# WHO Recommendations

**All recommendations are taken from the WHO Monograph on *Artemisia annua* [1]**
**and the WHO Guidelines on Good Agricultural and Collection Practices for Medicinal Plants [2].**

# Personnel

## 1. General

National and/or regional regulations governing labour should be respected in the employment of staff for all phases of medicinal plant materials production. [1]

All production of medicinal plant materials by agriculture and collection should conform to national and/or regional regulations on safety, materials handling, sanitation and hygiene. [1]

All personnel must have sufficient knowledge of the medicinal plant, namely: its botanical identification, cultivation characteristics and environmental requirements (soil type, soil pH, fertility, plant spacing and light requirements), harvesting methods (method and stage of harvesting) and post-harvest handling of the plants.[1-2]

All this information is included in the Artemisia cultivation and processing manual.

Personnel should be instructed on all relevant issues regarding environmental protection, the conservation of plant species and proper soil management to conserve fields for cultivation and for soil erosion control [1-2]. (See Artemisia cultivation and processing manual and Guide d'Agroécologie [3] for more details).

Producers must have received appropriate training and have sufficient knowledge of the techniques used to harvest, maintain and protect the medicinal plants to be cultivated. [2] (See Artemisia cultivation and processing manual).

## 2. Health, hygiene and sanitation

All those involved in the handling and processing of cultivated or collected medicinal plants should in all processing procedures comply with national and/or regional regulations on hygiene. [1-2]

All personnel (including field workers) involved in the propagation, cultivation, harvesting and post-harvest process of production must maintain appropriate personal hygiene and be **trained in their hygiene responsibilities!** [1-2]

### a. Health status

All personnel known, or suspected, to be suffering from or to be a carrier of a disease or illness likely to be transmitted through medicinal plant material, should not be allowed to enter any harvest, production or processing area if there is a likelihood of their contaminating medicinal plant materials. Any persons suffering from diseases or symptoms of illness should immediately report to the management. A medical examination of personnel should be carried out if clinically or epidemiologically indicated. [1-2]

### b. Illness and injuries

All personnel with open wounds, inflammations or skin diseases should be suspended from work or required to wear protective clothing and gloves until full recovery. Persons suffering from known airborne or food-borne communicable diseases, including dysentery and diarrhoea, should be suspended from work in all areas of production and processing, in accordance with local and/or national regulations [1-2]

Health conditions that should be reported to the management for consideration regarding medical examination and/or possible exclusion from handling of medicinal plant materials include: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected lesions (boils, cuts, etc.) and discharges from the ear, nose or eye. Any personnel who have cuts or wounds and are permitted to continue working should cover their injuries with suitable waterproof dressings. [1-2]

### c. Personal cleanliness

Personnel who handle medicinal plant materials should maintain a high degree of personal cleanliness, and, where appropriate, wear suitable protective clothing and gloves, including head covering and footwear. [1-2]

Personnel should always wash their hands at the start of handling activities, after using the toilet, and after handling medicinal plant materials or any contaminated material. [1-2]

### d. Personal behaviour

Smoking and eating should not be permitted in medicinal plant processing areas. Personnel who handle medicinal plant materials should refrain from behaviours that could result in contamination of the materials, for example, spitting, sneezing or coughing over unprotected materials. [1-2]

Personal effects such as jewellery, watches or other items should not be worn or brought into areas where medicinal plant materials are handled if they pose a threat to the safety or quality of the materials. [1-2]

### e. Visitors

Visitors to processing and handling areas should wear appropriate protective clothing and adhere to all of the personal hygiene provisions mentioned above. [1-2]

**Bibliography:**

1. World Health Organisation. WHO monograph on good agricultural and collection practices (GACP) for *Artemisia annua* L. 2006.
Available at: http://www.who.int/malaria/publications/atoz/9241594438/en/

2. World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

3. AGRISUD. L'agroécologie en pratiques - GUIDE édition 2020. (Practical agroecology guide)
Available at: http://www.agrisud.org/wp-content/uploads/2020/04/Agrisud_Guide_Agroecologie_2020.pdf

# Equipment

Equipment used for the production and handling of crops should be easy to clean in order to minimise contamination. Dry cleaning is recommended. Where washing with water is unavoidable, the equipment should be dried as quickly as possible. All equipment should be installed in such a way that it is easily accessible and should be well maintained and regularly cleaned. Wooden equipment (e.g. pallets, hoppers, etc.) should not be chemically treated.

