REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 14 OF 2021
ON
CERTIFICATION OF GOOD MANUFACTURING PRACTICES
FOR TRADITIONAL MEDICINES

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that in order to protect the public from the traditional medicines which do not meet the requirements of safety, efficacy and quality, as well as to provide a guideline in conducting certification of Good Manufacturing Practices for Traditional Medicines, it is necessary to regulate the certification of Good Manufacturing Practices for Traditional Medicines;

b. that in order to improve the competitiveness of traditional medicine industries, especially for small enterprises of traditional medicines and micro enterprises of traditional medicines, it is necessary to simplify the certification mechanism for Good Manufacturing Practices for Traditional Medicines;

c. that the provisions regarding the certification of Good Manufacturing Practices for Traditional Medicines as regulated in Regulation of the Chairperson of Indonesian Food and Drug Authority Number 35 of 2013 on Certification Procedures for Good Manufacturing Practices for Traditional Medicines are

no longer in line with the legal requirements and organizational needs of the Indonesian Food and Drug Authority, so it is necessary to be replaced;

d. that based on the considerations as referred to in point a, point b, and point c, as well as to implement the provisions of Article 35 section (2) of Regulation of the Minister of Health Number 006 of 2012 on Traditional Medicine Industries and Enterprises and Article 6 section (2) of Regulation of the Minister of Health Number 007 of 2012 on Traditional Medicine Registration, it is necessary to establish Regulation of the Indonesian Food and Drug Authority on Certification Procedures for Good Manufacturing Practices for Traditional Medicines;

Observing : 1. Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);

2. Regulation of the Chairperson of Indonesian Food and Drug Authority Number HK.03.1.23.06.11.5629 of 2011 on Technical Requirements of Good Manufacturing Practices for Traditional Medicines (State Bulletin of the Republic of Indonesia of 2011 Number 393);
3. Regulation of the Minister of Health Number 006 of 2012 on Traditional Medicine Industries and Enterprises (State Bulletin of the Republic of Indonesia of 2012 Number 225);
4. Regulation of the Minister of Health Number 007 of 2012 on Traditional Medicine Registration (State Bulletin of the Republic of Indonesia of 2012 Number 226);
5. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1002);

6. Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1003);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON CERTIFICATION OF GOOD MANUFACTURING PRACTICES FOR TRADITIONAL MEDICINES.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. Traditional Medicine mean any materials or ingredients derived from plants, animals, minerals, galenics, or mixture of those ingredients which have been used for generations for treatment, and can be applied in accordance with the prevailing norms in the public.
2. Traditional Medicine Industry (*Industri Obat Tradisional*), hereinafter abbreviated as IOT, means an industry which can manufacture all Dosage Forms of Traditional Medicines.
3. Industry of Natural Ingredient Extract *(Industri Ekstrak Bahan Alam*), hereinafter abbreviated as IEBA, means an industry which specializes in manufacturing dosage in the form of extracts as the final product.
4. Small Enterprise of Traditional Medicine *(Usaha Kecil Obat Tradisional*), hereinafter abbreviated as UKOT, means an enterprise which can manufacture all Dosage Forms of Traditional Medicines, excluding tablet, effervescent, suppository, and soft capsule Dosage Forms.

5. Micro Enterprise of Traditional Medicine (*Usaha Mikro Obat Tradisional*), hereinafter abbreviated as UMOT, means an enterprise which exclusively produces dosage forms of Traditional Medicines in the forms of param, tapel, pilis, topical liquid and chopped plant or animal.
6. Good Manufacturing Practice for Traditional Medicines, hereinafter abbreviated as GMP for TM, means all aspects of manufacturing Traditional Medicines aiming to ensure that the products consistently meet the quality requirements established in accordance with their intended use.
7. Dosage Form means identification of Traditional Medicine from the physical forms related to physical appearance and route of administration of Traditional Medicines.
8. Audit of compliance with technical requirements of GMP for TM, hereinafter referred to as Inspection, means a local inspection conducted directly in Traditional Medicine Industry and Enterprise in order to determine their compliance with the technical requirements of GMP for TM.
9. Certificate of GMP for TM means an official document proving that the Traditional Medicine Industry and Enterprise have complied with all the technical requirements of GMP for TM in manufacturing one type of Traditional Medicine Dosage Form.
10. Certificate of Staged GMP For TM Staged GMP for TM Aspects means an official document proving that the Traditional Medicine enterprise has gradually complied with the technical requirements of GMP for TM in manufacturing one type of Traditional Medicine Dosage Form.
11. Technical Implementing Unit (*Unit Pelaksana Teknis*) within Indonesian Food and Drug Authority, hereinafter abbreviated as UPT of Indonesian FDA, means an independent work unit that carries out certain operational technical duties and/or certain supporting technical duties in the field of drug and food control.

12. Head of UPT of Indonesian FDA means the Head of Provincial Office/District Office of Indonesian Food and Drug Authority throughout Indonesia.
13. Indonesian Food and Drug Authority, hereinafter referred to as Indonesian FDA, means a non-ministerial government institution administering government affairs in the field of food and drug control.
14. Chairperson of the Authority means the Chairperson of Indonesian Food and Drug Authority.
15. Day means a work day.

CHAPTER II
IMPLEMENTATION

Article 2

(1) IOT, UKOT, and UMOT in manufacturing Traditional Medicine referring to the Dosage Forms and IEBA in the manufacture of extracts must have the GMP Certificate for TM.

(2) Certificate of GMP for TM as referred to in section (1) for IOT, UKOT, and UMOT is applied for one of the requirements to obtain the marketing authorization.

(3) In order to obtain Certificate of GMP for TM as referred to in section (1), certification is conducted on the manufacturing process of Traditional Medicines by IOT, IEBA, UKOT or UMOT.

Article 3

(1) Certificate of GMP for TM as referred to in Article 2 section (1) consists of:
   a. Certificate of GMP for TM; or
   b. Certificate of Staged GMP for TM Aspects.

