

## **Indonesian FDA Regulations on Indonesian Traditional Nutraceuticals (Herbs)Contributors:**

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The national goal of the Indonesia as stated in the opening of the 1945 Constitution is to protect the entire nation and Indonesia's bloodshed, as well as to bring forward public welfare, educate the life of the nation, and be involved in the implementation of world order based on independence, eternal peace and social justice.

To achieve these objectives, a national development program is performed in a comprehensive and sustainable manner. Health development is part of the national development program that aims to increase awareness, willingness and capability of every citizen to live healthy, thereby increasing the degree of public health. This health development program is an effort made by all potential Indonesian parties, both private and public.

To ensure that the health development goals are achieved, a strong support of a National Health System (SKN) is required. In Indonesia, the National Health System was established in 1982. This SKN has played a big role as a reference for the formation of the State Policy Outline (GBHN) in the healthcare sector, Constitution number 23 of 1992 regarding Health and has been revised into Constitution No. 39 of 2009. This SKN is used as a guideline and reference for the direction of health development in Indonesia.

To support the success of health development policies renewal that have been carried out, it is necessary to revise the SKN, so that it is able to deal with various health development challenges, both for the present and for the future. The expected result is an improvement in the quality of human resources (human development index), hence increasing the Indonesian nation's competitiveness in facing health globalization era.

As a basis, direction and guideline for the implementation of health development for all health providers in the central, regional, community and business world, as well as other related parties, the government has established a National Health System (SKN) through the decision of the Minister of Health Republic of Indonesia No. 131/Menkes/SK/II/2004.

In one of the SKN subsystems, it is stated that the development and improvement of traditional medicines are intended to generate traditional medicines with high-quality, safe, real scientifically-tested efficacy, and widely used for medication both by the community themselves, as well as in formal healthcare services.

It is mentioned in the Constitution No. 36 of 2009 regarding Health that traditional medicines are ingredients in the form of plant materials, animal materials, mineral materials, galenic formulation or a mixture of these materials which have been used for medication from generation to generation, and can be applied in accordance with norms that are valid in the community.

Indonesian traditional medicines have been widely accepted by the Indonesian community both in rural and urban areas. In some developing countries, traditional medicines have even been used in healthcare services, especially in the first strata of healthcare services.

Indonesia has 17,000 large and small islands with population over 230 million people, 400 ethnic groups (ethnic and sub-ethnic) with diverse religions, beliefs and customs. With more than 600 regional languages, the country certainly has various names and types of traditional medicine.

The Bugis-Makassar tribe has long been familiar with traditional medicine. This is evident in the palm leaf manuscript named *Lontaraqabbura*. They used Sanrego wood plants (*Lunasiaamara* Blanco) to increase male stamina and fresh paliasa leaves (*Kleinhovia hospita* Linn) were used for hepatitis and were already available on the market packed in 400 mg capsules, each containing 40 mg of paliasa extract.

Proof that Indonesian traditional medicine has been used since centuries ago within the country, among others, can be seen in the Prambanan temple and Borobudur temple reliefs in Central Java. The authentic historical proof of herbs can be seen in *Serat Kawruh* and *Serat Centhini* books, which are available in Surakarta Kraton library. *Serat Centhini* has 12 volumes and contains 725 songs (cantos) composed by Kanjeng Susuhunan Pakubuwono IV's son, King of Surakarta (1778-1820). The Centhini fiber manuscript is thought to have been compiled in 1814, containing health issues at that time. In addition to containing health

recipes or formulas, the book also reveals folklore contents during that time, as well as illustrations of the daily use of herbs.

SeratKawruh book provides information about herbs and contains 1,734 natural ingredients and how they are used, as well as equipped with spells. These spells, in addition to overcoming certain health problems, protect the owner from black magic attacks.

For Javanese and Madurese communities, traditional medicines are more commonly known as herbs, both in chopped and in powder forms, ready to be brewed and consumed. They have long been drinking steamed ginger (*Curcuma xanthorrhiza*) to maintain their health condition.

Sundanese residents in Kampung Naga, Tasikmalaya, West Java have used around 113 types of medicinal plants for the treatment and maintenance of the body, while the Subang community, West Java has used about 75 types of local plants for traditional treatments.

The traditional Malay communities outside Java island, such as in Riau and Jambi provinces, have about 45 traditional herbs with 195 species of medicinal plants; Traditional Talang Mamak tribe community has 58 herbs with 115 species;

Anak Dalam tribe community has 72 types of herbs derived from 116 species; The Southeast Maluku community has used fruit and nutmeg twigs for rheumatism, myalgia and increasing libido; South Maluku has 216 types of medicinal plants;

The Papuans utilize *keybar* grass for female fertility, *akwai* (*Dymisanthon*) to increase sexual activity and *Watu* (*Piper methysticom*) for sedation;

Lombok island community has been familiar with the benefits of 19 types of plants as contraceptive drugs; Residents in Sumbawa have known 7 types of traditional plants for sequential oil (*salban* root, *sawak* root, kesumang root, *batangmalang*, sticky wood, sekeal wood, bone wood); The community of Bengkulu province has been familiar with 71 types of local plants for medicinal purposes, one of them is for anti-malaria, which contains 10 kinds of mixtures; (Tilaar, M, 2010)

As a tropical rain area, Kalimantan stores at least 4000 new species of medicinal plants. The Kalimantan community is familiar with *peg of the earth* or *Eurycomalongifolia*, which is used to increase male sexual activity. Barito (*Ficus deltoide*) is used for female libido and is known as *Love Herb Tablet*. Another plant is *Strychnosignati*, whose roots are very bitter in increasing stamina.

Seram Island (Central Maluku), which is still a virgin, is also rich in medicinal plants. The island is known to have around 30 types of plants used to treat diseases such as cough, diarrhea, fever and headaches, swelling, as well as itching.

The use of traditional plants is not only beneficial to humans, but also to livestock. For example, West Java people have used about 47 types of plants to maintain livestock health, particularly goats and sheep. These plants, among others, include spinach, jambe, temulawak, dadap, kelor, lempuyang, katuk; The Alor community, East Nusa Tenggara, has 45 types of livestock ingredients, such as jackfruit bark mixed with sea water to prevent goat diarrhea; Residents of East Java and Madura have 57 types of traditional livestock herbs, for example the ginger family (*curcuma*);

The use of traditional medicinal plants as cosmetics has also been widely known in the Indonesian territory; Javanese people use flowers such as jasmine, rose, sandalwood, cananga, *murrayapaniculata* for fragrances; Yogyakarta community introduces scrubs for smoothing body skin using 9 types of plants, such as *murrayapaniculata*; garden balsam for nail polish; A combination of mangkokan leaves, pandanus, jasmine and coconut oil for hair relaxants; Javanese community also introduces *ratus*, a mixture of 19 types of plants, to be used as fragrances for clothes and rooms, as well as protection for clothes; furthermore, Indonesian people own 62 types of plants for natural dyes, such as kayumalam and secang wood for batik coloring, as well as suji leaves for food coloring;

Even though Indonesia's land area is only 1.32% of the total land area in the world (Bappenas, 1993), the country has about 30,000 types of plants and approximately 7,000 of them were indicated to have medicinal properties. About 90% of medicinal plants in the Asian region grow in Indonesia (Sampurno, 2004). Of the total 940 types of plants that have been utilized by the community, only 120 types of plants are mentioned in the "*Materia Medica Indonesia*" book.