All equipment and utensils used in the handling of medicinal plants should be made of materials that do not transmit toxic substances, odour or taste, are non-absorbent, are resistant to corrosion and are capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices.

Equipment is stored in a dry, pest-free place out of the reach of livestock and domestic animals.

**Source :** World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.

Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

# Storage

Buildings used for storage, drying and processing must be dry, clean, ventilated and never be used to house livestock. They must be constructed to protect the harvest from birds, insects, rodents, livestock and domestic animals (screened doors and windows) and other sources of contamination AND decomposition!

Care must be taken to store medicinal materials away from other crops AND ESPECIALLY chemicals!

Storage facilities should be well aerated, dry and protected from light, and should be provided with humidity control equipment as well as facilities to protect against rodents and insects.

The floor should be smooth, without cracks and easy to clean (e.g. concrete).

Shelves on which to keep the materials should be built at a sufficient distance from the floor and the walls to prevent the occurrence of pest infestation, mould formation or rotting.

According to feedback from La Maison de l'Artemisia, herbal tea can be kept for up to 10 years, while the powder (sections of less than 1 cm) can be kept for a maximum of 6 months.

**Source :** World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.

Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

# Transport

Vehicles used for transporting bulk medicinal plant materials should be well ventilated (to remove moisture and prevent condensation) and cleaned between loads.! [1]

Medicinal plant materials from organic farming should be transported and stored separately or in such a way that their integrity is preserved. [2]

Fumigation should be carried out only when necessary (infestation); the fumigation equipment should be operated by licensed or trained personnel. Only registered chemical agents authorised by the regulatory authorities of the source country and the countries of intended end-use should be used.

All fumigation operations, fumigants used and dates of treatments must be recorded. [2] (Batch and cultivation record)

NB: Methyl bromide is a fumigant used by organic farmers to control spiders, mites, fungi, plants, insects, nematodes and rodents. Animal studies show that methyl bromide can affect the kidneys, brain, nose, heart, adrenal glands, liver, testes and lungs. Methyl bromide also contributes to the destruction of the ozone layer. Because of the high risk of intoxication, it is strongly advised that organic farmers use professionals for the application of methyl bromide.

**Bibliography:**

1. World Health Organization. WHO monograph on good agricultural and collection practices (GACP) for Artemisia annua L. 2006.
Available at: http://www.who.int/malaria/publications/atoz/9241594438/en/

2. World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

# Processing facilities

These guidelines are taken from the general measures provided by the WHO to ensure the quality of medicinal plant materials.

1. Location

Facilities should preferably be located in areas that are free from objectionable odours, smoke, dust or other contaminants, and are not subject to flooding.

2. Roadways and areas used by wheeled vehicles

Roadways and areas serving the establishment, within its boundaries or in the immediate vicinity, should have a hard paved surface suitable for wheeled vehicles. There should be adequate drainage, and provision should be made for cleaning.

3. Buildings

Buildings should be of sound construction and maintained in good repair. Dirty areas, such as those used for drying and milling, must be isolated from clean areas, preferably in separate buildings. All construction materials should be such that they do not transmit any undesirable substance to medicinal plant materials. Once construction is completed, construction materials should not emit toxic vapours. The use of materials that cannot be adequately cleaned and disinfected, such as wood, should be avoided unless they would clearly not be a source of contamination.

Buildings should be designed to:

- provide adequate working space and storage room to allow for satisfactory performance of all operations;
- facilitate efficient and hygienic operations by allowing a regulated flow in processing from the arrival of the raw medicinal plant materials at the premises to the dispatch of the processed medicinal plant materials;
- permit appropriate control of temperature and humidity;
- permit the separation by partition or other means of processes that may cause cross-contamination, especially to isolate dirty areas (drying and milling) from clean areas;
- permit easy and adequate cleaning and facilitate proper supervision of hygiene;
- prevent the entry of environmental contaminants such as smoke, dust, etc.;
- prevent the entrance and harbouring of pests, livestock and domesticated animals.