(2) Certificate of GMP for TM as referred to in section (1) point a is awarded by the Chairperson of the Authority to IOT, IEBA, UKOT or UMOT that has complied with all aspects of GMP for TM in accordance with the Dosage Forms through an online application.

(3) Certificate of GMP for TM as referred in section (2) has a validity period of 5 (five) years from the issuance.

(4) The Certificate of Staged GMP for TM Aspects as referred to in section (1) point b is awarded by the Chairperson of the Authority to UKOT or UMOT that has complied with Staged GMP for TM in accordance with the Dosage Forms through an online application.

(5) The Certificate of Staged GMP for TM Aspects as referred to in section (4) has a validity period of 3 (three) years from the issuance.

(6) The format of Certificate of GMP for TM and the Certificate of Staged GMP for TM Aspects as referred to in section (1) is included in Annex I as an integral part of this Authority Regulation.

(7) The Dosage Forms as referred to in section (2) and section (4) are included in Annex II as an integral part of this Authority Regulation.

CHAPTER III
PROCEDURES

Part One
Certification of GMP for TM

Paragraph 1
Account Registration

Article 4

(1) IOT, IEBA, UKOT or UMOT applying for GMP for TM certification services must initially register an account to obtain a username and password.

(2) The account registration as referred to in section (1) is applied by filling out the data and uploading relevant documents through the official website of Indonesian FDA e-certification service by accessing http://www.e-certification.pom.go.id.

(3) Indonesian FDA verifies the data and supporting documents as referred to in section (2) within a maximum period of 3 (three) Days from the date of data entry and upload of supporting documents for GMP for TM certification.

(4) When the verification results are declared complete and correct, IOT, IEBA, UKOT, or UMOT is given a username and password.

Article 5

(1) The account registration as referred to in Article 4 is only carried out 1 (one) time as long as there is no data change.

(2) In the event of data change as referred to in section (1), IOT, IEBA, UKOT or UMOT must apply for an account change.

Article 6

IOT, IEBA, UKOT or UMOT that has obtained the username and password as referred to in Article 4 section (4) may apply for:

a. new certification;
b. certificate renewal; or
c. certificate change.

Paragraph 2
New Certification

Article 7

(1) IOT, IEBA, UKOT or UMOT applying for new certification issuance services must upload technical documents in the form of:
   a. a statement of commitment for the application for GMP for TM Certificate;
   b. site master file of IOT, IEBA, UKOT or UMOT;
   c. a letter of approval for the use of shared facilities that is still valid with the Dosage Form in

accordance with the application for production facilities that use shared facilities with the medicine; and

d. good manufacturing practice certificate that remains valid for the Dosage Form in accordance with the application if using the shared facilities with the medicine.

(2) Indonesian FDA issues a payment order notification if the document is declared complete and correct based on the verification.

(3) IOT, IEBA, UKOT, or UMOT pays the amount as stated in the payment order notification as referred to in section (2) not later than 7 (seven) calendar days as of the date of payment order notification.

Article 8

(1) Indonesian FDA conducts the Inspection not later than 5 (five) Days since the proof of payment is received in accordance with the amount as stated in the payment order notification as referred to in Article 7 section (3).

(2) Indonesian FDA issues a decision in the form of Inspection result not later than 7 (seven) Days after the Inspection as referred to in section (1) is carried out.

(3) The Inspection result as referred to in section (2) is in the form of:

a. a corrective action and preventive action by additional data;

b. an approval; or

c. a rejection.

Article 9

(1) In the event that the Inspection result is in the form of corrective action and preventive action by additional data as referred to in Article 8 section (3) point a, the calculation of the evaluation period is clocked off until IOT, IEBA, UKOT or UMOT submits the corrective action and preventive action by additional data.

(2) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data within a time limit of not later than 40 (forty) Days from the receipt date of Inspection result as referred to in section (1).

(3) The calculation of the evaluation period will be clocked on after IOT, IEBA, UKOT, or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).

(4) In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), IOT, IEBA, UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.

(5) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to Indonesian FDA within a time limit of not later than 20 (twenty) Days for each entity from the application date of extension of corrective action and preventive action by additional data.

(6) The evaluation is clocked on within a maximum period of 20 (twenty) Days from the date the corrective action and preventive action by additional data as referred to in section (5) is received by Indonesian FDA.

(7) In the event that IOT, IEBA, UKOT or UMOT is declared to comply with the GMP for TM requirements based on the evaluation, Chairperson of the Authority issues a GMP for TM Certificate not later than 3 (three) Days from the date of the evaluation result.

(8) In the event that based on the evaluation, IOT, IEBA, UKOT or UMOT is declared to:

a. commit violations related to safety and quality requirements;

b. fail to implement and report the corrective action and preventive action within a period of 6 (six) months as of the issuance of the Inspection result from the Chairperson of the Authority; and/or

c. fail to meet the technical requirements of GMP for TM after submitting the corrective action and preventive action through additional data for a maximum of 3 (three) times,

Indonesian FDA issues a decision in the form of rejection which is conveyed to IOT, IEBA, UKOT or UMOT not later than 3 (three) Days from the date of the evaluation result.

Article 10

In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in Article 9 section (5) or obtains a decision in the form of a rejection, the application is considered invalid and the fees paid are non-refundable.

Paragraph 3

Renewal of Certificate of GMP for TM

Article 11

(1) The renewal application for Certificate of GMP for TM is submitted by IOT, IEBA, UKOT or UMOT to Indonesian FDA not later than 6 (six) months prior to the expiration of Certificate of GMP for TM.

(2) The renewal application for Certificate of GMP for TM as referred to in section (1) must be submitted by uploading technical documents in the form of:

a. site master file of IOT, IEBA, UKOT or UMOT;

b. a letter of approval for the use of shared facilities that is still valid with the Dosage Form in accordance with the application for production facilities that use shared facilities with the medicine; and

c. certificate of good manufacturing practice that is still valid for the Dosage Form in accordance with the application if using the shared facilities with the medicine.
d. Certificate of GMP for TM; and
e. minutes of inspection from routine Inspection, along with the progress of Corrective Action and Preventive Action (CAPA) for the last 2 (two) years and/or the results of the last self-Inspection.

