



## INDONESIAN TRADITIONAL HERBAL MEDICINE AS AN ANTI-VIRAL AGENT

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### Abstract

**Background.** Traditional herbal medicine has been effectively used to treat various diseases for hundreds or even thousands of years, as mentioned in ancient manuscripts, textbooks, and pharmacopoeias. Since ancient times, herbal therapy has played a crucial role in combating infectious diseases. BPOM distribution permits are needed to maintain the safety of drugs in circulation. A distribution permit is a permit for Drugs and Food produced by manufacturers and/or imported by importers of Drugs and Food that will be distributed in the territory of the Republic of Indonesia based on an assessment of safety, quality, and usefulness.

**Aims.** This study aims to investigate the legal process of HV Care as an antiviral, as per the Indonesian Food and Drug Control Agency (BPOM).

**Method.** The experimental method is used in the research, from preparing raw materials to processing, until it becomes a finished product, followed by the legal process to obtain a distribution permit.

**Result.** The herbal medicine formulation utilizes extracts obtained from vendors who have already received certification from BPOM. The raw materials are then mixed according to the predetermined dose, mashed, sifted, and packaged into capsules. The distribution permit process is submitted to BPOM through various stages, including registration and laboratory results for the submitted formula, as well as the Standard Operating Procedure (SOP) for formula preparation.

**Conclusion.** HV Care is an herbal medicine with the composition of meniran (*Phyllanthus Urinaria Folium*), Temu mango (*Curcuma amada Rhizome*), Curcuma Zanthorrhiza Rhizome, Sambiloto (*Andrographis Paniculata Folium*). It is helpful as an antiviral for HIV sufferers in particular and other viral diseases. HV Care has been processed by the standards of the Indonesian Food and Drug Control Agency (BPOM) and holds a POMTR223008931 distribution permit, enabling it to be distributed in the community.

**Keywords:** HV Care, anti-virus, agent, BPOM, medicine, herbs

### INTRODUCTION

Traditional medicine comprises singular or composite components derived from botanical, zoological, or mineral sources, including galenic formulations or their combinations, utilized for medicinal purposes over generations. It can be implemented in accordance with the existing



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standards within the community. Numerous items, including illicit traditional medicines, pose significant dangers in the marketplace. Numerous conventional illicit pharmaceutical items are imported from nations such as China, Canada, Thailand, and Malaysia. It is readily disseminated in the Indonesian market, which is accessible and affordable, particularly among the economically disadvantaged who lack comprehension of licensing and product requirements, including safety considerations. BPOM distribution permits are essential for ensuring the safety of circulating pharmaceuticals. Distribution permits are authorizations for Drugs and Food manufactured by producers and/or imported by importers intended for distribution within the Republic of Indonesia, contingent upon an evaluation of safety, quality, and efficacy (Rahayu, 2019).

Immunity is the body's response to foreign chemicals that infiltrate at the molecular or cellular level. The immune system comprises T cells, generated by the thymus, and B cells, produced in the bone marrow. The incorporation of an immunomodulator can enhance the proliferation and functionality of T cells. Immunomodulators are agents that can alter the function and activity of the immune system. Immunomodulators are categorized into three groups: 1) Immunostimulators enhance the function and activity of the immune system; 2) immunoregulators modulate the immune system; and 3) immunosuppressors block or suppress immune system activity. An immunomodulator is clinically utilized for patients with compromised immunity, including those with cancer, HIV/AIDS, malnutrition, allergies, and other conditions. Nevertheless, its application leads to numerous adverse effects, including nonsteroidal anti-inflammatory agents (microscopic gastrointestinal bleeding, diminished platelet counts, respiratory depression, etc.), immunostimulants (elevated uric acid levels, urticaria, agranulocytosis, among others), and immunosuppressants (hepatotoxicity, gastrointestinal disturbances, etc.) Consequently, it is imperative to seek alternative immunomodulators produced from medicinal plants that exhibit substantial side effects. Reduced in size for the body. Medicinal plants serve as immunostimulants to mitigate intracellular viral and bacterial infections, address immunodeficiency, or enhance the proliferation of immune system defense cells (Alkandahri et al., 2018).