The Indonesian Health Minister has published 6 *Materia Medica Indonesia* books, namely *Materia Medica Indonesia I* (1977) containing 20 medicinal plants, *Materia Medica Indonesia II* (1978) containing 20 medicinal plants, *Materia Medica Indonesia III* (1979) containing 20 medicinal plants, *Materia Medica Indonesia IV* (1980) containing 18 medicinal plants, *Materia Medica Indonesia V* (1989) containing 119 medicinal plants and *Materia Medica Batu VI* (1995) containing 60 medicinal plants.

Moreover, the government has issued 5 volumes of a book titled *Vademekum* medicinal plants, containing various species of medicinal plants that are often used as herbal ingredients in the context of Indonesian herbal medicine scientification. This book is a technical guideline on the use of medicinal

plants, which contains botanical identity, ecology and distribution, cultivation techniques, safety, benefits and efficacy, side effects and formulas,

In addition to the abovementioned guideline, the Indonesian government has published **Farmakope Herbal Indonesia** (Ed.1, 2008), along with supplementary guidelines containing quality standards of pharmaceutical ingredients, testing methods, standard solutions creation for testing methods, calculation methods and other information.

The use of traditional Indonesian medicines is part of the national culture and has been widely utilized by the society since centuries ago. However, in general, the effectiveness and safety of traditional medicines have not been fully supported by adequate research. Nonetheless, the government has an obligation to protect those ancestral heritages in the form of regulations, so that the traditional medicine culture can be sustained.

The government is aware of this matter, and as one of the world's main growers of medicinal plants, it is necessary for the government to develop a national policy for traditional medicines, which can be used as a reference for all parties involved.

The national policy regarding traditional medicine is hereinafter referred to as KOSTRANAS, an official document declaring commitment of all parties who set national objectives and targets in the field of traditional medicine along with priorities, strategies and roles of various parties in the implementation of key policy components for achieving the national development goals, particularly in the healthcare sector (Regulation of the Health Minister number 31/MENKES/SK/III/2007).

The goals of KOSTRANAS are: 1) to encourage the use of natural resources and traditional herbs in a sustainable manner for traditional medicines as a means to improve healthcare services; 2) to guarantee the management of Indonesia's natural potential in a cross-sector manner, thereby increasing the country's level of competitiveness in terms of sustainability in economic resources and foreign exchange; 3) to provide traditional medicines with quality, efficacy and safety that have been scientifically tested and widely used both for self-medication and formal healthcare services; 4) Making traditional medicine a superior commodity that provides multiple benefits, which ultimately contribute to improved economic growth through employment opportunities and poverty alleviation.

KOSTRANAS is the Indonesian government's policy on traditional medicine in its entirety from upstream to downstream, involving cultivation and conservation of medicinal resources, safety and efficacy of traditional medicines, quality, accessibility, proper usage, supervision, research and development, industrialization and commercialization, documentation and database, human resources development, as well as monitoring and evaluation.

Traditional medicines in KOSTRANAS comprise of plant ingredients, animal ingredients, minerals including marine biota or galenic preparations that have been used from generation to generation, as well as those that have passed through pre-clinical/clinical tests, such as standardized herbal medicine (OHT) and phytopharmaca (FF), to promote the development of traditional medicine towards utilization in healthcare services and usage of Indonesia's natural resources.

Traditional medicines based on the "hereditary inheritance" approach are recognized by the government as an "empirical" approach and called herbs. Meanwhile, traditional medicines that are based on scientific approach through pre-clinical tests are called standardized herbal medicines, while those that have undergone clinical trials are called phytopharmaca. Currently, there are 62 standardized herbal medicine products (Table 1), while the total number of phytopharmaca products reached 20 (Table 2)

Initially, Indonesian traditional medicines were reproduced by traditional healers for their patients or for only few people. Traditional medicines were later developed into home industry and subsequently being mass-produced both by the small traditional medicine industry (IKOT) and traditional medicine industry (IOT) by following the development technology. The classifications of IKOT and IOT are based on Regulation of the Health Minister of the Republic Indonesia number 246/Menkes/Per/V/1990 regarding Business License for Traditional Medicine Industry and Registration of Traditional Medicine, as well as according to the size of assets owned by the company. Assets amounting less than 600 million rupiah are categorized as IKOT, while assets amounting more than 600 million rupiah are classified as IOT.

Regulation of the Health Minister of the Republic Indonesia number 246/Menkes/Per/1990 was later altered into 2 regulations, namely Minister of Health Regulation No. 006 of 2012 concerning Industrial and Business of Traditional Medicines and Minister of Health Regulation No. 007 of 2012 about Registration of Traditional Medicines.

Regulations concerning the form of industry and business of traditional medicine are explained in more detail within Regulation of the Health Minister of the Republic Indonesia number 006 of 2012. What is considered to be the industry here is the Natural Material Extract industry (IEBA) and the Traditional Medicine industry (IOT). The organizers of IEBA and IOT must be legal entities in the form of limited liability companies or cooperatives.

IEBA is an industry that specializes in making preparations in the form of extracts as final products; OT is an industry that produces all forms of traditional drug preparations, which means this industry has the ability to perform all and/or some of the processes of making traditional medicines. IOT requires permit from BPOM if it only performs part of the processes.

What can be considered as business here are Small-Scale Traditional Medicine business (UKOT), Micro Traditional Medicine business (UMOT), herbal medicine concoctions business (UJR) and gendong herb business (UJG).

The classifications of IOT, UKOT and UMOT are based on the form of produced preparations; IOT is able to manufacture all dosage forms of traditional medicine. UKOT can make all preparations of traditional medicines, with the exception of tablets and effervescent. Meanwhile, UMOT is only permitted to produce several forms of traditional medicine preparations, such as parem, tapel, pilis, topical solution and rajangan.

Parem is a traditional medicine in the form of solid, paste or porridge like which is used by means of lubricating on the legs and arms or on other body parts. Tapel is a traditional medicine in the form of solid, paste or porridge like which is used by smearing on the entire surface of the stomach. Pilis is a traditional medicine in the form of a solid or paste that is used by blasting it on the forehead. Rajangan is a traditional medicine preparation in the form of crude drugs (simplicia), a mixture of simplicia, or a mixture of simplicia with galenic preparations, which is used by boiling or brewing with hot water, while galenic preparations are the result of extracting materials or mixtures of ingredients derived from plants or animals.