4. Medicinal plant material handling areas

- Floors, where appropriate, should be of waterproof, non-absorbent, washable, nonslip and non-toxic material, without crevices, and should be easy to clean and disinfect
- Walls, where possible, should be light coloured. Up to a height appropriate for handling operations, they should be smooth and without crevices, and should be easy to clean and disinfect.
- Ceilings should be designed, constructed and finished so as to prevent the accumulation of dirt and minimise condensation, mould development and flaking, and should be easy to clean.
- Windows and other openings should be constructed so as to avoid accumulation of dirt, and those that open should be fitted with insect-proof screens. Screens should be easily removable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.
- Doors should have smooth, non-absorbent surfaces and, where appropriate, be self-closing and close-fitting.
- Living quarters, food preparation and eating areas, changing facilities, toilets and areas where animals are kept should be completely separated from and should not open directly on to medicinal plant material handling areas.
- For lighting, see the summary of WHO guidelines for Traditional Medicine in Africa.

5. Water supply

An ample supply of water, under adequate pressure and at suitable temperature, should be available with appropriate facilities for its storage, where necessary, and distribution, and with proper protection against contamination.

Potable water should be used for washing and wet sterilisation procedures!

6. Changing facilities and toilets

Adequate, suitable and conveniently located changing facilities and toilets should be provided. Toilets should be designed so as to ensure hygienic removal of waste matter. These areas should be well lit, ventilated and, where appropriate, heated. Hand-washing facilities with warm or hot and cold water, a

suitable hand-cleaning preparation and hygienic means of drying should be provided adjacent to toilets and located so that employees have to pass them when returning to the processing area. Notices should be posted directing personnel to wash their hands after using the toilet.

7. Hand-washing facilities in processing areas

Adequate and conveniently located facilities for hand-washing and a hygienic means of drying should be provided whenever the process demands. Where appropriate, facilities for hand disinfection should also be provided. Warm or hot and cold water and a suitable hand-cleaning preparation should be provided. If paper towels are supplied, a sufficient number of towel dispensers and waste receptacles should be provided adjacent to each washing facility. The facilities should be furnished with properly trapped waste pipes leading to drains.

8. Ventilation

Adequate ventilation should be provided to prevent excessive heat, steam condensation and dust and to remove contaminated air. Air should never flow from a dirty area to a clean area. Ventilator openings should be provided with a screen or other protective enclosure of non-corrosive material. Screens should be easily removable for cleaning.

9. Storage of waste and unusable materials

Facilities should be provided for the storage of waste and unusable materials prior to removal from the premises. These facilities should be designed so as to prevent access to the waste or unusable materials by pests and to avoid contamination of medicinal plant materials, potable water, equipment and buildings of the premises. Clearly marked waste bins should be provided and emptied daily

Containers for unusable materials and waste must be leakproof, made of metal or other impermeable material, easy to clean or disposable, and close tightly.

**Source :** World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

# Quality control

**IMPORTANT: Medicinal plant materials must meet all applicable national and/or regional quality standards. Guidelines may therefore have to be adapted to the regulations in force in the various countries.**[1].

**Continuous in-process quality control measures** shall be implemented to remove substandard materials, contaminants and foreign matter **prior to and during final packaging operations.**[1].

Compliance with quality assurance measures (see WHO GACP) will be ensured by a designated quality manager for each House of Artemisia and will be monitored through: [1-2]

- regular auditing visits to cultivation or collection sites and processing facilities by expert representatives of producers and buyers competent in the field of good agricultural practices and good hygiene practices.
- inspection by national and/or local regulatory authorities.

Inspection reports must be signed by the persons who carried out the inspection and by the persons in charge of the quality control services. These reports should be filed. Low quality materials should not be distributed or sold.[1]

**➔ Each House of the Artemisia will appoint a quality manager in order to :**

- **train and monitor staff in hygiene measures** (see WHO Guidelines for Personnel).
- **control equipment, storage, transport and, where possible, processing facilities** (see WHO Guidelines for Equipment, Storage, Transport and Processing Facilities).
- **monitor environmental health.**
- **complete and sign the quality information record.**
- **assist, if necessary, the production manager to fill in the batch and cultivation record.**
- **review and sign the batch and cultivation record to vouch for the quality of each batch.**
- **carry out any sample analyses.**

**➔ La Maison de l'Artemisia head office will set up a quality control department in order to ensure that the following measures are adhered to by the quality manager.**

## 1. WHO health warning and recommendation from the Maison de l'Artemisia [1]

Some adverse reactions reported following the use of certain herbal medicines can be explained in several ways:

- Inadvertent use of another plant species.