(3) Indonesian FDA issues a payment order notification if the document is declared complete and correct based on the verification.

(4) IOT, IEBA, UKOT, or UMOT pays the amount as stated in the payment order notification as referred to in section (3) not later than 7 (seven) calendar days as of the date of payment order notification.

(5) Renewal of Certificate of GMP for TM as referred to in section (1) includes:
a. renewal of Certificate of GMP for TM with Inspection; and/or
b. renewal of Certificate of GMP for TM without Inspection.

(6) Renewal of Certificate of GMP for TM that requires Inspection as referred to in section (5) point a is conducted if IOT, IEBA, UKOT or UMOT as referred to in section (1) has a history of GMP for TM requirement compliance based on the results of the latest supervision with any finding and/or potential as follows:
a. a decrease in the safety, efficacy, and quality of Traditional Medicine products; and/or
b. abuse in the distribution of Traditional Medicines to facilities or parties who do not have the authority.

(7) Renewal of Certificate of GMP for TM that does not require Inspection as referred to in section (5) point b is conducted if IOT, IEBA, UKOT or UMOT as referred to in section (1) has a history of GMP for TM requirement compliance based on the results of the latest supervision with no findings and/or potential as follows:

a. a decrease in the safety, efficacy, and quality of Traditional Medicine products; and/or
b. abuse in the distribution of Traditional Medicines to facilities or parties who do not have the authority.

(8) The evaluation of the application for renewal of Certificate of GMP for TM as referred to in section (1) is conducted on the compliance with the technical requirements of GMP for TM based on:
a. minutes of inspection from routine Inspection, along with the progress of Corrective Action and Preventive Action (CAPA) for the last 2 (two) years;
b. history of distributed products; and/or
c. Inspection result of certificate renewal.

Paragraph 4

Renewal of Certificate of GMP for TM with Inspection

Article 12

(1) Indonesian FDA conducts the Inspection on renewal of Certificate of GMP for TM which requires Inspection as referred to in Article 11 section (5) point a not later than 5 (five) Days since the proof of payment is received in accordance with the amount as stated in the payment order notification as referred to in Article 11 section (4).
(2) Indonesian FDA issues a decision in the form of Inspection result not later than 7 (seven) Days after the Inspection as referred to in section (1) is carried out.
(3) The Inspection result as referred to in section (2) is in the form of:
a. a corrective action and preventive action by additional data;
b. an approval; or
c. a rejection.

Article 13

(1) In the event that the Inspection result is in the form of corrective action and preventive action by additional data

as referred to in Article 12 section (3) point a, the calculation of the evaluation period is clocked off until IOT, IEBA, UKOT or UMOT submits the corrective action and preventive action by additional data.

(2) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data within a time limit of not later than 40 (forty) Days from the receipt date of Inspection result.

(3) The calculation of the evaluation period will be clocked on after IOT, IEBA, UKOT, or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).

(4) In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), IOT, IEBA, UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.

(5) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to Indonesian FDA within a time limit of not later than 20 (twenty) Days for each entity from the application date of extension of corrective action and preventive action by additional data.

(6) The evaluation is clocked on within a maximum period of 20 (twenty) Days from the date the corrective action and preventive action by additional data as referred to in section (5) is received by Indonesian FDA.

(7) In the event that IOT, IEBA, UKOT or UMOT is declared to comply with the GMP for TM requirements based on the evaluation, Chairperson of the Authority issues a renewal of GMP Certificate for TM not later than 3 (three) Days from the date of the evaluation result.

(8) In the event that based on the evaluation IOT, IEBA, UKOT or UMOT:

a. commits violations related to safety and quality requirements;

b. fails to implement and report the corrective action and preventive actionwithin a period of 6 (six) months as of the issuance of the Inspection result from Chairperson of the Authority; and/or

c. fails to meet the technical requirements of GMP for TM after submitting the corrective action and preventive action through additional data for a maximum of 3 (three) times,

Indonesian FDA issues a decision in the form of rejection which is conveyed to IOT, IEBA, UKOT or UMOT not later than 3 (three) Days from the date of the evaluation result.

Article 14

In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in Article 13 section (5) or obtains a decision in the form of a rejection, the application is considered invalid and the fees paid are non-refundable.

Paragraph 5

Renewal of GMP Certificate for TM without Inspection

Article 15

(1) Indonesian FDA conducts an evaluation on renewal of GMP Certificate for TM that does not require Inspection as referred to in Article 11 section (5) point b not later than 6 (six) Days since the proof of payment is received in accordance with the amount as stated in the payment order notification as referred to in Article 11 section (4).

(2) The evaluation result as referred to in section (1) is in the form of:

a. a corrective action and preventive action by additional data;
b. an approval; or
c. a rejection.

Article 16

(1) In the event that the evaluation is in the form of corrective action and preventive action by additional data as referred to in Article 15 section (2) point a, the calculation of the period is clocked off until IOT, IEBA, UKOT or UMOT submits the corrective action and preventive action by additional data.
(2) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data within a time limit of not later than 10 (ten) Days from the receipt date of evaluation result as referred to in section (1).
(3) The calculation of the evaluation period will be clocked on after IOT, IEBA, UKOT, or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).
(4) In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), IOT, IEBA, UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.
(5) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to Indonesian FDA within a time limit of not later than 10 (ten) Days for each entity from the application date of extension of corrective action and preventive action by additional data.
(6) The evaluation is clocked on within a maximum period of 5 (five) Days from the date the corrective action and

preventive action by additional data as referred to in section (5) is received by Indonesian FDA.