The herbal medicine concoctions business refers to businesses run by herbal depots or similar types of business owned by individuals, selling mixtures of ready-made preparations and/or fresh preparations of traditional medicines directly to consumers;

Gendong herb businesses are carried out by individuals using traditional medicinal ingredients in the form of fresh liquids with the aim of being sold directly to consumers.

This health minister regulation permits IOT, UKOT and UMOT to contract the making of traditional medicines to other IOT or UKOT as long as they have implemented CPOTB. Moreover, the contractor must already possess a distribution permit for the contracted products.

Industrial forms or businesses of traditional medicine are prohibited to make all types of traditional medicines that contain medicinal or synthetic chemicals with medicinal properties, intravaginal dosage forms, eye drops, parental preparations, suppositories except for hemorrhoids, a liquid form of the drug containing over 1% (one percent) of ethanol concentrate.

All industries and businesses must obtain permission from the Minister or appointed officials, namely the Directorate General for IOT and IEBA permits, the Head of Provincial Health Office for UKOT and the Head of District/City Health Office for UMOT, except for herbal concoction and gendong herb businesses. Permits issued by the Minister are valid as long as the industry or business is still in production and complies with the stipulated regulations.

The establishment of IOT and IEBA industries requires approval of principle permit issued by the Directorate General of Pharmaceuticals and Medical Devices Ministry of Health RI, which is valid for 3 years and can be extended for a maximum of 1 year. Foreign investments require investment approval from the agency that executes capital investment matters in accordance with the applicable laws.

In general, the principle approval for foreign investors requires completing the application for approval of the Development Master Plan (RIP) to the Head of the Indonesian National Agency of Drug and Food Control (Badan POM RI). Based on the recommendation of Badan POM RI, the Director General of Pharmaceuticals and Medical Devices of the Ministry of Health issues principle approval. After obtaining the principle approval, the investor must submit information about the progress of the construction of production facilities every 6 (six) months to the Directorate General with copies of the Badan POM RI.

The person in charge of UKOT, IOT and IEBA must be an Indonesian pharmacist, while that of UMOT, UJR and UJG is not necessarily a pharmacist. CPOTB guidelines are issued and stipulated by the Minister of Health, while requirements for Good Traditional Medicine Manufacturing Practice (CPOTB) application and the making of traditional medicines is stipulated by the head of Badan POM RI.

Procedures for the registration of traditional medicines comprise of general provisions, distribution permits, registration requirements, registration procedures, re-evaluation, and obligations of distribution permit number holders and sanctions stated in the Regulation of the Minister of Health number 007 of 2012.

This regulation sets the distribution permit for traditional medicines to be valid for 5 (five) years and can be extended as long as the requirements are met. These requirements do not apply to products made by herbal medicine concoctions business and gendong herb medicine business, simplicia and galenic preparations for industrial purposes and traditional medical services, traditional medicines used for research, non-traded samples for registration and exhibitions available in limited stocks.

Traditional drugs that will be registered are not allowed to contain: 1) ethyl alcohol more than 1%, except in the form of tincture used through dilution; 2) medicinal chemicals resulting from isolated or synthetic

medicinal properties; 3) narcotics or psychotropic drugs; and/or 4) other materials based on health considerations and/or based on research could endanger health; Other materials in question will be laid out in the regulations set by P.O.M Agency.

This Regulation of the Minister of Health also regulates the registration of licensed traditional medicines and imported traditional medicines. Licensed IOT and UKOT may register for traditional drug licenses, while those entitled to permit for registration of imported traditional medicines are IOT, UKOT and importers of traditional medicines that have obtained agency appointments and the right to register from industries in their home countries.

For importers who want to collaborate with IOT and UKOT in Indonesia, they must fulfill the following requirements: 1) have traditional drug distribution facilities in accordance with the applicable regulations; 2) has a person in charge of a pharmacist; 3) registration of 1 product only in 1 (one) IOT, UKOT or Importer; 4) foreign industries must have a CPOTB certificate in the country of origin;

IOT, UKOT and UMOT from Indonesia can export traditional medicines abroad as long as they have permits in accordance with statutory provisions, such as quality requirements in accordance with Indonesian Herbal Pharmacopoeia or other recognized requirements, have empiric, hereditary, and/or scientific efficacy, contain marked objective, complete and non-misleading information; Exceptions to these requirements do not apply if there is written approval from the destination country.

Drug registration evaluation is carried out by the National Committee for Traditional Medicine Appraisal and the Security Assessment Team, efficacy/benefits, and quality set by the P.O.M Agency.

### **Regulation of traditional medicine based on science**

In an effort to speed up the development of Indonesian traditional medicine, the Indonesian government has issued a regulation of the Minister of Health number 003/MENKES/PER/1/2010 regarding the scientification of herbs in a research based on healthcare service. This regulation explains in detail that what is meant by herb scientification is scientific proof through healthcare service-based research.

The objectives of herbal medicine scientification regulation are: 1) to provide a scientific basis (*evidence based*) for the empirical use of herbal medicine through healthcare service-based research; 2) to encourage the formation of a network of doctors or dentists and other healthcare practitioners as researchers in the context of preventive, promotive, rehabilitative and palliative efforts through the use of herbs; 3) to improve qualitative research activities on patients with the use of herbs; 4) to increase the supply of safe herbs, have real efficacy that is scientifically tested, and widely utilized both for self-medication and in healthcare facilities.

Herbs or ingredients used in this healthcare service-based research must already be registered in *vademecum*, or materials determined by the National Herbal Medicine Scientification Commission. *Vademecum Medicinal Plants* for the scientification of this herbal medicine add up to 5 volumes, namely the revised edition of *Vademecum I* (2012), *Vademecum II* (2011), *Vademecum III* (2012) and *Vademecum IV* (2013), *Vademecum V* (2014); previously, there was *Vademecum for Natural Medicine* (1989). Herbs provided to patients for the purpose of this study can only be given after an informed consent from the patient is obtained. Patient approval is obtained after an oral or written explanation from the officer is received and recorded in the medical record. The implementation of research activities and ethical clearance of herbal medicine research refers to the provisions of applicable laws.

