09 July 2025
EMA/HMPC/246816/2005 Rev. 1
Committee on Herbal Medicinal Products (HMPC)

Guideline on Good Agricultural and Collection Practice (GACP) for starting materials of herbal origin

Final – Revision 1

Draft adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	July 2005
End of consultation (deadline for comments)	30 October 2005
Agreed by HMPC Quality Drafting Group (QDG)	January 2006
Adoption by HMPC	12 January 2006
Date for coming into effect	01 August 2006
Draft Revision 1 agreed by HMPC QDG	December 2023
Draft Revision 1 agreed by Quality Working Party (QWP)	February 2024
Draft Revision 1 agreed by Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP) Inspectors Working Group (GMDP IWG)	March 2024
Draft Revision 1 adopted by HMPC for release for consultation	20 March 2024
Start of public consultation	15 April 2024
End of consultation (deadline for comments)	15 July 2024
Re-discussion in HMPC	January 2025 March 2025 May 2025 July 2025
Revision 1 agreed by QDG	April 2025
Revision 1 agreed by QWP	May 2025

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Revision 1 agreed by GMDP IWG	June 2025
Revision 1 adopted by HMPC	09 July 2025

Keywords	Committee on Herbal Medicinal Products; HMPC; herbal medicinal products; HMPs; traditional herbal medicinal products; THMPs; herbal substances; good agricultural and collection practice; GACP

Table of contents

EXECUTIVE SUMMARY

This guideline on Good Agricultural and Collection Practice (GACP) for starting materials of herbal origin came into effect in August 2006 and it was intended to provide guidance to ensure appropriate and consistent quality of herbal substances[1]. The current Revision 1 of the GACP guideline pertains to an update of the document to current standards taking into account advances over the last 10 years, as for instance, the increased development of indoor growing technologies and it also covers the established practice and legal interpretations published during this period. Additional provisions for indoor cultivation are outlined in Annex 1.

1. INTRODUCTION

Medicinal plants can be collected from the wild or cultivated. Cultivation is performed in open field (outdoors), in greenhouses, or as indoor cultivation. Outdoor cultivation is the most common cultivation system for medicinal plants. However, greenhouses and indoor cultivation provide better control on environmental factors such as light, temperature, and humidity.

Plant production (cultivation, harvesting and collection) and primary processing of the medicinal plant have a direct influence on the quality of the herbal substances and herbal preparations[2] used as active pharmaceutical ingredients (API). Due to the inherent complexity of medicinal plants and herbal substances the quality of these starting materials requires an adequate quality assurance system for the collection and/or cultivation, harvest, and primary processing.

The choice of preferred conditions of obtention of the plants, for instance, wild collection or cultivation (either outdoor, indoor or in greenhouses) should be carefully considered, since each of the mentioned types could have different problems and advantages. The used cultivation method may be dependent on the final application of the herbal medicinal product. Collection in wild habitats for instance, may present specific problems, especially with regard to confusion with similar plants, environmental disturbance, lack of regional regulation, habitat variability, hybridisation, and lack of control and poorly qualified personnel. Also, due to the possible non-uniformity between plants growing in the wild, variations in the composition can be a challenge exhibited by these plants. This Guideline should be used as a basis for the establishment of an appropriate quality assurance system for the collection and/or cultivation, harvest, and primary processing of herbal substances for use in the preparation of herbal medicinal products. For plant production that is certified as 'organic' in accordance with Regulation 2018/848/EU there may be some overlap with the recommendations in this Guideline.

Additional information specifically related to indoor cultivation is outlined in Annex 1.

2. SCOPE

This guideline is intended to address the specific concerns related to the cultivation, harvesting, collection, and primary processing of herbal substances that are used for the preparation of herbal medicinal products.

It addresses specific issues associated with outdoor, greenhouse and indoor cultivation, collection of medicinal plants from the wild, and production facilities for the primary processing of medicinal plants.

[1] The term "herbal substance" should be considered as equivalent to the term "herbal drug" as defined in the European Pharmacopoeia

[2] The term "herbal preparation" should be considered as equivalent to the term "herbal drug preparation" as defined in the European Pharmacopoeia

These considerations should be read in connection with EudraLex Volume 4 GMP guidelines Part II for APIs[3] and Annex 7[4] Manufacture of Herbal Medicinal Products and should apply to all methods of production in accordance with regional and/or national regulations.