(7) In the event that IOT, IEBA, UKOT or UMOT is declared to comply with the GMP for TM requirements based on the evaluation, Chairperson of the Authority issues a Certificate of GMP for TM not later than 3 (three) Days from the date of the evaluation result.

(8) In the event that IOT, IEBA, UKOT or UMOT has committed violations related to safety and quality requirements, Indonesian FDA issues a decision in the form of rejection which is conveyed to IOT, IEBA, UKOT or UMOT not later than 3 (three) Days from the date of the evaluation result.

Article 17

In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in Article 16 section (5) or obtains a decision in the form of a rejection, the application is considered invalid and the fees paid are non-refundable.

Paragraph 6

Change in Certificate of GMP for TM

Article 18

(1) Application for Certificate of GMP for TM changes is submitted by IOT, IEBA, UKOT or UMOT to Indonesian FDA not later than 6 (six) months prior to expiration of Certificate of GMP for TM.

(2) The change in Certificate of GMP for TM as referred in section (1) is in the form of:
    a. administrative changes to the Certificate of GMP for TM which are changes with legal impact; and/or
    b. facility changes:
        1. with Inspection; or
        2. without Inspection.

(3) The administrative changes as referred to in section (2) point a may include the following changes:
   a. name of the legal entity; and/or
   b. address without location changes.

(4) The facility changes which require Inspection as referred to in section (2) point b point 1 may include the following changes:
   a. additional rooms related to changes in production capacity with changes to cleanliness classes;
   b. changes in the heating ventilation and air conditioning system in the production room;
   c. additional warehouse outside the address stated in the facility permit;
   d. changes in equipment that have a direct impact on product quality; and/or
   e. additional warehouse in one location of IOT, IEBA, UKOT or UMOT.

(5) IOT, IEBA, UKOT or UMOT applying for facility change that does not require Inspection as referred to in section (2) point b point 2, includes:
   a. additional production capacity by changing the function of the room without changing the cleanliness classes and/or by changing the equipment; and/or
   b. changes to the water treatment system that do not affect product quality and system qualifications.

Paragraph 7
Administrative Changes

Article 19

(1) IOT, IEBA, UKOT or UMOT applying for change in Certificate of GMP for TM in the form of administrative changes as referred to in Article 18 section (3) must meet the following requirements:
   a. adminstrative document in the form of application letter, and

b. technical document in the form of supporting document related to administrative changes.

(2) Indonesian FDA issues a payment order notification if the document is declared complete and correct based on the verification.

(3) IOT, IEBA, UKOT, or UMOT pays the amount as stated in the payment order notification as referred to in section (2) not later than 7 (seven) calendar days as of the date of payment order notification.

(4) Indonesian FDA conducts an evaluation to the application for administrative changes as referred to in Article 18 section (2) point a not later than 6 (six) Days as of receipt of proof of payment in accordance with the amount as stated in the payment order notification as referred to in section (3).

(5) Indonesian FDA issues a decision in the form of approval of change in Certificate of GMP for TM not later than 5 (five) Days since the application document of Certificate of GMP for TM change is declared complete and correct based on the evaluation.

(6) In the event that IOT, IEBA, UKOT or UMOT is declared to comply with the GMP for TM requirements based on the evaluation, Chairperson of the Authority issues a Certificate of GMP for TM not later than 3 (three) Days from the date of the evaluation result.

(7) The validity period of the certificate as referred to in section (6) follows the validity period of the previously issued Certificate.

Paragraph 8

Facility Changes with Inspection

Article 20

(1) IOT, IEBA, UKOT or UMOT applying for facility changes which require Inspection as referred in Article 18 section (2) point b point 1 must meet the following requirements:

a. administrative document in the form of application letter, and
b. technical document in the form of:
   1. list of facility changes; and
   2. change control document and supporting document related to the change.

(2) Facility changes which require Inspection as referred to in section (1) only take place after IOT, IEBA, UKOT or UMOT has obtained an approval from Chairperson of the Authority.

Article 21

(1) Indonesian FDA conducts a verification using a clock on and clock off mechanism for the compliance with the requirements as referred to in Article 20 not later than 5 (five) Days from the submission date of the application.
(2) Indonesian FDA issues a payment order notification if the document is declared complete and correct based on the verification.
(3) IOT, IEBA, UKOT, or UMOT pays the amount as stated in the payment order notification as referred to in section (2) not later than 7 (seven) calendar days as of the date of payment order notification.
(4) The verification on the application for change in Certificate of GMP for TM as referred to in section (1) is implemented on the compliance of the technical requirements of GMP for TM based on the following:
   a. minutes of inspection from routine Inspection, along with the development of Corrective Action and Preventive Action (CAPA) for the last 2 (two) years;
   b. history of distributed products; and/or
   c. Inspection result of certificate renewal.
(5) Indonesian FDA conducts the facility Inspection not later than 5 (five) Days if the document is declared complete and correct based on the evaluation as referred to in section (4).

(6) Indonesian FDA issues a decision in the form of Inspection result not later than 7 (seven) Days after the Inspection is conducted as referred to in section (5).

(7) The Inspection result as referred to in section (5) is in the form of:

a. a corrective action and preventive action by additional data;

b. an approval; or

c. a rejection.

Article 22

(1) In the event that the Inspection result is in the form of corrective action and preventive action by additional data as referred to in Article 21 section (7) point a, the calculation of the period is clocked off until IOT, IEBA, UKOT or UMOT submits the corrective action and preventive action by additional data.

(2) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data within a time limit of not later than 40 (forty) Days from the receipt date of Inspection result.

(3) The calculation of the evaluation period will be clocked on after IOT, IEBA, UKOT, or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).

(4) In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), IOT, IEBA, UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.

(5) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to Indonesian FDA within a time

limit of not later than 20 (twenty) Days for each entity from the application date of extension of corrective action and preventive action by additional data.

(6) The evaluation is clocked on within a maximum period of 20 (twenty) Days since the corrective action and preventive action by additional data as referred to in section (5) is received by Indonesian FDA.