The National Herbal Medicine Scientification Commission formed by the minister has the following duties: 1) foster the implementation of herbal medicine scientification; 2) improve the implementation of ethics enforcement in herbal medicine research; 3) compile national guidelines in relation to the implementation of herbal medicine scientification; 4) propose to the Head of the Agency for Health Research and Development on medicinal ingredients, particularly in terms of culture, formulation, distribution and quality, as well as safety that are feasible to be used for research; 5) coordinate with researchers, research institutions and universities, as well as professional organizations within and outside the home country, government and private sectors in the field of herbal medicine production; 6) form networks and assists researchers of doctors or dentists and other health workers who practice herbal medicine in all aspects of their research; 7) form a forum between health workers in herbal medicine scientification; 8) give consideration to the process and results of research whose ethical, legal and methodological aspects need to be specifically reviewed to parties who need it; 9) conduct sustainable education, which involves forming a lecturers' council, determining and implementing syllabus and curriculum, as well as competency certification; 10) separately or together evaluate the results of the research, including the transfer of methods/efforts between curative and non-curative results of the research on herbal medicine practices/clinics; 11) propose the feasibility of the study results to be a synergy, integration and referral program for herbal medicine services to ministers through the head of the Health Research and Development Agency; 12) foster the Herb Scientification regional commission in the province or district/city; 13) provide recommendations for improvement and sustainability of Herb Scientification program to the minister;

The National/Regional Scientification Committee of Herbal Medicine comprises of experts in their respective fields from various scientific disciplines, institutions related to herbal medicine, specific professional organizations/dentistry, as well as representatives of consumers and producers.

This service-based research can only be performed at licensed Healthcare Service Facilities, such as: 1) Clinics at the Center for Research and Development of Traditional Medicinal Plants and Medicines (B2P2TOOT); 2) Herbal Medicine Clinics; 3) Centers of Development and Application of Traditional Medicine (SP3T) available in each province; 4) Community Traditional Health Center (BKTM) / Community Traditional Health Workshop (LKTM); 5) Specified hospitals;

### **GriyaSehat**

In order to further support the development of traditional medicines and their utilization, the Ministry of Health has issued Regulation of the Minister of Health number 15 of 2018 regarding complementary traditional healthcare services. This regulation is a follow-up to Regulation of the Government number 103 of 2014 about traditional healthcare services;

What is referred to as traditional healthcare services here is treatment and/or care based on experiences and skills from generation to generation empirically, which can be accounted for and applied in accordance with the prevailing norms in the community.

The facility used to deliver traditional empiric services in this regulation is called GriyaSehat; GriyaSehat is a traditional healthcare service facility that organizes traditional care/treatment and complementary by traditional health workers. The traditional health personnel in question are people who devote themselves to the field of traditional health and possess knowledge and/or skills through education in the field of traditional health, which for certain types require the authority to carry out traditional health efforts. These traditional healthcare practitioners consist of professional and vocational health workers.

The preparations used in this GriyaSehat are traditional medicines with distribution authorization from Badan POM RI or self-concocted traditional medicines, and are not allowed to provide and/or use medicinal chemicals, including over-the-counter medicines, over-the-counter medicines with limitation, prescribed medicines, narcotics, psychotropic substances and hazardous materials; Sellers of traditional medicine are prohibited to sell and/or distribute their own concocted traditional medicines without obtaining permits as stated in the provisions of the legislation.

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**Table 1 List of standardized herbal medicine products**

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition		Indication
	Glucogard HT.142300 381	Capsule/Box, 3 Blisters @ 10 Capsules	PT. Phapros	Morindae Folium Extract MomordicaeFructus Extract	19 mg 306 mg	Helps relieve diabetes symptoms
	Hi-Stimuno HT.163300 601 Valid until23-08- 21	Capsule/Bottle, 100 Capsules @ 375 mg	PJ. Tradimun	Kaempferia rotunda Rhiz. Extract MorindaeFructus Extract	99,75 mg 99,75 mg	Helps maintain body endurance
	KirantiPega lLinu HT.142600 401 Valid until19-03- 19	Oral Liquid Medicine/Bottle @ 150 ml	PT. Ultra Prima Abadi	ZingiberisRhizoma CurcumaedomesticaRhizoma Tamarindi pulp, Arengaepinnata Fructose Honey KaempferiaeRhizomaCinnam omi Cortex Paulinaecupana MyristicaeFlos CaryophylliFlos Water up to	10 gr 6 gr 1,4 gr 7,5 gr 5,5 gr 1 gr 0,45 gr 0,23 gr 0,15 gr 0,09 gr 150 ml	Helps relieve rheumatic aches, pain in joints and refresh the body  Currently: Helps relieve rheumatic aches, relieve pain in joints and warm the body.
	KirantiSeha tDatangBul an HT142600 441 Valid until22-04- 19	Oral Liquid Medicine/ Bottle @ 150 ml	PT. Ultra Prima Abadi	CurcumaDomesticaeRhizom a TamarindipulpaCrudum KaempferiaeRhizoma ZingiberisRhizoma Arengaepinnatae Radix Cinnamomi Cortex Paulina cupana Water up to	30 g  6g 2g 0,8 g 2,5g 0,1 g 0,23 g 150 ml	Helps smooth menstrual flow and relieve period pain.  Changed in 2012 Helps reduce menstrual complaints, such as menstrual pain and bad body odor, as well and helps facilitate menstruation Helps refresh the body
	Kuat Segar ( Chang Sheuw Tian Ran Ling Yao ) HT133300 311 Valid until19-08- 18	Capsule/Bottle @ 30 Capsules	PJ. DaunTeratai	Form. JapoicusFructus Herb Extract Pseudo Ginseng Extract Atractylodesmacrocephala Rhiz. Extract LigustrinumRhizoma Extract	81 mg 12,87 mg 6,5 mg 24,63 mg	Traditionally used for cancer patients

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition		Indication
	Lelap HT142500 451 Valid until 5 May 2019	Film Coated Caplet: Box, 3, 25 Strips @ 4 Caplets  Box, 5 Strips @ 6 Caplets  Bottle @ 30 Caplets  Box, 3 Blisters @ 10 Caplets  Box, Blister @ 10 Caplets Dus, 1 strip @ 10 kaplet	PT. SohoIndustri Farmasi	Eleuthro Ginseng Radix Valerianae Radix Myristicae Semen Polygalae Radix	100 mg 250 mg 115 mg 135 mg	Helps overcome sleep disorders
	Psidii HT142300 431 Valid until 22-04- 19	Capsule/Bottle 50 Capsules @ 700 mg  Box, 3 & 25 Strips @ 4 Film Coated Caplets  Box, 5 Strips @ 6 Film Coated Caplets  Box, 1 Strip @ 10 kapletsalutselaput Dus, 25 strip @ 4 kapletsalutselaput Dus, 2 strip @ 6 kapletsalutselaput	PJ. Tradimun	Psidii Folium Extract	499,8 mg	Helps increase the number of blood cells in necessary conditions  New indication: Helps increase platelet count
	Psidii HT142600 421 Valid until 22-04- 19	COD/ Bottle @ 120 ml	Contract Provider : PT. DexaMedica  Contract Receiver : Ferron Par Pharmaceutic al	Psidii Folium Extract	250 mg	Helps increase the number of blood cells in necessary conditions  New indication: Helps increase platelet count
	Rheumakur HT122300 141 Valid until 2 Mei 2022	Capsule/ 5 Strips @ 6 Soft Capsules	PT. Phytochemin doReksa	Curcuma domesticata Extract Curcuma exanthorrhizae Extract	75 mg  25 mg	-Helps relieve gout and joint pain -Helps relieve digestive disorders
11.	KUAT SEGAR (CHANG SHEUW TIAN RAN LING YAO) HT133300 311 Valid until 19-08- 2018	Capsule Blister @ 30 Capsules	PT DAUN TERATAI	Form japoicus fructus extract Pseudoginseng radix extract Ligustilwallichii fructus extract Atractylodes macrocephalarhiz oma extract	178.2 mg  28.3 mg  54.2 mg  14.3 mg	Helps maintain health condition in cancer patients

