALIST REPUBLIC OF VIETNAM

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IMPLICATION FOR RESEARCH APPROVAL

DRUG BIOequivalence

To: Ethics Committee in Biomedical Research .....

1. Full name of main researcher Full name:

Work place:

Address: Telephone: Fax:

2. Research name

Research on bioequivalence of drugs (drug name, concentration, content, dosage form, route of administration, name of manufacturer of reagent) compared with drugs (drug name, concentration, content, dosage form, route of administration, name of the manufacturer of the control drug)

3. Name of the host unit

Name of

Unit: Address: Telephone: Fax:

4. Location and time of research implementation

- Location:
  - Sampling volunteers:
  - Analysis:
- Time: **5.**

Dossier to be sent together with the assessment application includes

5.1.

5.2.

……

The main researcher and the bioequivalence testing facility commit to absolutely no conflict of interest between the parties involved in the clinical trial, strictly complying with the research protocol approved by the Ministry of Health and principles of good practice in clinical trials.

Day month Year……

Principal Investigator (sign)	**Head of the facility bioequivalence test**

Form No. 05 – Application for acceptance of a drug bioequivalence trial

SOCIALIST REPUBLIC OF VIETNAM

Independence - Freedom - Happiness

APPLICATION FOR RESULTS APPROVAL

DRUG BIOequivalence

To: Ethics Committee in Biomedical Research .....

1. Full name of principal investigator

First and last name:

Working place:

Address:

Phone, Fax:

2. Research name

Research on bioequivalence of drugs (drug name, concentration, content, dosage form, route of administration, name of manufacturer of reagent) compared with drugs (drug name, concentration, content, dosage form, route of administration, name of the manufacturer of the control drug)

3. Name of the host unit

Name of

Unit: Address:

Phone, Fax: **4.**

Location and time of research implementation

- Location:
  - Sampling volunteers:
  - Analysis:
- Time: **5.**

Dossier to be sent together with the evaluation application includes:

5.1. Summary report on research results

5.2.

……

Day month Year……

Principal Investigator (sign)	**Head of the facility bioequivalence test**

Appendix

GOOD PRACTICE IN CLINICAL DRUG TRIAL

(Issued together with the Circular No. 10/2020/ TT-BYT dated June 11, 2020 of the Minister of Health)

Chapter I

TERMS AND PRINCIPLES IN CLINICAL TRIAL GOOD PRACTICE

Article 1. Terminology

1. *Organizations and individuals that have clinical reagents or bioequivalent reagents* are organizations or individuals that own research drugs, have a need for clinical trials and commit to provide financial support for drug trials. on clinical.

2. *Researcher* is the person responsible for conducting research at the site research point.

3. The main researcher is the directing and responsible researcher directly for the completion of research and direct reports on the process and results research with sponsors.

4. *Standard Operating Procedures (SOPs)* are detailed guidelines for achieving consistency in the implementation of a specific tasks and tasks in clinical drug research.

5. *Research monitoring and supervision* is the process of checking and monitoring the research progress, the researcher's compliance with the approved outline and the provisions of the law on research.

6. *Examination of the Ethics Committee or the examination of organizations and individuals having clinical reagents or bioequivalent reagents (audit)* is a systematic and independent examination of activities and documents. relevant to the clinical trial to determine whether the activities involved in the clinical trial are being evaluated, and whether the data are accurately recorded, analyzed, and reported in accordance with outline, sponsor SOPs, GCP and the provisions of the law.

7. *Inspection* is an activity by a regulatory authority to conduct a formal review of research-related documents, facilities, records, and other resources. clinical trial of drugs.

Testing by the Regulatory Authority may be conducted at the testing site, the facility of an organization or individual that has clinical reagents or a research support organization, or at other facilities deemed appropriate by the regulatory authority.

8. *An adverse event (AE)* is a medical event or condition including any sign, symptom, medical condition, or adverse test result that occurs during, Clinical trial duration affects clinical trial participants, with or without clinical trial involvement.

9. A *serious adverse event (SAE)* is an adverse event that can lead to one of the following situations in a clinical trial participant:

a) Death;

b) Threats to life;

c) Hospitalization or prolonged hospital stay;

d) Permanent or serious disability or injury;

dd) Birth defects or malformations in the fetus of a drug trial participant;

e) A situation where appropriate medical intervention is required to prevent or avoid one of the situations specified at Points a, b, c, d, dd of this Clause or other situations of medical significance. faculty according to the opinion of the researcher at the study site.

10. *Unexpected Adverse Events (Unexpected SAEs)* are adverse events occurring in a clinical trial of which the nature or severity or specificity or patient consequences of the adverse event occurred. incident that is not the same as described or is not foreseen in detail in the protocol or documents whether research is relevant.

Article 2. Principles of Good Practice in Clinical Trial

1. Principle 1:

Clinical trials must be conducted according to the following principles: The basic principles of biomedical research ethics in the Declaration of Helsinki were first adopted by the World Medical Association (WMA) in 1964 in Helsinki (Finland) and updated periodically.

2. Principle 2:

The benefits and risks or inconveniences to clinical trial participants, to society or to the general population need to be considered, fully and carefully considered before commencing a study. clinical trial of drugs on the basis of ensuring the safety, health and interests of participants in clinical trials.

3. Principle 3:

Clinical trials only begin if the anticipated benefits to the clinical trial participants and to society outweigh the possible risks. The scientific and social benefits need to be weighed,
fully and carefully considered on the basis of ensuring the safety, health and interests of participants in clinical trials.

4. Principle 4:

Clinical trials must be conducted on the basis of strict adherence to the research protocol and procedures approved by the Ethics Council, the Scientific Council and approved by the competent regulatory agency. Any changes in the research protocol or process must be promptly reported and fully approved by the competent authority.

5. Principle 5:

The review of clinical trial studies should be comprehensive and thorough on the basis of being provided with sufficient preclinical, clinical and other relevant results. arrive
reagents (if any).

6. Principle 6:

Participants in clinical drug trials are guaranteed the following rights: provide all relevant information according to Form No. 09 in the Appendix III promulgated together with Circular 29/2018/TT-BYT; request explanation and clarification of research-related information when necessary; respecting the specific characteristics of culture and habits of individuals, regions and ethnic groups and deciding whether to participate or not to participate in clinical drug trial research; provide appropriate medical services free of charge; Research participants who are underage, have limited civil act capacity or have lost their civil act capacity must obtain the consent of their representatives as prescribed by law on participating in drug trials on clinical.

7. Principle 7:

Establishments that receive clinical trials are responsible for arranging appropriately qualified doctors to provide medical care and make medical decisions for participants in clinical trials in clinical trials. necessary and in accordance with the law.

8. Principle 8:

Each individual participating in the conduct of clinical drug trials should ensure standards of professional qualifications, training, retraining and experience in order to perform their respective tasks in clinical trials. .

9. Principle 9:

All information on clinical trials must be recorded, handled, managed and kept in accordance with regulations in order to be able to accurately report, interpret, monitor, and check the accuracy and reliability of such information. information and data on drug trials on clinical.

10. Principle 10:

Records used to identify participants in clinical trials must be protected and maintained to ensure their right to keep private secrets in accordance with the provisions of law.

11. Principle 11:

Reagents must be manufactured, managed as prescribed, stored in accordance with relevant good practice guidelines, and used only for research in accordance with an approved study protocol.

12. Principle 12:

The quality assurance system and methods to ensure quality in clinical trials must be fully and accurately implemented in accordance with the quality assurance provisions of this guideline and legal regulations. on quality assurance of drugs used in research.

13. Principle 13:

Respect the culture, identity, traditions and customs of the local community where clinical drug trials are conducted.

chapter II

RIGHTS AND RESPONSIBILITIES OF ORGANIZATIONS AND INDIVIDUALS Clinical Trial Study, Equivalence Trials

BIOLOGY OF DRUGS

Article 3. Rights and responsibilities of organizations and individuals possessing clinical reagents or bioequivalent reagents

1. Organizations and individuals having drugs for clinical trial have rights and responsibilities according to the provisions of Article 92 of the Law on Pharmacy.

2. Organizations and individuals having bioequivalent reagents have the right and responsibility responsibilities as prescribed in Article 98 of the Law on Pharmacy.

Article 4. Rights and responsibilities of establishments that receive clinical trials and bioequivalence tests of drugs

1. A clinical trial facility has the rights and responsibilities as prescribed in Article 93 of the Law on Pharmacy.

2. Establishments that receive bioequivalence testing of drugs have the rights and responsibilities as prescribed in Article 99 of the Law on Pharmacy.

Article 5. Rights and responsibilities of researchers

1. Researcher has the following rights:

a) Enjoy financial benefits according to agreements with organizations and individuals having clinical trial drugs;

b) Sign a research contract with the main researcher or the clinical trial receiving facility to coordinate in performing a number of specific contents of the clinical trial on the basis of compliance with the above drug trial research protocol. forest
approved sieves;

c) Propose to the principal investigator to change the clinical trial research protocol in case of necessity;

d) Propose to the principal investigator to stop or prematurely terminate a clinical trial if an adverse event is detected that seriously affects the safety and health of the trial participant or the community.

2. Researcher has the following responsibilities:

a) Contribute to the clinical trial drug research outline, research information supply form and the participant's volunteer participation form in the clinical trial together with relevant documents;

b) Cooperate with the clinical trial receiving facility and the organization or individual having the drug for clinical trial in formulating and completing the application file for approval of the clinical trial drug research;

c) Carry out the tasks assigned by the main researcher related to the research implementation; selection of drug trial participants; record and keep source documents and essential documents; periodic and extraordinary reports as prescribed; Monitor and supervise the implementation of research according to the research protocol
approved research and applicable regulations;

d) Adhere to approved study protocol and procedures except where immediate changes are needed to ensure participant safety

Try medicine;

d) Propose the main researcher to change the research proposal in case of necessity. The implementation of the revised outline can only be carried out after it has been approved by a competent agency or organization;

e) Compensation for damage to drug trial participants when an adverse event causes serious damage to the safety and health of drug trial participants because the researcher violates the research protocol ;

g) Cooperate with organizations and individuals that have clinical trial drugs to complete the application for approval of clinical trial results and submit them to competent agencies for appraisal and approval.

