

**DOC: NMPB-GAPMP-01(FD)**

**GOOD AGRICULTURAL PRACTICES STANDARD  
FOR MEDICINAL PLANTS-REQUIREMENTS**



**National Medicinal Plants Board  
Department of AYUSH, Ministry of Health and Family Welfare  
Government of India, Chanderlok Building , 36 Janpath  
New Delhi 100001**

## INTRODUCTION

0.1 India has a rich heritage of plant based healthcare systems like Ayurveda, Unani and Siddha with a very high degree of societal acceptance. There is a global upsurge in the use of traditional and complementary systems of medicine. This is primarily due to the fact that these systems of medicine, being largely plant based, are generally safe, efficacious and affordable. The increasing demand of natural/herbal products world over, therefore, creates a need not only for conserving medicinal plants in-situ but also their cultivation outside the forest areas in public and private lands.

0.2 Forests have been the main source of the raw material used in the manufacture of Ayurveda, Siddha and Unani medicines. But concern has been raised that unsustainable collection from the wild has resulted in a large number of species entering the red data book. The Department of AYUSH, through the schemes of the National Medicinal Plants Board (NMPB), has launched major initiatives to promote cultivation of medicinal plants and thereby integrate medicinal plants into the farming systems.

0.3 The major challenges facing growth and outreach of the traditional/herbal medicinal products is their quality, safety and efficacy. This inter-alia is dependent on the quality of the raw material used in the manufacture of the finished product. The National Medicinal Plants Board (NMPB), Department of AYUSH has prepared India specific guidelines on Good Agriculture Practices (GAPs) on the pattern of Good Agriculture and Field Collection Practices (GACPs) developed by the World Health Organization (WHO) for medicinal plants.

0.4 In the preparation of this standard assistance has been taken from Good Agriculture and Collection Practices (GACPs) developed by the World Health Organization (WHO) in 2003 and Good Agricultural Practices enunciated by the GLOBALGAP Secretariat which is being implemented in over 80 countries.

0.5 The requirements given in this standard are subject to the following statutory and regulatory provisions:

- a. The Drugs and Cosmetics Act and Rules (as amended up through 30th June 2005. New Delhi: Department of Health. 2005. Schedule T: Good Manufacturing Practices (GMPs) for Ayurveda, Siddha and Unani Medicines.
- b. The Ayurvedic Pharmacopoeia of India, 5 Volumes, Ministry of Health and Family Welfare, Govt. of India, New Delhi, 1989-2005
- c. The Siddha Pharmacopoeia of India, Part I(1), Ministry of Health and Family Welfare, Govt. of India, New Delhi, 2007
- d. The Unani Pharmacopoeia of India, Part-I, Ministry of Health and Family Welfare, Govt. of India, New Delhi

0.6 In preparation of this standard, considerable assistance has been derived from the following Technical committee members:

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Dr. G.A. Kinhal, ICIMD (International Center for Integrated Mountain Development )  
Mr. Singh, Chhattisgarh State Minor Forest Produce co-operative Federation  
Prof. P.Bhattacharya, IIFM

0.7 Acknowledgements are also due to the following Departments / members of the Steering Committee who gave guidance and inputs to the Technical committee for finalizing the standard.

Secretary, Department of AYUSH.  
Secretary, Department of Agriculture & Co-op.  
Secretary, Ministry of Environment & Forests  
Secretary, Department of Commerce  
Director General, Council of Scientific and Industrial Research ( CSIR ),  
Director General, Indian Council of Agricultural Research ( ICAR ),  
Director, National Accreditation Board for Testing & Calibration Laboratories (NABL) and  
Quality Council of India

0.8 All organizations engaged in Cultivation of medicinal plant produce can apply for certification to Independent Certification bodies duly accredited for this scheme and get certification for their produce if complying to the requirements of this Standard document.

## **1. SCOPE**

This standard covers good agricultural practices for cultivated medicinal plants in sustainable manner and maintaining quality of produce used by all stakeholders.

This standard does not cover the requirements for Good Field Collection Practices (GFCPs)

## **2. DEFINITIONS**

For common understanding by the stakeholder in uniform manner, applicable terms have been defined and is given in Annex A

## **3. DEVELOPING MONOGRAPHS ON GAP FOR INDIVIDUAL SPECIES OF MEDICINAL PLANTS**

A model structure for developing monograph on Good agricultural practices is given in Annex B

## **4. RECORD FOR CULTIVATED MEDICINAL PLANTS**

The record for cultivated medicinal plants is maintained in a prescribed format given in Annex C

## **5. REQUIREMENTS**

5.1 The requirement for good agricultural practices on different aspects from site selection to packaging storage and dispatch of produce for processing are given in Table 01

## **6. APPRAISALS AND ASSESMENT**

6.1 The requirements stated in Table 01 shall be evaluated to establish that growers comply with those requirements. An appraisal and assessment system has been developed. On evaluation of deficiencies that may appear in evaluation need to be resolved to establish compliance to the requirements. These deficiencies have been classified as:

### **Critical:**

When evidence shows that the grower has not complied with requirements in its documentation and implementation and which raises doubts on the operation and practice of GAP calling for an early correction and corrective actions within the time frame.

### **Major:**

When evidence suggests major break down in the implementation in certain elements of the criteria calling for the early corrective actions within a time frame

### **Minor:**

When evidence shows an isolated non-compliance to the GAP criteria and has negligible impact on the operation of the system and its results.

Note: Multiple Minor NCs with related impact on the operation of the system in one particular area may result in major NC

6.2 To develop a self assessment method against the criteria, a checklist has been developed and is given in Table 02. This will bring uniformity in evaluation of the system. This also indicates when a violation of a particular criteria leads to critical, major or minor nonconformities.