Indonesian medicinal herbs with potential antiviral properties include meniran (*Phyllanthus urinaria* folium), temu kunci (*Curcuma amada* rhizome), *Curcuma zanthorrhiza* rhizome, and sambiloto (*Andrographis paniculata* folium). This research sought to examine the abundance of Indonesian herbs, encompassing raw materials and production, while obtaining legal approval from BPOM.

## LITERATURE REVIEW

### Meniran (*Phyllanthus Urinaria Folium*)

*Phyllanthus niruri* L. is one of the plant extract constituents included in herbal immunostimulant products commonly manufactured in Indonesia. *Phyllanthus* is a herbaceous genus including more than 700 species. *Phyllanthus niruri* L., commonly referred to as meniran in Indonesia, is a plant that has been utilized as a traditional medicine for an extended period. This plant proliferates naturally in damp, rocky environments and is prevalent in the Asian continent,

particularly in Indonesia. *Phyllanthus niruri* L. exhibits immunostimulant, antihypertensive, antihyperglycemic, antimicrobial, and hepatoprotective properties. *Phyllanthus niruri* L. possesses flavonoids that bind to immune cells and deliver intracellular signals to activate their functions (Puspitasari, 2010).

Meniran comprises several flavonoids, including quercetin, quercitrin, isoquercitrin, astragalin, and rutin, as well as kaempferol-4-rhamnoglucoside, eriodictyol-7-rhamnoglucoside, nirurin, nirurid, filantine, hypophyllantin, triterpenes, and securinine alkaloids. Meniran exhibits properties as an immunostimulant, analgesic, antipyretic, ACE inhibitor, antibacterial, antifungal, antiviral, hepatitis B surface antigen inactivator, reverse transcriptase inhibitor, antihepatotoxic, antihypercholesterolemic, antihyperlipidemic, antihyperglycemic, antihypertensive, aldose reductase inhibitor, antimutagenic, anticarcinogenic, cytotoxic, antitumor, chromosomal aberration inhibitor, carminative, stomachic, cardiotoxic, antidiarrheal, and spasmolytic (Puspitasari, 2010).

Experimental research conducted on mice by Soeprapto Ma'at, as referenced by Puspitasari (2010), demonstrates that: Oral administration of *Phyllanthus niruri* L. extract enhances nonspecific immune response activity by augmenting phagocytosis in monocyte/macrophage cells, intensifying inflammatory responses through elevated chemotactic activity of monocytes/macrophages and neutrophils, and increasing the cytotoxicity of Natural Killer (NK) cells. Oral administration of *Phyllanthus niruri* L. extract in mice enhances specific immune response activity by promoting T lymphocyte proliferation, augmenting interleukin-4 (IL-4) secretion from T helper-2 lymphocytes (Th-2), increasing the production of specific antibodies IgG and IgM, stimulating B lymphocyte proliferation, and elevating TNF- $\alpha$  secretion from T helper-1 lymphocytes (Th-1).

### **Temu mango (*Curcuma amada* rhizome)**

Temu mango demonstrated phagocytic activity and capability. The immune system, as exemplified by the positive control of Stimuno. Observations of macrophage activity and phagocytic capacity against *S. epidermidis* demonstrated a disparity in the number of macrophages that phagocytosed bacteria from both water and alcohol extracts, with 70% of each type examined. Evaluation of screening for activity (SFA) and phagocytic capacity (IF) against water and alcohol extracts in vitro at logarithmic dose variations of 0.1 – 1000  $\mu$ g, with positive controls (Stimuno) at a concentration of 1000  $\mu$ g (*Phyllanthus niruri* extract) and negative controls (H<sub>2</sub>O). The observational results indicated that all investigated discoveries enhanced the activity (50 – 96%) and capacity (484 – 958) of phagocytosis in peritoneal macrophage cells of *Mus musculus* caused by *Staphylococcus epidermidis*, correlating with escalating eclectic dosages. Pratiwi and Chairu, 2010.

Antioxidant molecules are prevalent in mangoes. Vitamin C is one of the antioxidant chemicals found in mangoes. Vitamin C is a chemical that can enhance the body's production of white blood cells, the primary constituents of the immune system. The robust immune system can mitigate the impact of free radicals on the body. Moreover, curcumin molecules, characteristic of

this research domain, possess antioxidant characteristics that safeguard the body from both external and internal threats posed by free radicals. (Azizah, 2020). Temu mango possesses chemicals that inhibit the proliferation of cancer cells within the body. The curcumin present in mango mushrooms may contribute to the eradication and inhibition of cancer cells in the body, preventing their dissemination.