Article 6. Rights and responsibilities of principal researchers 1.

Principal researchers have the following rights:

a) Enjoy financial benefits according to agreements with organizations and individuals having clinical trial drugs;

b) Propose units to coordinate and list researchers with organizations and individuals having clinical reagents and management agencies;

c) Proposing a laboratory with a quality assurance system suitable for clinical drug research with organizations and individuals having clinical trial drugs.
and regulatory bodies;

d) Sign research contracts with agencies, organizations and individuals to coordinate in implementing a number of specific contents of clinical drug trials on the basis of compliance with the approved research outline;

dd) Proposing organizations or individuals having clinical trial drugs to change the protocol study in case of need;

e) Stop or terminate the study early if an adverse event is detected that seriously affects the safety and health of the trial participants or the community;

g) Publish research results according to agreements with organizations and individuals having clinical trial drugs.

2. Principal investigator has the following responsibilities:

a) Take the highest responsibility for the safety and health of drug trial participants at the clinical trial receiving facility;

b) Design or contribute to the research proposal, research information sheet and research volunteer form and documents.
relevant research;

c) Coordinating with clinical drug trial establishments and organizations and individuals having clinical trial drugs in formulating and completing dossiers of application for approval of clinical drug research studies;

d) Organizing research implementation; selection of drug trial participants; record and keep source documents and essential documents; periodic and extraordinary reports as prescribed; Monitor and supervise the implementation of research according to the research protocol approved research and applicable regulations;

dd) Comply with the approved research outline and process, except in cases where it is necessary to change immediately to ensure the safety of drug trial participants;

e) Make payments to drug trial participants according to the content of
The research information sheet and the research volunteer form have been approved;

g) Propose organizations and individuals having clinical reagents to change the research protocol in case of necessity. The implementation of the revised outline can only be carried out after it has been approved by a competent agency or organization;

h) Provide dossiers and documents related to clinical drug trial to competent agencies and organizations upon request for examination, supervision and inspection.
research;

i) Compensation for damage to drug trial participants when an adverse event occurs, causing serious damage to the safety and health of drug trial participants, which is caused by the main researcher's violation of the protocol.
research;

k) Cooperate with organizations and individuals that have clinical trial drugs to complete the application for approval of clinical trial results and submit them to competent agencies for appraisal and approval.

Article 7. Rights and obligations of participants in clinical trials and bioequivalence trials of drugs

1. Clinical trial participants have the rights and obligations of clinical trial participants as prescribed in Article 2 of this Law.

91 Pharmacy Law.

2. Participants in drug bioequivalence trials have the rights and obligations of participants in clinical trials as prescribed in Article 97 of the Law on Pharmacy.

Chapter III

OUTLINE OF THE CLINICAL TRIAL RESEARCH, DRUG BIOequivalence

Section 1. OUTLINE OF THE Clinical Trial of Drugs

Article 8. Clinical trial drug research outline

1. Organizations and individuals that have clinical trial drugs cooperate with researchers Responsible for developing clinical trial research protocols.

2. The clinical trial research protocol must be approved by the Ethical Council in Biomedical Research at the grassroots level, the National Ethical Council in Biomedical Research and the competent authority before proceeding. research practice assist.

3. Changing the clinical trial research protocol:

a) For administrative changes: the facility receiving the clinical trial shall report in writing to the Ethics Council at all levels and the competent management agency.

b) For changes that do not affect the health and interests of drug trial participants, research design, process and procedures: should be

Grassroots Biomedical Research Ethics Committee, National Biomedical Research Ethics Council appraised and approved. Dossier and appraisal process are made according to the provisions of Circular No. 04/2020/TT-BYT dated March 5, 2020 of the Minister of Health stipulating the establishment, functions, duties and powers of the Ethics Council in biomedical research.

c) For changes that affect the health and interests of drug trial participants or affect the research design, process and procedures: must be approved by the competent management agency. Dossier of application for approval of changes and procedures and order of approval for changes in clinical drug research protocol are specified in Articles 19 and 23 of Circular 29/2018/TT.

A FLAT.

Article 9. Design of clinical drug trial studies

The design of clinical trial drug research should ensure scientific, feasibility and suitability to each research stage as well as reagent characteristics, specifically as follows:

1. Phase 1 clinical drug trial is performed on lovers healthy volunteers or patients. The selection of a group of people to participate in a drug trial must be justified based on the consideration of the risks and benefits of the study drug.

2. Phase 2, 3, and 4 clinical trials are conducted on patients (for research to evaluate treatment effects) or participants in drug trials at high risk of disease (for researches to evaluate treatment effects). cost of prophylactic effect). In the event that the participation of another target group is required, there must be suitable explanation.

3. The selection of the control group, comparison in the above drug trial study clinical need to be considered and rationalized among the methods below this:

a) Compare the control with placebo;

b) Compare the control with the group without treatment with study drug;

c) Comparison of controls between different dose levels;

d) Compare the control with another active ingredient;

d) Compare and contrast with historical data.

4. Phase 3 clinical trial studies to serve the purpose of drug registration must be designed in a randomized, double-blind, controlled grouping design. In the case of randomized, double-blind or control grouping,

feasibility must have a suitable explanation.

5. For studies that confirm safety and efficacy in a phase 3 clinical trial, the following principles can be applied in study design to minimize bias:

a) Blinding in a phase 3 study is required in cases where the main study variable is subjective or difficult to measure accurately (e.g. pain, mass response). tumor on magnetic resonance imaging…) but is not required for studies where the key variable can be objectively and accurately measured. Where blinding is not possible, there must be a reasonable explanation of how to control and minimize errors to be used
in research.

b) Randomization is an important requirement for phase 3 clinical studies to ensure objectivity in grouping. The case where random grouping is not possible must have a reasonable explanation.

6. For drugs from herbal ingredients, traditional drugs, depending on experience, understanding and convincing level of evidence on safety and effectiveness of herbal ingredients, design in each phase The research section will be considered based on each specific profile and protocol.

7. Phase 4 clinical trial is the research after the drug has been licensed for circulation. Phase 4 studies can be designed
as a non-interventional observational study; a safety surveillance study based on existing medical databases or safety surveillance reporting systems, or rigorously designed as a phase 3 clinical trial to confirm safety or effectiveness of the drug under actual conditions of use.

Article 10. Research sample size

1. The sample size needs to be calculated and explained in a reasonable way to achieve the research objectives. Assumptions to be included in the calculation of the study sample size should clearly state the source of the reference. It is necessary to perform a sensitivity analysis of the sample size according to the variation of the assumed parameters.

2. In the course of research, if it is found that the assumptions to be included in the calculation of sample size are significantly different from the reality, the sample size must be recalculated and reported to the competent authority for approval.

3. The sample size in the phase 1 study should be carefully considered based on the results of preclinical studies. The recommended sample size is 10-30 subjects (including intervention and control groups, if any). In the case of small sample size

more reasonable explanation.

4. Sample size in phase 2 is recommended to be at least 50 subjects (including intervention and control groups, if any). For drugs from medicinal herbs, traditional drugs, the minimum recommended sample size is at least 30 subjects. In case the sample size is less, a reasonable explanation must be given.

5. The sample size in the phase 3 study must be fully calculated and justified. The sample size of the phase 3 study must be large enough to allow scientific verification of the efficacy and safety of the study drug. The recommended sample size is at least 100 subjects (including intervention and control groups, if applicable). For drugs from medicinal herbs and traditional drugs, the recommended minimum sample size is at least 50 subjects. In the case of a smaller sample size, it must be

reasonable solution.

6. The sample size in the phase 4 study must be made at the request of the regulatory agency or fully calculated and justified. The sample size should be large enough to allow continued scientific testing of the study drug's efficacy and safety. The recommended sample size is at least 200 subjects (including intervention and control groups, if applicable). In case the sample size is less then

must be properly explained.

Section 2. RESEARCH OUTCOME OF DRUGS

Article 11. Outline of bioequivalence testing of drugs

1. Organizations and individuals having bioequivalence reagents shall coordinate with the main researchers to develop the bioequivalence test protocol of the drug.

2. The drug's bioequivalence trial protocol must be evaluated and approved by the Ethical Council in biomedical research at grassroots level and approved by science and technology. Research ethics and bioequivalence testing grounds for approval prior to conducting research.

3. Changing the bioequivalence test protocol of the drug:

a) For administrative changes: the principal investigator has a written document Report of the grassroots Ethics Council.

b) For other changes: need to be approved by the Ethical Committee in Research grassroots-level biomedical research

approved. **Article 12. Bioequivalence trial design of drugs**

The bioequivalence test design and sample size for the study are carried out in accordance with the provisions in Appendix 1 of the Bioequivalence Test Guidelines of Circular 32/2018/TT-BYT dated November 12, 2018 on registration of storage. medicine, medicinal ingredients.

Chapter IV

IMPLEMENTATION OF Clinical Trial of Drugs

Article 13. Conducting clinical drug trial research

a) Clinical trials of drugs are only allowed to be carried out when approved by a competent regulatory agency;

b) The implementation of research on drug trial participants can only begin after the information about the study is fully communicated to the participants.

drug trial participants and the drug trial participants or their legal representatives signed The research information sheet and the research volunteer form;

c) The research team, the facility receiving the clinical trial is responsible for organizing and conducting the research in accordance with the research outline and research process. approved research;

d) Essential documents before conducting, during the implementation and after the end of the clinical trial study, according to Forms 01, 02 and 03 (for clinical drug research) and Form No. 05, 06 and 07 (for drug bioequivalence testing) issued together with this Appendix;

dd) The Ministry of Health encourages principal researchers to register and publish their work conduct research on reputable domestic and foreign databases.