**TABLE 01 REQUIREMENTS AND EVALUATION CRITERIA**

Parameters	Control criteria	Compliance criteria	Level of compliance
1	<b>SITE SELECTION</b>		
1.1	Is site free from toxic elements such as industrial wastes and effluents?	The information on soil condition and site on water logging, industrial waste and effluents	Major
1.2	Are the sites in proximity to graveyards, crematoria or having a traceable history of such usage.	The recorded site history must be available	Minor
1.3	Is the site having access to reliable source of irrigation water (where applicable/relevant)?	There should be sufficient source of irrigation water.	Major
1.4	Has a management plan been developed setting out strategies to minimize all identified risks in respect of parameter at 1.1 to 1.2? Are the results of this analysis recorded and used to justify that the site in question is suitable?	A management plan for mitigation of risk should be implemented to meet the objectives	Major
1.5	Has the meteorological data collated for preceding three years taken into account while judging the suitability of the site.	Three years meteorological data should be available with the farm management	Minor
2	<b>SOIL CONDITIONS</b>		
2.1	Has the soil map prepared for the farm	The type of soil is identified for each site, based on a soil profile or soil analysis.	Major
2.2	Is the soil optimal to the selected crop with reference to its water holding capacity and fertility?	Data on physico-chemical properties of soil-texture and structure be available	Major
2.3	If soils with low fertility levels use soil amendments as per the specific site and requirement of species, are the latest soil test report on physico-chemical parameters and nutrient profile to decide the nature and quantity of soil amendments available?	The soil analysis report from an independent lab should be available. Technical expertise for the quantity, quality and type of soil amendments to be used	Major
2.4	Has the quality of irrigation water been adequately understood and classified in the context of both soil type and the target crop in terms of total salt concentration, Sodium absorption ratio, Bicarbonate and Boron concentration etc.	The information on quality including salt concentration of water for each target crop	Major
2.5	Irrigation water is required to conform to standards of micro pollutants [disinfection by-products (DBPs), endocrine disrupting chemicals, antibiotics, polymers, pesticides and other bioactive chemicals], heavy metals and residual pesticides) if the water source is vulnerable like canal water etc.?	Analytical report on irrigation water should be available especially of heavy metals and pesticide residues	Major
2.6	When shade-loving crop is planned for, availability of shade across the field should be ascertained.	Study of cropping pattern and inter-cultivation practices should be introduced	Major
3	<b>SEEDS AND PROPAGATION MATERIAL</b>		
3.1	Do seed/planting material accompanied with the following information:-	Details of seed/ propagation material be available including	Critical

Parameters	Control criteria	Compliance criteria	Level of compliance
	a) Name (pharmacopoeial nomenclature and trade name) b) Botanical name c) Cultivar/Selection / Phenotype/ Chemotype / Genotype (If applicable)?	botanical description	
3.2	Is marker based analytical projection for the end-product is mandatory requirement when the crop is meant for phyto-pharmaceutical industries?.	Marker based analytical report should be available for examination	Major
3.3	When the planting material is obtained from wild resources, are efforts made to establish its correct identity? Is planting material obtained from a authorized source?	Correct identification report with botanical features should be available. Authorized source is listed	Major
3.4	Does the producer keep records on sowing/planting methods, seed/planting rate, sowing/planting date?	Records of sowing/ planting method, rate and date must be kept and be available.	Major
3.5	<b>Seed</b>		
3.5.1	The seeds chosen for cultivation purposes must meet the botanical and varietal purity.	A record/certificate of the seed quality is kept and available and states variety purity, variety name, batch number and seed vendor.	Critical
3.5.2	Are the seeds chosen for cultivation purposes physically free from pests, diseases, weeds, and foreign and inert matter?	Records should show that seeds chosen were free from pest and diseases	Critical
3.5.3	Does the producer keep records on sowing/ planting methods, seed/planting rate, sowing /planting date?	Records of sowing/ planting method, rate and date must be kept and be available.	Major
3.5.4	Are the seed collected from recently collected lots and are mature seeds in case seeds are collected from wild source?	Records should be available when seed is collected from wild sources to show that it is invariably from recently collected lots and only mature seed collected.	Major
3.5.5	Are prescribed seed treatment protocols for the target species, completed well in advance to match the planting season.	Seed treatment records be available including type of plant protection chemical used and diseases identified, where applicable	Major
3.5.6	When the process for seedling production under nursery conditions, is it initiated as per the recommended agronomic practices for the target species and carried out reasonably well before the actual schedule of field transplantation and only healthy seedlings transplanted.	Information of type of seed used and agronomic practices applied should be available	Major
<b>3.6</b>	<b>Stem cutting</b>		
3.6.1	Are sources of cuttings authenticated when root induction in stem cuttings under nursery conditions for transplantation into the field for both botanical identity and quality of vegetative	When the grower takes the responsibility of root induction in stem cuttings under nursery conditions for eventual	Critical

Parameters	Control criteria	Compliance criteria	Level of compliance
	propagules?	transplantation into the field, records on the source of cuttings authentication for both botanical identity and quality of vegetative propagules be available.	
3.6.2	Are only healthy stem cutting giving desired rooting used?	The stem cuttings collected for root induction should be of uniform dimensions in terms of length and diameter and should be in tune with the requirements laid down for the target species	Major
<b>3.7</b>	<b>Root cutting</b>		
3.7.1	Are 'ready-to-transplant saplings' or root cuttings of uniform size and maturity, both in terms of aerial and underground parts, and free from any disease and infection used?	Propagation materials in form of 'ready-to-transplant saplings' or root cuttings should be of uniform size and maturity, both in terms of aerial and underground parts, and must be free from any disease and infection.	Critical
4	<b>CROP MANAGEMENT FOR CULTIVATION</b>		
4.1	<b>Field preparation</b>		
4.1.1	Is soil brought to the desired tilth to facilitate favourable environment for growing seed and seedling?	Soil preparation for planting requires proper tilth condition for favourable growth of plants	Major
4.1.2	Do field operation performed provide better rhizospheric environment, soil structure and texture, and keep it free from weeds for initial 20-30 days?	Field operations performed should have recorded information for weed control	Major
<b>4.2</b>	<b>Sowing and transplanting</b>		
4.2.1	Are recommended rate of seedlings per unit of land area adhered to?	A chart of rate seedling per unit of land should be prepared and available the farm	Minor
4.2.2	Is placement of seeds taking place at the appropriate depth in the moist zone of the soil?	A plan for depth of seed placement should be prepared for uniform use	Major
4.2.3	Are saplings where used transplanted following the spacing norms in terms of row-to-row and plant-to-plant distance governed by the needs of target crop as envisaged in the agronomic protocol for target species?	Authorized data on row to row and plant to plant distance of saplings/seeds must be available. Agro-techniques available may be used	Minor
4.2.4	Are the seedling at optimum stage of transplanting uprooted and transplanted immediately thereafter?	An authentic data and information should be available on stage up rooting of seedlings for different crops	Major
4.2.5	Replenishment of plant populations to compensate mortality losses should be carried out within a reasonable timeframe and in consideration of the gestation period of the target crop.	Guidelines as when to compensate for population mortality	Minor
4.2.6	Is there a document that guarantees seed	A record/certificate of the seed	Minor