(7) In the event that based on the evaluation, IOT, IEBA, UKOT or UMOT has complied with the GMP for TM requirements, Chairperson of the Authority issues an approval in the form of facility changes not later than 3 (three) Days from the date of the evaluation result.

(8) The validity period of the change approval as referred to in section (7) follows the validity period of the previously issued Certificate.

Article 23

In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in Article 22 section (5), then Indonesian FDA issues a decision in the form of a rejection and the application is considered invalid and the fees paid are non-refundable.

Paragraph 9

Facility Changes without Inspection

Article 24

(1) IOT, IEBA, UKOT or UMOT applying for facility changes which do not require Inspection as referred in Article 18 section (2) point b point 2 must meet the following requirements:

a. administrative document in the form of application letter, and

b. technical document in the form of:

1. list of facility changes; and
2. change control document and supporting document related to the change.

(2) The application of facility changes which do not require Inspection as referred to in section (1) is submitted through a notification to Chairperson of the Authority.

(3) The facility changes which do not require Inspection may take place after the notification as referred to in section (2) is approved by Chairperson of the Authority.

(4) Indonesian FDA issues a payment order notification if the document is declared complete and correct based on the verification.

(5) IOT, IEBA, UKOT, or UMOT pays the amount as stated in the payment order notification as referred to in section (4) not later than 7 (seven) calendar days as of the date of payment order notification.

(6) Indonesian FDA conducts an evaluation to the application for facility changes which do not require Inspection not later than 6 (six) Days as of receipt of proof of payment in accordance with the amount as stated in the payment order notification as referred to in section (5).

(7) The Inspection result as referred to in section (1) is in the form of:

a. a corrective action and preventive action by additional data;
b. an approval; or
c. a rejection.

Article 25

(1) In the event that the evaluation result is in the form of corrective action and preventive action by additional data as referred to in Article 24 section (7) point a, the calculation of the period is clocked off until IOT, IEBA, UKOT or UMOT submits the corrective action and preventive action by additional data.

(2) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data within a time limit of not later than 20 (forty) Days from the receipt date of evaluation result as referred to in section (1).

(3) The calculation of the evaluation period will be clocked on after IOT, IEBA, UKOT, or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).

(4) In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), IOT, IEBA, UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.

(5) IOT, IEBA, UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to Indonesian FDA within a time limit of not later than 10 (ten) Days for each entity from the application date of extension of corrective action and preventive action by additional data.

(6) In the event that IOT, IEBA, UKOT or UMOT fails to submit the corrective action and preventive action by additional data as referred to in section (5), the application is considered invalid and the fees paid are non-refundable.

(7) The evaluation is clocked on within a maximum period of 5 (five) Days since the corrective action and preventive action by additional data as referred to in section (5) is received by Indonesian FDA.

(8) In the event that based on the evaluation, IOT, IEBA, UKOT or UMOT has complied with the GMP for TM requirements, Chairperson of the Authority issues an approval in the form of facility changes not later than 3 (three) Days from the date of the evaluation result.

(9) The validity period of the facility change approval as referred to in section (8) follows the validity period of the previously issued Certificate.

(10) In the event that IOT, IEBA, UKOT or UMOT is declared to commit violations related to safety and quality requirements based on the evaluation, Indonesian FDA issues a decision in the form of a rejection which is conveyed to IOT, IEBA, UKOT or UMOT not later than 3 (three) Days from the date of the evaluation result.

Part Two
Certification of Staged GMP for TM Aspects

Paragraph 1
General

Article 26

(1) UKOT and UMOT applying for the issuance service of Certificate of Staged GMP for TM Aspects are conducted in Stages in accordance with the provisions of the stages in GMP for TM compliance aspects.

(2) The Staged GMP for TM aspects as referred to in section (1) is conducted in accordance with technical instructions for the Staged GMP for TM aspects.

(3) The technical instructions for the Staged GMP for TM aspects as referred to in section (2) are stipulated by Chairperson of the Authority.

Paragraph 2
Account Registration

Article 27

(1) UKOT or UMOT applying for the issuance service of Certificate of Staged GMP for TM Aspects must initially register an account to obtain a username and password.

(2) The account registration as referred to in section (1) is conducted by filling out the data and uploading relevant

documents through the official website of Indonesian FDA e-certification service by accessing http://www.e-sertifikasi.pom.go.id.

(3) Indonesian FDA verifies the data and supporting documents that have been filled out and uploaded online as referred to in section (2) within a maximum period of 3 (three) Days from the date of data entry and upload of supporting documents for certification of compliance with GMP for TM aspects by UKOT or UMOT.

(4) When the verification results are declared complete and correct, UKOT or UMOT is given a username and password.

Article 28

(1) The account registration as referred to in Article 27 is only carried out 1 (one) time as long as there is no data change.

(2) In the event of data change as referred to in section (1), UKOT or UMOT must apply for an account change.

Article 29

UKOT or UMOT that has obtained the username and password as referred to in Article 27 section (4) may apply for:

a. new certification;

b. certificate renewal; or

c. certificate change.

Paragraph 3

New Certification

Article 30

(1) UKOT or UMOT applying for a new certification must submit technical document in the form of a commitment letter for application for Certification of Compliance with GMP for TM Aspects in addition to fulfilling the provision as referred to in Article 26 and Article 27.

(2) The commitment letter as referred to in section (1) is submitted online to the local UPT of Indonesian FDA.

(3) The UPT of Indonesian FDA conducts an inspection if the commitment letter as referred to in section (2) is declared complete and correct based on the online evaluation.

(4) In the event that the technical documents as referred to in section (1) are declared incomplete and incorrect based on the online evaluation, the application for certification of compliance with GMP for TM Aspects by UKOT or UMOT is rejected.

Article 31

(1) The UPT of Indonesian FDA conducts an Inspection not later than 6 (six) Days as of the date commitment letter as referred in Article 30 section (1) is declared complete and correct.