Article 14. Technical standards of facilities serving drug testing in clinical

1. The clinical area of the facility that receives the clinical trial (or according to the contract/ document associated with the medical examination and treatment facility in the case of the facility). receive a vaccine without a clinical area) must meet technical standards The following:

a) The reception area must have enough seats for at least 20 participants testing drugs, ensuring protection from rain, sun and ventilation;

b) The counseling area ensures privacy for drug trial participants conditions on temperature, light, ventilation;

c) Clinical clinics and treatment rooms ensure privacy for drug trial participants;

d) Room for injection, room for procedures, treatment room must be airtight, well ventilated and warm enough for the subject;

dd) The emergency room has sufficient area and facilities for emergency services as prescribed by the Minister of Health;

e) Room to save trial participants to monitor adverse events after using research drugs (for vaccine studies, studies need to save trial participants to monitor adverse events according to research outline

research…) must meet the conditions on temperature, light, ventilation; enough area to save the object;

g) Separate male and female restrooms for drug trial participants;

h) Ensuring hygiene and safety conditions for fire prevention and fighting and complying with the collection, management and treatment of medical waste in accordance with law;

i) The phase 1 clinical trial area needs to be arranged independently, with access control to ensure the following technical standards: Have at least 12 beds for inpatient treatment; medicine preparation room; The research room is set up
located near an emergency room or an intensive care unit with sufficient area and emergency facilities according to the regulations of the Minister of Health; sampling room; 24-hour central physiological monitoring room; room for drug trial participants; recreation room, dining room; separate toilets and baths for men and women; lockers for personal belongings of trial participants.

2. Areas for accommodation and monitoring of drug users in service of bioequivalence assessment (hereinafter referred to as clinical areas) should be arranged independently, with access control to ensure technical standards. The following:

a) Have a minimum size of 12 beds for volunteers participating in the research. The number of beds must be arranged in accordance with the number of volunteers of each study. b) The reception area must be arranged with enough seats for at least 20 people to participate in drug testing, ensuring that it is covered from rain, sun and well ventilated;

c) Room to consult and obtain consent form to participate in research to ensure privacy for drug trial participants who meet the conditions on temperature, light,
ventilatory;

d) Clinical clinic ensures privacy for trial participants
medicines, with adequate facilities for screening such as film reading lights, blood pressure monitors, stethoscopes;

dd) The drug preparation room has adequate facilities to retail drug samples
Research for each volunteer participating in the study to ensure hygiene, no cross-contamination.

e) Room for using research drugs for volunteers has enough tables, chairs and equipment for volunteers to use drugs according to the provisions of the project.
Research outline and equipment to ensure safety for users according to regulations. Ensure availability of means of prevention and treatment of anaphylaxis according to the provisions of Circular 51/2017/TT-BYT of the Minister of Health guiding the prevention and diagnosis of anaphylaxis. and anaphylactic treatment.

g) Room to collect blood, urine and biological fluid samples from drug test volunteers (specified in the research protocol approved by the Ethics Council). The sampling room must have adequate equipment for blood sampling and ensure safety and privacy for volunteers, avoiding infection, adulteration and cross-contamination during sampling.

h) The emergency room or the intensive care unit must be located near the room for taking medicine and taking blood samples, and must be arranged appropriately and convenient for handling adverse events that may occur when volunteers use drugs. ; having adequate means of anaphylaxis prevention and treatment as prescribed in Circular 51/2017/TT-BYT of the Minister of Health guiding the prevention, diagnosis and treatment of anaphylaxis must have a systematic bedside oxygen system or oxygen tank with medical mask, alarm system for each bed, system to monitor vital indicators (heart rate, breathing rate, pulse, blood pressure, SpO2, temperature) of each bed; the number of beds is enough for at least 1/10 of the number
the number of volunteers participating in the drug trial of each study. The emergency room must have enough area and emergency equipment ready to serve the emergency according to the regulations of the Minister of Health;

i) The central physiological monitoring room has a camera system to monitor the safety of volunteers and has medical staff (at least 01 doctor, 01 nurse) on duty 24 hours a day during the volunteer's trial period. Medicines are present in the forest area
ready.

k) Room for storing drug trial participants to monitor adverse variables after using research drugs must ensure conditions of temperature, light, and ventilation; maintain temperature, humidity, ventilation in all weather conditions. Room with enough space to hold objects with a minimum size of 12 beds for people

volunteer to participate in research. There are alarms for each bed. The number of accommodation beds must be arranged in accordance with the number of volunteers of each research.

l) Recreation room, dining room serving volunteers, lockers individual volunteers.

m) Separate male and female restrooms and bathrooms for trial participants medicine;

n) Ensuring hygiene and safety conditions for fire prevention and fighting and complying with the collection, management and treatment of medical waste in accordance with law;

3. The laboratory of the facility receiving the clinical trial (or according to the contract/ document associated with the professional establishment in case the clinical drug receiving establishment does not have a laboratory or is not qualified) perform specialized tests) must meet the following criteria:

a) Sufficient area to arrange professional equipment, separate storage area documents and workspaces for employees suitable to the scale of clinical trial activities;

b) Having an appropriate laboratory quality assurance system in accordance with regulations regulations of the Ministry of Health;

c) Competent to perform phased and protocol tests research.

4. Area for preservation of biological samples and research drugs; lake storage area Research dossiers and research documents of clinical trial receiving establishments must meet the following criteria:

a) A separate area for storing researched drugs, with limited access, ensuring conditions of temperature, humidity, light, area and volume to meet the requirements for drug preservation;

b) The place for taking samples, handling and preserving samples must be separate, avoiding contamination cross, meet the requirements on handling and preserving samples as prescribed;

c) Areas for preservation of records and documents ensure confidentiality, restricted access, fire and explosion prevention and control; Avoid the adverse effects of light, heat

temperature, humidity, penetration of insects and other animals.

5. The clinical trial management department is responsible for supervising, managing and coordinating the departments in the clinical trial receiving facility, which must meet the following standards:

a) There are working rooms, meeting rooms that are fully qualified in terms of area, tables and chairs job;

b) Sufficient office equipment, computers connected to the internet, security and limited access.

6. Office of the Ethical Council in Grassroots Biomedical Research of a clinical trial receiving facility must meet the following criteria:

a) There are working rooms, meeting rooms that are fully qualified in terms of area, tables and chairs job;

b) Sufficient office equipment, computers connected to the internet, security and limited access.

7. Equipment for clinical trials must meet the following criteria:

the following standards:

a) Having enough basic equipment for human health assessment and monitoring participate in research;

b) Having enough specialized equipment for clinical trials in a specialized field;

c) Having adequate emergency equipment according to regulations of the Ministry of Health;

d) Having testing equipment meeting the list of tests registered for clinical trial;

dd) Having sufficient equipment to preserve and monitor the storage conditions of the research drug in accordance with the storage requirements stated on the label;

e) Having enough injection equipment, tools, chemicals for disinfection, medical waste containers and necessary supplies according to regulations of the Ministry of Health;

g) Having sufficient equipment to meet the requirements on preservation of biological samples;

h) Having equipment to monitor temperature at the place of storage and during transportation of research drugs;

i) Equipment for testing, preserving research drugs, preserving biological samples must be arranged, appraised, used and maintained in accordance with the purpose of use, calibrated and periodically checked by method like
fit;

k) Having an emergency power backup system, ensuring uninterrupted power supply for important stages of the research; Suitable alarm and monitoring system for research drug storage equipment, biological samples, testing equipment
experience;

l) For the phase 1 clinical trial: a physiological monitoring system at the bedside is required; surveillance camera system to support safety monitoring; device
emergency services and drug preparation equipment according to regulations of the Ministry of Health;

m) Having equipment to preserve records and documents to avoid adverse effects of light, temperature and humidity; invasion of insects and other animals
and ensure fire prevention and fighting safety.

Article 15. Professional and technical documents, service quality management clinical trial of drugs

1. Professional and technical documents must meet the following standards:

a) There are adequate standards, guidelines and standard practice procedures for activities performed in clinical trials;

b) There is a document showing the scope of professional activities suitable to the field clinical trial registration area;

c) Having sufficient legal documents and instructions on drug testing above
clinical;

d) Having a document on management and handling of conflicts of interest in clinical drug trials
sieve;

dd) Having personnel files and training records of researchers updated at least once a year;

e) Having electronic records and databases managing drug trial studies on;
clinical;

g) Sufficient source and essential documents of trial studies are available

clinical drugs.

2. The quality management system applied in clinical trials has reached ISO 9001 or equivalent or higher.

Article 16. Professional standards for personnel

1. Professional standards of researchers:

a) Having a diploma or professional certificate granted or recognized in Vietnam Male suitable for the job position;

b) Having a valid practicing certificate suitable for the assigned work (for jobs specified that the performer must have a practicing certificate);

c) Have a certificate of completion of the GCP course issued by the Ministry of Health or the The department has the function of training on GCP, which is issued and updated every 3 years;

d) Have a certificate of completion of the safety reporting course in the test clinical drugs according to GCP issued by the Ministry of Health or facilities with training function on safety reports in clinical trials, updated every 3 years;

d) The team of researchers has a sufficient number and composition suitable for the work assignments and enough time for research.