Parameters	Control criteria	Compliance criteria	Level of compliance
	quality (free from injurious pests, diseases, virus, etc.)?	quality is kept and available and states variety purity, variety name, batch number and seed vendor.	
<b>4.3</b>	<b>Manures and Fertilizers</b>		
4.3.1	Source of information/material about manures and fertilizers used  Parameters used to accept or qualify the manure in case source is from outside.	Where the fertilizer records show that the technically responsible person making the choice of the fertilizer (organic or inorganic) is an external adviser, training and technical competence must be demonstrated.	Major
4.3.2	Is use of organic manure preferred for growing medicinal plants supplemented by mineral nutrition through inorganic source in consideration of the nutritional needs of the target crop vis-à-vis the soil characteristics?	Mineral supplements must be based on complete soil analysis in a competent laboratory for the target crops	Minor
4.3.3	Is use of compost, vermi-compost, green leafy manure and biofertilizers considered desirable?	These organic modes of supplementation of organic manure/fertilizer should be implemented	Minor
4.3.4	Are specialized nutritional care for distinct purposes such as root production or enhancement of leafy bio-mass etc opted for in the light of recommended agronomic practices for target species?	These practices must be based on scientific information and guided by specialists	Major
<b>4.4</b>	<b>Irrigation</b>		
4.4.1	How is the total water requirement of the crop estimated in the light of available agronomic protocol? How the irrigation cycles is planned for and implemented to ensure optimal plant growth.	There should be a water management plan to optimize water usage and reduce wastage. Records should be maintained for irrigation/fertigation and water usage.	Major
4.4.2	Is there a water management plan to optimise water usage and reduce waste in terms of method of irrigation?	The idea is to avoid wasting water. The irrigation system used should be the most efficient available for the crop and accepted. A documented plan is available which outlines the steps and actions to be taken to implement the management plan.	Major
4.4.3	How water harvesting and water conservation methods are followed, wherever possible	Water conservation measures should be followed	Minor
4.4.4	Is the quality of water considered in the light of prevailing soil conditions and soil and water analysis taken into account for this purpose.	Test report of water and soil from an accredited lab should be available	Major
4.4.5	How soils having the problem of drainage are dealt with in specific manner so as to provide outlet for excess water?	Written soil water management practice should be available. The impounding of water through heavy rains should not be allowed.	Major

Parameters	Control criteria	Compliance criteria	Level of compliance
<b>4.5</b>	<b>Weeding and inter-cultural operations</b>		
4.5.1	How initial flush of weeds are controlled effectively to ensure a weed free environment to young plants?.	A documented plan should be available for weed control. The weeding and hoeing cycles should be so arranged as to keep the field free from weeds	Major
4.5.2	Is the prescribed schedule of all inter-cultural operations such as weeding, hoeing, topping, nipping of buds, pruning, shading and earthing up etc. adhered to in a manner to optimize overall productivity.	Depending on the nature of medicinal crop, inter-cultivation practices should be used to reduce the incidence of weeds	Major
4.5.3	Are use of herbicides avoided as far as possible? In case of their inevitable usage, are available evidence of safety to the target crop considered adequately?	Systemic weedicides should not be used. Biological control measures preferred	Major
<b>4.6</b>	<b>Crop protection</b>		
4.6.1	Is there a comprehensive preventive and control measures enumerated in the agronomic protocol used for pest management to minimize loss of the final crop and its quality.	A comprehensive pest control procedure should be in place	Major
4.6.2	Is crop protection plans limited to the use of bio-control agents and bio-pesticides?	Biological route is preferred and plans for this should be available	Major
4.6.3	Integrated Pest Management protocols shall be in place in absence of the protocols at 4.6.1 and 4.6.2.	IPM practices are encouraged.	Critical
4.6.4	How under compulsive circumstances care is taken to use smallest effective dosage of pesticides on the basis of crop protection protocols prescribed for the target species	Specialist advice should be available for use of pesticides their dosages, time of application and mode of application	Major
4.6.5	When chemical pesticides are used for crop protection, is residue analysis of final product carried out through appropriate testing agencies following standard procedures?	A written procedure for pesticide use be available defining the dose, time and mode of application to reduce pesticide residue in plant body	Critical
<b>5</b>	<b>Harvest and post harvest management</b>		
5.1	Harvesting		
5.1.1	How the harvesting season is determined and followed on the basis of qualitative parameters set for the end product of the constituents rather than the total vegetative yield?	The grower must demonstrate the basis for determining the maturity of crop for harvesting	Major
5.1.2	How are cutting devices employed for harvesting selected to minimize the contamination by soil particles? How while harvesting, care is taken to avoid incidental and concurrent harvest of weeds?	Clear instruction should be available for farm worker to use proper cutting devices and avoid harvest of rogue plants	Major
5.1.3	How are the containers used for harvested materials kept clean? How care is taken to ensure freedom from the risks of cross contamination by other species, weeds and such other extraneous matter?	A documented procedure should exist for cleaning containers and avoiding mixed up and contamination of produce	Major