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition	Indication	
12	KUAT SEGAR (CHANG SHEUW TIAN RAN LING YAO) HT143300 411 Valid until 14-04-2019	Capsule/Bottle @ 300 Capsules	PT DAUN TERATAI	Form japoicusfructus extract Pseudoginseng radix extract Ligustilwallichiiifrufructus extract Atractylodesmacrocephalarhiz oma extract	178.2 mg 28.3 mg 54.2 mg 14.3 mg	Helps maintain health condition in cancer patients
13	Songgolangit HT143100 391 Valid until 16-03-19	Powder / Box @ 7 Sachets @ 10 gram	PT. Songgolangit Herbal Indonesia	TridaxprocumbenHerba	10 g	Helps reduce pain and swelling in rheumatism
14	Stop Diar Plus HT132500 321 Valid until 20-08-2018	Tablet/Strip @ 4 Tablets	PT. Air Mancur	CurcumaedomesticaeRhizoma Psidii Folium Jasminimultiflori Folium Brugmaniae Folium	144 mg 270 mg 180 mg 6 mg	Reduces the frequency of defecation, compresses feces and absorbs toxins in patients with diarrhea and not as a substitute for oral rehydration therapy (ORT)
15	Helmig's Sari Temulawak (Sugar Free) HT152200 521 Valid until 3-3-2020	Powder / Box, 10 Sachets @ 5 g	PT. Prima Sejahtera	CurcumaeRhizomaExtract	25 mg	Maintains healthy liver function and digestive function  Maintains endurance  Helps reduce fats in blood
16	Neurat HT152300 541 Valid until 9-9-2020	Capsule, Bottle @ 30 Capsules	PT. IndustriJamu dan FarmasiCapJ ago	SyzigiumpolyanthiFoliumEkst rak ApiumgraveolensHerbaEkstra k Nigellaedamascenae semen Ekstrak	325 mg 250 mg 175 mg	Helps reduce uric acid levels
17	TolakAngin HT122600 301 Valid until 03 November 2022	Oral Liquid Medicine/ Sachet @ 15 ml	PT. Sido Muncul	Oryza Sativae Foeniculi Fructus Isorae Fructus Caryophylli Folium Zingiberis Rhizoma Menthae Arvensis Herba Phyllanthi Herba Extract Honey	20 % 10 % 10 % 10 % 10 % 0.52 % 69.4 %	Good for colds characterized by fever, dizziness, stomach nausea, bloating, watery eyes, dry throat and chills, also good when taken to relieve abdominal pain, travel sickness, fatigue and lack of sleep. TolakAngin can maintain body endurance.

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition	Indication	
18	Diakur POM TR 032 321 441/ HT132300 331 Valid until16-09- 2018	Capsule/ Strip @ 4 Capsules	PT. Phytochemin doReksa	Guava Leaf Extract (Psidii Folium) Curcuma domestica Rhizoma extract Andrographis Herba Extract	65 mg  10 mg  25 mg	Reduces the frequency of defecation
19	Laxal POM TR. 032 321 381 29-08-2018	CapsuleBox,5 Strips @ 6 Capsules Box, 15 & 25 Strips @ 4 Capsules	PT. Phytochemin doReksa	Sennae Folium Extract Aloe vera Folium Extract	180 mg 33 mg	Smooth defecation when in constipation
20	Slimming Tea JamuCelup Pelangsing HT133200 341 Valid until17-12- 2018	Powder /Box, 15 & 30 Bags@ 2g	PT. MustikaRatu	Green tea Parameriae Cortex Extract Guazumae Folium Extract FoeniculiFructus Extract Curcuma Rhizome Extract	1.6 g 0.12 g 0.12 g 0.08 g 0.08 g	Helps reduce fat and slim the body
21	Neosendi POM HT. 122 300 201 Valid until04-12- 2021	CapsuleBottle @ 30, 60 & 100 Capsules	PT. I.J. Borobudur	<i>Kaempferiae Rhizome extract</i> <i>Zingiberis Rhizome extract</i> <i>Curcuma domesticae Rhizoma</i> <i>extract</i>	137,5 mg 137,5 mg 275 mg	<i>Relieves gout, aches and pain, as well as joint pain</i>
22	Neosendi POM HT. 122 300 221 Valid until04-12- 2021	CapsuleBox, 10 Strips @ 5 & 10 CapsulesBox, Strips @ 12 Capsules	PT. I.J. Borobudur	<i>Kaempferiae Rhizome extract</i> <i>Zingiberis Rhizome extract</i> <i>Curcuma domesticae Rhizoma</i> <i>extract</i>	137,5 mg 137,5 mg 275 mg	<i>Relieves gout, aches and pain, as well as joint pain</i>
23	Niran POM HT. 122 300 231 Valid until4-12- 2021	CapsuleBottle @ 30, 60 & 100 Capsules	PT. I.J. Borobudur	PhyllanthusNiruriHerba	550 mg	<i>Helps maintain body endurance</i>
24	Niran POM HT. 122 300 251 Valid until04-12- 2021	CapsuleBox, 10 Strips @ 5 & 10 CapsulesBox, Strips @ 12 Capsules	PT. I.J. Borobudur	PhyllanthusNiruriHerba	550 mg	<i>Helps maintain body endurance</i>
25	DISOLF HT142500 471 Valid until08-12- 2019	Capsule, Box, 5 Strips @ 6 Capsules Enteric Coated Tablet, Box, 5 Strips @ 6 Enteric Coated Tablets	PT. DexaMedica	<i>Lumbricus rubellus extract</i>  <i>Lumbricus rubellus extract</i>	367,5 mg / capsule  490 mg / film coated tablet	<i>Helps smooth blood circulation</i>  Marked to include Warning / Attention: <i>Only used by the doctor's advice</i>  <i>Consult a doctor regularly during the use of this product</i>