Curcumin is recognized for its ability to block the polyfermentation processes in cancer cells, hence preventing their proliferation and inducing apoptosis. Investigation of the cytotoxic effects of methanol extract and its fractions (hexane and ethyl acetate) derived from mango temu against six human cancer cell lines: hormone-dependent breast cell line (MCF-7), nasopharyngeal epidermoid cell line (KB), lung cell line (A549), cervical cell line (Ca Ski), colon cell lines (HCT 116 and HT-29), and one non-cancerous human fibroblast cell line (MRC-5). Henjani et al. (2018) Antioxidant chemicals are prevalent in mango collections. Vitamin C is one of the antioxidant chemicals found in mangoes. Vitamin C is a chemical that can enhance the body's production of white blood cells, the primary constituents of the immune system. The robust immune system can mitigate the impact of free radicals on the body. Moreover, curcumin compounds, which are characteristic of this class of results, has antioxidant characteristics that safeguard the body from both external and internal threats posed by free radicals. Purba et al. (2022). Mango rhizomes are traditionally employed to alleviate stomach disturbances, thoracic pain, fever, ulcers, and for postpartum care. Temu mango is effective as an antipyretic, antitoxic, laxative, and antioxidant. Additional advantages include cancer mitigation, alleviation of abdominal discomfort, uterine contraction post-partum, reduction of visceral adiposity, enhancement of appetite, fortification of orgasm, relief from vaginal pruritus, management of pruritus, treatment of lesions, alleviation of dyspnea (asthma), reduction of airway inflammation (bronchitis), fever management, alleviation of bloating, and relief from common colds. (Susiloningrum & Sari, 2021)

The scientific name of *Curcuma mango* Val. (CM), usually referred to as temu mango, contains polyphenols, which are classified as antioxidant chemicals. These antioxidant chemicals can counteract free radicals. The research seeks to assess the impact of rhizome components and soil varieties on the antioxidant characteristics of CM. The study phases encompass sorting, peeling, washing, blanching, drying, and compositional analysis, including antioxidant activity, total phenolic content, flavonoids, and tannins. The research employed a Completely Randomized Design (CRD) incorporating rhizome segments (main, first tiller, and second tiller) and soil types (clay, lime, and sand) as variables. The rhizome component and soil type significantly influence the antioxidant activity and components of CM. The selected CM, particularly the primary rhizome with clay soil type, demonstrates an antioxidant activity of 82.50% RSA, total phenolics of 647.50 mg GAE/100 g db, flavonoids of 620.2 mg QE/100 g db, and tannins of 167.07 mg CE/100 g db. (Uningtya et al., 2024).

### ***Curcuma Zanthorrhiza Rhizome Interview***

Temulawak, or *Curcuma xanthorrhiza* Roxb, is a medicinal plant from the Zingiberaceae family, commonly found in tropical forest regions. Temulawak contains numerous secondary

metabolites that are advantageous for health. The temulawak plant has a significant amount of starch. Starch constitutes the predominant metabolite in temulawak. Cucumber starch comprises curcuminoids that facilitate the metabolic and physiological functions of the body's organs. Moreover, curcuma comprises essential oils, including fragrant lemonade, while its flavonoid content alleviates inflammation. Historically, temulawak has been extensively utilized by the community as a remedy for numerous ailments. In some tribes, this cucumber is utilized for various ailments. Temulawak is utilized in traditional medicine for the treatment of dyspepsia, jaundice, vaginal discharge, enhancing immunity, and promoting health (Syamsudin et al., 2018).