(2) Head of UPT of Indonesian FDA issues a decision based on Inspection Result not later than 14 (fourteen) Days after Inspection as referred to in section (1) is carried out.

(3) The decision as referred to in section (2) is in the form of:

a. a corrective action and preventive action by additional data; if based on the results of UKOT or UMOT Inspection, it is necessary to improve the GMP for TM aspects that have not been fulfilled;

b. an approval in the form of a recommendation to Chairperson of the Authority to issue a Certificate of Staged GMP for TM Aspects; if based on the results of the UKOT or UMOT Inspection, it complies with the required GMP for TM aspects; or

c. a rejection; if based on the results of the UKOT or UMOT Inspection, it does not comply with the required GMP for TM aspects.

(4) The decision on Inspection result as referred to in section (3) becomes the basis for Chairperson of the Authority to issue a Certificate of Staged GMP for TM Aspects.

Article 32

(1) In the event that the Inspection result is in the form of corrective action and preventive action by additional data as referred to in Article 31 section (3) point a, the calculation of the period is clocked off until UKOT or UMOT submits the corrective action and preventive action by additional data.

(2) UKOT or UMOT must submit the corrective action and preventive action by additional data within a time limit of not later than 40 (forty) Days from the receipt date of Inspection result as referred to in section (1).

(3) The calculation of the evaluation period will be clocked on after UKOT or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).

(4) In the event that UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.

(5) UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to UPT of Indonesian FDA within a time limit of not later than 20 (twenty) Days for each entity from the application date of extension of corrective action and preventive action by additional data.

(6) In the event that UKOT or UMOT fails to submit the corrective action and preventive action by additional data as referred to in section (5), the application is declared invalid.

(7) The evaluation is clocked on within a maximum period of 22 (twenty-two) Days from the date the corrective action and preventive action by additional data as referred to in section (5) is received by the UPT of Indonesian FDA.

(8) In the event that based on the evaluation, UKOT or UMOT has complied with the required GMP for TM aspects, the Head of UPT of Indonesian FDA issues an approval in the form of a recommendation as referred to in Article 31 section (3) point b.

(9) The approval in the form of recommendation as referred to in section (8) is submitted by Head of the UPT of Indonesian FDA to Chairperson of the Authority not later than 6 (six) Days from the date of the evaluation result.

(10) In the event that UKOT or UMOT based on the evaluation:

a. commits violations related to safety and quality requirements; and/or

b. fails to meet the technical requirements of GMP for TM after submitting the corrective action and preventive action by additional data for a maximum of 3 (three) times,

Head of UPT of Indonesian FDA issues a decision in the form of rejection which is copied to Chairperson of the Authority not later than 6 (six) Days from the date of the evaluation result.

Article 33

(1) Chairperson of the Authority issues the Certificate of Staged GMP for TM Aspects not later than 7 (seven) Days from the receipt of the recommendation letter for approval as referred to in Article 32 section (9).

(2) The Certificate of Staged GMP for TM Aspects as referred to in section (1) has a validity period of 3 (three) years and can be renewed through a certificate renewal mechanism.

Paragraph 4

Renewal of Certificate of Staged GMP for TM Aspects

Article 34

(1) The renewal application for Certificate of Staged GMP for TM Aspects is submitted by UKOT or UMOT to

Indonesian FDA not later than 6 (six) months prior to the expiration of the Certificate of Staged GMP for TM Aspects.

(2) The renewal application for Certificate of Staged GMP for TM Aspects as referred to in section (1) is submitted with the requirement of Certificate of Staged GMP for TM Aspects.

(3) In the event that based on the verification result of Certificate of Staged GMP for TM Aspects as referred to in section (2) is declared complete and correct, Indonesian FDA conducts an evaluation based on:
   a. minutes of inspection from routine Inspection, along with the progress of Corrective Action and Preventive Action (CAPA) for the last 2 (two) years;
   b. history of distributed products; and/or
   c. Inspection result of certificate renewal.

Article 35

(1) UPT of Indonesian FDA conducts an Inspection not later than 6 (six) Days from the date of the verification result as referred in Article 34 section (3) is declared complete and correct.

(2) Head of UPT of Indonesian FDA issues a decision based on the Inspection result not later than 14 (fourteen) Days after the Inspection as referred to in section (1) is carried out.

(3) The decision as referred to in section (2) is in the form of:
   a. a corrective action and preventive action by additional data if based on the results of UKOT or UMOT Inspection, it is necessary to improve the GMP for TM aspects that have not been fulfilled;
   b. an approval in the form of a recommendation to Chairperson of the Authority to issue a Certificate of Staged GMP for TM Aspects; if based on the results of UKOT or UMOT Inspection, it complies with the required GMP for TM aspects; or

c. a rejection; if based on the results of UKOT or UMOT Inspection, it does not comply with the required GMP for TM aspects.

(4) The decision on the Inspection result as referred to in section (3) becomes the basis for Chairperson of the Authority to issue a Certificate of Staged GMP for TM Aspects.

Article 36

(1) In the event that the Inspection result is in the form of corrective action and preventive action by additional data as referred to in Article 35 section (3) point a, the calculation of the period is clocked off until UKOT or UMOT submits the corrective action and preventive action by additional data.

(2) UKOT or UMOT submits the corrective action and preventive action by additional data within a time limit of not later than 40 (forty) Days from the receipt date of Inspection result as referred to in section (1).

(3) The calculation of the evaluation period will be clocked on after UKOT or UMOT submits the corrective action and preventive action by additional data completely and correctly within the time limit as referred to in section (2).

(4) In the event that UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in section (2), UKOT or UMOT may apply for an extension of corrective action and preventive action by additional data for a maximum of 2 (two) times supported by a justification for corrective action and preventive action.

(5) UKOT or UMOT must submit the corrective action and preventive action by additional data as referred to in section (4) to UPT of Indonesian FDA within a time limit of not later than 20 (twenty) Days for each entity from the application date of extension of corrective action and preventive action by additional data.