  ➔ The quality manager is responsible for checking the species using the botanical description in this manual (File 0).

- Adulteration (addition of a lower value product) by means of other undeclared drugs and/or active ingredients.

  ➔ Artemisia herbal tea has the advantage of being difficult to falsify by its appearance, smell and taste.

- Contamination by toxic and/or dangerous undeclared substances.

  ➔ Following the standards published in this manual helps to avoid any contamination of this type, all the more so in organic farming.

- Overdosage.

  ➔ A study reports that hundreds of grams of Artemisia stems and leaves would have to be consumed per day to overdose ! [3]

- Inappropriate use by health workers or consumers.

  ➔ Therapeutic training, creation of an accurate and complete dosage form, labels in accordance with WHO standards and a leaflet on the proven benefits to prevent misuse of Artemisia herbal tea wherever possible.

- Interaction with other drugs resulting in adverse reactions.

  ➔ Pharmacovigilance is a permanent concern of La Maison de l'Artemisia. To date, we know that the simultaneous intake of vitamin C as a dietary supplement should be avoided. This is well indicated in the Dosage file and on the official label.

- Poor quality of finished products.

  ➔ Each House of Artemisia designates a quality manager.

- Use of poor quality crude plant materials.

  ➔ The purpose of this manual is to ensure the highest quality of Artemisia herbal tea.

However, different tests can be carried out. For information purposes, the Ministry of Health can request the following tests to grant authorisation for sale.

Identification tests : Chemical, biological or physical tests. [4] (See below for WHO identification requirements.)

➔ In our case, physical identification is sufficient. The organoleptic properties are also interesting to determine when the product is packaged in order to avoid any type of counterfeiting.

Purity tests: Microbiological and chemical - Foreign organic matter - Determination of total ash, acid insoluble ash, sulphated ash - Extractive value for aqueous and alcoholic extracts - Loss on drying - Swelling index - Pesticide residues, heavy metals, radioactive residues - Other purity tests.[4]

➔ The microbiological test seems to be the most important for the authorities.

**IMPORTANT ! « All traditional health care providers should be required to have good training in traditional and conventional medicine as their care is based on their knowledge and skills. Furthermore, their knowledge and skills must be constantly updated so that they can undertake clinical research in their area of specialisation when necessary. » [1]**

**➔ The managers of the Houses of Artemisia pledge, through the sharing of knowledge and common communication stipulated in the Charter, to always disclose the official and updated dosage of La Maison de l'Artemisia.**

## 2. WHO quality control requirements for *Artemisia annua* [2] and by extension for *Artemisia afra* :

**Basic quality requirements for medicinal plants [2]**

a. **Selection of botanical species or variety**

**The botanical identity** – scientific name (genus, species, subspecies/variety, author, and family) – of each medicinal plant under cultivation should be **verified and recorded in the national pharmacopeia.** If available, the local and English common names should also be recorded. Other relevant information, such as the cultivar name, ecotype, chemotype or phenotype, may also be provided, as appropriate. [2]

In the case of the first registration in a producer's country of a medicinal plant or where reasonable doubt exists as to the identity of a botanical species, a voucher botanical specimen should be submitted to a regional or national herbarium for identification. Where possible, a genetic pattern should be compared to that of an authentic specimen. Documentation of the botanical identity should be included in the registration file [1]

b. **National quality specification and prerequisites for medicinal materials** [2]

➔ The official quality standards of *Artemisia annua* based on artemisinin levels do not apply to *Artemisia annua* herbal tea and even less to *Artemisia afra* herbal tea which does not contain artemisinin.

Numerous analyses of different cultivars have been carried out in different locations at different times. Their results give constant active molecule concentration intervals. This ensures therapeutic efficacy of Artemisia tea above 95% due to a synergy of these molecules: It is a true polytherapy that ensures the consistency of the therapeutic response and therefore the quality of the product.