2. Criteria of principal investigator:

a) Having a diploma or professional certificate granted or recognized in Vietnam Male suitable for the job position;

b) Having a valid practicing certificate suitable for the assigned work (for jobs specified that the performer must have a practicing certificate);

c) Have a certificate of completion of the GCP course issued by the Ministry of Health or the The department has the function of training on GCP, which is issued and updated every 3 years;

d) Have a certificate of completion of the safety reporting course in the test clinical drugs according to GCP issued by the Ministry of Health or facilities with training function on safety reports in clinical trials, updated every 3 years; dd) Having sufficient specialized knowledge, clinical experience, practical ability to ensure GCP principles, mastering regulations on testing;

drugs in clinical practice, capable of implementing the research protocol fully and on schedule;

e) At the same time, each principal investigator must not lead more than 03 clinical trials or more than 05 clinical trials.

bioequivalence of the drug.

3. Member of clinical trial management department:

a) Having a university degree or higher in the field of health;

b) Have a certificate of completion of the GCP course issued by the Ministry of Health or the The department has the function of training on GCP issued and updated every 3 years.

4. The Ethical Council in Biomedical Research at grassroots level shall comply with the provisions of Circular No. 04/2020/TT-BYT dated March 5, 2020 of the Minister of Health regulating the establishment, functions, duties and powers of the Ethics Committee in biomedical research.

Article 17. Recording, reporting and statistical analysis

a) Record and report:

The principal investigator is responsible for ensuring the accuracy, truthfulness, confidentiality, integrity and verifiability of the research data. Correction of data must comply with regulations: do not delete original data, researchers

assigned to name, sign for certification and specify the date of repair. The lead investigator must submit an encrypted list of trial participants to the regulatory agency after the clinical trial ends. The retention and submission of the list of participants after decryption must be kept. secret.

b) Statistical analysis:

- The planning and execution of statistical analysis should be done and

appraised by a statistician with sufficient experience and competence;

- The statistical analysis plan must fully and detail describe the descriptive or inferential statistics of the variables to be performed in the study according to the approved protocol; must describe the means to ensure data blindness in the case of studies using a design where the statistical analyst is partially blinded to the study data;

- The statistical analysis needs to comply with the analysis plan. In case the statistical analysis has changed from the plan, detailed description and appropriate explanation should be provided. The mid-term analysis (if applicable) must be clearly defined in the statistical analysis outline and plan;

- The results of statistical analysis must be consistent with the research objectives and answer the research question.

Article 18. Supervision and inspection of clinical drug trial research

1. Monitoring:

a) Purpose: to protect the rights and health of drug trial participants; ensure the accuracy, completeness and truthfulness of research data; job guarantee
conduct drug trials in compliance with protocol, GCP, and regulations
related legislation.

b) Supervision authority:

- Organizations and individuals having clinical trial drugs shall appoint supervisors to periodically supervise the research. Supervisors shall be appointed by organizations or individuals having clinical reagents and shall comply with the provisions of Circular No. 08/2014/TT-BYT dated February 26, 2014 of the Minister of Health on activities. support clinical trial research in Vietnam. During the monitoring process, if a serious protocol violation is detected that harms the safety of subjects or the accuracy and truthfulness of data, organizations and individuals having clinical reagents are entitled to stop the research and send notices to the Ethics Councils at all levels and management agencies, and at the same time notify the establishments receiving clinical trials and researches.
main lifeguard.

- The Ethics Committee irregularly or periodically supervises the study.

c) Monitoring process:

- Organizations and individuals that have clinical trial drugs or the Ethics Council send a notice of the surveillance phase to the clinical trial receiving facility and the main researcher at least 5 days before the monitoring time.

- Monitoring minutes or reports should be completed and sent to the clinical trial recipient and the main investigator no later than 20 days after the end of monitoring.

d) Scale and frequency of supervision:

Based on the objective, purpose, design, complexity, blinding technique, scale and outcome of the study, organizations and individuals having clinical reagents and the Ethics Committee decide on the scale and frequency of monitoring before, during, after drug trial on clinical.

d) Supervision contents:

- Resources of the facility receiving the clinical trial before conducting the clinical trial;

- Research information sheet and Voluntary participation form

research, the process of collecting volunteer votes to participate in the research;

- Dossiers, source documents, essential documents of the research;

- Research drugs (expiry date, storage conditions, management, and distribution to drug trial participants);

- Compliance with the study protocol (including protocol changes) has been researcher's approval;

- Record and report adverse events in clinical trials;

- Other contents related to the research.

2. Inspection by organizations or individuals having clinical reagents or the Council morality:

a) Purpose: to assess the appropriateness of clinical trial performance with the study's quality system, with the study's SOPs, study protocol, GCP and related legal requirements. Inspection as part of quality assurance should focus on systematic and possibly quality control of supervision.

b) Authority:

- Organizations and individuals having clinical trial drugs shall appoint inspectors to periodically check the research. Inspectors appointed by organizations or individuals having clinical reagents

and is implemented in accordance with the provisions of Circular No. 08/2014/TT-BYT dated February 26, 2014 of the Minister of Health providing for activities to support clinical trial research in Vietnam. During the examination, if a serious protocol violation is detected, affecting the safety of subjects or the accuracy and truthfulness of data, organizations and individuals that have clinical reagents are entitled to stop the research and send notices to the Ethics Councils at all levels and management agencies, and at the same time notify the establishments receiving clinical trials and researches.

main lifeguard.

- The Ethics Committee for irregular or periodic inspection of the study.

c) Process:

- Organizations and individuals that have clinical reagents or the Ethics Council shall send a notice of the inspection to the clinical trial receiving facility and the main researcher at least 05 days before the time of testing.

- The inspection record or report should be completed and sent to the clinical trial recipient and the main investigator no later than 20 days after the end of the test.

d) Scale and frequency:

Based on the objective, purpose, design, complexity, blinding technique, scale and outcome of the study, organizations and individuals having clinical reagents and the Ethics Committee decide on the scale and frequency of testing before, during, and after drug testing
on clinical. d)

Inspection contents:

The contents are similar to the supervision content in Clause 1, point dd of this Article

3. Inspection by competent management agencies:

a) Purpose: to ensure the rights and health of drug trial participants, to ensure the quality and integrity of research data, to ensure the responsibility of drug trial participants.
The responsibilities of stakeholders in the research are carried out in accordance with regulations, timely detecting violations of the research protocol.

b) Authority: Department of Science, Technology and Training - Ministry of Health is in charge clinical testing of drugs in Vietnam.

c) Process:

- The Ministry of Health shall send a notice of the inspection to organizations and individuals having clinical trial drugs and establishments receiving clinical trial at least 05 days before the time of inspection.

- The inspection record should be completed and sent to the organization or individual that has the drug in clinical trial and the facility that receives the drug in clinical trial no later than 20 days after the end of the test.

d) Scale and frequency: based on the objective, purpose, design, complexity, blinding technique, scale and outcome of the study, the Ministry of Health decides the scale and frequency of examination. before, during, and after a clinical trial.

d) Content:

- For establishments that receive drugs in clinical trials: resources for research; The research information sheet and the research volunteer form, the process of obtaining consent for volunteering to participate in the research; collect research data; recording and archiving source and essential documents; contents related to research drugs (management, preservation, inventory, use)
use...).

- For organizations and individuals having clinical reagents: resources for research, supervision and inspection activities of organizations and individuals having reagents; compliance with SOPs; keep records, research materials; research data management and other relevant information.

- Activities of coordination establishments related to clinical drug trials
sieve;

- Supervision and inspection activities of the Ethics Council and organizations and individuals having clinical reagents.

Article 19. Management of adverse events (AEs) in drug trial studies in clinical practice in Vietnam

1. In the event of an AE that is dangerous, life-threatening or fatal to a drug trial participant in a clinical trial, the principal investigator and the facility receiving the clinical trial must immediately stop the drug trial. above

that subject, give first aid, overcome and deal with consequences, make a record in case of death, and immediately report urgently by phone or email to the Ethics Council in biomedical research at grassroots level. Department, National Council on Ethics in Biomedical Research, Department of Science, Technology and Training - Ministry of Health and National Center for Drug Information, Monitoring of Drug Adverse Reactions and written reports. copies as prescribed in Article 20 of this Annex.

2. In case an AE occurs leading to health injury to a drug trial participant in a clinical trial, the principal investigator or assigned researcher must treat and monitor the subject's health developments. until stabilized, record and report events in accordance with Article 18 of this Annex.

Article 20. Reports of AEs in clinical trial studies at Vietnam

1. Contents of AE reporting in clinical drug trial research in Vietnam include:

a) Monitor, detect, and report information related to AEs in clinical drug trials implemented in Vietnam or multinational trials
to which Vietnam participates;

b) Collect and process information about reported AEs; assessment of benefits, risks, and risk management associated with clinical trial studies AEs are reported;

c) Publication of conclusions of competent authorities on related issues to follow up on AE reports of clinical trials.

2. Scope of

reporting: a) All SAEs that occurred at the study sites in Vietnam, especially those that resulted in fatal, life-threatening or unexpected SAEs. These SAEs include situations where the study protocol failed to have a therapeutic effect that was fatal, life-threatening, or required medical interventions to prevent these outcomes, except for SAE has been approved by the agency the authority to approve the research protocol is not required to report;

b) SAEs occurring at research sites outside Vietnam of multinational studies involving Vietnam that lead to termination, suspension of research, withdrawal of subjects from the study, or change of topic diamond research;

c) All other AEs in clinical trials at research sites in Vietnam.

