AFRICAN CONFORMITY ASSESSMENT PROGRAMME

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Certification scheme for medicinal plant produce — Part 1: General requirements

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Foreword

The African Regional Organisation for Standardisation (ARSO) is an African Intergovernmental organization made of Member States of the United Nations Economic Commission for Africa (UNECA) and the African Union (AU). One of the fundamental mandates of ARSO is the establishment of a conformity assessment system to promote the quality of African goods and services as a means of facilitating intra-African trade as well as accessing global markets.

The ARSO Conformity Assessment Programme (ACAP) is supported by a coherent set of documents which are developed under the auspices of the ARSO Conformity Assessment Committee (ARSO CACO) which comprises experts from Member States. Member States participate in the committee on a voluntary basis and the documents developed follow the principles and procedures for the development of African Standards outlined in the African Standards Harmonization Model (ASHAM) with the exception of the stages and voting thresholds. Being conformity assessment instruments, ACAP documents are subject to dynamic adaptations which must timeously respond to changes in the conformity assessment fields.

ACAP documents will be revised on a flexible basis to fit in with changes in global conformity assessment systems.

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Introduction

This certification document seeks to ensure an objective assessment and certification of the medicinal plant produce at the farm or collected in the wild and promote uniformity in its operation and the interaction between the Certification Bodies (CBs), the producer/collector seeking certification.

Certification scheme for medicinal plant produce — Part 1 General requirements

1 Scope

This covers certification of produce of medicinal plants both from Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) in the wild. Producers /collectors can achieve certification under any one of the two options described in this certification procedure.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17011, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 9001, *Quality management systems — Requirements*

ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*

ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*

ISO/IEC 17065, *Conformity assessment — Requirements for bodies certifying products, processes and services*

ISO/IEC 17067, *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

ISO 19011, *Guidelines for auditing management systems*

3 Terms and definitions

For the purpose of this document the terms and definitions in, ARS 950, ARS 951 and ISO/IEC 17000 apply.

4 Certification options and certification body

4.1 Option 1: Individual certification

Individual producer/collector applies for certification and gets certification for his/her produce.

4.2 Option 2: Group certification

A producer/collector group applies for group certification and the producer group, as legal entity, gets certification.

4.3 Certification scope

4.3.1 The Scheme is open to all organizations engaged in GAP and GFCP of medicinal plant produce and are legal entities.

4.3.2 The information on how to obtain certification for medicinal plant produce is also available on the website of ARSO (www.arso-oran.org).

4.3.3 The certification shall be carried out by the Certification Body (CB) duly accredited for the certification scheme as per ISO/IEC 17065. To operate under the Scheme the CBs will require an extension of scope within the accreditation for ISO/IEC 17065.

5 Certification process

5.1 Application for certification

5.1.1 Any producer/collector or group of producers/collectors forming an entity can apply for certification to an approved accredited Certification Body.

5.1.2 All relevant information concerning producers/collectors applying for certification must be recorded for the producer to become registered. This information will be used to supply the registered party with a unique client number, which will be used as a unique identifier for all certification activities.

5.1.3 The information required is consistent with the information of Certification Agreement signed between the producer/collector and the CB. The following information is required for each producer/collector wishing to be registered:

i) Producer/collector to be certified

ii) Annual Area under production/collection,

iii) Covered medicinal produce

iv) First harvest or further harvest

5.1.4 The certification body shall maintain and make publicly available accurate information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates. The information shall include:

a) Reference to the Certification Criteria,

b) procedure for obtaining Certification,

c) an Application form,

d) list of documents required to be submitted along with the application,

e) information on fee for application, initial certification and continuing certification,

f) documents describing the rights and duties of certified clients, and

g) information on procedures for handling complaints and appeals.

5.1.5 The CB shall respond to all enquiries received from prospective applicants for certification with complete information for facilitating a registration of an applicant, within seven days of receipt of the query.

5.1.6 The prospective applicant organization shall apply to the Certification Body on the Application format prescribed by the CB, and provide as a minimum information on the name and address of applicant with contact details, proof of legal entity, location, produce being handled, relevant certification criteria GAP/GFCP against which certification is being sought, Produce handling area and number and competence of manpower.

5.1.7 The prospective applicant shall along with the application declare any judicial proceedings relating to their operations / product, any proceedings by any Regulatory body or suspension / cancellation / withdrawal of any certification / approvals under any Regulations or otherwise.

5.1.8 Certification is granted only against the latest relevant certification criteria GAP/GFCP. The certification body shall review all applications for the above and ensure the same.