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition	Indication	
26	PHALECA RPS TR1523881 31 Persetujuan OHT 29-03-2011 Valid until 27-07-2020	Capsule, Box, 5 Strips @ 6 Capsules	PT. DexaMedica	Phaleria macrocarpa fructus extract	90 mg	<i>Helps in treating breast cancer</i> Marked to include Warning / Attention: <i>Only used in patients diagnosed with breast cancer by a doctor</i> <i>Consult a doctor regularly during the use of this product</i>
27	TULAK HT 112 300 091 Valid until 23-08-2021	Capsule Box, 10 Strips @ 5 & 10 Capsules	PT. I.J. Borobudur	<i>Curcuma</i> Rhizoma extract	550 mg	<i>Maintain healthy liver function</i>
28	TULAK HT112300 081 Valid until 23-08-2021	Capsule Bottle @ 30, 60 & 100 Capsules	PT. I.J. Borobudur	<i>Curcuma</i> Rhizoma extract	550 mg	<i>Maintain healthy liver function</i>
29	Diapet NR TR. 032 326 881	Box, 25 Strips @ 4 Capsules	PT. SohoIndustri Pharmasi	<i>Attapulgite</i> <i>Norit / activated carbon</i> <i>Psidium Folium Extract 48 mg</i> <i>Curcuma domesticae Rhizoma Extract</i> <i>Coicis Cement Extract 82 mg</i> <i>Chebulae Fructus Extract 16 mg</i> <i>Granati Pericarpium Extract</i>	200 mg 50 mg 48 mg 40 mg 82 mg 16 mg 14 mg	<i>Reduces the frequency of defecation in patients with diarrhea, and not as a substitute for oral rehydration therapy (ORT)</i>
30	Antangin JRG + Madu POM HT. 112 600 041 valid until 20-11-2021	Oral Liquid Medicine/ Sachet @ 15 mL	PT. Deltomed	<i>Every 15 mL contains:</i> <i>Zingiberis Rhizome Panax</i> <i>Ginseng</i> <i>Royal Jelly</i> <i>Blumeae folium</i> <i>Menthae Folia</i> <i>Curcuma domestica rhizome</i> <i>Cement myristicae</i> <i>Glycyrrhizae radix</i> <i>Mel depuratum</i>	7,336 g 1,00 g 0,03 g 2,445 g 4,89 g 0,100 g 0,562 g 0,400 g 800 g	<i>Relieves indications of colds, such as chills, nausea, flatulence, cold sweat, as well as dry throat</i>
31	BILON POM HT. 112 300 061 valid until 2-09-2021	Capsule/ Box, 10 Strips @ 5, 10 Capsules @ 550 mg	PT. I.J. Borobudur	Each capsule contains: <i>MomordicaeFructus extract</i>	550 gram	<i>Helps relieve diabetes".</i>
32	BILON POM HT. 112 300 071 valid until 23-08-2021	Bottle @ 60 and 100 Capsules @ 550 mg	PT. I.J. Borobudur	Each capsule contains: <i>MomordicaeFructus extract</i>	550 gram	<i>Helps relieve diabetes".</i>

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition		Indication
33	OB Herbal POM HT. 112 600 121 Valid until 20-11-2021	Oral Liquid Medicine/ Box, 10 Sachets @ 15 mL	PT. Deltomed	Zingiberis Rhizome Kaempferiae Rhizome Citrus Aurantiifructus Herbal Thymi Menthae folium Cement myristicae Glycyrrhizaeglabra radix Mel depuratum	4,5 gr 1,5 gr 1,5 gr 1,5 gr 0,75 gr 0,75 gr 0,25 gr Ad 15 mL	Helps relieve cough Helps relieve sore throat
34	OB Herbal POM HT. 112 600 131 Valid until 06-01-2022	Oral Liquid Medicine/ Bottle @ 60 and 100 mL	PT. Deltomed	Zingiberis rhizome Kaempferiae rhizome Citrus Aurantiifructus Thymherba Menthae folium Myristicae semen Glycyrrhizaeglabra radix Mel depuratum	4,5 gr 1,5 gr 1,5 gr 1,5 gr 0,75 gr 0,75 gr 0,25 gr Ad 15 mL	Helps relieve cough Helps relieve sore throat
35	KENIS HT. 112 300 011 Valid until 31-08-2021	Blister @ 12 Capsules	PT. I.J. Borobudur	Momordicae Folium extract Orthosiphonis Folium Extract AndrographidisHerba Extract	275 mg 137,5 mg 137,5 mg	Helps relieve diabetes
36	KENIS HT. 112 300 021 Valid until 23-08-2021	Bottle @ 60, 80 Capsules	PT. I.J. Borobudur	Momordicae Folium extract Orthosiphonis Folium Extract AndrographidisHerba Extract	275 mg 137,5 mg 137,5 mg	Helps relieve diabetes
37	KENIS HT. 112 300 111 Valid until 31-08-2021	Box, 10 Strips @ 10 & 5 Capsules	PT. I.J. Borobudur	Momordicae Folium extract Orthosiphonis Folium Extract AndrographidisHerba Extract	275 mg 137,5 mg 137,5 mg	Helps relieve diabetes
38	MASTIN POM HT. 122 300 181 Valid until 6-01-2022	Box, 10 Strips @ 5 & 10 Capsules	PT. I.J. Borobudur	Each capsule contains: Garcinia Fructus Cortex	550 mg	Helps maintain body health
39	MASTIN POM HT. 112 300 191 Valid until 04-12-2021	Bottle @ 60 & 100 Capsules	PT. I.J. Borobudur	Each capsule contains: Garcinia Fructus Cortex	550 mg	Helps maintain body health
40	KIRANTI SEHAT DATANG BULAN PLUS JUICE POM HT. 122 600 261/	Oral Liquid Medicine / Bottle @ 150 mL	PT. Ultra Prima Abadi	Every 150 ml contains: Curcuma domesticate Rhizoma KaempferiaeRhizoma Arengaepinnata Fructose ZingiberisRhizoma Curcumin Extract	12 g 2,5 g 2 g 0,8 g 0,25 g	Helps smooth Helps reduce menstrual complaints, such as menstrual pain and bad body odor, and helps facilitate