The operations that should fall under the scope of GACP, GMP part II (for APIs) or GMP part I (for medicinal products) depend on the application of the finished medicinal product. In general, the closer the preparation is to the final product, the stricter the requirements are. For instance, the requirements applicable to a comminuted herbal substance sold as a herbal tea should be higher than the requirements applicable for a herbal substance which will be subject to further processing steps, such as extraction. Manufacturers should ensure that all the steps are carried out in accordance with the marketing authorisation/registration and therefore establish an appropriate quality assurance system in different source circumstances. This Guideline provides recommendations for good agricultural and collection practices for the production of medicinal plants and processing of herbal substances insofar as they mainly focus on identifying those critical production steps that are needed to ensure good quality.

The main aim is to ensure patient's safety by establishing adequate practices for obtaining medicinal plants and herbal substances, ensuring that they are handled appropriately throughout all stages of cultivation, collection, processing, and storage.

The handling of the herbal substance should be in accordance with good hygiene practices, to ensure microbiological load is kept to a minimum. Therefore, care should be taken to avoid agricultural inputs, e.g. fertilisers or growth media/promoters being a source of contamination.

During cultivation, harvest, collection, and primary processing, medicinal plants and related herbal substances may be exposed to environmental contaminants of both biotic and abiotic origin. This Guideline provides recommendations for producers to reduce contamination to a minimum.

Considerations and recommendations in this Guideline are intended for all participants from cultivators, harvesters, collectors, producers, traders, and processors of medicinal plants and herbal substances. Therefore, they each should comply with these considerations, document all relevant activities in batch documentation and demand that their partners do likewise, unless it can be justified.

Growers and collectors of medicinal plants must ensure that they avoid damage to existing wildlife habitats and must adhere to CITES[5] (Convention on International Trade in Endangered species of Wild Fauna and Flora), Nagoya Protocol[6] and the Global Biodiversity Framework (GBF)[7].

3. QUALITY MANAGEMENT

Agreements between the producer and the buyer/manufacturer of medicinal plants/herbal substances should make reference to the GACP Guideline and should be laid down in written form.

GACP compliance should be verified through regular audits of the cultivation and/or collection sites and processing facilities by expert representatives of the buyer/manufacturer of medicinal plants/herbal substances.

[3] https://health.ec.europa.eu/document/download/bd537ccf-9271-4230-bca1-2d8cb655fd83_en?filename=2014-08_gmp_part1.pdf
[4] https://health.ec.europa.eu/document/download/fd318dd6-2404-4e67-82b0-2324825e4d90_en?filename=vol4_an7_2008_09_en.pdf
[5] https://cites.org/eng/disc/text.php
[6] https://www.cbd.int/abs/text
[7] https://www.cbd.int/convention/text

4. PERSONNEL AND TRAINING

All primary processing procedures should fully conform with regional or national guidelines on hygiene and personnel entrusted with handling of medicinal plants and herbal substances. The personnel, whether working in a cultivation system or collecting from the wild, should be required to have a high degree of personal hygiene and have received adequate training regarding their hygiene responsibilities.

1. Personnel must be protected from contact with toxic or potentially allergenic medicinal plants via skin, eyes or inhalation, by means of adequate protective clothing or other adequate measures.
2. Persons suffering from known infectious transmittable diseases, must be suspended from areas where they are in contact with medicinal plants and herbal substances, according to regional and/or national regulations.
3. Persons with open wounds, inflammations and skin-infections should be suspended from areas where the plant processing takes place or should have to wear appropriate protective clothing/gloves until their complete recuperation. Special care should be applied when the herbal material is intended to be used in a further unprocessed state (irrespective to the route of administration).
4. There should be an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise all related operations. Training should be regularly conducted by qualified individuals and should be periodically assessed. Records of training should be maintained, including at least: topic, date, name of participants and trainer, including additional requirements if requested by the buyer/manufacturer.
5. Collectors must have sufficient knowledge of the plant they have to collect. This includes identification, characteristics and habitat requirements. The collectors must be able to differentiate between the collected species and botanically related and/or morphologically similar species to avoid any risk to public health and environmental damage. Collectors must have sufficient knowledge about the appearance of plant pests and pathogens to recognize diseased plants/plant parts in order to take appropriate measures, e.g. perform selective collection. Collectors should have sufficient knowledge about the best time to harvest as well as harvesting, post-harvesting practices and/or primary processing, to guarantee the quality. Collectors should be instructed on all issues relevant to the protection of the environment and conservation of plant species, including information on regulations related to protected species. If collectors are lacking the adequate knowledge, a local supervisor should verify and approve the training, supervision, and documentation.
6. Collectors should be instructed on all local issues relevant to risks of contamination of medicinal plants by biotic or abiotic sources of the immediate environment of the plants (e.g. roads, industrial areas, presence of poisonous weeds) which may lead to contamination with toxic substances in such medicinal plants, e.g. pyrrolizidine alkaloids (PAs), tropane alkaloids (TAs), polycyclic aromatic hydrocarbons (PAHs), heavy metals.
7. Personnel dealing with the medicinal plant and all those engaged in its cultivation should receive adequate botanical and agronomical training before performing particular cultivation steps (e.g. pruning) and regarding cultivation techniques, including appropriate use of herbicides and pesticides or the implementation of Integrated Pest Management techniques (IPM)". Personnel should receive adequate training in handling the plants (e.g. under controlled climate circumstances in case of indoor cultivation). Personnel must have sufficient knowledge about the appearance of plant pests and pathogens to recognize diseased plants/plant parts to enable to decide on what to collect.