5.1.9 All applications for certification shall be reviewed by the certification body for adequacy and deficiencies observed, if any, shall be informed to applicant within seven days of receipt of application. Review of applications shall be done by a competent person. Records of review shall be maintained.

5.1.10 The applications found to be complete and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration should be done within seven days of receipt.

5.1.11 Antecedents of applications shall be verified. If punished under the law, or the earlier product certification had been cancelled, the application from the same organization will not be entertained.

5.1.12 Applications from Organizations who have earlier either misused the Certification Mark, or have been implicated / convicted by the court, or whose earlier certificate was cancelled because of violation of terms & conditions / misuse of certification mark shall not be registered within one years of conviction / strictures by the court / cancellation of the certificate by any CB.

5.1.13 Applications from organizations found to be misusing the Certification Mark while their application is being processed for grant of certificate, shall not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them shall be treated as per clause 5.1.12 given above.

5.1.14 Requests for grant of certificates from ex applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to.

5.1.15 Certification Bodies shall reject or close all Application under the following conditions;

a) If Initial Evaluation is not carried out within six months of registration of application

b) Lack of competent personnel for production and handling,

c) If organizations shows no progress towards completion of corrective actions within three months of Initial Evaluation and six months of Registration of application.

d) Misuse of Certification Mark

e) Evidence of malpractice and

f) Voluntary withdrawal of application.

5.1.16 In the event of a closure/rejection of an Application, the application fee submitted with the application may be refunded as decided by the certification body.

5.2 Certification process

5.2.1 Control Criteria and Compliance Criteria (CCCC)

The Control Criteria and Compliance Criteria (CCCC) checklist (See Annex A & Annex B) based on respective standards shall be used both for internal and external evaluation.

5.2.2 Initial evaluation

5.2.2.1 Initial evaluation shall be carried out in two stages (Stage 1 & Stage 2) by a competent evaluation/audit team.

5.2.2.2 Initial Evaluation of the product and the processes at the site of the applicant shall be conducted within one month of registration of application and/or satisfactory fulfilment of all application requirements.

5.2.2.3 The certification body shall communicate the composition of the teams and duration of Initial Evaluation to the applicant for verifying any conflict of interest and any objections to the team composition by the applicant should be examined on merit.

5.2.2.4 Timings and date of Initial Evaluation shall be fixed with the consent of the applicant ensuring that processes such as harvesting time representative of normal operations will be open for witnessing during the planned Evaluations:

a) Inspection timings

i) The inspection of a producer/collector takes place after registration with the CB depending on the produce to be inspected. The ideal timing for inspecting all control criteria shall be when sufficient records/evidence is available during harvest time, especially to facilitate verification of the control points related to harvest.

ii) Alternative timing options may be followed where inspection during harvest time is not possible. The first inspection therefore takes place before or after harvest. Justification for alternative timing may be logistics and time constraints of producer/collector and inspector, variation in harvest dates, perennial crop not yet producing mature produce, etc. Practically, inspection of records and visual evidence requires that the inspection must take place as close to harvest as possible, for the evaluators to verify as many control points as possible.

b) First Inspection Timing for Multiple produce Certification

i) The producer/collector may be seeking certification for more than one produce, and the produce may not all have the same seasonal timing, i.e. harvest of one produce does not necessarily coincide with the harvest of other produce,

ii) Where the crops to be included in the certification scope are concurrent, i.e. harvested at the same time, then the first inspection will be timed so that the principal crop can be inspected as close to harvest as possible, making an assumption that the other crops will be compliant to the same degree,

iii) Where the crops to be included in the certification scope are consecutive, i.e. the production of one crop finalises before the production of the next one commences, then in the first year a full inspection of the first crop must be made during harvesting. Subsequent crops grown in that same first year can be added to the certificate only when compliance has been verified for each crop, either through a site inspection at harvest of each crop or through data collection and discussion with the applicant

5.2.2.5 During the Stage 1 evaluation the certification body shall check the applicant's state of preparedness for the Stage 2 evaluation, and availability of competent personnel and adequate records of producers/ collectors on CCCC.

5.2.2.6 Deficiencies observed with respect to the certification criteria during the Stage 1 evaluation shall be informed in writing to the applicant.

5.2.2.7 The Stage 2 evaluation by certification body shall take place only after necessary actions on the identified deficiencies have been taken and confirmed by applicant. The CB may seek documentary evidence or organize an onsite visit, if necessary, to verify the implementation of corrective actions.