3. Regulations on reporting

a) For SAE cases occurring at study sites in Vietnam, Male:

- All SAEs occurring at research sites in Vietnam during clinical trials must be reported according to Form No. 04 attached to this Appendix to the Ethics Committee in Biomedical Research. National Administration of Science, Technology and Training - Ministry of Health and National Center for Science and Technolo Drug information and Adverse drug reaction monitoring;

- Reporting deadlines: Fatal or life-threatening SAEs must be reported urgently within 07 working days of receiving information about the SAE. Other SAEs must be reported within 15 business days of receiving information about the SAE. Information on SAE progression must continue to be updated in supplemental reports until the participant has tested the drug recovered or stabilized;

b) For SAE cases occurring at study sites outside of Vietnam:

- All SAEs occurring at study sites outside Vietnam of multinational studies involving Vietnam that lead to withdrawal of trial participants or change of study protocol must be be reported to the Department of Science, Technology and Training - Ministry of Health, the National Ethical Council in Biomedical Research and the National Center for Drug Information and Adverse Drug Reaction Monitoring;

- The time limit for reporting is no more than 10 working days from the date of decision to stop or suspend the research or withdraw drug trial participants from the study.
or change the research protocol;

c) Non-serious AEs occurring in Vietnam must be recorded, summarized and reported briefly in periodic reports and full-text reports on clinical trial research results to the Department of Science and Technology and Train -
Ministry of Health and National Ethics Council in Biomedical Research.

4. Responsibilities of parties in reporting AEs in clinical drug trials in Vietnam:

a) Principal investigator and researcher at the study site: detect and treat AEs in a timely manner, ensuring the safety of drug trial participants; fully monitor and record information; report SAE and periodically update information on AE and SAE for organizations and individuals with clinical reagents, Ethics Council in biomedical research at grassroots level, Ethics Council in biomedical research National Administration of Science, Technology and Training - Ministry of Health and the National Center for Drug Information and Monitoring of Drug Adverse Reactions within the prescribed time limit. In case the level and frequency of AEs and SAEs exceed the allowable limits, the researcher can propose to organizations and individuals having clinical reagents, the Ethics Committee and temporary competent regulatory agencies. stop trying the drug on
clinical;

b) Establishments that receive clinical trials: manage and supervise the detection, handling and monitoring of AE and SAE reports at the research site to ensure safety for drug trial participants.

c) The grassroots ethics committee: to review and give professional opinions on AEs and SAEs occurring at the research site, ensuring absolute safety for drug trial participants;

d) Organizations and individuals that have clinical reagents and authorized research support organizations:

- Collaborate with the main researcher to report AEs and SAEs occurring at research sites in Vietnam to the Ethics Committee in biomedical research

grassroots level of the facility receiving clinical trials, the National Ethical Council in Biomedical Research, the Department of Science, Technology and Training - Ministry of Health, National Center for Drug Information and Adverse Drug Reactions Monitoring;

- Report on SAEs occurring at research sites outside of Vietnamese territory Leading to stopping, suspending the study, withdrawing drug trial participants from the study or changing the research protocol of multinational studies to which Vietnam participates;

- Synthesize data of AEs and SAEs;

Report findings from clinical trial studies, epidemiological studies, animal studies, in vitro studies, information in the literature, and from other sources that may lead to a serious risk associated with the study drug;

d) National Ethical Council in Biomedical Research:

- Review, evaluate, and respond to reports if necessary Individual SAE and SAE information in annual progress reports and full-text reports on clinical trial results;

- Organize supervision and inspection of research sites in case of necessity;

- Advise the regulatory agency to promptly direct the clinical trial recipient, the organization or individual that has the clinical trial drug in order to ensure absolute safety for the drug trial participants;

e) The National Center for Drug Information and Adverse Drug Reactions Monitoring receives SAE reports in clinical trial studies; coordinate with the National Council on Ethics in Biomedical Research to review and evaluate the SAE report; statistics, data analysis of SAE reports in clinical trials; report, advise and propose competent authorities on contents related to ensuring safety for drug trial participants.

Article 21. Finance and payment for drug trial participants in clinical trial of drugs

1. Funding for clinical trial drug research:

a) Funds for clinical trial drug research include professional contracting, consumables, support for drug trial participants, insurance...
discussed by the lead researcher, the facility receiving the clinical trial drug in collaboration with the organization or individual having the drug in clinical trial, or the research support organization authorized by the organization or individual having the drug in clinical trial, construction and signing under the contract;

b) Funds for management and supervision of clinical drug trial research for the following activities: survey and evaluation of research sites; research-related meetings, conferences and seminars; training for research staff; supervision, inspection, inspection, etc., by the main researcher, the clinical trial receiving facility in collaboration with the organization or individual having the drug in clinical trial or the organization supporting the research. authorized clinical reagents to discuss, develop and sign contracts;

c) Organizations and individuals that have drugs for clinical trial are responsible for paying expenses for research into clinical trials.

2. The payment and compensation for damage (if any) for clinical trial participants must be clearly shown in the research information provision and the trial participant's volunteer form. in clinical practice and in research protocols.

Article 22. Termination of clinical drug trial studies

1. At the end of the research, the lead researcher must inventory the research drugs, make payment for the funding, and coordinate with the organizations and individuals having clinical reagents in formulating and completing research dossiers and documents. According to the List of documents required after the end of the study, made according to Form No. 03 (for clinical trial drug research) and Form No. 07 (for drug bioequivalence trial study) issued together with Appendix. this continent.

2. Research dossiers and documents should be archived and preserved according to the contract between the organization or individual having the drug for clinical trial and the facility receiving the clinical trial. For research and development of new products, documentation needs to be kept for at least 10 years.

3. Organizations and individuals that have clinical trial drugs are responsible for keeping research drug samples after clinical trials are over in strict accordance with current regulations. onion.

4. Organizations and individuals having clinical reagents shall coordinate with clinical trial receiving establishments to recall and destroy residual drugs in accordance with regulations. current regulations.

Article 23. Reporting and publication of research results.

1. For clinical trial of drugs for the purpose of registration of drug circulation in Vietnam, within 01 year from the date on which the last trial participant finishes the last visit, the establishment receives the drug trial on The clinician has the responsibility to coordinate with the organization or individual having the drug in clinical trial to complete the application for approval of the clinical trial result and submit it to the competent management agency for approval.

2. The full report on clinical trial results should be presented according to Form No. 12 in Appendix III issued with Circular 29/2018/TT-BYT. For multinational studies, in addition to analyzing the general results, separate analyzes of the main safety and efficacy variables in the Asian or Vietnamese study populations for drugs that are weak Racial factors are considered to affect efficacy and safety.

3. The publication of research results must be made within 03 years from the date of issuance of the decision approving the clinical trial results by the competent regulatory agency and must comply with the regulations on the nature of the drug. authorship in the publication of research results.

4. Encourage principal researchers to publish research results in prestigious national and international journals.

Form 01 – List of essential documents before conducting clinical drug research studies

STT	file name	Purpose	Requirements for		Guide mat
			Principal Investigator/ Testing facility clinical medicine	Organizations and individuals having drugs for clinical trial	
1.1	Application for registration of a clinical trial of a drug	Provide brief product information Proposing the trial and recommending the main investigator/facility to receive the drug in clinical trials		ÿ	Model No. 06 Appendix III (issued attached follow Pine private 29/2018/ TT A FLAT)
1.2	Product information records	To prove the product (IB) Scientific information regarding clinical reagents has been provided to Research main lifeguard	ÿ	ÿ	
1.3	Application for approval of a clinical trial drug study		ÿ		Denominator 07 Appendix III Circular 29
1.4	Explanation of outline Research outline of drug trial research in detail according to regulations, clinical records and medical records research supervision (CRF)	practice procedure standards, monitoring, monitoring, evaluation ... and research case samples.	ÿ	ÿ	Model No. 08 Appendix III Circular 29
1.5	Contracts for clinical trials between organizations and individuals	To demonstrate financial agreement	ÿ	ÿ	

STT	file name	Purpose	Requirements for		Guide mat
			Principal Investigator/ Testing facility clinical medicine	Organizations and individuals having drugs for clinical trial	
	clinical trial drug holder and principal investigator/clinical trial recipient	between the main researcher/recipient of clinical trial and the organization or individual that has clinical reagents for clinical trial.			
1.6 A written confirmation of participation in the study is signed between the parties involved, for example: - Principal Investigator - Branch principal researchers and organizations and individuals that have clinical reagents. - Lead researcher/clinical trial recipient and local authority at the study site (if required).		To confirm consent to participate in the study in accordance with current regulations.	ÿ ÿ ÿ	ÿ ÿ (where required)	
1.7 Information provided to clinical trial participants: - Information form - To confirm the research and Voluntary form to volunteer to participate in the research. research (including all relevant information to be communicated to the subject). - Any other information in written form.		- To demonstrate that drug trial participants will be provided with relevant information	ÿ ÿ	ÿ ÿ	Denominator 09 Appendix III Circular 29

STT	file name	Purpose	Requirements for		Guide mat
			Principal Investigator/ Testing facility clinical medicine	Organizations and individuals having drugs for clinical trial	
	Notice of selection for participating in drug trials	To demonstrate the subjects the measure). incorporated in written form (content and wording) to fully support the decision Sign a volunteer form to participate in the study. used of selection (if is appropriate and not coercive, ensure ethics in research.	ÿ		
1.8 Insurance contract		To prove that drug trial participants are compensated if they are injured during clinical trial participation.	ÿ	ÿ	
1.9 Certificate of approval from the Ethical Council in Biomedical Research at all levels		Demonstrate approval of the Ethics Committee in Biomedical Research at all levels.			
1.10 Date of approval of the document/ approval of the Ethics Committee at all levels for the following contents: - Research outline (including revised version); - Case report - Voluntary form to participate in drug trial - Other information in the form		To confirm that the clinical trial has been evaluated by the Ethics Committees at all levels and given approval/ approval. To confirm the version number and approval date of the document (documents)	ÿ	ÿ	Certificate of approval from the Ethics Co