Parameters	Control criteria	Compliance criteria	Level of compliance
5.2	<b>Primary processing</b>		
5.2.1	Are the washing and cleaning methods for freshly harvested materials laid down in consideration of the target plant part?	The procedure for this purpose should be present to ensure removal of soil particles adhering to the materials.	Critical
5.2.2	Is the freshly harvested materials not be stored as such and the drying process initiated in a continuum? How is the length of storage minimized and handled in a manner to prevent degradation or rotting?	Proper drying techniques and technology be adopted for drying and storage of harvested medicinal plant material	Critical
5.2.3	How processing yards or sites are kept clean, well ventilated, and have the facilities for protection against sunlight, dust, rain, rodents, insects and livestock?.	Processing yard must be clean preferable pucca platform with proper shade	Major
5.2.4	Are the drying procedure and the temperature employed for this purpose in conformity with the quality needs of the farm produce?	It should be ensured that agronomic package prescribing specific procedures for this phase is complied with. In high humidity conditions, it may be necessary to dry the produce appropriately	Critical
5.2.5	Whether sorting procedure is carried out after completion of drying phase and before the material is packed?	Proper instruction for sorting should be in place and it should be done after drying and before packing	Major
<b>5.3</b>	<b>Packaging, storage and transportation</b>		
5.3.1	Is the selection of packaging material based on the quality requirements and possible length of storage before consumption and kept clean, dry and undamaged?	Norms for packaging material should be fixed for different types of crop produce	Major
5.3.2	While packaging, are mechanical damages and undue compacting of the dried plant material that may result in undesirable quality changes avoided? Is care taken to avoid overfilling of the containers?	Proper norms be in place to define packaging practices to avoid damage or deterioration of the packed material	Major
5.3.3	Is the storage area kept dry and protected from insects and rodents and such other factors that may be detrimental to the quality of the product?.	Storage area must be kept clean and free from insect pests	Major
5.3.4	Are organic herbs stored separately from the non-organic products?	Practices for separating organic and nonorganic herbs be clear to handlers	Major
5.3.5	When multiple commodities are handled in the same storage area, is care exercised to prevent product mix up and cross contamination.	Proper segregation be exercised to keep different products separate to avoid mix up	Minor
5.3.6	Are plant materials having strong aromatic compounds kept at a reasonably away from others?	High aromatic plant material is segregated from other material & stored at reasonable distance	Minor
<b>6</b>	<b>IDENTIFICATION AND TRACEABILITY</b>		
6.1	<b>Identification</b>		
6.1.1	Are packs legibly labeled inscribing on every	Each pack must be legibly	Major

Parameters	Control criteria	Compliance criteria	Level of compliance
	pack with the product name, plant part, month and year of harvest and the name of farmer/farming agency? If the material was tested before, an appropriate label may be used indicating quality approval	marked with details following trade practices/legal requirements	
6.2	<b>Traceability</b>		
6.2.1	Is registered product traceable back to and trackable from the registered farm (and other relevant registered areas) where it has been grown?	There is a documented identification and traceability system that allows registered product to be traced back to the registered farm and tracked forward to the immediate customer. Harvest information must link a batch to the production records or the farms of specific producers.	Critical
7	<b>PERSONNEL AND EQUIPMENT</b>		
7.1	Key resource persons engaged at the site (such as farm owner/ supervisor) must be conversant with all aspects related to the target crop such as, quality requirements of the end product, crop husbandry etc.	Personnel should be trained and training records must be available	Major
7.2	The personnel should have basic exposure to subject matters like safety and hygiene	Special training on safety should be imparted to personnel	Major
7.3	The machinery used in fertilizer and pesticide application must be calibrated at prescribed schedules and calibration certificates / records should be maintained.	Calibration schedule should be available and calibration record in line with the schedule from the weights and measures or from an accredited calibration agency	Major
7.4	Equipments must be clean and mounted where applicable, in an easily accessible manner. Scheduled servicing procedures must be adhered to keep them in working order	Equipment and machinery used should have maintenance schedule	Major
7.5	Additional care should be taken for cleaning those machine parts that get into direct contact with the harvested medicinal plant	Special care should be taken for equipment that comes directly in contact with plant material	Major
7.6	The material used for the equipment, particularly that coming into direct contact, should be safe. Equipments that pose a risk of hazardous metallic contamination of the harvested crop should be avoided	Quality of material for equipment should of such that it does not contaminate plant material in contact with it	Critical
8	<b>WORKERS HEALTH, SAFETY AND WELFARE</b>		
8.1	<b>Risk Assessments</b>		
8.1.1	Does the farm have a written risk assessment for safe and healthy working conditions?	The written risk assessment can be a generic one but it must be appropriate for conditions on the farm. The risk assessment must be reviewed and updated when changes in the organisation.	Major
8.1.2	Does the farm have a written health, safety and	The health, safety and hygiene	Major