5.2.2.8 During the Stage 2 evaluation of the applicant, the team shall witness the processes covering as many CCCC as possible keeping in view 5.2.2.4. Any nonconformity observed during Stage 2 evaluation with respect to the conformance criteria shall be informed in writing to the applicant for taking necessary action. The nonconformities shall be classified as Critical, major or minor depending on their severity as defined in the respective standards. In case of group certification, selection of producers is made by taking a random sample that, as a minimum, is the square root of the total number of registered producers within the producer group. For the first inspection, the square root of the producers in a producer group must be inspected in full by the CB. If Producer Group X has 25 registered members, and the CB sets the square root as the sample, 5 producers ($\sqrt{25}$) must be inspected at this first inspection.

A representative sample would be drawn for testing in an independent laboratory. Since there would be several types of produce and with varietal differences, efforts should be made to cover most of the produce during a certification cycle.

5.2.3 Compliance levels for certification

The producer is required to comply with three types of compliance criteria set out in the GAP/GFCP standard besides the plant requirements as set out in API in order to obtain certification. These are Critical, Major and Minor, which must be fulfilled in all respects before certification.

5.2.3.1 Compliance Verification and Comments

Compliance is indicated with a “Yes” (for compliant), “No” (for not compliant) on the checklist (See Annex A & Annex B). Evidence/comments should be provided for each control criteria- these shall enable the audit trail to be reviewed after the event, and will include details of references taken during the inspection. It is, however, obligatory to give evidence /comments for all the critical and major compliance criteria inspected/audited in all external inspections, self-assessments, and internal inspections.

5.2.3.2 Certification Body shall maintain records of all certification activities—application registration, documents provided by applicant, on site evaluation report.

5.2.4 Internal quality assurance

5.2.4.1 Individual producer/collector

The internal self-assessment must be carried out at least once a year. This self-assessment will be carried out under the responsibility of the producer/collector.

The self-assessment shall be against the complete checklist (Critical, Major and Minor) of the applicable scope(s). The completed checklist must be available on site for review by the evaluator during the external evaluation.

5.2.4.2 Producer/collector Group

A minimum of one internal inspection per annum of each registered producer within the producer group must be carried out by qualified internal producer group inspectors within the producer group or subcontracted to an external verification body, different from the certification body responsible for the external certification inspections of the group. The internal inspection shall be based on the complete checklist (Critical, Major and Minor) of the applicable scope(s).

In certification all the farms group shall be audited once in each cycle.

5.3 Grant of certification

5.3.1 Validity of certification

The validity of the certificate will be 3 years subject to any suspensions and extensions in accordance with the scope described. A certificate cannot be issued with a validity period of less than 3 years.

5.3.2 Brand name

A Brand Name declaration shall be obtained from the applicant indicating the Brand names the producer/collector intends to use on produce covered under the Certification Scheme. The applicant shall have to provide proof of ownership of the Brand name, and to facilitate any product recall if such a situation were ever to arise during the operation of the certification of scheme.

5.3.3 Scope of certification

The product scope is linked to the location where that product is produced. Certificate is issued to the registered producer/collector, on the farms/in wild where the products are produced and for the products declared. The legal entity of the places certified must be declared by the certificate holder.

The entire production/ collection process of the declared and registered produce must comply with requirements. Certified locations cannot be separated into growing areas or handling facilities that are certified and other growing areas or handling facilities of the same product that are excluded from certification.

5.3.4 The certification Body shall grant certification after ensuring complete compliance to the Certification Criteria (GAP/GFCP), certification scheme requirements, conformance to product requirements and satisfactory resolution of nonconformities raised. There shall be no conditional grant of certification.

5.3.5 On grant of certification, the Certification body shall inform the organization and issue a Certificate, uniquely identified, to the organization indicating the names of the produce certified, the certification criteria against which the certification has been awarded, effective date, validity date, and the name and address of the organization site where certified as a minimum.

5.3.6 No Brand names shall be mentioned on the Certificate document or any other document intimating grant of certification.

5.3.7 The effective date of certification shall not be before the date of decision to grant the certification to the organization.

5.3.8 The certificate for produce certification shall be for a maximum period of 3 years from the date of decision to grant the produce certification.

5.4 Surveillance evaluation

5.4.1 Surveillance evaluations of the certified sites shall be carried out at least once a year, ensuring that the gap between two surveillance evaluations does not exceed one year. The Certification Body may allow a grace period of one month based on valid grounds beyond which delays shall lead to suspension of the certificate.

5.4.2 The full checklist and verification process must be completed by the inspector annually. There must be at least one produce registered in the field or in the storage evaluated to give the CB confidence that any other registered crops not present at that time, are handled in compliance with the standard.