## 3. Control for traditional medicine plants in China

For information: Control for traditional Chinese herbal medicine in China requires before any packaging that the quality control department inspects each batch of medicinal material, referring to the national standards for traditional Chinese medicinal materials or to standards reviewed and approved by the authorities. At the very minimum, this inspection covers the properties and identification of the medicinal material, foreign matter, moisture content, ash content, acid insoluble ash content, leaks, tracers or active ingredient content. In addition, restrictions on the content of pesticide residues, heavy metals and microorganisms must be in accordance with national standards and other regulations. [1]

**Bibliography :**

1. World Health Organisation.  WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

2. World Health Organisation. WHO monograph on good agricultural and collection practices (GACP) for *Artemisia annua L*. 2006.
Available at: http://www.who.int/malaria/publications/atoz/9241594438/en/

3. Muzemil A. Determination of Artemisinin and essential oil contents of *Artemisia annua* L. grown in Ethiopia and In vivo antimalarial activity of its crude extracts against *Plasmodium berghei* in mice. Department of Pharmaceutical Chemistry, School of Pharmacy, Addis Ababa University. 2008.
Available at: file:///C:/Users/User/Downloads/ahmedandMekuria.pdf

4. World Health Organisation. Guidelines for Registration of Traditional Medicines in the WHO African Region. WHO Regional Office for Africa, Brazzaville. WHO/AFRO/TRM. 2004.
Available at: http://apps.who.int/medicinedocs/documents/s20127en/s20127en.pdf

# WHO labelling standards

« Intended use : Product labels and package inserts should be understandable to the consumer or patient. The package information should include all necessary information on the proper use of the product.

The following elements of information will usually suffice:
• name of the product
• quantitative list of active ingredient(s)
• dosage form
• indications
    - dosage (if appropriate, specified for children and the elderly)
    - mode of administration
    - duration of use
    - major adverse effects, if any
    - overdosage information
    - contraindications, warnings, precautions and major drug interactions
    - use during pregnancy and breastfeeding
• expiry date
• lot number
• holder of the marketing authorisation.

Identification of the active ingredient(s) by the Latin botanical name, in addition to the common name in the language of preference of the national regulatory authority, is recommended. Sometimes not all information that is ideally required may be available, so drug regulatory authorities should determine their minimal requirements.» [1]

**! « Promotion : Advertisements and other promotional material directed to health personnel and the general public should be fully consistent with the approved package information. »** [2]

**« If a monograph exists in a pharmacopoeia, reference to it should suffice. »** [2]

**➔ GACP monograph *Artemisia annua* :** [3]

**The product name, specification, origin, batch number, packaging date and manufacturer should be indicated on each package of product.**
The label should also contain information indicating quality approval and should comply with other national and/or regional labelling requirements.
**To enable the product to be traced back to its origin, the batch number on the label should include information related to quality, cultivation date, date of harvesting or collection, producer, collector and processor.**

➔ **GACP :** [1]

A label affixed to the packaging should clearly indicate the scientific name of the medicinal plant, the plant part, the place of origin (cultivation or collection site), the cultivation or collection date and the names of the grower/collector and the processor, and quantitative information. The label should also contain information indicating quality approval and comply with other national and/or regional labelling requirements.
The label should bear a number that clearly identifies the production batch. Additional information about the production and quality parameters of the medicinal plant materials may be added in a separate certificate, which is clearly linked to the package carrying the same batch number. [1]

**Batch definition** : « a defined quantity of a raw material, packaging material or product, manufactured in one operation or in a series of operations, such that it can be considered homogeneous». [4]

➔ **1 cutting = 1 batch !**

The batch numbers must clearly and rigorously identify all batches in each cultivation or harvest area. Batch numbers must be assigned from the start of production. [1].
It is strongly recommended that records be kept of fertiliser and pesticide use on each batch of harvested material.[1].
**Records should be kept of batch packaging, and should include the product name, place of origin, batch number, weight, assignment number and date.** [1].