Parameters	Control criteria	Compliance criteria	Level of compliance
	hygiene policy and procedures?	policy must at least include the points identified in the risk assessment. This could include accident and emergency procedures, hygiene procedures, dealing with any identified risks in the working situation, etc. The policy must be reviewed and updated when the risk assessment changes.	
8.2	<b>Training</b>		
8.2.1	Do all workers handling and/or administering plant chemicals, disinfectants, plant protection products, biocides or other hazardous substances and all workers operating dangerous or complex equipment have certificates of competence, and/or details of other such qualifications?	Records must identify workers who carry out such tasks, and show certificates of training or proof of competence.	Major
8.2.2	Have all workers received adequate health and safety training and are they instructed according to the risk assessment?	Workers can demonstrate competency in responsibilities and tasks through visual observation. If at time of inspection there are no activities, there must be evidence of instructions.	Major
8.2.3	Is there always an appropriate number of persons (at least one person) trained in first aid present on each farm whenever on-farm activities are being carried out?	There is always at least one person trained in First Aid present on the farm whenever on-farm activities are being carried out.	Major
8.3	<b>Hazards and First Aid</b>		
8.3.1	Do accident and emergency procedures exist; are they visually displayed and communicated to all persons associated with the farm activities?	Permanent accident procedures must be clearly displayed in accessible, and visible location(s). These instructions are available in the predominant language(s) of the workforce and/or pictograms. The procedures must identify, where appropriate the following: - farm's map reference or farm address - contact person(s) - location of the nearest means of communication (telephone, radio) - an up-to-date list of relevant phone numbers (police, ambulance, hospital, fire-brigade, access to emergency health care on site or by means of transport, electricity and water supplier); - how and where to contact the local medical services, Hospital and other emergency services.	Major

Parameters	Control criteria	Compliance criteria	Level of compliance
		<ul style="list-style-type: none"> <li>- location of fire extinguisher;</li> <li>- emergency exits;</li> <li>- emergency cut-offs for electricity, gas and water supplies.</li> <li>- how to report accidents or dangerous incidents.</li> </ul>	
8.3.2	Are potential hazards clearly identified by warning signs and placed where appropriate?	Permanent and legible signs must indicate potential hazards, e.g.waste pits, fuel tanks, workshops, access doors of the plant protection product / fertiliser / any other chemical storage facilities as well as the treated crop etc. Warning signs must be present.	Minor
8.4	<b>Protective Clothing/Equipment</b>		
	Are workers (including subcontractors) equipped with suitable protective clothing in accordance with legal requirements and/or label instructions or as authorized by a competent authority?	Complete sets of protective clothing, (e.g. rubber boots, waterproof clothing, protective overalls, rubber gloves, face masks, etc.) which enable label instructions and/or legal requirements and/or requirements as authorized by a competent authority to be complied with are available, used and in a good state of repair.	Major
9	<b>RECORD KEEPING AND INTERNAL SELF-ASSESSMENT/ INTERNAL INSPECTION</b>		
9.1	Are all records requested during the external inspection accessible and kept for a minimum period of time of two years, unless a longer requirement is stated in specific control points?	Producers keep up to date records for a minimum of two years from the date of first inspection, unless legally required to do so for a longer period.	Major
9.2	Does the producer take responsibility to undertake a minimum of one internal self-assessment per year against the requirements of this standard?	There is documentary evidence that internal self-assessment under responsibility of the producer has been carried out and are recorded annually	Major
9.3	Are effective corrective actions taken as a result of non-conformances detected during the internal self-assessment ?	Effective corrective actions are documented and have been implemented.	Major

**TABLE 02 CHECKLISTS FOR SELF-ASSESSMENT**

Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
1	<b>SITE SELECTION</b>				
1.1	Is site free from toxic elements such as industrial wastes and effluents?	Major			
1.2	Are the sites in proximity to graveyards, crematoria or having a traceable history of such usage.	Minor			
1.3	Is the site having access to reliable source of irrigation water (where applicable/relevant)?	Major			
1.4	Has a management plan been developed setting out strategies to minimize all identified risks in respect of parameter at 1.1 to 1.2? Are the results of this analysis recorded and used to justify that the site in question is suitable?	Major			
1.5	Has the meteorological data collated for preceding three years taken into account while judging the suitability of the site.	Minor			
2	<b>SOIL CONDITIONS</b>				
2.1	Has the soil map prepared for the farm	Major			
2.2	Is the soil optimal to the selected crop with reference to its water holding capacity and fertility?	Major			
2.3	If soils with low fertility levels use soil amendments as per the specific site and requirement of species, are the latest soil test report on physico-chemical parameters and nutrient profile to decide the nature and quantity of soil amendments available?	Major			
2.4	Has the quality of irrigation water been adequately understood and classified in the context of both soil type and the target crop in terms of total salt concentration, Sodium absorption ratio, Bicarbonate and Boron concentration etc.	Major			
2.5	Irrigation water is required to conform to standards of micro pollutants [disinfection by-products (DBPs), endocrine disrupting chemicals, antibiotics, polymers, pesticides and other bioactive chemicals], heavy metals and residual pesticides) if the water source is vulnerable like canal water etc.?	Major			
2.6	When shade-loving crop is planned for, availability of shade across the field should be ascertained.	Major			
3	<b>SEEDS AND PROPAGATION MATERIAL</b>				
3.1	Do seed/planting material accompanied with the following information:- a) Name (pharmacopoeial nomenclature and trade name) b) Botanical name c) Cultivar/Selection / Phenotype/ Chemotype / Genotype (If applicable)?	Critical			
3.2	Is marker based analytical projection for the end-product is mandatory requirement when the crop is meant for phyto-pharmaceutical industries?.	Major			
3.3	When the planting material is obtained from wild resources, are efforts made to establish its correct identity? Is planting material obtained from a authorized source?	Major			
3.4	Does the producer keep records on sowing/planting methods, seed/planting rate, sowing/planting date?	Major			

Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
3.5	<b>Seed</b>				
3.5.1	The seeds chosen for cultivation purposes must meet the botanical and varietal purity.	Critical			
3.5.2	Are the seeds chosen for cultivation purposes physically free from pests, diseases, weeds, and foreign and inert matter?	Critical			
3.5.3	Does the producer keep records on sowing/ planting methods, seed/planting rate, sowing /planting date?	Major			
3.5.4	Are the seed collected from recently collected lots and are mature seeds in case seeds are collected from wild source?	Major			
3.5.5	Are prescribed seed treatment protocols for the target species, completed well in advance to match the planting season.	Major			
3.5.6	When the process for seedling production under nursery conditions, is it initiated as per the recommended agronomic practices for the target species and carried out reasonably well before the actual schedule of field transplantation and only healthy seedlings transplanted.	Major			
<b>3.6</b>	<b>Stem cutting</b>				
3.6.1	Are sources of cuttings authenticated when root induction in stem cuttings under nursery conditions for transplantation into the field for both botanical identity and quality of vegetative propagules?	Critical			
3.6.2	Are only healthy stem cutting giving desired rooting used?	Major			
<b>3.7</b>	<b>Root cutting</b>				
3.7.1	Are ‘ready-to-transplant saplings’ or root cuttings of uniform size and maturity, both in terms of aerial and underground parts, and free from any disease and infection used?	Critical			
4	<b>CROP MANAGEMENT FOR CULTIVATION</b>				
4.1	<b>Field preparation</b>				
4.1.1	Is soil brought to the desired tilth to facilitate favourable environment for growing seed and seedling?	Major			
4.1.2	Do field operation performed provide better rhizospheric environment, soil structure and texture, and keep it free from weeds for initial 20-30 days?	Major			
4.2	<b>Sowing and transplanting</b>				
4.2.1	Are recommended rate of seedlings per unit of land area adhered to?	Minor			
4.2.2	Is placement of seeds taking place at the appropriate depth in the moist zone of the soil?	Major			
4.2.3	Are saplings where used transplanted following the spacing norms in terms of row-to-row and plant-to-plant distance governed by the needs of target crop as envisaged in the agronomic protocol for target species?	Minor			
4.2.4	Are the seedling at optimum stage of transplanting uprooted and transplanted immediately thereafter?	Major			
4.2.5	Replenishment of plant populations to compensate mortality losses should be carried out within a reasonable timeframe and in consideration of the gestation period of the target crop.	Minor			
4.2.6	Is there a document that guarantees seed quality (free from	Minor			



Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
	injurious pests, diseases, virus, etc.)?)				
<b>4.3</b>	<b>Manures and Fertilizers</b>				
4.3.1	Source of information/material about manures and fertilizers used  Parameters used to accept or qualify the manure in case source is from outside.	Major			
4.3.2	Is use of organic manure preferred for growing medicinal plants supplemented by mineral nutrition through inorganic source in consideration of the nutritional needs of the target crop vis-à-vis the soil characteristics?	Minor			
4.3.3	Is use of compost, vermi-compost, green leafy manure and biofertilizers considered desirable?	Minor			
4.3.4	Are specialized nutritional care for distinct purposes such as root production or enhancement of leafy bio-mass etc opted for in the light of recommended agronomic practices for target species?	Major			
<b>4.4</b>	<b>Irrigation</b>				
4.4.1	How is the total water requirement of the crop estimated in the light of available agronomic protocol? How the irrigation cycles is planned for and implemented to ensure optimal plant growth.	Major			
4.4.2	Is there a water management plan to optimise water usage and reduce waste in terms of method of irrigation?	Major			
4.4.3	How water harvesting and water conservation methods are followed, wherever possible	Minor			
4.4.4	Is the quality of water considered in the light of prevailing soil conditions and soil and water analysis taken into account for this purpose.	Major			
4.4.5	How soils having the problem of drainage are dealt with in specific manner so as to provide outlet for excess water?	Major			
<b>4.5</b>	<b>Weeding and inter-cultural operations</b>				
4.5.1	How initial flush of weeds are controlled effectively to ensure a weed free environment to young plants?.	Major			
4.5.2	Is the prescribed schedule of all inter-cultural operations such as weeding, hoeing, topping, nipping of buds, pruning, shading and earthing up etc. adhered to in a manner to optimize overall productivity.	Major			
4.5.3	Are use of herbicides avoided as far as possible? In case of their inevitable usage, are available evidence of safety to the target crop considered adequately?	Major			
<b>4.6</b>	<b>Crop protection</b>				
4.6.1	Is there a comprehensive preventive and control measures enumerated in the agronomic protocol used for pest management to minimize loss of the final crop and its quality.	Major			
4.6.2	Is crop protection plans limited to the use of bio-control agents and bio-pesticides?	Major			
4.6.3	Integrated Pest Management protocols shall be in place in absence	Critical			

Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
	of the protocols at 4.6.1 and 4.6.2.				
4.6.4	How under compulsive circumstances care is taken to use smallest effective dosage of pesticides on the basis of crop protection protocols prescribed for the target species	Major			
4.6.5	When chemical pesticides are used for crop protection, is residue analysis of final product carried out through appropriate testing agencies following standard procedures?	Critical			
<b>5</b>	<b>Harvest and post harvest management</b>				
5.1	Harvesting				
5.1.1	How the harvesting season is determined and followed on the basis of qualitative parameters set for the end product of the constituents rather than the total vegetative yield?	Major			
5.1.2	How are cutting devices employed for harvesting selected to minimize the contamination by soil particles? How while harvesting, care is taken to avoid incidental and concurrent harvest of weeds?	Major			
5.1.3	How are the containers used for harvested materials kept clean? How care is taken to ensure freedom from the risks of cross contamination by other species, weeds and such other extraneous matter?	Major			
5.2	<b>Primary processing</b>				
5.2.1	Are the washing and cleaning methods for freshly harvested materials laid down in consideration of the target plant part?	Critical			
5.2.2	Is the freshly harvested materials not be stored as such and the drying process initiated in a continuum? How is the length of storage minimized and handled in a manner to prevent degradation or rotting?	Critical			
5.2.3	How processing yards or sites are kept clean, well ventilated, and have the facilities for protection against sunlight, dust, rain, rodents, insects and livestock?.	Major			
5.2.4	Are the drying procedure and the temperature employed for this purpose in conformity with the quality needs of the farm produce?	Critical			
5.2.5	Whether sorting procedure is carried out after completion of drying phase and before the material is packed?	Major			
<b>5.3</b>	<b>Packaging, storage and transportation</b>				
5.3.1	Is the selection of packaging material based on the quality requirements and possible length of storage before consumption and kept clean, dry and undamaged?	Major			
5.3.2	While packaging, are mechanical damages and undue compacting of the dried plant material that may result in undesirable quality changes avoided? Is care taken to avoid overfilling of the containers?	Major			
5.3.3	Is the storage area kept dry and protected from insects and rodents and such other factors that may be detrimental to the quality of the product?.	Major			
5.3.4	Are organic herbs stored separately from the non-organic products?	Major			
5.3.5	When multiple commodities are handled in the same storage area,	Minor			

Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
	is care exercised to prevent product mix up and cross contamination.				
5.3.6	Are plant materials having strong aromatic compounds kept at a reasonably away from others?	Minor			
<b>6</b>	<b>IDENTIFICATION AND TRACEABILITY</b>				
6.1	<b>Identification</b>				
6.1.1	Are packs legibly labeled inscribing on every pack with the product name, plant part, month and year of harvest and the name of farmer/farming agency? If the material was tested before, an appropriate label may be used indicating quality approval	Major			
6.2	<b>Traceability</b>				
6.2.1	Is registered product traceable back to and trackable from the registered farm (and other relevant registered areas) where it has been grown?	Critical			
7	<b>PERSONNEL AND EQUIPMENT</b>				
7.1	Key resource persons engaged at the site (such as farm owner/ supervisor) must be conversant with all aspects related to the target crop such as, quality requirements of the end product, crop husbandry etc.	Major			
7.2	The personnel should have basic exposure to subject matters like safety and hygiene	Major			
7.3	The machinery used in fertilizer and pesticide application must be calibrated at prescribed schedules and calibration certificates / records should be maintained.	Major			
7.4	Equipments must be clean and mounted where applicable, in an easily accessible manner. Scheduled servicing procedures must be adhered to keep them in working order	Major			
7.5	Additional care should be taken for cleaning those machine parts that get into direct contact with the harvested medicinal plant	Major			
7.6	The material used for the equipment, particularly that coming into direct contact, should be safe. Equipments that pose a risk of hazardous metallic contamination of the harvested crop should be avoided	Critical			
8	<b>WORKERS HEALTH, SAFETY AND WELFARE</b>				
8.1	<b>Risk Assessments</b>				
8.1.1	Does the farm have a written risk assessment for safe and healthy working conditions?	Major			
8.1.2	Does the farm have a written health, safety and hygiene policy and procedures?	Major			
8.2	<b>Training</b>				
8.2.1	Do all workers handling and/or administering plant chemicals, disinfectants, plant protection products, biocides or other hazardous substances and all workers operating dangerous or complex equipment have certificates of competence, and/or details of other such qualifications?	Major			
8.2.2	Have all workers received adequate health and safety training and	Major			

Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
	are they instructed according to the risk assessment?				
8.2.3	Is there always an appropriate number of persons (at least one person) trained in first aid present on each farm whenever on-farm activities are being carried out?	Major			
<b>8.3</b>	<b>Hazards and First Aid</b>				
8.3.1	Do accident and emergency procedures exist; are they visually displayed and communicated to all persons associated with the farm activities?	Major			
8.3.2	Are potential hazards clearly identified by warning signs and placed where appropriate?	Minor			
8.4	<b>Protective Clothing/Equipment</b>				
	Are workers (including subcontractors) equipped with suitable protective clothing in accordance with legal requirements and/or label instructions or as authorized by a competent authority?	Major			
9	<b>RECORD KEEPING AND INTERNAL SELF-ASSESSMENT/ INTERNAL INSPECTION</b>				
9.1	Are all records requested during the external inspection accessible and kept for a minimum period of time of two years, unless a longer requirement is stated in specific control points?	Major			
9.2	Does the producer take responsibility to undertake a minimum of one internal self-assessment per year against the requirements of this standard?	Major			
9.3	Are effective corrective actions taken as a result of non-conformances detected during the internal self-assessment ?	Major			

## TERMINOLOGY

- Chemotype** : It is a chemically distinct entity in a plant or organism, with differences in the chemical constituents.
- or
- Phenotypically similar species i.e. indistinguishable morphological, when distinguished through chemical constituents are called chemotype
- or
- Plants of the same species that is chemically different but otherwise indistinguishable.
- Genotype** : The genetic constitution (the genome) of a cell, an individual or an organism.
- or
- Phenotypically dissimilar species with minor mutation when identify through DNA profiling or genotypes.
- Irrigation** : The application of water to soil to assist in the production of crops, especially during stress periods.
- Irrigation water** : Water which is artificially applied in the process of irrigation. It does not include precipitation.
- Inter crop** : The crops raised in an orchard or other widely spaced crops for increasing the income from the same piece of land. e.g. short duration vegetables, pulses, oilseeds etc.
- Inter cropping** : Refers to growing of two or more generally dissimilar crops simultaneously on the same piece of land, base crop necessarily in distinct row arrangement. The recommended optimum plant population of the base crop is suitably combined with appropriate additional plant density of the associated crop, and there is crop intensification in both time and space dimensions.
- Integrated Pest Management** : In agriculture, integrated pest management (IPM) is a pest control strategy that uses a variety of complementary strategies including: mechanical devices, physical devices, genetic, biological, cultural management, and chemical management  
IPM is a sustainable approach to managing pests by combining biological, cultural, mechanical and chemical tools in a way that  
: minimizes economic, health and environmental risks.
- Phenotype** : The physical appearance of an organism as distinguished from its Genetic make- up.
- Ploughing** : Operations carried out with the help of tractor drawn or bullock drawn implements known as plough, before the crops are sown.
- Pollution** : Contamination of natural environment by the addition to air or water of substances potentially toxic or otherwise harmful to man and animals for example, SO<sub>2</sub>, CO<sub>2</sub>, radio-active fall out insecticides etc.