5.4.3 The certification body shall ensure that basic operations and their controls are witnessed during the surveillance evaluation. Surveillance planning must keep in view the crop maturity timings to coincide visit with harvest time as for as possible (See 5.2.24).

5.4.3 In case where the organization is certified to a number of produce of different types under the same certificate, certification body shall plan for surveillance evaluation with a view to covering as much of the entire range of medicinal plant produce during the certification period.

5.4.4 During the surveillance evaluation, the evaluators shall as a minimum check and report on the following;

a) Status of compliance to the requirements of the certification criteria,

b) Internal inspection/audit,

c) Handling and disposal of nonconforming products,

d) Drawing samples for testing in independent laboratory

e) Actions taken on nonconformities observed during the previous evaluation,

f) Redressal of complaints if any,

g) Information on production of produce and the names of consignees to whom certified produce have been supplied.

5.4.5 If any nonconformity is observed, the same shall be categorized as either a Critical, Major or Minor. The nonconformity report shall be provided to the client in writing, generally on site, for correction and corrective action. Details of the same shall be reported in the Surveillance evaluation report.

5.4.6 The certification body may increase or decrease the frequency of surveillance evaluation based on the performance of the organization.

5.4.8 If the surveillance evaluation results in an in fructuous visit due to any reason, the CB shall conduct another surveillance evaluation. Such additional evaluations may be charged to the certified unit as decided by the Certification Body.

5.5 Market samples

5.5.1 Samples of certified produce shall be purchased from the market or procured from organized consumers and tested in independent laboratories for ascertaining compliance to requirements of the Certification Criteria.

5.5.2 The certification body shall draw a minimum of 2 samples from the market for each client in a year.

5.5.3 In case where the unit is certified to a number of produce of different types under the same certificate, certification body shall attempt to draw the market samples in a manner so that practically the entire range is covered in sampling within a certification cycle.

5.5.4 Market samples shall be drawn in the original packaging, where practicable and produce integrity shall be ensured by the certification body.

5.5.5 Failure of sample of certified produce, drawn from the market, to comply with criteria requirements shall be communicated to the certified unit for investigation, root cause analysis and proposed corrective actions within 15 days of intimation. The CB shall respond to the proposed corrective actions within 5 days and the producer shall implement the corrective actions within one month from acceptance of the corrective actions by the CB.

5.5.6 Depending on the nature of the failure reported, the CB shall decide on one or any of the following;

a) Draw additional samples of the produce around the same time from the market,

b) Organize for an additional surveillance evaluation immediately,

c) Increase the frequency of surveillance evaluation,

d) Increase the number of market samples.

The manufacturer shall be informed of the decision taken.

5.5.7 When there is repetitive failure of the sample, the CB shall suspend the certification, till adequate and effective corrective actions are taken (See 5.6).

5.6 Suspension of certification

5.6.1 The certification body shall issue due notice of at least one week for suspension of certification to the unit. In case of serious failures, the notice may not be required.

5.6.2 A Suspension is issued when:

a) two consecutive samples , from the market fail to conform to the requirements of the criteria,

b) Unsatisfactory performance during two consecutive Surveillance evaluations on account of any of these aspects is observed:

   i) Failure of sample in independent testing,

   ii) Non implementation of Internal Quality Assurance Protocol,

   iii) producer cannot show sufficient corrective action on nonconformities raised.

c) A suspension may also be issued to the producer who voluntarily asks for it, for some (partial) or all (complete) of his products.

5.6.3 After the Suspension is issued, a time period allowed for correction and corrective action will be set by the CB not exceeding 6 months. If the suspension is voluntary, the period for corrections and corrective actions is set by the producer/collector himself, which must be agreed upon with the CB, but not exceed 6 months.

5.6.4 A Partial Suspension may be issued to the group whereby one producer is suspended and not the whole group. A nonconformity is detected at one producer in a producer group, and after the CB having investigated by increasing the sample size to determine the seriousness of the nonconformities within the producer group, decided that the one producer is noncompliant.

5.6.5 During the period of suspension, the producer will be prevented from using the logo/trademark, Licence/certificate or any other type of document that has any relation to certification.

5.6.6 The producer/collector unit shall be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.

5.6.7 The certification body shall revoke suspension only when corrective actions have been taken and verified by the certification body.

5.6.8 Suspension shall not exceed a period of six months. If the cause of the Suspension is not resolved within the time period set, the certification shall be cancelled.