Harvesters should have sufficient knowledge about the best time to harvest and harvesting/post-harvesting techniques and the importance of primary processing to guarantee the quality.

8. Personnel should be trained in the maintenance and cleaning of the equipment. Schedules and procedures (including assignment of responsibility) should be established for the equipment maintenance and cleaning as a preventive measure against contamination.
9. In general, personnel should be trained not to engage in activities such as smoking, chewing tobacco, drinking, eating and storing food or personal medicines in the direct proximity of the plants to avoid contamination. For indoor cultivation these activities should be restricted to separate designated areas.

5. BUILDING AND FACILITIES

Buildings used in the processing of harvested medicinal plants must be clean, as well as thoroughly aerated and must never be used for housing livestock.

Buildings must provide adequate protection for the harvested medicinal plants against birds, insects, rodents and domestic animals. In all storage and processing areas suitable pest control measures such as rodent traps, baits and electric insect killing machines must be operated and maintained by professionally qualified staff or contractors. In such areas, measures to protect against fire episodes should be considered.

It is recommended that the packaged medicinal plant/herbal substance is stored:

- in buildings with concrete or similar easy to clean floors;
- on pallets and/or racks;
- with a sufficient distance from the roof and walls;
- well separated from other herbal substances to avoid cross-contamination.

Buildings where plant processing is carried out, must have changing facilities as well as toilets including hand-washing facilities, according to regional and/or national regulations.

6. EQUIPMENT

Equipment used in plant cultivation and processing should comply with the following points:

- Equipment should be clean, regularly serviced and maintained to ensure good working order and mounted, where applicable, in an easily accessible way. Furthermore, equipment used in fertiliser and pesticide application, or other operations should be appropriate for the intended use and should be regularly calibrated, where applicable.
- Those machine parts that are in direct contact with the harvested medicinal plant, must be cleaned after use to ensure that remaining residue does not result in subsequent cross-contamination.
- The equipment should be made from appropriate materials so that cross-contamination of medicinal plants and herbal substances with chemicals and other non-desirable substances is prevented.

Equipment and other supportive systems used in the critical steps of cultivation, processing, packaging and storage, should be appropriate for the intended use.

7. DOCUMENTATION

Procedures should be established for retaining all appropriate documents. The following should be documented in a field record as agreed between the producer of the medicinal plant and herbal substance and buyer/manufacturer of the medicinal product:

- All processes and procedures that may impact the quality of the product and are deemed necessary within the cultivation or collection procedure/s such as training, personal hygiene, cleaning and maintenance activities, irrigation, fertilisation, applications of pesticides and herbicides, harvesting, processing, packaging, residual plant material and management.
- Any extraordinary circumstances occurring during the growing period that may influence the chemical composition of the medicinal plant, e.g. extreme weather conditions, pests and plant diseases (particularly in the harvest period).
- For cultivated medicinal plants: the geographical location, i.e. country and region/area/ province (as precise as possible). The type, quantity, and the date/period of harvest as well as the chemicals and other agricultural inputs used during production. Site records showing previous crops, varieties and/or cultivars and plant protection products used, in case of conventional cultivation.
- For wild collection of medicinal plants: the geographical location, i.e. country and region/area/ province (as precise as possible). The type, quantity, and the date/period of collection.
- The use of fumigant products.
- Batches of herbal substances should be unambiguously and unmistakeably traceable to their sources. Therefore, appropriate labelling and batch assignment should take place as early as possible in the process. Wild collected and cultivated material should be assigned different batch numbers. In the case of combined (sub-)batches of the same plant species harvested/ collected in different geographical locations and/or subject to different growing conditions, the country and region/area/province should be well documented. Batches from different geographical areas shall be mixed only if it can be guaranteed that the resulting batch will be homogenous. Such processes should be well documented. Agreements between each producer/collector and the buyer/manufacturer, e.g. production guidelines, contracts, etc., should be in written form.
- The audit reports, including those by or on behalf of the GMP licensed manufacturers or other parties. Copies of all documents, audit reports, agreement/s analysis reports, etc., should be stored (physically and/or digitally).

8. SEEDS AND PROPAGATION MATERIAL

Seeds should originate from plants that have been accurately identified in terms of genus, species, variety/cultivar/chemotype and origin and should be traceable. The same applies to vegetatively propagated medicinal plants. Seeds and/or vegetatively propagated medicinal plants used in organic production must be certified as organic. The starting material should be as far as reasonably achievable free from pests and diseases, in order to guarantee healthy plant growth. Where possible, stable varieties and cultivars naturally resistant or tolerant to disease should preferably be used. Seeds and propagation materials should be free from seeds of other species, especially seeds of plants that contain toxic components, like pyrrolizidine alkaloids.

The presence of different species, varieties, or different plant parts must be controlled during the entire production process, and such adulteration should be avoided. The use of genetically modified medicinal plants or seeds must comply with regional and/or national regulations.

Suppliers of seeds and propagation materials used in cultivation must be evaluated. Along the supply chain, a change in seeds and propagation material can affect the quality of the product. All changes should be documented.

9. CULTIVATION

The chosen method of cultivation should be described and documented, taking care to avoid any negative environmental impact in accordance with relevant local regulations. The principles of good crop husbandry must be followed and include appropriate rotation of crops if applicable.

- Soil and fertilisation:
    - Medicinal plants shall not be grown in soil or substrate contaminated with sludge, heavy metals, pesticide residues, plant protection products or other chemicals. Any products used in the growth or protection of the crop should be kept to a minimum and its use should be justified.
    - In cases where the area considered for the cultivation of the medicinal plant is potentially contaminated or is in close proximity to contaminated areas, the responsible person should take suitable measures (including testing) prior to the commencement of the cultivation process.
    - Manure should be thoroughly composted (transformed to be free from gross microbial contamination) or applied before the beginning of the crop cycle and shall be void of human faeces. The use of compost containing toxic plants must be avoided.
    - All other fertilising agents should be applied in accordance with the needs of the particular plant species. Fertilisers should be applied in such a manner as to minimise leaching.
    - All fertilising agents should be used appropriately in order to avoid contamination with heavy metals and organic contaminants, such as polychlorinated biphenyls (PCBs) and PAHs.
- Irrigation:
    - Irrigation should be controlled and carried out according to the needs of the medicinal plant.
    - Water used in irrigation should comply with regional/national quality standards or with the international standards, if requested.
- Crop maintenance and plant protection:
    - Tillage practices should be adapted to plant growth and requirements. During the cultivation season, toxic weeds that represent a risk of contamination should be removed from the field and it should be considered not to compost them.
    - Pesticide applications should be avoided as far as possible. When necessary, approved plant protection products should be applied at the minimum effective level in accordance with the recommendations from the manufacturer and approved by the authorities of the country of application; however, avoiding the use of pesticides that

are not allowed in the country of destination. The application should be carried out only by qualified staff using suitable equipment. The preharvest interval for a plant protection product application is based on official legal requirements or, if not applicable, on the recommendations of the pesticide manufacturer. The buyer/manufacturer of the medicinal product can request a longer pre-harvest interval. Regulations on maximum residue limits according to the European Pharmacopoeia, European Directives, Codex Alimentarius, etc., should be complied with.

- In situations where the cultivation site is located in an area of other cultivation activities, the risk for possible contamination with pesticides and herbicides from neighbouring fields should be assessed.
- The cultivated plant should be monitored for signs of defects, regardless of whether these are of biotic or abiotic origin.