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition	Indication	
	HT142600 461 Valid until 18-12-2019			Paulliniacupana Cinnamomi Cortex TamarindiPulpa Orange concentrate	0.23 g 0.1 g 0.1 g 18.5 g	menstruation.H elps refresh the body
41	Redacid POM HT. 132 500 351 Valid until 20-01-2019	Caplet, Box, 5 Strips @ 6 Caplets	PT. DexaMedica	dlbs2411 cinnamomumburmanii	250.00 mg	Relieve stomach disorders
42	Redacid POM HT. 162600591 Valid until 21-04-2021	COD/ Bottle @ 60 ml	PT. DexaMedica	dlbs2411 cinnamomumburmanii	250.00 mg	Relieve stomach disorders
43	Dismeno POM HT. 152 300 481 Valid until 3-02-2020	Capsule, Box, 5 Strips @ 6 Capsules	PT. DexaMedica	Mahkota Dewa Fruit (phaleriaMacrocarpaFructus)	100 mg	Helps relieve menstrual pain
44	Murat HT152300 501 Valid until 3-06-2020	Capsule, Box 10 Strips @ 5 & 10 Capsules Box, 6 Strips @ 10 Capsules Box, Strips @ 12 Capsules	PT. Borobudur	Syzygiipolyanthi Folium extract ApiiGraveolentis Folium extract Orthosiphonisaristatus Folium extract	275 mg 137,5 mg 137,5 mg	Helps relieve rheumatic aches and joint pain
45	Murat HT152300 491 Valid until 3-06-2020	Bottle @ 60, 80 and 100 Capsules	PT. Borobudur	Syzygiipolyanthi Folium extract ApiiGraveolentis Folium extract Orthosiphonisaristatus Folium extract	275 mg 137,5 mg 137,5 mg	Helps relieve rheumatic aches and joint pain
46	Murat HT152300 511 Valid until 3-06-2020	Box @ 1,10,25 Blisters @ 12 Capsules	PT. Borobudur	Syzygiipolyanthi Folium extract ApiiGraveolentis Folium extract Orthosiphonisaristatus Folium extract	275 mg 137,5 mg 137,5 mg	Helps relieve rheumatic aches and joint pain
47	Degrade HT152500 531 Valid until 22-05-2020	Enteric Coated Tablets, Box @5 Strips @ 6 Enteric Coated Tablets	PT. DexaMedica	DLBS 1033 Lumbricusrubellus	490 mg	Helps smooth blood circulation
48	Stolenza HT152500 551 Valid until 17-11-2020	Box, 5 Strips @ 6 Film Coated Tablets	PT. DexaMedica	Black cumin extract (nigella sativa) PhaleriaMacrocarpafructus extract	150 mg	Helps relieve pain due to swelling
49	Keling HT162300 581 Valid until 2-02-2021	Bottle @ 60,80 and 100 Capsules	PT. Borobudur	Each capsule contains: Sonchi Folium Extract Orthosiphonis Folium Extract Sericocalycis Folium Extract PhyllanthiHerba Extract Imperatae Radix Extract CubebaeFructus Extract Caricae Folium Extract	121.5 mg 121.5 mg 110 mg 110 mg 55 mg 16.5 mg 16.5 mg	Helps shed oxalate stones in kidneys and urinary tract, smooth urination and relieve waist pain

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition		Indication
50	Keling HT162300 571 Valid until 02-02-2021	Box, 6 Strips @ 10 Capsules Box, 10 Strips @ 5, 10 Capsules	PT. Borobudur	Each capsule contains: Sonchi Folium Extract Orthosiphonis Folium Extract Sericoalycis Folium Extract PhyllanthiHerba Extract Imperatae Radix Extract CubebaeFructus Extract Caricae Folium Extract	121.5 mg	Helps shed oxalate stones in kidneys and urinary tract, smooth urination and relieve waist pain
51	Keling HT.162300 561	Box, blister @ 12 Capsules Box, Strip @ 12 Capsules			121.5 mg 110 mg 110 mg 55 mg 16.5 mg 16.5 mg	
52	Losterol HT172300 621 Valid until 17-01-2022	Plastic bottle @ 30, 60, 100 Capsules	PT. Borobudur	GuazumaeUlmifolia Folium Extract	550 Mg	Helps reduce blood fat
53	Losterol HT172300 631 Valid until 17-01-2022	Box, 10 Strips @ 5 & 10 CapsulesBox, Strips @ 12	PT. Borobudur	GuazumaeUlmifolia Folium Extract	550 Mg	Helps reduce blood fat
54	Losterol Plus HT172300 651 Valid until 30-01-2022	Box, 10 Strips @ 5 & 10 Capsules Box, Strips @ 12 Capsules	PT. Borobudur	GuazumaeUlmifolia Folium Extract Camellia SinensisFolium Extract	412.5 mg 137.5 mg	Helps reduce blood fat
55	Losterol Plus HT172300 641 Valid until 30-01-2022	Plastic bottle @ 30,60 & 100 Capsules	PT. Borobudur	GuazumaeUlmifolia Folium Extract Camellia SinensisFolium Extract	412.5 mg 137.5 mg	Helps reduce blood fat
56	Herbapain HT172500 611 Valid until 30-01-2022	Box, 10 Catch Cover @ 1 Strip @ 4 Tablets	PT DexaMedica	PhaleriaMacrocarpa Dlbs1442	200 mg	Helps relieve pain, such as headaches and muscle aches
57	Kirantidata ngbulanrs sour sop HT.172600 661 Valid until 08-09-2022	COD / Bottle @ 150 ml	PT. Ultra Prima Abadi	Curcuma domesticaerhizoma	12 g	Helps reduce menstrual complaints, such as menstrual pain and bad body odor, and helps facilitate menstruation Helps refresh the body
				Soursop concentrate	10,5 g	
				Sacharum album	3 g	
				Kaempferiaegalangrhizoma	2,5 g	
				Arengapinnatarhizoma	2 g	
				Zingiberofficinalerhizoma	0,8 g	
				Curcumin extract	0,25 g	
				Pandaniamaryllidolious folium	0,25 g	
				Paulliniacupanafructus	0,1 g	
				Cinnamomunverun cortex	0,1 g	
				Tamarindi pulp	0,1 g	
				Sodium benzoate	0,03 g	
				Water	Up to 150 ml	
58	Kirantidata ngbulanrs mango HT.172600 671 Valid until 08-09-2022	COD/ Bottle @ 150 ml	PT. Ultra Prima Abdi	Different concentrate (Mango)		
59	Tolakangin kemasanbot ol HT.172600	COD/ Bottle @ 30 ml	PT. IndustriJamu danFarmasiSi doMuncul	Ekstrakbahan yang terdiri dari	30 %	Good for colds characterized by fever, dizziness,
				Oryza sativa	20 %	
				Foeniculum vulgare fructus	10 %	