5.7 Cancellation of certification

5.7.1 A Cancellation shall be issued when:

a) A producer cannot show sufficient corrective action after a Partial or Complete Suspension has been issued and six months have elapsed,

b) A nonconformity in one scope leads to doubt about the integrity of the produce,

c) When major contractual nonconformities are detected.

d) Certified unit contravenes the terms and conditions of certification and provisions of certification scheme like suspension of certificate, inadequate corrective actions, lack of compliance to criteria for Certification etc

5.7.2 A Cancellation of the contract will result in the total prohibition of the use of the logo/trademark, Licence/certificate.

5.7.3 A producer that has had a Cancellation applied may not re-submit for certification until 12 months after the date of Cancellation.

5.7.4 The producer must either resolve the nonconformities communicated or appeal to the CB in writing against the nonconformities explaining the reasons for the appeal.

5.7.5 Certification body shall cancel the certification at the request of the certified unit, if the operation(s) in the certified units premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.

5.8 Recertification

5.8.1 The certification body shall send the recertification notice to the certified units at least four months prior to expiry of certificate validity period.

5.8.2 The certified organization shall apply for recertification in the prescribed format along with fee, if any prescribed by the CB at least 3 months before expiry of the certification.

5.8.3 The certification body shall review the performance of the certified unit who has sought recertification of the Certificate, with respect to compliance to certification criteria during the certification cycle the period of validity of the certificate, prior to a decision on the recertification of the certificate.

5.8.4 The review shall be based on:

a) The surveillance evaluation reports,

b) Handling and disposition of nonconforming products,

c) Any suspension of certificate during the previous validity period,

d) Corrective actions taken,

e) Complaints, if any received, and

f) Adverse information, if any.

5.8.5 Recertification of certificate shall be based on the satisfactory performance of the certified units.

5.8.6 The certification Body shall not recertify with conditions for compliance to be verified subsequently. There shall be no conditional recertification of certification.

5.8.7 When performance of the certified units is not satisfactory, the certification body shall withhold the recertification of the certificate to the certified organization clearly stating the reasons and give time for effecting corrective actions. The verification and decision on recertification should be taken within 3 months of the expiry date.

5.8.8 The corrective actions shall be verified generally on site unless the CB can verify the same off site prior to considering for recertification.

5.8.9 The recertification shall be affected from the date of the expiry of the previous certificate and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The certified unit shall not claim certification or use the Certification during this period.

5.8.10 In case the certified unit does not complete satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.

5.9 Change of location / Ownership / Name

5.9.1 The certified Unit shall inform the CB of any change in the location of its operations.

5.9.2 The certified unit shall be subject to an evaluation at the new site like an Initial Evaluation of an applicant.

5.9.3 If the evaluation is satisfactory the CB shall transfer the Certificate to the new location and the certified unit be permitted to operate certification from the new site.

5.9.4 The CB shall endorse the change of premises on the Certificate.

5.9.5 In the event of change of Ownership, the Unit shall submit their acceptance to the agreements for Certification with the CB regarding the operation and payment of fees. CB shall ask the unit for proof of legal entity afresh. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

5.9.6 In case of change of Name, the certified unit shall inform the change in the name to the CB supported with documentary evidence, and if satisfied the CB shall endorse the Certificate in the new name.

5.10 Extension of scope

5.10.1 Extension of scope of certificate for inclusion of additional produce, varieties of the under the same certificate shall be done after ascertaining that the certified unit has requisite resources required for the new produce/variety and technical skills.

5.10.2 The extension of scope shall be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

5.11 Certificate

5.11.1 The CB shall provide a certification document to the certified client that clearly conveys, or permits identification of:

a) the name and geographic location of the client ,

b) the dates of granting, extending or renewing certification,

c) the expiry date or recertification due date consistent with the recertification cycle,

d) a unique identification code,

e) the certification criteria, including issue number and/or revision, against which the product(s) are certified,

f) the scope of certification with respect to product(s) as applicable at the identified site,

g) the name, address and certification mark of the certification body; other marks (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous,

h) any other information required by the certification criteria used for certification,

i) in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents

5.11.2 The effective date on a certification document shall not be before the date of the certification / recertification decision.

5.11.3 The formal certification documentation shall include the signature of the individual(s) of the certification body assigned such responsibility.

5.12 Fee

5.12.1 A fee to be charged to the organization for various activities of the scheme, without any discrimination between units, geographical location, size of the unit.

5.12.2 The CBs fee structure shall be publicly accessible and also be provided on request.

5.12.3 CB shall notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the manufacturing units certified under this scheme of certification for their acceptance.