10. COLLECTION

Designated individuals should supervise the collectors of the medicinal plants/herbal substances and also identify and verify the collected material (see 4.5, 4.6 and 4.7).

Collection must be carried out in compliance with existing regional and national, and/or national species conservation legislation. Collection methods must not damage the growth environment ensuring optimum conditions for regeneration of the medicinal plant.

Medicinal plants from species that are listed as endangered (CITES, Convention on International Trade in Endangered Species of Wild Fauna and Flora) must not be collected unless the relevant competent authority has given its authorisation. For species included in the Appendices II or III of CITES, the collection of wild plants or the exporting/importing of wild or cultivated plants must be carried out only after carefully verifying the requirements of CITES regulations and local CITES management and scientific authorities. Wild species listed in CITES Appendix I cannot be collected.

Species and habitats that are rare, threatened, or endangered (section 10.3) require careful consideration. It is essential to be aware of the conservation status of the species and populations being targeted. Over-exploitation should be avoided.

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union has to be taken into account.

Provisions mentioned under section 11 (‘Harvesting’) must be taken into account for the collection as well, as long as they are applicable.

11. HARVESTING

Medicinal plants should be harvested when they are at the suitable quality for the proposed use. The following requirements apply:

- Damaged plants or plant parts need to be limited.
- Ensure the best possible conditions avoiding wet soil, dew, rain, or exceptionally high air humidity. Harvesting in wet conditions can have adverse effects on the medicinal plant (e.g. postharvest spoilage).

- Cutting devices or harvesters must be fit for purpose and appropriately maintained according to the respective national, or regional legislation and should be food compliant. Especially contamination from foreign matter, leaking lubricants, and other extraneous agents and/ or particles should be reduced to a minimum. Such devices should always be maintained in good working order. Recommendations in section 6. Equipment must be followed and documented.
- The harvested medicinal plant should not come into direct contact with the soil or floor. It must be promptly collected in suitable containers and transported in dry, clean conditions. For roots and rhizomes contact with soil cannot be avoided and for practical reasons contact with a clean floor is possible for a short time, e.g. in the unloading area before drying.
- Care should be taken to ensure that toxic weeds are not co-harvested, as far as reasonably achieved, with medicinal plants.
- All containers used during harvesting must be clean and free of contamination from previous harvests and other uses. When containers are not in use, they must be kept in dry conditions free of pests and inaccessible to rodents, livestock and domestic animals.
- Mechanical damage and compacting of the harvested medicinal plant that would/could result in undesirable quality changes must be avoided. In this respect, attention must be paid to:
    - overfilling of containers;
    - stacking up of containers;
    - bulk height in case of loose transport.
- Freshly harvested medicinal plants must be delivered as quickly as possible to the processing facility to prevent physical or chemical degradation or microbial growth.
- The harvested crop must be protected from pests, rodents, livestock and domestic animals. Any pest control measures taken must be documented.
- Following crop harvesting, the crop residues may be used either as a mulch or a green manure for the next crop cycle. Crop residues can be used for tillage prior to planting when plant residues are incorporated into the soil. Another farming practice is reduced tillage or no-till farming, where crop residues are left on the surface and planting is carried out without soil tillage.

12. PRIMARY PROCESSING

Primary processing, such as washing, cutting before drying, microbial decontamination, freezing, distillation, primary and secondary drying, etc., must be carried out as soon as possible after harvesting. Where applicable, all these processes must conform to the competent authority regulations.

In some circumstances drying and cutting should be performed according to EudraLex Volume 4 GMP part I or II (refer the GMP Table[8] in Annex 7).

In exceptional circumstances, which must be justified in the marketing authorisation/registration, some of these steps, like expression and distillation, may be performed in the field, but only if it is necessary for these activities to be an integral part of harvesting in order to maintain the quality of the product within the approved specification (see note to the Table of GMP Annex 7).

[8] Table illustrating the application of good practices to the manufacture of herbal medicinal products is found in EudraLex Vol. 4 Annex 7, page 3.