(6) The evaluation is clocked on within a maximum period of 22 (twenty-two) Days from the date the corrective action and preventive action by additional data as referred to in section (5) is received by UPT of Indonesian FDA.

(7) In the event that based on the evaluation, UKOT or UMOT has complied with the required GMP for TM aspects, Head of UPT of Indonesian FDA issues an approval in the form of a recommendation as referred to in Article 35 section (3) point b.

(8) The approval in the form of recommendation as referred to in section (7) is submitted by Head of UPT of Indonesian FDA to Chairperson of the Authority not later than 6 (six) Days from the date of the evaluation result.

(9) In the event that UKOT or UMOT based on the evaluation:

a. commits violations related to safety and quality requirements; and/or

b. fails to meet the technical requirements of GMP for TM after submitting the corrective action and preventive action by additional data for a maximum of 3 (three) times,

Head of UPT of Indonesian FDA issues a decision in the form of rejection which is copied to Chairperson of the Authority not later than 6 (six) Days from the date of the evaluation result.

Article 37

In the event that UKOT or UMOT fails to submit the corrective action and preventive action by additional data within the time limit as referred to in Article 36 section (5) or has obtained a decision in the form of a rejection, then the application is declared invalid.

Article 38

Chairperson of the Authority issues the Certificate renewal of Staged GMP for TM Aspects not later than 7 (seven) Days from the receipt of the recommendation letter for approval as referred in Article 36 section (8).

Article 39

(1) The Certificate renewal of Staged GMP for TM Aspects as referred to in Article 38 can be conducted at most:
   a. 2 (two) times at each stage for UKOT which produces capsules and oral liquid;
   b. 3 (three) times at each stage for UKOT which produces dosage forms other than capsules and oral liquid; and
   c. 3 (three) times at each stage for UMOT.

(2) In the event that Certificate renewal of Staged GMP for TM Aspects has expired, UKOT or UMOT is obligated to apply for certification of compliance with GMP for TM aspects in accordance with the stages stated in the technical instructions for the implementation of Staged GMP for TM aspects as referred to in Article 26.

(3) In the event that Certificate of Staged GMP for TM Aspects has been fulfilled by UKOT for all the stages, it is necessary for UKOT to apply for GMP for TM certification and implement GMP for TM requirements in accordance with the provisions of the legislation.

Paragraph 5

Change in Certificate of Staged GMP for TM Aspects

Article 40

(1) UKOT or UMOT which has obtained the Certificate of Staged GMP for TM Aspects applies for a certificate change.

(2) The certificate change as referred to in section (1) is in the form of administrative changes.

(3) The administrative changes as referred to in section (2) include the following changes:
   a. name of the legal entity; and/or
   b. address without location changes.

(4) The application for administrative changes as referred to in section (2) is submitted through the official website of the Indonesian FDA e-certification service by accessing

http://www.e-sertifikasi.pom.go.id and completing the requirements in the form of a technical document for the changes.

(5) Head of UPT of Indonesian FDA issues a decision in the form of a recommendation for approval of administrative changes to the Certificate of Staged GMP for TM Aspects not later than 7 (seven) Days since the application document for a certificate change based on the evaluation is declared complete and correct.

(6) Chairperson of the Authority issues a decision in the form of approval for administrative changes to Certificate of Staged GMP for TM Aspects not later than 7 (seven) Days from the receipt of the recommendation letter as referred to in section (5).

(7) The validity period of the administrative changes as referred to in section (6) follows the validity period of Certificate of Staged GMP for TM Aspects which has been issued by Chairperson of the Authority.

Paragraph 6

Cost

Article 41

Certification of Staged GMP for TM Aspects for UKOT and UMOT is subject to a fee of Rp0,00 (zero rupiah).

CHAPTER IV

TRANSITIONAL PROVISION

Article 42

(1) Applications for GMP for TM Certification that have been submitted prior to the enforcement of this Regulation, will still be processed based on Regulation of the Chairperson of Indonesian Food and Drug Authority Number 35 of 2013 on Certification Procedures of Good Manufacturing Practice for Traditional Medicines.

(2) IOT, IEBA, UKOT or UMOT which have already obtained Certificate of GMP for TM prior to the enforcement of this Authority Regulation are declared valid until the expiration of the certificate validity period.

CHAPTER V
CLOSING PROVISIONS

Article 43

At the time this Regulation comes into force, Regulation of the Chairperson of Indonesian Food and Drug Authority Number 35 of 2013 on Certification Procedures of Good Manufacturing Practice for Traditional Medicines (State Bulletin of the Republic of Indonesia of 2013 Number 907) is repealed and declared ineffective.

Article 44

This Authority Regulation comes into force on the date of its promulgation.

In order that every person may know thereof, it is ordered to promulgate this Authority Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 3 May 2021

CHAIRPERSON OF INDONESIAN FOOD AND DRUG AUTHORITY,

Signed

PENNY K. LUKITO

Promulgated in Jakarta
on 4 May 2021

DIRECTOR GENERAL OF LEGISLATION
OF THE MINISTRY OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

Signed

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2021 NUMBER 474

Jakarta, 24 November 2022
Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia
DIRECTOR GENERAL OF LEGISLATION AD INTERIM,

DIREKTUR JENDERAL PERATURAN PERUNDANG-UNDANGAN

DHAHANA PUTRA

ANNEX I TO
REGULATION OF THE INDONESIAN FOOD
AND DRUG AUTHORITY
NUMBER 14 OF 2021
ON
CERTIFICATION OF GOOD MANUFACTURING
PRACTICES FOR TRADITIONAL MEDICINES

CERTIFICATE FORMAT

A. Certificate Format of GMP for Traditional Medicines

Indonesian Food and Drug Authority

By virtue of Decree of the Chairperson of Indonesian Food and Drug Authority (Indonesian FDA) No. HK.03.1.23.06.11.5629 of 2011 on the Technical Requirements on Good Manufacturing Practices for Traditional Medicines, hereby the Chairperson of Indonesian Food and Drug Authority confers:

A CERTIFICATE

ON

GOOD MANUFACTURING PRACTICES FOR TRADITIONAL MEDICINES

Certificate Number	:
To	:
Address	:
Building/Area	:
Dosage Form	:
Activity	:
Valid Until	:

Should there occurs any change resulting in dissatisfaction of Technical Requirements on Good Manufacturing Practices for Traditional Medicines in pursuance of the Decree of the Head of the Decree of the Chairperson of Indonesian Food and Drug Authority No.HK.03.1.23.06.11.5629 of 2011, this certificate will be revoked.