Annex A
(informative)

Checklists for self-assessment for good agricultural practices (GAP) for medicinal plant produce

No.	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
1	**Site Selection**				
1.1	Is site free from toxic elements such as industrial wastes and effluents?	Major			
1.2	Are the sites located remotely far away from 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	**Soil Conditions**				
2.1	Has the soil map been 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 the soil uses soil amendments as per the requirements of site and/or specie, 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	**Seeds and Propagation Materials**				
3.1	Are the seeds/planting materials accompanied with the following information: a) Name (pharmacopoeial nomenclature and trade name) b) Botanical name c) Cultivar/Selection/Phenotype/Chemotype/ Genotype (If applicable) (d) Origin of seed/planting material.	Critical			
3.2	Is marker based analytical projection for the end-product a 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 an authorized source?	Major			

3.4	Does the producer keep records on sowing/planting methods, seed/planting rate, sowing/planting date?	Major			
3.5	**Seed**				
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 seeds collected from recently collected lots and are they 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 is carried out 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			
3.6	**Stem cutting**				
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			
3.7	**Root cutting**				
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	**Crop Management for Cultivation**				
4.1	**Field preparation**				
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	**Sowing and transplanting**				
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 seedlings 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 injurious pests, diseases, virus, etc.)?	Minor			
4.3	**Manures and Fertilizers**				
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	Minor			

	through inorganic source in consideration of the nutritional needs of the target crop vis-à-vis the soil characteristics?				
4.3.3	Is **the** 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			
4.4	**Irrigation**				
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			
4.5	**Weeding and intercultural operations**				
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 uses 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			
4.6	**Crop protection**				
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	Are 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 of the protocols at 4.6.1 and 4.6.2.	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	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? May add Brand/type/quantity/date of use of chemical pesticides must be provided to buyer.	Critical			
5	**Harvest and Post-Harvest Management**				
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, toxic weeds and such other extraneous matter?	Major			
5.2	**Primary processing**				
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? Are the freshly harvested materials not be stored as such and the drying process initiated in a continuum?	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			
5.3	**Packaging, storage and transportation**				
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, is care exercised to prevent product mix up and cross contamination.	Minor			
5.3.6	Are plant materials having strong aromatic compounds kept at a place reasonably away from others?	Minor			
6	**Identification and Traceability**				
6.1	**Identification**				
6.1.1	Are packs legibly labelled 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	**Traceability**				
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	**Personnel and Equipment**				
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, hygiene and quality	Major			
7.3	The machinery used in fertilizer and pesticide application must be calibrated at prescribed	Major			

	schedules and calibration certificates / records should be maintained.				
7.4	Equipment 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. Equipment that pose a risk of hazardous metallic contamination of the harvested crop should be avoided	Critical			
8	**Workers Health, Safety and Welfare**				
8.1	**Risk Assessments**				
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 and are they fully implemented?	Major			
8.2	**Training**				
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 as qualifications?	Major			
8.2.2	Have all workers received adequate health and safety training and are they instructed according to the risk assessment?	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?	Major			
8.3	**Hazards and First Aid**				
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	**Protective Clothing/Equipment**				
	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	**Record Keeping and Internal Self-Assessment / Internal Inspection**				
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			

Annex B
(informative)

Checklists for self-assessment for good field collection practices for medicinal plant produce

No.	Control criteria	Level of compliance	Compliance		Remarks
			Yes	No	
1	**Site Selection for Collection**				
1.1	The site for collection of medicinal plant produce should be free from toxic elements and from places not prone to contamination	Major			
1.2	Are the sites close to road with heavy vehicular traffic?	Minor			
1.3	**Is** the site known as a reliable source for the species intended to collect?	Major			
1.4	Does the site have gregarious populations of the intended species?	Major			
2	**Compliance to Regulatory Requirement**				
2.1	**General**				
2.1.1	Are the collection, processing, storage and sale of medicinal plant produce carried out in accordance with the existing laws	Critical			
2.1.2	Are the collection, processing, storage and sale of medicinal plant produce carried out in accordance with the international treaties and conventions signed by relevant country?	Critical			
2.2	**International Regulation and Guidelines**				
2.2.1	Are the provisions laid down in the CITES regulations adhered to while collecting any medicinal plant produce from the wild?	Critical			
2.2.2	**Do** the collection managers and collectors of the medicinal plant produce meant for export, honour existing laws of the importing countries?	Critical			
2.3	**National Regulations**				
2.3.1.	Whether the provisions of national laws are followed?	Critical			
2.3.2	Whether collectors and collection managers keep themselves updated about the provisions in such Acts, Rules and abide by the conditions laid down in them	Major			
2.3.3	Whether managers and collectors are aware of Export-import policy and the negative list of export in order to comply with the provisions laid down in such policy documents?	Major			
2.4	**Local Regulations**				
2.4.1	Are the collectors/collection managers aware of the local regulations governing the collection, transit and sale of the medicinal plant produce in specific areas and abide by them?	Critical			
2.5	**Permission for Collections**				
2.5.1	Have the collectors/collection managers taken prior written permission from the authorized agency for collection, possession, transit and sale of the medicinal plant produce, when required under law?	Critical			
3	**Harvest / Collection Management**				
3.1	**Quality Considerations**				
3.1.1	**Botanical authenticity of species**: Are the botanical identity established before a plant species are collected from the wild. Is the identity of the plant from which the produce is being collected verified and records maintained? The information sought should include - genus, species, sub-species, if any, along with author citation.	Critical			
3.1.2	**Botanical authenticity of new plants**: How is the identity of new medicinal plant species being collected, which does not have any monographs in any of the pharmacopoeias or reference books **is** maintained?	Major			
3.1.3	Is Field Collection Protocol available?	Major			
3.1.4	**Collection of healthy plants** Are only healthy individuals of desired plant species harvested except when the medicinal value of the species	Major			