- On arrival at the processing facility, the harvested medicinal plant must be promptly unloaded and unpacked. Prior to processing, the material should not be exposed directly to the sun (except in cases where there is a specific need) and must be protected from rainfall, insect infestation and other unfavourable conditions.
- In the case of natural open-air drying, the medicinal plant must be spread out in a thin layer. To secure adequate air circulation, the drying frames must be located at a sufficient distance from the ground. Drying directly on the ground must be avoided. Drying under direct exposure to the sunlight should be avoided unless specifically required or if there is no negative influence on the quality. Attempts must be made to achieve uniform drying of the medicinal plant and thus avoid mould formation and to maintain quality.
- The drying conditions such as maximum temperature, duration and air circulation must be selected taking into consideration the medicinal plant part to be dried, such as root, leaf or flower, and the nature of its active constituents, such as essential oils. Individual conditions must be recorded in detail (e.g. drying temperature, duration, method). In case of artificial drying, gas or electrical ovens should be considered, and the use of wood and petrol ovens minimised, to reduce to possible contamination with PAHs. Indirect drying is always recommended (e.g. convection drying or oven drying).
- In case of distillation in the field (refer the GMP Table[8] in Annex 7), this can be performed at a suitable facility in the field, which should be audited by the API manufacturer or the finished product manufacturer and produced according to GMP principles.
- All herbal materials must be inspected and where necessary sieved to eliminate sub-standard product and foreign matters. Sieves must be maintained in a clean state and should be serviced regularly. Cleaning of sieves before product change is mandatory, to avoid mixing of products or cross contamination.
- Clearly marked waste-bins, for waste plant materials and cultivation-related wastes, should be available, emptied daily and cleaned. Toxic or contaminated waste plant materials may be segregated from growing media and the materials for the cultivation of plants and may require incineration for destruction according to the national/regional legislation.
- Fumigation should be limited as far as possible and only be used when a real need is identified and after consultation with the buyer/manufacturer of the medicinal product. In such cases, treatment should be carried out at the earliest possible stage, according to the specific recommendations for use[9].
- Fumigation against pest attack should be carried out only where necessary and must be carried out exclusively by licensed personnel. Only registered chemicals must be used, according to the specific recommendations for use. The use of ethylene oxide and 1,3-dichloropropene is prohibited. Any fumigation against pests must be documented (see section 7).
- For fumigation of warehouses, only substances permitted by the regional and/or national regulations should be used, documented and in accordance with the buyer/manufacturer of the medicinal product (see section 7).
- When frozen storage or saturated steam is used for pests and microbial contamination control, the humidity of the material must be controlled after treatment.

[9] Reflection paper on the use of fumigants (EMEA/HMPC/125562/2006)

13. PACKAGING

To protect the herbal material and to reduce the risk of pest attacks, early packaging is advisable.

Following processing monitored by in-process controls, the product should be packaged in clean and dry, preferably new sacks, bags or boxes. The label must be clear, permanently fixed and made from non-toxic material, including solvents and chemicals used in inks for labelling. Information must conform with regional and/or labelling regulations of the country of destination.

Reusable packaging material should be well cleaned and properly dried prior to use. No contamination should occur through the reusing of packaging materials.

Packaging materials must be stored in a clean and dry place that is free of pests and inaccessible to livestock and domestic animals.

It must be guaranteed that the packaging materials do not cause contamination of the product, particularly in the case of fibre bags. All packaging material should be suitable to be in contact with food following the specific requirement (e.g. food legislation such as Commission Regulation (EU) No. 10/2011, as amended, in case of plastic materials).

14. STORAGE AND DISTRIBUTION

Packaged dried medicinal plants, herbal substances and essential oils, should be stored in a dry, well-aerated building, in which environmental conditions are controlled and limited.

In humid environments storage in airtight rooms/containers/bags could be used to avoid unwanted moisture absorption of the product.

In the case of bulk transport, it is important to secure dry conditions. Furthermore, to reduce the risk of mould formation or fermentation it is advisable to use aerated containers. As a substitute, the use of sufficiently aerated transport vehicles and other aerated facilities is recommended, whereby special care should be taken to avoid contamination through exhaust gases, smoke, etc. When using airtight containers/bags in humid conditions, the packed medicinal plants/herbal substance have to be dried sufficiently to avoid mould formation during transport. Essential oil transport must conform with appropriate regulations. Regional and/ or national regulations on transport must be respected.

Before shipment, a control of the quality and hygiene of the truck(s) before loading should be done and recorded.

For every batch sent to the buyer/manufacturer of medicinal product a representative sample should be stored for 3 years. This is to provide a possibility to control the quality in case of deficiencies detected/reported by buyer/manufacturer of medicinal product.