Jakarta, Date Month Year

CHAIRPERSON OF INDONESIAN FOOD AND DRUG AUTHORITY

(Electronic signature)

Chairperson of Indonesian Food and Drug Authority

B. Certificate Format of Staged GMP for Traditional Medicines Aspects Stage I/II/III for UKOT

CERTIFICATE
GOOD MANUFACTURING PRACTICES FOR TRADITIONAL MEDICINE
STAGE I/II/III

FOR USAHA KECIL OBAT TRADITIONAL (*UKOT*)/
SMALL ENTERPRISES OF TRADITIONAL MEDICINE

Certificate Number :

To	:	
Company	:	
Address	:	
Dosage Form	:	
Activity	:	
Aspect	:	
Valid Until	:	Month Date, Year

Should there occurs any change resulting in dissatisfaction of Technical Requirements on Good Manufacturing Practices Stage I/II/III for Traditional Medicines in pursuance of the Decree of the Chairperson of Indonesian Food and Drug Authority, this certificate will be revoked.

Jakarta, Date Month Year

on behalf of
CHAIRPERSON OF INDONESIAN FOOD AND DRUG AUTHORITY
DEPUTY OF TRADITIONAL MEDICINE, HEALTH SUPPLEMENT,
AND COSMETIC PRODUCTS CONTROL

(Electronic signature)
Deputy of Traditional Medicine, Health Supplement,
and Cosmetic Products Control

C. Certificate Format of Staged GMP for Traditional Medicines Aspects Stage I/II for UMOT

CERTIFICATE
GOOD MANUFACTURING PRACTICES FOR TRADITIONAL MEDICINE
STAGE I/II

FOR USAHA MIKRO OBAT TRADISIONAL (UMOT)/ MICRO ENTERPRISES OF TRADITIONAL MEDICINE

Certificate Number :

To	:
Company	:
Address	:
Dosage Form	:
Activity	:
Aspect	:
Valid Until	: Month Date, Year

Should there occurs any change resulting in dissatisfaction of Technical Requirements on Good Manufacturing Practices Stage I/II for Traditional Medicines in pursuance of the Decree of the Chairperson of Indonesian Food and Drug Authority, this certificate will be revoked.

Jakarta, Date Month Year

on behalf of
CHAIRPERSON OF INDONESIAN FOOD AND DRUG AUTHORITY
DEPUTY OF TRADITIONAL MEDICINE, HEALTH SUPPLEMENT,
AND COSMETIC PRODUCTS CONTROL

(Electronic signature)
Deputy of Traditional Medicine, Health Supplement,
and Cosmetic Products Control

CHAIRPERSON OF INDONESIAN FOOD
AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX II TO
REGULATION OF THE INDONESIAN FOOD
AND DRUG AUTHORITY
NUMBER 14 OF 2021
ON
CERTIFICATION OF GOOD MANUFACTURING
PRACTICES FOR TRADITIONAL MEDICINES

DOSAGE FORM

Scope	No.	Dosage Form	Activity Facilities
Solid Dosage Form	1	Tablet	Tablet
			Lozenge
			Caplet
			Packaging
	2	Coated Tablet	Tablets
			Film Coated Tablet
			Sugar Coated Tablet
			Packaging
	3	Gummy Chewable	Gummy Chewable
			Packaging
	4	Effervescent Tablet	Effervescent tablet
			Packaging
	5	Soft Capsule	Soft Capsule
			Packaging
	6	Oral Powder	Powder
			Instant powder
			Packaging
	7	Effervescent Powder	Effervescent Powder
			Packaging
	8	Topical Powder	Topical Powder
			Mangir /Mask/*Lulur*
			Packaging
	9	Capsule	Capsule
			Packaging
	10	Edible Film	Edible Film
			Packaging

Scope	No.	Dosage Form	Activity Facilities
	11	Pill	Pill
			Packaging
	12	Granule	Granule
			Instant Granule
			Solid Granule
			Packaging
	13	Cone	Cone
			Packaging
	14	Suppository	Suppository (for hemorrhoids)
			Packaging
	15	Chopped plant or animal	Chopped plant or animal
			Packaging
	16	*Pilis/Parem/Tapel*	*Pilis*
			Parem
			Tapel
			Packaging
Semi Solid Dosage Form	1	Topical Semi Solid	Ointment
			Balm
			Cream
			Gel
			Packaging
	2	Oral Semi Solid	Oral Gel
			Packaging
Liquid Dosage Form	1	Oral Liquid	Suspension
			Emulsion
			Elixir
			Tincture
			Viscous Liquid
			Liquid
			Packaging
	2	Topical Liquid	Suspension
			Emulsion
			Liquid
			Packaging
	3	Plaster	Patch

Scope	No.	Dosage Form	Activity Facilities
			Packaging
Aerosol Dosage Form*	1	Topical Aerosol	Aerosol
			Packaging
Natural Ingredient Extract	1	Viscous Extract	Viscous extract
			Packaging
	2	Liquid Extract	Liquid extract
			Packaging
	3	Dry Extract	Dry extract
			Packaging

*Only for IOT

CHAIRPERSON OF INDONESIAN FOOD
AND DRUG AUTHORITY,

signed

PENNY K. LUKITO