➔ **The Maison de l'Artemisia has therefore created a complete record sheet serving both as a cultivation follow-up sheet for each batch and as a record of the packaging of the batches.**

➔ **The quality manager is in charge of completing the batch and cultivation record, starting <ith sowing! He/She can be helped by the production manager. This record will be signed by the production manager (cultivation monitoring) and the quality manager (batch monitoring).**

**The records should be retained for a period of three years or as required by national and/or regional authorities. [1] ➔ This is the responsibility of the Administrative Manager.**

**Batch number = plot number + harvest date + processing location** (e.g. 5-130318-2)
Each plot must be identified by a unique number that cannot be confused with another.

**All products must be clearly identified by a batch number, right from the time of harvest!**
**To ensure complete traceability, all transported plant material must be accompanied by its batch number.**

➔ **Maison de l'Artemisia label to WHO standards (GCP and GACP mono)**

- **Product name :** Artemisia herbal tea
- **Composition (quantitative list of active ingredients) :** *Artemisia annua a*nd/or *Artemisia afra* leaves and stems (100%)
- **Pharmaceutical form** Dried and shredded
- **Specification :** Organic
- **Indications** : Artemisia prevents and cures medically-diagnosed malaria in semi-immune subjects (living in malaria infected areas) and treats bilharzia (schistosomiasis). No clinical studies on non-immune subjects (travellers, diaspora etc.) have been published.
    - **Dosage (if appropriate, specified for children and the elderly) : Preparation** Add 5 g (a small handful) herbal tea to 1 L boiling water (100°C). Remove from the heat, cover, leave to infuse for 15 minutes then strain.
      **To cure medically diagnosed malaria in semi-immune subjects or bilharzia (schistosomiasis)** Drink **1 L** of herbal tea a day (1 x 33 cl cup morning, midday and evening) for **7 days**. **Continue the treatment for a full 7 days even if symptoms disappear**. For children under 5 (under 15 kg), reduce dose by half : 50 cl of herbal tea (5 g/L) OR 2.5g (one large pinch) in 50 cl boiling water, to drink during the day, every day for 7 days.
      **To prevent malaria in semi-immune subjects** Drink **one cup** (33 cl) of herbal tea **every 2 days** (adults and children).
    - **Mode of administration** Herbal tea
    - **Duration of use** See dosage
    - **Major adverse effects, if any** No side effects or toxicity
    - **Overdosage information** Dose so high that it cannot be ingested
    - **Contraindications, warnings, precautions and major drug interactions** Consume within 24 hours. Do not reboil. Can be accompanied by a little sugar, honey (except contraindication), lemon juice against bitterness or powdered formula milk to make a bottle. Avoid taking vitamin C tablets at the same time. Store closed in a cool and dry place.
    - **Use during pregnancy and breastfeeding** Suitable for babies, children and pregnant women. Avoid during the first trimester of pregnancy.
- **Origin :** name of producer, "produced in" country, name of producer/processor.
- **Date of packaging :** stamp on the underside of the bag indicating packaging serial number
- **Optimal use-by date (expiry date) :** 3 years after date of packaging
- **Name of producer :** Production farm = **holder of marketing authorisation, with complete address!**
- **Batch number :** stamp on the underside of the bag

Facebook logo, Maison de l'Artemisia website, email address and telephone number for House of Artemisia, logo, and address if required.

**On the underside of the packaging :**

- **Package serial number ➔ Stamp date of packaging**
- **Batch number = plot number + harvest date + processing location (e.g. 5-130318-2)**
  **➔ Stamp harvest date in the center and write the plot number by hand in front and the processing location number afterwards!**

**Bibliography:**


1. World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://apps.who.int/iris/bitstream/handle/10665/42783/9241546271.pdf?sequence=1

2. World Health Organisation. General guidelines for methodologies on research and evaluation of traditional medicine. 2000.
Available at: https://apps.who.int/iris/bitstream/handle/10665/66783/WHO_EDM_TRM_2000.1.pdf

3. World Health Organisation. WHO monograph on good agricultural and collection practices (GACP) for *Artemisia annua L.* 2006.
Available at: http://www.who.int/malaria/publications/atoz/9241594438/en/

4. World Health Organisation. WHO Good manufacturing practices for pharmaceutical products : main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations, 37th report. Geneva, WHO, 2003, Annexe 4 (WHO Technical Report Series, N° 908).