Temulawak has been widely utilized as a medicinal agent in traditional Indonesian medicine. In Aceh, temulawak is referred to as turmeric ketumbu. The rhizomes are utilized in herbal remedies to enhance circulation or combat malaria. The Sakai ethnic group in Bengkalis, Riau, utilizes temulawak rhizomes to stimulate appetite. In Sunda and Java, utilized for the treatment of jaundice and dyspepsia. The Balinese utilize it as a remedy for abdominal discomfort and distension. The Madura ethnic community employs the rhizome of temulawak as a remedy for vaginal discharge, while enthusiasts of jamu gendong utilize the decoction of the rhizome as an immune enhancer against disease. 18 In Banjarbaru, Kalimantan, temulawak is utilized in internal medicine and for blood neutralization. The Kaili Ledo tribe, Sigi, in Central Sulawesi, addresses low back pain treatment. In West Java and East Java, it is utilized for the treatment of urinary calculi and as an appetite stimulant, whereas the Tengger tribe of Kab. Probolinggo employs temulawak as a febrifuge (Syamsudin et al., 2018).

The inhabitants of Waringin District, Bondowoso Regency, employ the Zingiberaceae family for therapeutic applications, citing 17 advantages, including temulawak. The inhabitants of Keseneng Village, Sumowono District, Semarang Regency utilize temulawak as a remedy for digestive disorders, hunger stimulation, post-typhus recovery, post-hepatic illness treatment, and weariness alleviation. Simultaneously, the new Banjar populace of South Kalimantan employs temulawak as a remedy for fever, internal ailments, blood purification, respiratory issues, muscular disorders, headaches, and angina. The Enggano people utilize temulawak as a herbal remedy post-childbirth, in conjunction with other botanical species. In Sukajaya, Bogor Regency, temulawak is among the components of 40 herbs utilized postpartum. The inhabitants of Sukolilo Village utilize Temulawak to preserve health, alleviate weariness, and sustain physical fitness. Temulawak, in conjunction with galangal and chili peppers, is utilized as a herbal remedy around the Surakarta Hadiningrat Kasunanan Palace to enhance the performance of the bride-to-be. The herbal medicine is administered during the pre-wedding ceremony procession or began a week before to the wedding ceremony. Curcuma is a plant closely associated with traditional medicine in Indonesia. Temulawak demonstrates antiviral efficacy against the virus responsible for immunological deterioration in monkeys (K/SAIDS), particularly Simian Retrovirus Serotype-2 (SRV-2), exhibiting a wide-ranging spectrum of activity. It targets lymphoid cells and additional cellular types located in many tissues and organs of monkeys, as determined by the polymerase chain reaction (PCR) technique. Extracts of Meniran and Temulawak at concentrations of 100 ppm, 250 ppm, and 500 ppm can impede the proliferation of the SRV-2 virus cultured in A549 cells (human

lung carcinoma cells). The health benefits of temulawak primarily include enhancing hunger and sustaining bodily stamina. Clinical experiments of temulawak demonstrated that the consumption of temulawak extract beverages can diminish the population of B lymphocyte cells, leading to a reduction in humoral immune function. Temulawak is a plant known for its analgesic properties. The oral administration of methanol extract from temulawak in experimental mice can alleviate pain induced by acetic acid injection. The amalgamation of curcuminoid rhizome essential oil and curcuminoids exerts an analgesic effect on the central nervous system and peripheral regions by  $(26.85 \pm 2.73\%)$  and  $(75.08 \pm 0.86\%)$ , respectively, whereas curcuminoids alone can only mitigate peripheral pain stimuli  $(44.80 \pm 1.46\%)$  without affecting central pain perception. The amalgamation of curcuminoid rhizome essential oil and curcuminoids exhibits an analgesic impact on the central nervous system. Rodents. The pain inhibition in the central nervous system and periphery was  $42.16 \pm 2.53\%$  and  $67.56 \pm 0.59\%$ , respectively. The pain phases suppressed by the combination of essential oils and curcuminoids occur in phases I (central nervous system) and II (peripheral). Pain inhibition in essential oils occurs in both the central nervous system and the periphery (Arko, 2015).

### **Sambiloto ( *Andrographis paniculata* folium).**

Andrographolide is an extract derived from the herbal plant *Andrographis paniculata*, also known as green chiretta. This component serves various medical purposes owing to its exceptional biological activity, including immunological modulation, anti-hyperglycemic effects, antibacterial, antiviral, antiparasitic, and antitumor properties. Prior studies have demonstrated that andrographolide had the capability to combat numerous viruses, including influenza A virus (IAV), human immunodeficiency virus (HIV), Enterovirus D68 (EV-D68), dengue virus (DENV) 1, and Chikungunya virus (CHIKV), due to its diverse antiviral capabilities. Enmozhi et al. have discovered that andrographolide may serve as an effective inhibitor for SARS-CoV-2 through in silico research by targeting the cysteine protease (3CLpro), which is analogous to viral 3-chymotrypsin. Andrographolide is generally abundant, inexpensive, and has low cytotoxicity; yet, its potent antiviral efficacy against many viruses requires additional investigation (Syamsu et al., 2021).