STT	file name	Purpose	Requirements for		
			Principal Investigator/ Testing facility clinical medicine	Organizations and individuals having drugs for clinical trial	Guide mat
	text provided to trial participants - Notice of selection of participants (if used) - Compensation for participants (if any) - Any other documents showing approval/approval				
1.11 Decision to establish the Society	To demonstrate that co-ethics in research The grassroots biomedical research ethics committee was established in accordance with the requirements of the current regulations. mandarin	To demonstrate that the establishment of the GCP requirements of the	ÿ	ÿ (where required)	Decided to become Set up a Council
1.12 Approval of the competent authority for the research protocol.		To confirm the approval of the competent authority before commencing clinical trials according to current regulations.	ÿ	ÿ Decision	approving the topic Minister's Diamond A FLAT
1.13 Scientific curriculum vitae and GCP certificate issued by the Ministry of Health of the Principal Investigator and researchers (including managers) Researcher, pharmacist, nurse, laboratory technician...)		Prove capacity and uniformity, suitable to conduct clinical trials and medical monitoring and supervision of drug trial participants.	ÿ	ÿ	
1.14 GCP-certified clinical trial facility (Clinical Zone)		To demonstrate the capacity of the test facility	ÿ	ÿ	

STT	file name	Purpose	Requirements for		Guide mat
			Principal Investigator/ Testing facility clinical medicine	Organizations and individuals having drugs for clinical trial	
	preparation, file storage area, monitoring and supervision area, meeting rooms, office equipment...) and appropriate quality standards (standard laboratories, standard technical procedures, .. .) or approval of the Ministry of Health for clinical trial facilities.	drugs, equipment to meet the conduct of paraclinical tests for research and testing.			
1.15	Sample of reagent label attached to clinical reagent composition	To demonstrate compliance with relevant labeling regulations and the appropriateness of instructions provided to drug trial participants.		ÿ	
1.16	Instructions for the management of clinical reagents and trial-related materials (if not included in the protocol or product file)	To demonstrate the necessary instructions for storage, packaging, preparation, destroy clinical reagents and materials related to drug testing in accordance with current regulations.	ÿ	ÿ	
1.17	Transport Records To demonstrate shipment of trial products shipment date, clinical reagents trial-related materials	lot number, and method of shipping, and sieves and materials related to drug testing. Give	ÿ	ÿ	

STT	file name	Purpose	Requirements for		Guide mat
			Principal Investigator/ Testing facility clinical medicine	Organizations and individuals having drugs for clinical trial	
		batch number tracking, verification of shipping conditions and accountability.			

STT	file name	Purpose	Requirements for		
			Principal Investigator/ Establishments that receive drugs in clinical trials	Organizations and individuals having drugs for clinical trial	Guide mat
1.18	Certification of analysis of tested products	To prove the type, purity and strength of the product will be clinically tested.		ÿ	
1.19	Re-coding procedures for blind clinical trials	To demonstrate in an emergency, test products Blinded trials can be revealed without breaking the blinding principle to the remaining subjects being treated.	ÿ	ÿ	
1.20	Proven and Assured Standard Practices (SOPs) for techniques to ensure uniformity, objectivity, accurate research of research techniques	To demonstrate in a scientific, technique used in the study.			
1.21	Random process or list	To demonstrate the method of random selection of test subjects.		ÿ	

Form 02 - List of essential documents in the process of conducting clinical drug research research

ST T	file name	Purpose	Requirements for		Guide mat
			Principal Researcher/Foundation take a test clinical medicine	Organizations and individuals having drugs for clinical trial	
2.1 Records Updates To Prove Products		researchers are promptly informed of information related to research drugs.	ÿ	ÿ	
2.2 Any changes To demonstrate	records - Clinical trial protocol assist - Voluntary form to participate in the study - Any other written information provided to trial participants - Notice for the selection of drug trial participants (if)	change to: Changes of clinical trial their effect throughout the trial	ÿ	ÿ	
2.3 Approval decision To prove approval/certificate of approval. To determine the	changes approved by the following items: - Change of research proposal - Changes to: + Voluntary form to participate in the study	Ethics Council and Ethics Approval/ of this record number and date	ÿ	ÿ	

ST T	file name	Purpose	Requirements for		Guide mat
			Principal Researcher/Foundation take a test clinical medicine	Organizations and individuals having drugs for clinical trial	
	+ Any other information provided in writing to participants + Notice for the selection of participants (if any) + Any other documents giving consent + Constant appraisal five				
2.4 Curriculum vitae, GCP	certificate issued by the Ministry of Health of the researcher or supervisor.	Demonstrate capacity and suitability to conduct clinical trials and medical supervision at the study site.	ÿ	ÿ	
2.5 Update values considered to	be normal in medicine/test/ engineering procedures/ tests mentioned in research protocol	To demonstrate the values/ ranges considered normal were adjusted during the test.	ÿ	ÿ	
2.6 Medical facility/laboratory	Certificate throughout the period established quality and/or external quality assessment - Other validations 2.7 Transport documentation	To demonstrate testing is still valid/ technical procedures/tests Properly maintained - tested Controlled substance	ÿ	ÿ	
			ÿ	ÿ	

ST T	file name	Purpose	Requirements for		Guide mat
			Principal Researcher/Foundation take a test clinical medicine	Organizations and individuals having drugs for clinical trial	
	transfer of test products and test-related materials				
2.8 Test certificates for	New batch of products test product			ÿ	
2.9 Report of the waves	To demonstrate the monitoring the monitoring waves.	and monitoring results of		ÿ	
2.10 Other forms of	communication other than field monitoring, through via: - Letters - Meeting memos - Memorization of phone calls	To document any significant agreements in discussions regarding trial administration, protocol violations, trial conduct, reporting AE/SAE.	ÿ	ÿ	
2.11 The research information	supply and the signed research volunteer form	To prove that the Voluntary Form is consistent with GCP and protocol, signed before the subject participates in drug testing. Record consent directly. To prove the existence of	ÿ		
2.12 Source documents		research subjects along with the data obtained through drug testing. This document includes all the original information related to the test			

ST T	file name	Purpose	Requirements for		Guide mat
			Principal Researcher/Foundation take a test clinical medicine	Organizations and individuals having drugs for clinical trial	
		medications, medical treatments, and history of study subjects.			
2.13	The medical record is signed, date of signing and completion	To demonstrate that the investigator or an authorized member of the Principal Investigator takes notes to confirm observations.	ÿ (copy)	ÿ (original)	
2.14	Efficacy Documentation To substantiate all changes/ records	corrections to medical Supplements or corrections to the medical record after the start of data collection were recorded.	ÿ (copy)	ÿ (original)	
2.15	SAE report to home sponsor	SAE report of Lead researcher for organizations or individuals having clinical trial drugs.	ÿ	ÿ	
2.16	SAE report to the Ethics Committee	SAE report of organizations and individuals having clinical reagents and main researchers to the Ethics Council 2.17 Notice of the	ÿ	ÿ	
team	Notice of organizations, individuals and the above clinical reagents clinical studies for investigators information the safety and concurrent drugs. full		ÿ	ÿ (where required)	
2.18	Mid-term reports	Mid-term reports or	ÿ	ÿ	

ST T	file name	Purpose	Requirements for		Guide mat
			Principal Researcher/Foundation take a test clinical medicine	Organizations and individuals having drugs for clinical trial	
	or annually for each year for Council and governing body Object Identifiers	the Ethics and Co-Ethics management agency. To		(where required)	
		lead researcher/clinical trial recipient maintains a confidential list of trial participants' names associated with a trial number to identify the trial participant.	ÿ		
2.20	Correspondence Log To Prove	Participation Join in chronological order of subjects by test code.	ÿ		
2.21	Product Explanation To demon	strate that the research product has been studied used in accordance with the outline.	ÿ	ÿ	
2.22	Signatures List To verify the sig	natures and initials of those authorized to participate and/or edit medical records.	ÿ	ÿ	
2.23	Records of tissue/biological fluid samples have been archived (if needed)	To confirm storage and identification of stored samples if experiments need to be repeated.	ÿ	ÿ	

Form 03 - List of essential documents after finishing clinical trial of drugs

After completing or stopping the test, all documents are verified specified in items 1 and 2 should be compiled with the following sections:

No.	Document name	Purpose	Requirements for		Guide mat
			Principal investigator/ research facility	Organizations and individuals having drugs for clinical trial	
3.1	Product explanation research products at drug testing sites	To demonstrate clinical reagents used in accordance with the research protocol, received at the research site, distributed to the subjects, returned by the subjects, and returned to the organizations or individuals that have clinical reagents.	ÿ	ÿ	
3.2	Documents on To confirm cancellations of non-clinical reagents	use is performed by organizations or individuals that have clinical reagents or at the research site in accordance with current regulations.	ÿ (if canceled at the research site)	ÿ	
3.3	List of codes To enable identification of all subjects including subjects who participated in a pilot drug trial	Case of completed drug trial in the follow. This list must be kept confidential for an agreed time.	ÿ		
3.4	Monitoring report on the end of drug trial	To demonstrate that all activities required for trial termination have been completed, and		ÿ	

No.	Document name	Purpose	Requirements for		
			Principal investigator/research facility	Organizations and individuals having drugs for clinical trial	Guidance
		Copies of the required documents have been stored in the appropriate files.			
3.5	Periodic and irregular monitoring reports	Demonstrate the trial's compliance with the protocol, GCP, and relevant regulatory requirements mandarin.	ÿ	ÿ	
3.6	Treatment Classification and Decoding Guidelines blind in case of need	In order for organizations and individuals with clinical reagents to know and properly perform grouping, as well as to know how to decipher to have appropriate interventions when serious adverse events occur.		ÿ	
3.7	Report text request approval for a drug trial clinical drug of the principal investigator to the Ethics Council and the governing body	To confirm the refund and drug results. approve clinical	ÿ		
3.8	Full text report interpretation of the clinical trial of a rescue drug. in clinical	To confirm the results and	ÿ	ÿ	Model No. 12 Appendix III Circular 29
3.9	Database of Vietnamese patients (in case of male	To check the accuracy and truthfulness of research results.	ÿ	ÿ	