	comes from such associations as in the case of insect galls, agar wood etc.?				
3.1.5	**Harvesting at right phenological stage:** In order to ensure optimum quantity of biologically active substances in the medicinal plant produce, is harvesting done at the right phenological developmental stage?	Critical			
3.1.6	Weather conditions for collection: Is harvesting done under right weather condition? When harvesting in wet conditions becomes inevitable, do provisions exist to dry the water content as soon as possible from the produce?	Major			
	Is the collection avoided during early hours to avoid dew?	Minor			
3.1.7	**Sorting of produce:** Are the medicinal plant produce sorted out from any immature or over matured produce, which may downgrade the overall quality of the lot?	Major			
	When trading is based on the grades of produce, is parameter of sorting and grading defined objectively?	Major			
3.1.8	**Foreign matter**				
	Are care taken to avoid any accidental mixing of foreign matter with medicinal plant produce such as soil particles, organic matters like leaves, stems, wood pieces or food articles being inadvertently mixed?	Major			
	Are collectors vigilant to avoid mixing and cross-contamination with other medicinal plant produce being harvested or processed simultaneously?	Major			
3.1.9	**Mixing of Toxic weeds:** Are care taken to ensure that while harvesting, no toxic weeds growing in close vicinity get mixed with medicinal plant produce?	Major			
3.2	**Environmental Considerations**				
3.2.1	**Conservation status of species:** Are Regulators (e.g. forest and wild life field officials) and the collectors aware of the current conservation status of the desired plant species?	Critical			
3.2.2	**Sensitive species:** Are collection managers aware of endemic plant species available in the areas of collection?	Major			
3.2.3	**Distribution of species:** Are quantity of collection of any plant species in proportion to the distribution of the species in the area of collection?	Major			
3.2.4	**Regeneration of species:** Are medicinal plant species harvested within the limits of their capacity for regeneration?	Major			
3.2.5	**Baseline Assessment and Monitoring**				
3.2.5a	Is baseline assessment done of availability of medicinal plant produce in the wild?	Major			
3.2.5b	Are assessments done on sustainable level of harvest?	Major			
3.2.6	**Frequency of collection:** Are enough gaps left irrespective of the demand of any medicinal plant produce, in its collection cycle to synchronize with the regeneration cycle of the plant species or the produce?	Minor			
3.2.7	Minimizing the harm to source plant: While collecting the desired plant parts such as leaves, fruits, flowers, seeds etc. are efforts made to minimize harm to the plant from which these parts are being harvested?	Minor			
3.2.8	**Habitat management:** While harvesting, do collectors ensure minimum damage to habitat of the species to ensure sustainability?	Major			
3.3	**Social Considerations:**				
3.3.1	Local use of the species: Does the organized collection of medicinal plant produce from the wild affect the bonafide rights and availability of species for use by local people?	Major			
3.3.2	**Equity and Fair Pricing**				
3.3.2.1	Do the collectors of medicinal plant produce get returns commensurate with their efforts?	Major			
3.3.2.2	**Benefit Sharing:** Is there a mechanism evolved for a fair and equitable benefit sharing that are adhered to by all the stakeholders of medicinal plant produce?	Major			
3.3.2.3	Cultural Considerations: Are the harvest and the post-harvest management of medicinal plant produce carried out in accordance with ethical codes and norms of local	Minor			