The immunomodulatory properties of the sambiloto plant (*Andrographis paniculata* Nees.), utilized as an alternative therapy, enhance the body's immune system. *Andrographis paniculata* Nees, often known as Sambiloto, is a plant indigenous to Indonesia that is extensively studied for its immunomodulatory properties. The immunomodulatory properties of sambiloto arise from its active components, including deoxyandrographolide, andrographolide, 14-deoxy-11, neoandrographolide, 12-didehydroandrographolide, homoandrographolide, diterpenoids, and flavonoids. Sambiloto functions as an immunomodulatory drug, serving both as an immunostimulator to enhance immune response during diminished immunity and as an immunosuppressant to attenuate immunological response when it exceeds normal physiological levels. Moreover, sambiloto functions as an immunomodulator, capable of restoring the body's equilibrium even in the presence of infection (Alkandahri et al., 2018).



Sambiloto can enhance the immune system by eliciting specific antigen responses and nonspecific immunological responses to generate phagocytic cells. The particular antigen response elicited will result in the generation of substantial quantities of lymphocytes, predominantly B lymphocytes. B cells generate antibodies, which are plasma glycoproteins that attach to antigens and promote phagocytosis. The use of sambiloto filtrate (*Andrographis paniculata*) can enhance the leukocyte count in white rats (*Rattus norvegicus*) subjected to benzene exposure. The dosage of 0.45 ml is referenced by Khumairoh et al. (2013). Patients with HIV frequently experience dyspepsia and elevated liver enzymes when administered high doses of andrographolide due to isolation (Muhlisah, 2006). This finding aligns with prior studies by Puri et al. (1993), which indicated that sambiloto serves both as an immunostimulant and an immunosuppressant. Rahayu's (2015) study indicates that the n-hexane fraction functions as an immunostimulator by elevating IgG levels.

## METHOD

### How to Make HV-Care

#### Raw Material Inspection

1. Raw Materials of Dried Extract *Phyllanthus Urinaria Folium*, *Curcuma amada Rhizome*, *Curcuma Zanthorrhiza Rhizome*, and *Andrographis Paniculata Folium* checked for conformity of raw material specifications
2. After being inspected and meeting the specifications, it was moved to the weighing room

#### Weighing Raw Materials

1. Raw material of dried extract of *Phyllanthus Urinaria Folium*, weighed as much as 125 mg
2. The raw material of *Curcuma amada Rhizome extract* is weighted as much as 125 mg
3. Raw material of *Curcuma Zanthorrhiza Rhizome extract*, weighed as much as 125 mg
4. The raw material of *Andrographis Paniculata Folium extract* is weighed as much as 125 mg

#### Mixing Raw Materials

1. The raw materials of dried extracts of *Phyllanthus Urinaria Folium* and *Curcuma amada Rhizome* are put little by little in a stainless container (which has been sterilized with 70% alcohol and wiped using a dry and clean microfiber) stirred until homogeneous
2. Then add dried extracts of *Curcuma Zanthorrhiza Rhizome* and *Andrographis Paniculata Folium* and stir until homogeneous
3. After completion, the material is transferred to a new container that has been sterilized using 70% alcohol and dried with a dry and clean microfiber cloth

#### Drying

1. The materials that have been mixed (mixing process) are then carried out a drying process
2. Ingredients are put in the oven for  $\pm 30$  minutes

#### Raw Material Refining

1. After drying the raw materials, the next step is the smoothing of the raw materials using a mesh sieve of size 100 and also a special blender
2. The ingredients are sifted first and the remaining ingredients are in the mesh sieve that is still coarse then blended
3. After completion, the material is weighed again for further capsule filling (capsule filling)