- Rouging** : To remove weeds or off-type or diseased plants from a standing field crop.
- Seedling** : The juvenile stage of a plant grown from seed. Usually indicates plants which have up to and including about 4 true leaves.
- Seed certification** : A means to maintain and make available to the public, sources of high quality seeds and propagating materials of superior varieties so grown and distributed as to insure genetic identity. This is done by means of inspections of fields and seeds and by regulations for checking on the production, harvesting and cleaning of each lot of seed.
- Tillage** : The use of implements for mechanical manipulation to prepare seed beds conducive for field crop production

**A MODEL STRUCTURE FOR DEVELOPING MONOGRAPHS ON GAP FOR INDIVIDUAL SPECIES OF MEDICINAL PLANTS**

**1. Name of medicinal plant**

- a) Scientific name -----
- b) Pharmacopoeial name of the medicinal plant -----
- c) Local name (specify language) -----

**2. Part to be employed as the medicinal plant material**

(Description of the part of the plant used for medicinal purposes)

-----  
-----

**3. Characteristics of the medicinal plant**

(Describe the agro-morphological characters including the key character following standard descriptors and descriptor state.)

-----  
-----

Major production areas of the medicinal plant material should be mentioned

-----

**5. Characteristics of strain(s) for cultivation**

- (1) Taxonomical identity -----
- (2) Ecological characteristics -----
- (3) Major chemical compound responsible for drug value along with chemical profile -----
- (4) Preferred growing conditions -----
  - a) Climatic conditions -----  
(Rain fall, Temperature and Daylight length)
  - b) Soil conditions -----  
Soil type -----

Soil condition (pH; Water retention capacity; nutrient status as per soil test report etc.)

- c) Shade requirements, if any. -----

**2. Cultivation methods**

- (1) *Propagation methods* -----  
-----
- (2) *Cultivation*
  - a) Suitable cultivation conditions:
  - b) Propagation
  - c) Sowing
  - d) Planting/nursery

- e) Manures & fertilizers including microbial fertilizers
- f) Crop management
- g) Diseases and pests management
- h) Harvesting stage, time & procedures
- i) Post harvest handling & processing
- j) Expected yield with desired quality

**7. Quality evaluation of the medicinal plant material**

- (1) *National quality standard of the medicinal plant material*  
(Defined as the quality and quantity standard)
- (2) *Name of major chemical/ chemicals constituents and its percentage*
- (3) *Chemical structure of selected major constituents*
- (4) *Chemical profile, if known*

**8. Comparative summary table of the characteristics of different cultivated strains, if any**

Morphological characteristics of each strain chemotype, morphotype etc. being cultivated, including height, growth, morphology/shape of root, stem, leaf, flower, fruit and 'seed, resistance/tolerance to diseases/pests, and composition and quantitative indications of major chemical constituents of the medicinal plant.

**9. Cultivation calendar**

A tabulated schedule of cultivation practices whichever to be followed indicating the type of care and management work/ actions and their timing during the entire growing period.

**10. Background data and other information**

- (1) *Source of seed, propagation material, etc*  
-----

To assess the appropriateness/suitability of cultivation and characteristics of seed/ propagation material. Cultivation should be carried out according to the recommended cultivation practices.

- (2) *Photographs (3-5)*

Plant and plant part material; also showing working methods/ equipment as appropriate.



## SAMPLE RECORD FOR CULTIVATED MEDICINAL PLANTS

### 1. Identification of cultivated medicinal plant

Scientific name -----  
 Pharmacopoeial name -----  
 Local name (language for) -----  
 Plant part for medicinal use & harvested -----  
 Identification of cultivation site -----  
 Field location -----  
 State/District/Village -----

### 2. Identification of cultivator

Name of cultivator -----  
 Contact address -----  
 Period of cultivation -----

### 3. Seeds and propagation materials

Source of the planted material -----  
 Physical description of the planted material -----  
 Commercially available (circle): Yes/No  
     If yes, name of cultivar----- Name of supplier-----

### 4. Cultivation

#### 4.1 Method of propagation materials establishment (circle): direct seed sowing/transplants

Date of sowing/transplanting----- Percentage emergence-----  
 Date of re-sowing/replanting----- Percentage stand establishment-----

#### 4.2 Spacing

I. Row x Row (cm)-----  
 II. Plant x Plant (cm)----- Covered area (m<sup>2</sup>)-----  
 Number of plants per unit area -----  
 Crop rotation -----  
 Soil and irrigation water analysis as per the standards methods:

#### 4.3 Fertilizers and chemicals (if used)

Fertilizer applied before planting (circle):      organic (composted animal manure)/chemical  
     Name----- Method-----

Time/date (d/m/y) ----- Rate-----

Fertilizer applied after planting (top dressing): organic (composted animal manure)/chemical

Name ----- Method-----

Time/date (d/m/y) ----- Rate -----

**4.4 Herbicides applied before planting, if any**

Name----- Method-----

Time/date (d/m/y) ----- Rate -----

**4.5 Herbicides applied after planting, if any**

Name ----- Method-----

Time/date (d/m/y) ----- Rate -----

**4.6 Special operations done, if any**

Name ----- Method-----

Time/date (d/m/y) ----- Rate -----

**4.7 Plant protection chemicals applied, if any**

Name ----- Method-----

Time/date (d/m/y) ----- Rate -----

**5. Harvest/Collection**

Date of harvest ----- Time of day -----

Conditions ----- Method-----

Yield -----

**6. Drying practices**

Drying method -----

(Sun drying/Shade/Mechanical)

Duration of drying (days) -----

Moisture content (after drying) (%) -----

**7. Unusual circumstances that may influence quality**

(Extreme weather conditions, exposure to hazardous substances, pest outbreaks, etc):

**INFORMATION ON CONTAINER LABEL**

The Label of the container of medicinal produce should bear following information

1. Name of the produce			2. Grade, if any	
3. Quantity		4. Date of Cultivation		
5. Lot No.			6. Lot size	
7. Cultivated at			8. Storage Conditions	
Signature of the Store Manager			Date:	