No.	Document name	Purpose	Requirements for		
			Principal investigator/research facility	Organizations and individuals having drugs for clinical trial	Guidemat
	request)				

Form 04 - Serious adverse event report in clinical drug trials

Reporting number of the unit: ……

SERIOUS EVENT REPORTING FORM (SAE) IN CLINICAL TRIAL RESEARCH

1. SUMMARY OF REPORT

Report Type: ☐ First report ☐ Additional reporting

Classification according to the severity of the event:

☐ Dead
☐ Life threatening
☐ Hospitalization/prolonged hospital stay
☐ Disability/permanent/serious disability
☐ Birth defects / birth defects pediatric
☐ Requires medical intervention to prevent one of the above situations or is judged to be medically meaningful by researcher or researcher main

Research name ……
……

Study Design If this is a blinded study, will SAE lead to an open-blind?
☐ Open label ☐ Single blind ☐ Double blind
☐ Have ☐ No ☐ No information

Donors ……

Name of principal investigator SAE-recognized study site ……

When to receive information about SAE ……

Time of appearance of SAE ……

SAE end time (or check *"Ongoing"* box if SAE is ongoing) …… Ongoing ☐

SAE name (diagnosis of SAE or ……
main symptoms of SAE) ……
Abbreviated name of participant ……
in clinical trial ……
Number of participants in ……
clinical trials ……

2. DESCRIPTION AND HANDLING OF SAE

Provide information on clinical signs, symptoms, laboratory tests related to SAE, measures to manage SAE if any (including discontinuation/ reducing dose of clinical reagents/ study protocol) , developments after taking such remedial measures and other necessary information with specific timelines (if any).

……
……
……
……
……

Result after SAE treatment:

☐ Recovery does not leave sequelae ☐ Recovering ☐ Death (date of death: ……)

☐ Recover but have to sequelae again ☐ Not recovered yet ☐ No information

3. CLINICAL TRIAL PARTICIPANTS

Date of birth ……
Age ……
Sex ☐ Male ☐ Female For Female: ☐ Pregnant (week ……)
Weight (Kg) ……
Medical history ……
related to SAE ……

4. CLINICAL TRIAL DRUGS/RESEARCH PROGRAMS

TT	Clinical reagents or research protocol (a)	Dosage forms, content	Street use	Dosage	Date *(day month Year)*	
					Start	End
I						
Ii						
Iii						
Iv						
IN						
We						

(a) Specify the clinical trial drug/research protocol used by the clinical trial participant. For blinded studies and SAE that did not lead to an open-blind/ unidentified clinical trial/research protocol used by the clinical trial participant, specify the protocol used in the study and arm of the participant in a clinical trial (described in section 2) (if information is available).

5. INTERVENTION FOR CLINICAL TRIAL DRUG/RESEARCH REGION AFTER SAE Occurrence

STT (b)	Has the clinical trial drug dose been discontinued/reduced/ researched in the clinical trial participants experiencing SAE?		If the clinical trial/ research regimen is stopped/reduced/reduced (or open-blind), will the severity of SAE be improved?			If the clinical reagent/study protocol is reused, will the event reoccur?			
	Have	No	Yes	No	No information	Yes	No	No information	Do not reuse
I	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ii	☐	☐	☐	☐	☐	☐	☐	☐	☐
iii	☐	☐	☐	☐	☐	☐	☐	☐	☐
Iv	☐	☐	☐	☐	☐	☐	☐	☐	☐
IN	☐	☐	☐	☐	☐	☐	☐	☐	☐
we	☐	☐	☐	☐	☐	☐	☐	☐	☐

(b) The serial number (STT) corresponding to item 4.

6. MEDICATIONS/PRODUCTS USE CONcurrently MAY RELATED TO SAE AS FINDED BY THE RESEARCH

(excluding drugs used to manage SAE)

STT	Drugs/preparations used concurrently (original name, trade name)	Dosage form, content	Usage route	Dosage	Date *(day month Year)*	
					Start	End
1						
2						
3						
4						
5						
6						

7. ASSESSMENT OF THE MAIN STUDENT/MAIN RESEARCH

ABOUT THE CAUSEAL RELATIONSHIP BETWEEN SAE AND TRIALAM DRUGS

STUDY READY/PROGRAMS

STT (b)	Evaluation of the causal relationship between SAE and clinical reagents/research protocols			If relevant, was this an expected or unexpected response to the clinical reagent/study regimen?(c)	
	May be related	Irrelevant	Can't conclude yet	Known/ is expected	Out of expectation
i	☐	☐	☐	☐	☐
ii	☐	☐	☐	☐	☐
iii	☐	☐	☐	☐	☐
iv	☐	☐	☐	☐	☐
in	☐	☐	☐	☐	☐
we	☐	☐	☐	☐	☐

(b) The serial number (STT) corresponding to item 4.

(c) Whether SAE is *“expected”* or *“unexpected”* should be assessed against the clinical trial/study protocol literature such as the most up-to-date study protocol if the drug unlicensed clinical trial, or the latest version of the User Guide if the clinical trial has been approved for registration.

onion.

- Explain the rationale for the assessment of causality and the predictive nature of SAE: ……

……..

……..

- How many SAEs or similar AEs have occurred in this study up to the time of reporting:

+ At the study site, SAE/AE mentioned in this report was recorded: ……..

+ At other research sites: ……..…

8. OPINION OF THE REPRESENTATIVE OF THE Ethics/ Scientific Council of the Clinical Trial Receipt (if any)

Recommendations for participants in clinical trials *(not applicable in case of death of clinical trial participants):*

☐ Continue to participate in research ☐ Suspend participation in the study ☐ Withdrawal from the study

Research proposal:

☐ Continue to conduct research ☐ Suspension of research implementation ☐ Stop conducting research

Other recommendations (if any):

……

……

……

9. REPORTER (lead researcher or authorized researcher)

Signature: ……

Signed *date (day/ month/ year):* ……

Full name: ……

Position, department/department: ……

Phone number: ……

Email address: ……

REPRESENTATIVE OF THE Ethics Council /SCIENCE COUNCIL OF DRUG TRIAL RECEIVING FACILITIES IN CLINICAL

(sign, write full name)(d)

FACILITY LEADERSHIP RECEIVES CARDS CLINICAL DRUGS

(sign, write full name and seal)

(d)Applies only if comments in section 8 are made.

Form 05 - List of essential documents before conducting bioequivalence testing of drugs

STT	file name	Purpose	Requirements for		Reference
			Individual researcher Bioequivalence facility	Organization, with main drug testing biological	
5.1	Application for bioequivalence testing of drugs	Provide summary information Brief about the product to be tested and propose the main researcher/institution to receive the bioequivalence test		ÿ	
5.2	Product information records (IB)	To prove product information Scientific information related to clinical reagents has been made available to Principal Investigator	ÿ	ÿ	
5.3	Application for approval of drug bioequivalence test		ÿ		
5.4	Explanation of trial protocol of drugs and sample medical records monitoring and research (CRF)	Detailed research outline according to standard practice, bioequivalence regulations, procedures monitoring, evaluation... and research case samples.	ÿ	ÿ	
5.5	Equivalence Trial Contract between a team of individuals having researcher and the principal/institution that accepts the principal facility biological, and organizations and individuals that have a bioequivalence reagents	To demonstrate bioequivalence agreement on their finances, between investigator/equivalence facility to receive bioequivalence test	ÿ	ÿ	

STT	file name	Purpose	Requirements for		Reference
			Individual researcher with drug/ Bioequivalence testing facility	Organization, biological	
5.6	The written confirmation of participation in the study is signed between the relevant parties, for example, in accordance with the following requirements:	To confirm consent current.	ÿ ÿ		
	- Principal Investigator - Branch principal researchers and organizations and individuals that have clinical reagents.		ÿ	ÿ (where required)	
	- Lead researcher/ bioequivalence testing facility and local authority at the study site (if required).		ÿ		
5.7	Information to be provided to bioequivalence trial participants:				
	- Information form - To confirm form to volunteer to participate in the research (including all relevant information to be communicated to the subject).	the research and Voluntary	ÿ	ÿ	
	- Any other information - To prove	the person taking the drug test will be in writing. be provided with appropriate written information (content and wording) to fully support the decision to sign the Research Voluntary Form.	ÿ	ÿ	
	Selection Notice for	To demonstrate the	ÿ		

STT	file name	Purpose	Requirements for		Reference
			Individual researcher main drug/ Bioequivalence facility	Organization, with testing biological	
	drug trial participants selection	measure (if used). is appropriate and non-coercive, ensuring the ethics of research.			
5.8	Insurance policy	To demonstrate that drug trial participants are compensated if they are injured during bioequivalence testing.	ÿ	ÿ	
5.9	Certificate of Acceptance/Proof of Approval of Co-Ethics Committee for Research Biomedical Research	Certificate of Approval of Committee for Research Ethics in biomedical research at all levels.			
5.10	Date of approval of the document approval of bioequivalence, the Committee has been appraised by the Department of Ethics and - Research proposal and consent/opinion (including changes); Voluntary slip to participate in the trial as - Other information in written form is provided to drug trial participants - Notice of participant selection (if used) - Compensation for participants (if any) - Any other documents	To confirm the approval/ Committee Ethics of Ethics at all levels for ant agree. To confirm the version number and - the approval date of the material (documents)	ÿ	ÿ	Certificate of approv