#### **Capsule Filling ( Capsule Filling )**

1. Prepare a semi-automatic capsule filling tool on a tray / parchment paper that has been sterilized using 70 % alcohol and then open/slide the clamp
2. Put the capsule shell size 1 into the capsule filling device first then sprinkle the powder and flatten it using a clean arc line and has been sterilized with 70% alcohol
3. Then the capsule is closed and then install the filling device of the capsule on the top and press until there is a sound and after that the capsule is removed
4. After that, the capsules are removed and cleaned using a clean, dry panel cloth and stored in a newly labeled container for further processing

#### **In Process Control (IPC)**

1. After filling the capsule, In Process Control is carried out, namely the Weight Uniformity Test
2. A total of 20 capsules were taken and then weighed and the results were recorded
3. Then the contents of each capsule are weighed one by one and the results are recorded
4. The empty shell of the capsule that has been removed is also weighed
5. Of the 20 capsules, no more than 2 capsules, each of whose contents weight deviated from the average content weight was greater than 10 % and not a single capsule whose content weight deviated from the average content weight was greater than 25 %
6. After passing the requirements, proceed to the next process

#### **Packaging Demand**

1. After passing the weight uniformity test, then the next step is packaging
2. The production department requests packaging materials to the warehouse department by filling out the material request form submitted through RAB
3. The warehouse section prepares the packaging materials (material and lid, silica gel)
4. Then it is submitted through RAB

#### **In Process Control (IPC)**

1. Before packaging, an inspection or leak test of the container is carried out in the IPC room
2. The leak test work carried out is:
  - a. Prepare a measuring cup that has been filled with water
  - b. Prepare the bottle that will be tested for leakage
  - c. Dip the test bottle in the measuring cup until it is completely submerged
  - d. Be silent and observe the changes that occur
  - e. If there are bubbles that appear from the surface of the bottle, then the bottle is leaking
  - f. Test results are recorded and reports are made



## RESULTS AND DISCUSSION

### HV care specifications

Hard capsule preparation. The capsule is shelled in Purple White, capsule size number 1, which contains a blackish-brown powder, a bitter taste, and a distinctive aromatic smell. Capsule weight: 500-550 mg. Size 1. Bottle packaging made of Polyethylene Terephthalate (PET) plastic with a volume size of 30 ml, (Primary) and a cardboard box (secondary packaging), and stored in a room with a maximum temperature. 30 °C and dry, and protected from Light. The circulation period is 1 year. Composition of *Phyllanthus Urinary Folium Extract*, *Extract Curcuma amada Rhizome*, *Extract Curcuma*, *Zanthorrhiza Rhizome*, *Extract Andrographis Paniculata Folium*.

### Hv-Care Finished Product Inspection Method

1. The quality assurance department carries out inspection of the Finished Product
2. Ensure the Product meets quality requirements in all processing and packaging specifications. The Quality Security requirements carried out are: Organoleptic (shape, taste, smell, and color); Testing is carried out in the Chemistry Physics lab by the Quality Control Section; Officers wear complete PPE. Testing steps
  - a. Observe shapes and colors by looking at the finished product specification literature
  - b. Smell the product, and compare it according to the finished product specification literature.
  - c. Write the results of the observations in the form provided
3. Time Ruined
4. Weight Uniformity Check.
  - a. Keep the balance sheet clean
  - b. Before conducting the test, the officer who has been authorized to conduct the test wears lab suit equipment, gloves, and masks
  - c. Keep the balance sheet in a "Zero" state
  - d. Weighing 20 capsules at once and recording the results
  - e. Weighing again, one by one, the contents of each capsule are recorded
  - f. Weigh the empty shell of the capsule from the 20 capsules.
  - g. Calculate the weight of the capsule contents and the average weight of the capsule contents.
  - h. Of the 20 capsules, no more than 2 capsules each of which deviated from the average weight of contents by more than 10% and not a single capsule whose weight of contents deviated from the average weight of contents was greater than 25%

### 5. Microbial Contamination

Microbial Contamination Testing is carried out at the External Lab with KAN standards, namely at Vicma Lab Indonesia, which is located at Ruko Graha Cibinong Blok G No.8.