# Document management

## 1. Documentation of production management

Standard operating procedures for handling *Artemisia annua* should be adopted and documented.[1].

**All processes and procedures (eg. sowing, transplanting, application of fertiliser or pesticides, irrigation and harvesting), dates on which they are carried out and names of operators should be documented!** [1]

**➔ A production manager should therefore be appointed to be in charge of all operators and complete the batch cultivation and processing record.**

**The batch record created by the Maison de l'Artemisia is based, among others, on the following source and the designated appendix:**

**« Documentation**

**All processes and procedures involved in the production of medicinal plant materials and the dates on which they are carried out should be documented. An example of a cultivation record is provided in Annex 5. The types of information that should be collected include:**

- **seeds and other propagation materials;**
- **propagation;**
- **cultivation or collection site;**
- **crop rotation at the site;**
- **cultivation;**
- **application of fertilisers, growth regulators, pesticides and herbicides;**
- **unusual circumstances that may influence the quality (including chemical composition) of the medicinal plant materials (e.g. extreme weather conditions, exposure to hazardous substances and other contaminants, or pest outbreaks) ;**
- **harvest or collection;**
- **all processing operations;**
- **transportation;**
- **storage;**
- **application of fumigation agents.**

Batch numbers should unambiguously and clearly identify all batches from each cultivation or collection area. Assignment of batch numbers should take place at an early stage of production.. » [2]

## 2. Documentation of quality control management

All information related to quality control of *Artemisia annua*, such as testing method, sample provider, testing agency, testing item, testing results, date of testing and signatures of authorised personnel should be documented. [1]

Where applicable, the results of audits should be documented in an audit report which contains copies of all documents, analysis reports, and local, national and/or regional regulations, and which are stored according to their requirements.[2].

**➔ A quality manager should therefore be appointed to complete and sign the quality sheet and any samples. He/She will also be responsible for printing the afore-mentioned documents required by the WHO. The Artemisia culture and processing manual should also be printed and filed to indicate the method used.**

## 3. Original records and others

Multiple sets of good herbarium specimens should be prepared and preserved for confirmation of plant identity and reference use.[2].

All original records relating to *Artemisia annua*, including the production plan, record of implementation, contracts and written agreements should be put on file and kept for at least 5 years. Files and archives should be maintained by specially designated personnel. [1]

All agreements between the grower or collector, processor and purchaser, and intellectual property and benefit-sharing agreements should be recorded [1].

**➔ An administrative manager should therefore be designated for these tasks.**

## 4. Export and import permits

For export of *A. annua* from the country of origin to another country, export permits, phytosanitary certificates, Convention on International Trade in Endangered Species (CITES) permit(s), and any other necessary permits must be obtained. [1].

**Bibliography:**

1. World Health Organisation. WHO monograph on good agricultural and collection practices (GACP) for *Artemisia annua L*. 2006.
Available at: http://www.who.int/malaria/publications/atoz/9241594438/en/

2. World Health Organisation. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/

# Ethical and legal considerations

The cultivation, collection and harvesting of medicinal plants, as well as the post-harvest processing of medicinal plant materials, must be carried out in accordance with legal and environmental requirements and with the ethical codes or norms of the community and country in which the activities take place. The provisions of the Convention on Biological Diversity must be respected.

# Intellectual property rights and benefits-sharing

Agreements on the return of immediate and/or long-term benefits and compensation for the use of source medicinal plant materials must be discussed and concluded, in writing, prior to collection or cultivation.

# Research needs

A national and/or regional inventory of medicinal plants may facilitate the identification of medicinal plants used by communities (including endangered species), outline their distribution and assess their abundance.

Research is greatly needed to improve the agronomy of cultivated medicinal plants, promote the exchange of information on agricultural production and investigate the social and environmental impact of medicinal plant cultivation and collection.

Data sheets and monographs should be developed on medicinal plants that take into account the particular situation of regions and countries. Such information materials can be useful instruments for promoting technical advancement. General as well as specific education and training materials should be developed for local growers and collectors of medicinal plants.

**Source:** World Health Organization. WHO guidelines on good agricultural and collection practices (GACP) for médicinal plants. 2003.
Available at: https://www.who.int/medicines/publications/traditional/gacp2004/en/