STT	file name	Purpose	Requirements for Individual researcher with main Bioequivalence testing facility	Organization, drugs/ biological	Reference
	express approval/approval				
5.11	The decision to establish the Association research The grassroots biomedical research ethics committee, the notification letter for the grant of the cipher, was established with the document in accordance with the requirements.	To prove that the co-ethical in biomedical research, their members and the authorized demand of rights. GCP and related applicable regulations	ÿ	ÿ (where required)	Decision on establishment of the Council and authorized documents
5.12	Institutional/Institutional Approval relevant institution with the study protocol.	To confirm authoritative approval of the authority before commencing bioequivalence testing in accordance with applicable regulations.	ÿ	ÿ	Decision approving the topic Outline of - trial acceptance facility Similar student
5.13	Scientific curriculum vitae and Certificate issued by the Ministry of Health of the Research Department suitable for conducting bioequivalence testing chemistry (including staff and and supervision for the personnel managing the AN. Medical monitoring nurses,...)	Proof of competence and uniformity, in accordance with GCP of the main students and following pharmacists, participate in drug trials.	ÿ	ÿ	
5.14	Bioequivalence testing facility meets GCP (treatment area, clinical equipment, storage area, etc.)	To demonstrate facility strength	ÿ	ÿ	

STT	file name	Purpose	Requirements for: Individual drug/ Bioequivalence testing facility	Organization, researcher with main biological	Reference
	records, monitoring area, meeting rooms, laboratory testing of office suitable for research (laboratory) standards, standard technical procedures....) or approval of the Ministry of Health for bioequivalence testing establishments.	supervision, meeting equipment quality standards experiment.			
5.15	Sample of reagent label attached to the clinical reagent label and the soundness of the clinical guidelines	To demonstrate compliance with regulations the sample is instructions provided to drug trial participants.		ÿ	
5.16	Guidelines for Work reagent management guidelines involved in packaging, reconstitution, and disposal (if available). equivalent in protocol records)	In order to demonstrate the necessary storage, materials and for bioequivalence are compatible reagents for microbiology and product related to drug testing in accordance with current regulations.	ÿ	ÿ	
5.17	Transport Records test products for shipment, batch number and bioequivalence of reagents and materials involved in the testing.	To demonstrate the shipping date of the and the method of transport bioequivalence and materials related to drug testing. Allows tracking of batch numbers, verification of shipping conditions and liability	ÿ	ÿ	

STT	file name	Purpose	Requirements for		Reference
			Individual researcher main drug/ Bioequivalent facility	Organization, with testing biological	
		accountability.			
5.18	Certification analysis of products tested	To test for purity and degree strength of products to be tested.		ÿ	
		clinical trial.			
Recoding procedures for emergency unblinding in Clinically tested products		To demonstrate 5.19 Blinded trials can be revealed without breaking the blinding principle to the remaining subjects being treated.	ÿ	ÿ	
5.20	Proven and Assured Standard techniques to ensure uniformity, research	Practices (SOPs) for accuracy of the techniques used in the study.			
Process or random list		To demonstrate 5.21 method of random selection of test subjects.		ÿ	

Form 06 - List of essential documents in the process of conducting bioequivalence testing of drugs

No.	Document name	Purpose	Requirements for		Lead
			Researcher main/mechanical approval facility Similar student	Organizations and individuals with drug bioequivalence test	
6.1	Updates to Records	To demonstrate product studies Researchers are promptly informed of information related to research drugs assist.	ÿ	ÿ	
6.2	Any change outline volunteer study voucher is valid throughout the drug trial. participate in research - Any other written information provided to trial participants - Notice for the selection of drug trial participants (if any)	To demonstrate a change to: of related records - Research come to trial equivalent - The	ÿ	ÿ	
6.3	Approval Decision To prove the change approvals/certificates have been /Society's approval/Ethics Council/approval/ following items: - Change of research outline - Changes to: + Voluntary form to participate in the study + Any information	under approval/approval. To determine the version number and date of the record	ÿ	ÿ	

No.	Document name	Purpose	Requirements for		Lead
			Researcher main/mechanical approval facility Similar student	Organizations and individuals with drug bioequivalence test	
	other is provided in writing to participants + Notice for the selection of participants (if any) + Any other documents giving consent + Constant appraisal five				
6.4	Curriculum Vitae, Certificate of competence and certification issued by the Ministry of Health of GCP bioequivalence tester or medical supervisor at the Supervisor.	suitability to conduct the study site.	ÿ	ÿ	
6.5	Update values that are considered normal ranges/ have been adjusted normally in medical/laboratory/ question. in the research outline assist	To demonstrate values/ procedural procedures during the procedure/test in	ÿ	ÿ	
6.6	Medical facility/reviewing laboratory accordance with appropriate - Certificate - Established quality control and/or external quality assessment - Other appraisals	To demonstrate that testing/procedures is maintained throughout the engineering/testing phase test.	ÿ	ÿ	

No.	Document name	Purpose	Requirements for		Lead
			Researcher main/mechanical approval facility Similar student	Organizations and individuals with drug bioequivalence test	
6.7	Documentation of the transport of test products and test-related materials		ÿ	ÿ	
6.8	Test certificates for New batch of products test product			ÿ	
6.9	Reports of episodes	To demonstrate monitoring and results of monitoring sessions monitoring.		ÿ	
6.10	Other forms of communication or discussions validation, protocol violations, via: - Letters - Meeting memos - Memorization of phone calls	To record any agreements on, drug testing and AE/ SAE reporting.	ÿ	ÿ	
6.11	Information Release To and volunteer information forms and protocols, signed before the trial	To demonstrate that the research for GCP Volunteers consistent with in the trial of its participate Record the signed thing consent directly.	ÿ		
6.12	Source documents	To prove the existence of the research subjects along with the data collected through the test			

No.	Document name	Purpose	Requirements for		Lead
			Researcher main/mechanical approval facility Similar student	Organizations and individuals with drug bioequivalence test	
		medicine. This document includes original information regarding the drug trial, medical treatments, and the subject's medical history.			
	signed and completed medical records	To prove research 6.13 Signed, The principal investigator or authorized members of the Principal Investigator took notes to confirm the observations.	ÿ (copy)	ÿ (original)	
6.14	Validation Documentation To edit medical records	To substantiate all changes/ additions or corrections to the medical record after data collection commenced were recorded.	ÿ (copy)	ÿ (original)	
6.15	SAE report to home sponsor	SAE report of the principal investigator for the organization or individual having bioequivalence reagents.	ÿ	ÿ	
6.16	SAE Report to the Ethics Committee	Organizational SAE Report, bioequivalent reagent individual and principal investigator for the Ethics Committee	ÿ	ÿ	
6.17	Notice of the team Notification and individuals that have per equivalent to researchers about safe medications. safe	of organizations, individuals, in clinical trials with drugs tested ous safety information drug information trial and concomitant	ÿ	ÿ (where required)	

No.	Document name	Purpose	Requirements for		Lead
			Researcher main/mechanical approval facility Similar student	Organizations and individuals with drug bioequivalence test	
6.18	Mid-term reports	Report midterm or annually to the Ethics Board	ÿ	ÿ (where required)	
	the Ethics Board and the government	the Ethics Board or annually to			
	management agency.				
List of object identifiers		To demonstrate research 6.19 The lead investigator/ bioequivalence trial establishment maintains a confidential list of trial participants' names associated with a trial number to identify the trial participant.	ÿ		
6.20	Correspondence Log To Prove Participation	chronological increment of subjects by trial number	ÿ		
6.21	Product justification To demonstrate that the research		ÿ	ÿ	
	product at the trial site has been administered				
	used in accordance with the outline.				
6.22	List of signatures To verify the signatures and initials of	those authorized to participate and/or edit medical records.	ÿ	ÿ	
6.23	Sample Records To confirm	the storage and identification of biological tissue/fluid samples stored if experiments need to be repeated.	ÿ	ÿ	
	stored (if needed)				

Form 07 - List of essential documents after the end

bioequivalence testing of drugs

Upon completion or cessation of testing, all documents identified in sections 5 and 6 should be documented with the following sections:

No.	Document name	Purpose	Requirements for		Guide mat
			Principal investigator/ research facility	Organization, individuals with bioequivalence reagents	
7.1	Product explanation research products at drug testing sites	To demonstrate that bioequivalence reagents were used correctly according to the study protocol, were received at the study site, were distributed to subjects, were returned by subjects, were returned to the institution , individuals with bioequivalence reagents.	ÿ	ÿ	
7.2	Bioequivalence Reagent Disposal Documents	To confirm that the destruction of unused bioequivalent reagents is carried out by organizations or individuals that have reagents in clinical practice or at the research site in accordance with current regulations.	ÿ (if canceled at the research site)	ÿ	
7.3	List of identification numbers of subjects who completed the study	To enable identification of all subjects who participated in a drug trial where follow-up is required. This list must be kept confidential for an agreed time.	ÿ		
7.4	End of trial monitoring report	To demonstrate that all activities required for trial termination have been completed, and copies of required documentation have been obtained.		ÿ	

No.	Document name	Purpose	Requirements for		Guide
			Principal investigator/ research facility	Organization, individuals with bioequivalenc	mat
		are stored in the appropriate files.			
7.5	Periodic and irregular monitoring reports	Demonstrate the trial's compliance with the study protocol, GCP, and relevant regulatory requirements.	ÿ	ÿ	
7.6	Guidelines for treatment grouping and decoding of blindness in case of need	In order for organizations and individuals with bioequivalent reagents to know and properly perform grouping, as well as know how to decipher to take appropriate interventions when serious adverse events occur.		ÿ	
7.7	Written report and request approval of the main researcher's bioequivalence test results to the Ethics Committee and regulatory agencies	To confirm the completion of a drug bioequivalence test.	ÿ		
7.8	Full text report drug bioequivalence test results	To confirm the results and interpret the bioequivalence test.	ÿ	ÿ	
7.9	Database of Vietnamese patients (in case of request)	To check the accuracy and truthfulness of the research results assist.	ÿ	ÿ	