15. DEFINITIONS

Abiotic:	Physical instead of biological factors or compounds. Examples are sunlight, water, air, type of soil, minerals, etc.
Adulteration:	The illegal and fraudulent mixing of ingredients that are not declared.
Agricultural inputs:	Any incoming material (e.g. seeds, fertilizers, including compost, water, agricultural chemicals, plant support) used for the primary production of herbal substances.

Batch (or Lot):	Defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.
Batch (or Lot) number:	A distinctive combination of numbers and/or letters, which specifically identifies a batch.
Biotic:	Relating to living organisms.
Buyer:	An intermediary or a manufacturer.
CITES:	Convention on International Trade in Endangered Species of Wild Fauna and Flora.
Collection:	The gathering of plant species from wild/spontaneous sources.
Comminuted herbal:	According to the Ph. Eur. monograph on herbal drug preparations (1434), the term comminuted used in EU legislation on herbal medicinal products describes a herbal drug that has been either cut or powdered.
Convection drying:	Also known as air drying. In this method warm air is passed over the material to remove moisture. The heat is transferred from the air to the material, causing it to lose water. This is commonly used for drying grains, fruits, and herbs.
Cultivar:	A plant variety that has been produced in cultivation by selective breeding.
Field record:	A document (also digital) that gather any information about the cultivation such as: previous crop, seed used, name of the plant cultivated, exact location of the field, any treatment with pesticide, fertilizer and growth regulator or any chemical plant protection (specified as: name of the product, date, quantity and reason of the treatments) and person performing the work.
Fumigation:	The process of disinfecting a batch in a closed container with the fumes of certain chemicals.
Greenhouse:	A facility designed for the cultivation of plants under automated and/or manually semi-controlled climate conditions. They can be of glass or other light transparent materials. They can be open and in contact with the external environment if needed, depending on the internal/external climate conditions. In a greenhouse setup there is control over environmental factors such as light, temperature, and humidity.
Habitat:	The natural home or environment of a plant species.
Habitat variability:	This refers to the range of different environmental conditions and habitats that a species occupies within

	its geographical distribution, which includes the diversity in climate, terrain, vegetation, and other ecological factors that a species can tolerate and utilize for survival and reproduction.
Harvesting:	The gathering of plant species from cultivated sources.
Herbal substances:	Are mainly whole, fragmented or cut, plants, parts of plants, algae, fungi, lichen in an unprocessed state, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binominal system (genus, species, variety and author). Definition according to Ph. Eur. monograph on herbal drugs (1433).
Herbal preparations:	Are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates. Definition according to Ph. Eur. monograph on herbal drug preparations (1434).
Hybridisation:	A process of crossing two genetically different plant species, subspecies, or varieties to produce a new hybrid offspring that combines traits from both parent plants. This can be natural or artificially.
Indoor cultivation:	Cultivation in a closed environment with artificial light and equipped with air filtration to avoid cross-pollination, pollutants, insects, etc.
Manufacturer:	An entity that intends to process the herbal raw material or herbal preparation for medicinal purposes.
Medicinal plant:	Generic term used for plants that are known for their medicinal use.
Organic production:	A sustainable agricultural system that uses ecologically based pest controls and biological fertilizers derived largely from animal and plant wastes and nitrogen-fixing cover crops. For further information see Regulation (EU) 2018/848.
Outdoor cultivation:	Live plants growing in an area (open field) exposed to natural sunlight and environmental conditions including variable temperature, precipitation, and wind.
Oven drying:	In this method hot air circulates inside an oven to dry the material indirectly. The heat is transferred to the material through air circulation, typically used for