No	Name of Product	Dosage Form / Packaging	Name of Factory	Composition		Indication
	681 Valid until 25-08-2022			Helicteresisoraefructus	10 %	stomach nausea, bloating, watery eyes, dry throat and chills. Also good when taken to relieve abdominal pain, travel sickness, fatigue and lack of sleep.
				Eugenia caryophilata folium	10 %	
				Zingiberofficionalerhizoma	10 %	
				Amomifructus compactus	5 %	
				Fragrantismyristica cement	5 %	
				Cinnamomumburmanni cortex	5 %	
				Centellaasiatica herb	5 %	
				Parkiaroxburgii semen	5 %	
				Herbal Menthaarvensis	10 %	
				Usnea thallus	5 %	
				Mel depuratum	70 %	
				Sodium benzoate	0,04 %	
				Potassium Sorbate	0,04 %	
60	LIPIDCAR E HT.170300 691	Capsule / 3 Blisters @ 10 Capsules	PT. Deltomed	Curcumaexanthorrhiza extract	81,5 mg	Helps reduce blood fat
				Syzygiipolyanthi folium	83,5 mg	
				Sechiumedulespissum extract	75 mg	
				Na Bicarbonat	110 mg	
				Microcel 102	100 mg	
				Talcum	50 mg	
61	LIPIDCAR E HT172300 711 Valid until 29-12-2022	Capsule/ Bottle @ 30 & 60 Capsules	PT. Deltomed	Curcumaexanthorrhiza extract	81,5 mg	Helps reduce blood fat
				Syzygiipolyanthi folium	83,5 mg	
				Sechiumedulespissum extract	75 mg	
				Na Bicarbonat	110 mg	
				Microcel 102	100 mg	
				Talc	50 mg	
62	DISOLF HT172500 701 Valid until 27-12-2022	Enteric Coated Tablet / Box, Bottle @ 30 & 50 Enteric Coated Tablets	PT DexaMedica	Eachentericcoated tablet contains: DLBS1033 Lumbricusrubellus	490 mg	Helps relieve blood circulation

**Table 2:DATA OF PHYTOPHARMACEUTICAL PRODUCTS**

No	Name of Product	Name of Company	Packaging	Distribution License Number	Approved Efficacy
1	RHEUMANEER	PT NJONJA MENEER	Capsule/ Box, 10 Strips @ 4 Capsules @ 500 mg	FF092300521 02 February 2009	Cure mild to moderate arthralgia joint pain
2	RHEUMANEER	PT NJONJA MENEER	Capsule/ Box, 2 Blisters @ 10 Capsules @ 500 mg	FF152300661 15 June 2015	Cure mild to moderate arthralgia joint pain
3	NODIAR	PT KIMIA FARMA	Tablet/ Box, 2 Strips @ 10 Tablets Box, Catchcover @ 25 strips @ 4 Tablets	FF142500601 Published 2003	To treat non-specific diarrhea
4	STIMUNO RASA ANGGUR	PT. DexaMedica	Oral Liquid Medicine/ Box, Bottle 60 & 100 ml	FF152600651 03 December 2014	Improving the immune system (Immunomodulator)
5	STIMUNO syrup	PT. DexaMedica	Oral Liquid Medicine/Box, Bottle 60 & 100 ml	FF152600631 18 December 2014	Improving the immune system (Immunomodulator)
6	STIMUNO FORTE	PT. DexaMedica	Capsule/ Box, 3 and 5 Blisters @ 10 Capsules Box, 10 Boxes @ 1 Blister @ 10 Capsules	FF152300641 Published 2004	Improving the immune system (Immunomodulator))
7	STIMUNO kapsul	PT. DexaMedica	Capsule/ Box, Bottle @ 30 Capsules	FF152300671 15 June 2015	Improving the immune system (Immunomodulator)
8	LIVITENS	PT. DexaMedica	Film Coated Caplet/	FF162500701	Lower blood pressure in

			Box, 5 Strips @ 6 Film Coated Caplet	10 November 2011	patients with mild hypertension (Level 1)
9	RESINDEX 50	PT. Ferron Par Pharmaceutical	Capsule/ Box, 5 Strips @ 6 Capsules	FF162300681 03 August 2016	As a combination therapy with other oral anti-diabetic drugs in type 2 Diabetes Mellitus patients
10	RESINDEX 100	PT. Ferron Par Pharmaceutical	Capsule/ Box, 5 Strips @ 6 Capsules	FF162300691 03 August 2016	As a combination therapy with other oral anti-diabetic drugs in type 2 Diabetes Mellitus patients
11	TENSIGARD	PT. Phapros	Capsule/ Box, 3 Blisters @ 10 Capsules	FF142300591 Published 2003	Used to reduce systolic and diastolic blood pressure in patients with mild to moderate hypertension without affecting plasma electrolyte levels, plasma lipid levels
12	X – GRA	PT. Phapros	Capsule/ Box, 3 Blisters @ 10 Capsules Box, 4 Catch Cover @ 10 Capsules	FF142300581 Published 2003	For erectile dysfunction with or without premature ejaculation.
13	INLACIN 100	PT. DexaMedica	Capsule/ Box, 5 Strips @ 6 Capsules	FF152300621 03 February 2015	As a combination therapy with other oral anti-diabetic drugs in type 2 Diabetes Mellitus patients
14	INLACIN 50	PT. DexaMedica	Capsule / Box, 5 Strip @ 6 Capsules	FF152300611 03 February 2015	As a combination therapy with other oral anti-diabetic drugs in type 2 Diabetes Mellitus patients
15	STIMUNO RASA JERUK BERI	Contract Provider : PT. DexaMedica  Contract Receiver : PT Ferron Par Pharmaceuticals	Oral Liquid Medicine/ Box, Bottle @ 60 & 100 mL	FF172600721 20 March 2017	As an immunomodulator (improving the immune system)
16	NEW DIVENS	Contract provider : PT Ferron Par Pharmaceuticals Contract receiver : PT. DexaMedica	Capsule/ Box, 6 Blisters @ 10 Capsules	FF172300711 20 March 2017	As an immunomodulator (improving the immune system)
17	NEW DIVENS RASA JERUK BERI	Contract provider : PT. DexaMedica Contract receiver : PT Ferron Par Pharmaceuticals	Oral Liquid Medicine/ Box, bottle @ 100 mL	FF172600741 25 September 2017	As an immunomodulator (improving the immune system)
18	STIMUNO RASA JERUK BERI	Contract provider : PT. DexaMedica Contract receiver : PT Ferron Par Pharmaceuticals	Oral Liquid Medicine/Box, 5, 12 & 24 Stickpacks @ 5 mL	FF172600731 25 September 2017	As an immunomodulator (improving the immune system)
19	HERBAWELL DIABETADEX 50	Contract provider : PT Ferron Par Pharmaceuticals Contract receiver : PT. DexaMedica	Box, bottle @ 30 & 50 Capsules	FF172300761 29 December 2017	As a combination therapy with other oral anti-diabetic drugs in type 2 Diabetes Mellitus patients
20	HERBAWELL DIABETADEX 100	Contract provider : PT Ferron Par Pharmaceuticals Contract receiver : PT. DexaMedica	Box, Bottle @ 30 & 50 Capsules	FF172300751 29 December 2017	As a combination therapy with other oral anti-diabetic drugs in type 2 Diabetes Mellitus patients

Dr. Drs.Husin R. Mallaleng, et. al. "Indonesian FDA Regulations on Indonesian Traditional Nutraceuticals (Herbs) Contributors:" International Refereed Journal of Engineering and Science (IRJES), vol. 09, no. 03, 2020, pp 25-40.