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The tests carried out include:

- Total Plate Number (ALT)

- Khmer Mold Number (AKK)
  - Angka Enterobacteriaceae
  - Escherichia coli
  - Salmonella Sp
  - Stuart O'Neill
  - Shigella
6. Heavy Metal Contamination
- Heavy metal contamination testing is carried out at the External Lab with KAN standards, namely at Vicma Lab Indonesia, which is located at Ruko Graha Cibinong Blok G No.8. Copyright © 2019 All Rights Reserved. All rights reserved.
- The tests carried out include:
- Lead (Pb)
  - Cadmium (cd)
  - Mercury (Hg)
  - Arsen (Ace)
7. Moisture Content Testing
- Water Content Testing is carried out at the External Lab with KAN standards, namely at Vicma Lab Indonesia, which is located at Ruko Graha Cibinong Blok G No.8. Copyright © 2019 All Rights Reserved. All rights reserved.
8. Packaging and marking inspections must meet all requirements according to the results of the inspection by the quality control department
9. Reconciliation Check. That is, the reconciliation of packaging materials can be accepted
10. Inspection of finished products received in the quarantine area must be under the amount stated on the goods delivery document (finished product)

### **Bet Numbering System**

#### **Intermediate Products/Intermediate Products/ Finished Products**

1. The first digit shows the year of production, which is coded as follows:  
1 means 2020. 2 means 2021 onwards
2. The second and third digits indicate the type of preparation. Coded as follows  
02 for capsule preparations. 03 for liquid preparations
3. The fourth, fifth, and sixth digits show the order of production coded:  
001,002, up to 999 in the same year
4. The number seven indicates the order of the lots in a batch. Coded:  
AC first batch, BD second batch, ED third batch.

#### **Reprocessed and Restored Products**

1. For reprocessed and restored products, the letter R is added in front of the
2. The associated batch number, for example, R102001AC, which means that the preparation has experienced
3. Reprocessing or recovery

## Processing and Packaging

1. Processing Procedure for 8,000 capsules
  - a. Mixing: Andrographis Paniculata extract powder, Phyllanthus Urinaria extract powder, Curcuma Amada extract powder, and Curcuma Zanthorrhiza extract powder are mixed little by little in a sterilized stainless container and stirred until homogeneous using a sterilized stainless stirrer, then stored in a sterilized container for further sifting and powder smoothing
  - b. Styling and refinement
  - c. Prepare the sterilized mesh sieve No. 100
  - d. Prepare a sterilized powder blender
  - e. Blend the ingredients or powder using a blender
  - f. Sieve the powder that has been refined using a blender
  - g. Drying: Perform powder drying using the oven for 15 minutes at 40 °C- 50 °C to avoid contamination
2. Charging  
Perform powder filling into the capsule shell using a capsule filling device with a weight range of 450 – 550 mg/capsule
3. Polishing  
Remove the powders that stick to the outer shell of the capsule by applying using appropriate methods and tools

## COA HV-Care Capsule Analysis Certificate

Yes	TESTING PARAMETERS	SPECIFICATIONS
1.	Description	The capsule is shelled in Purple White, capsule size number 1, which contains a blackish-brown powder, a bitter taste, and a distinctive aromatic smell.
2.	Time is ruined	≤ 30 minutes
3.	Moisture Rate	≤10%
4.	Microbial Contamination <ul style="list-style-type: none"> <li>- Total Plate Number ( ALT)</li> <li>- Khmer Mold Number (AKK)</li> <li>- Enterobacteria Numbers</li> <li>- Escherichia coli</li> <li>- Salmonella</li> <li>- Stuart O'Neill</li> <li>- Shigella</li> </ul>	≤10 <sup>5</sup> colonies/g ≤10 <sup>3</sup> colonies/g ≤10 <sup>3</sup> colonies/g ≤10 colonies/g Negative Negative Negative
5.	Heavy Metal Contamination	

	<ul style="list-style-type: none"> <li>- Lead (Pb)</li> <li>- Cadmium (Cd)</li> <li>- Arsen (Ace)</li> <li>- Mercury (Hg)</li> </ul>	$\leq 10$ $\leq 0.3$ $\leq 5$ $\leq 0.5$
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Food and Drug Control Agency Decree



## BADAN PENGAWAS OBAT DAN MAKANAN

Jl. Percetakan Negara No. 23 Jakarta Pusat 10560 Indonesia  
 Tel. (021) 4244691, 4248119, Fax : 4244819  
 Email : penilaian\_kas@pom.go.id ; Website : www.pom.go.id

### KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN

REPUBLIK INDONESIA

Nomor : 0361 / Reg / TR / 2022

Tentang

PERSETUJUAN PENDAFTARAN

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN REPUBLIK INDONESIA



- Menimbang** : Bahwa berdasarkan hasil penilaian mutu, keamanan dan khasiat dengan semua kelengkapan pendaftaran Obat Tradisional yang diajukan oleh **Usaha Kecil Obat Tradisional : PT AUTOIMUN CARE INDONESIA** perlu diberikan surat keputusan.
- Mengingat** :
1. Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan
  2. Peraturan Pemerintah No.32 tahun 2017 tentang Jenis dan Tarif Atas Jenis Penerimaan Negara Bukan Pajak yg berlaku di Badan Pengawas Obat dan Makanan
  3. Keputusan Presiden Nomor 80 tahun 2017 tentang Badan Pengawas Obat dan Makanan (Lembaga Negara Republik Indonesia Tahun 2017 Nomor 180)
  4. Peraturan Menteri Kesehatan Nomor 007 Tahun 2012 tentang Registrasi Obat Tradisional;
  5. Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.00.05.41.1384 tahun 2005 tentang Kriteria dan Tata Laksana Pendaftaran Obat Tradisional, Obat Herbal Terstandar dan Fitofarmaka.

#### MEMUTUSKAN

**Menetapkan** :

**Pertama** : Persetujuan Pendaftaran Produk di bawah ini :

**Nama Produk** : HV-CARE  
**Bentuk Sediaan** : Kapsul  
**Kemasan** : Dus, Botol @ 30 Kapsul  
**Nama Pendaftar** : PT AUTOIMUN CARE INDONESIA  
**Alamat Pendaftar** : Jl. Saladara No. 18, Kel. Kartamulya, Kec. Kesambi, Kota Cirebon, Jawa Barat  
**Nama Produsen** : PT AUTOIMUN CARE INDONESIA  
**Alamat Produsen** : Jl. Saladara No. 18, Kel. Kartamulya, Kec. Kesambi, Kota Cirebon, Jawa Barat, Indonesia

dengan nomor izin edar :

**POM TR223008931**

- Kedua** : Persetujuan pendaftaran ini diberikan termasuk ketentuan sebagaimana tercantum dalam lampiran yang merupakan bagian tidak terpisahkan dari keputusan ini.
- Ketiga** : Penandaan siap edar sesuai yang telah disetujui harus diserahkan selambat-lambatnya 1 (satu) bulan sebelum dibuat, dan pelanggaran terhadap ketentuan ini dapat dikenai sanksi pembatalan izin edar.
- Keempat** : Apabila ternyata merek dagang tersebut di atas, termasuk nama produk dan atau desain kemasan terbukti secara hukum ada pihak lain yang lebih berhak menggunakan sebelum tanggal Surat Keputusan ini, maka pendaftar bersedia mengganti merek dagang termasuk nama produk dan atau desain kemasan tersebut di atas.
- Kelima** : Persetujuan ini berlaku 5 (lima) tahun sampai dengan **31 Januari 2027** dan dapat dibatalkan jika tidak memenuhi persyaratan dan atau ketentuan yang berlaku.
- Keenam** : Keputusan ini berlaku sejak tanggal ditetapkan.

Jakarta, 31 Januari 2022

a.n. Kepala Badan Pengawas Obat dan Makanan  
 Deputi Bidang Pengawasan Obat Tradisional,  
 Suplemen Kesehatan dan Kosmetik

Dra. Reri Indriani, Apt., M.Si.  
 NIP 19630527 198903 2 001

## CONCLUSION

1. HV Care is an herbal medicine with the composition of meniran (*Phyllanthus Urinaria Folium*), Temu mango (*Curcuma amada Rhizome*), Curcuma Zanthorrhiza Rhizome, and Sambiloto (*Andrographis Paniculata Folium*). It is helpful as an antiviral for HIV sufferers in particular and other viral diseases.
2. HV Care has been processed in accordance with the standards of the Indonesian Food and Drug Control Agency (BPOM). It has a POMTR223008931 distribution permit so that it can be distributed in the community.

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