	drying smaller quantities of substances like herbs, spices, or laboratory samples.
Pesticide:	Any substance or mixture of substances intended for preventing, destroying or controlling any pest, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of herbal drugs. The item includes substances intended for use as growth-regulators, defoliants or desiccants and any substance applied to crops, either before or after harvest, to protect the commodity from deterioration during storage and transport.
Post-harvest spoilage:	The presence of moulds and other organisms that may impact negatively on the quality of the herbal material.
Producer:	An individual or entity that harvests cultivated species, and/or collects species from the wild, for medicinal purposes.
Pyrrolizidine alkaloids (PAs):	Pyrrolizidine alkaloids are a group of naturally occurring alkaloids in certain plants that are based on the structure of pyrrolizidine that are toxic to the liver.
Polycyclic aromatic hydrocarbons (PAHs):	Polycyclic aromatic hydrocarbons are a class of organic compounds produced by incomplete combustion or high-pressure processes. PAHs form when complex organic substances are exposed to high temperatures or pressures. These may affect organs leading to cancer, developmental and reproductive defects and hepatic problems.
Polychlorinated biphenyls (PCBs):	Polychlorinated biphenyls are organochlorine compounds. These may affect organs leading to cancer, developmental and reproductive defects, endocrine disruption and hepatic problems.
Plant production:	The cultivation and harvesting of plants obtained from production units, including collection of wild plants from natural habitats, for commercial purpose.
Residual plant materials:	Are crop materials such as stems, leaves and roots that are left on the field after the harvest.
Stable varieties:	Plant varieties that, when grown over multiple generations, consistently exhibit specific desirable traits such as size, shape, colour, yield, or resistance to diseases. These traits are reliably passed down from one generation to the next, ensuring that the plant remains uniform and true to its characteristics, even when reproduced through methods like seeds or vegetative propagation.

Tillage practices:	Agricultural preparation of the soil by mechanical agitation in preparation for growing crops.
Tropane alkaloids (TAs):	Tropane alkaloids are a class of bicyclic alkaloids and secondary metabolites that contain a tropane ring in their chemical structure.
Variety:	Taxonomic category that ranks below subspecies (where present) or species, its members differing from others of the same subspecies or species in minor but permanent or heritable characteristics.
Vegetative propagation:	The process that plants are reproduced through methods other than seed production, using parts of the plant like stems, roots, or leaves to grow new plants. This process ensures that the new plants are genetically identical to the parent plant, preserving the specific medicinal properties. In some cultivation practices, this may be referred to as cloning.

16. REFERENCES

1. EudraLex, Volume 4 Good Manufacturing Practices (GMP) guidelines, Part II Basic Requirements for Active Substances used as Starting Materials

2. EudraLex, Volume 4 Good Manufacturing Practices (GMP) guidelines, Annex 7 Manufacture of herbal medicinal products

3. European Pharmacopoeia General Monograph "Herbal Drugs" 07/2017:1433

4. European Pharmacopoeia General Monograph "Herbal Drug Preparations" n° 07/2010:1434

5. Reflection paper on the use of fumigants (EMEA/HMPC/125562/2006)

6. Reflection paper on quality of essential oils as active substances in herbal medicinal products/ traditional herbal medicinal products (EMA/HMPC/84789/2013)

7. Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

ANNEX 1 - Additional provisions for indoor cultivation

5. BUILDING AND FACILITIES

Indoor cultivation facilities should contain adequate systems for air, climate and humidity control, light, water treatment, ventilation and air filtration systems. They are designed to:

- control access to personnel;
- minimise potential contamination;
- facilitate cleaning, maintenance and other operations;
- be impermeable to cleaning and disinfecting agents.

Designated areas for different stages of cultivation may be assigned.

7. DOCUMENTATION

For indoor cultivation (and greenhouse, if applicable) the agronomic conditions and all materials used during cultivation which are relevant with respect to quality should be fully documented. Acceptance criteria for cultivation conditions to obtain the specified quality should be laid down and documented for each batch. All documents related to the cultivation and production should be prepared, reviewed, approved and distributed according to standard operating procedures. A procedure should be established for retaining all appropriate documents. All the specifications related to the process (e.g. cultivation and production process) and to the product should be developed and documented for each batch. All cleaning activities should be recorded in the batch records and appropriate logbooks. For indoor cultivation daily (digital) records of critical process parameters must be kept and reviewed.

9. CULTIVATION

- Crop maintenance and plant protection:
    - In case of indoor cultivation (and if applicable to greenhouse setups), and if the following aspects should also be considered. There should be written procedures describing the receipt, identification, storage, handling, sampling and approval or rejection of materials. The company's overall policy, intentions, and approach to validation, including the validation of production processes, cleaning procedures and persons responsible for design, review, approval and documentation of each validation phase, should be documented. Equipment involved in the cultivation process must be calibrated according to the established procedure and schedule, where applicable. Before a new cultivation cycle, all materials used should be verified and approved by the person responsible for quality.
    - For indoor cultivation any critical quality attributes and critical process parameters should be identified. Appropriate in-process acceptance criteria and controls should be established. Cultivation process should be standardised in order to ensure reproducible results. Qualification of critical equipment and ancillary systems should be completed.