	community and the region in which the activities take place and Due respect given to these values?				
4	**Post-Harvest Management**				
4.1	**Primary Processing: Cleaning**				
4.1.1	Does timely and right processing of medicinal plant produce after it has been harvested take place to preserve the quality and enhance shelf life of the produce?	Major			
4.2	**Sorting**				
4.2.1	Are unrelated material stuck with the produce removed?	Major			
4.2.2	Are the harvested producewhichis morphologically thick, fleshy or of bigger size, cut or sliced into small/ thin pieces to ensure proper drying of the produce?	Major			
4.3	**Drying**				
4.3.1	Are the medicinal plant produce properly dried before packing for shipping or storage?	Major			
4.3.2	Where the delicate plant parts and aromatic parts constitute the produce, are they dried only under shade?	Major			
4.3.3	In case of open sun or air-drying, is the medicinal plant produce spread out in a thin layer on a drying frame?	Minor			
4.3.4	During drying cycles (sun drying or shade drying), are care taken to move the materials into covered/ partially covered spaces during evening hours?	Minor			
4.3.5	When artificial means of drying like oven or hot air are used, are the procedures standardized?	Major			
5	**Package and Storage**				
5.1	**Packaging**				
5.1.1	**Do** the storage containers of medicinal plant produce provide protection from heat, humidity and temperature and not contaminate the produce?	Critical			
5.1.2	Is compaction/bale packing done while handling material in bulk by using, manually/ mechanically operated compactors?	Minor			
5.1.3	Is each container of medicinal plant produce labelled properly?	Major			
5.2	**Storage**				
5.2.1	Are medicinal plant produce stored in a dedicated storehouse, constructed in such a way as to avoid entry of rodents, birds and other animals and are free from dampness, dirt and dust?	Major			
5.2.3	Are sealed and labelled containers/ packages of medicinal plant produce kept in cool and dry place and on wooden pallets?	Major			
5.2.4	Are storage management-receipt, storage and issue/dispatch- properly followed?	Major			
5.2.5	Whether each lot contains shelf-life declaration on its label and FIFO (First in first out) is followed for its movement?	Critical			
5.2.6	Is there a provision for separate climate (temperature and humidity) controlled facility to store hygroscopic material and volatile material?	Minor			
5.2.7	Is inflammable produce like resins, gum-resins, oils etc. stored at isolated place in closed containers?	Major			
6	**Machinery and Equipment Used in Different Operations**				
6.1	Are the measuring **equipment** calibrated at prescribed schedules and calibration certificates / records maintained?	Major			
6.2	Do equipment and machinery used follow scheduled servicing procedures to keep them in working order?	Critical			
6.3	Additional care should be taken for cleaning those machine/machine parts that come in direct contact with the harvested medicinal plant	Major			
6.4	Are equipment used for digging, cutting, sorting, peeling and any other activity suitable and made of nontoxic material?	Major			
6.5	Are equipment and tools, especially that come in contact with the produce clean and free from any potential contaminant like paint, lubricant etc., and are maintained in proper working condition to avoid cross-contamination?	Major			
7	**Identification and Traceability**				
7.1	**Identification**				
7.1.1	Are packages/containers legibly labelled with product name, plant part, month and year of harvest and the name of collection centre?	Major			

7.2	**Traceability**				
7.2.1	Is the plant produce traceable to collection centre from where it has been grown?	Critical			
7.3	**Documentation**				
7.3.1	Is the basic information about the plant species, area of collection, and time of collection, regulatory information etc., captured?	Critical			
7.3.2	Are all processes/events affecting quality of produce maintained?	Major			
7.3.3	Are documents on different agreements maintained?	Critical			
7.3.4	Are records of drying conditions and temperature range for artificial drying maintained?	Major			
7.3.5	Are documents of all permissions taken from authorities maintained?	Critical			
8	**Training and Monitoring**				
8.1	**Training and Capacity Building:**				
8.1.1	Are training on (i) medicinal plants in general, (ii) good collection procedure, and (iii) hygiene procedure to be followed imparted to the collectors for ensuring the quality collection produce without any negative impact on the environment?	Major			
8.1.2	Are collectors aware of environmental impact of harvest of medicinal plant produce?	Major			
8.1.3	Are proper training imparted to the collectors for ensuring the collection of quality produce without any negative impact on the environment?	Major			
8.1.4	Have the collectors received adequate training on various aspects of medicinal plants?	Major			
8.1.5	Are collectors given training and awareness on appropriate collection seasons/time of different medicinal plants?	Major			
9	**Workers Health, Safety and Welfare**				
9.1	**Risk Assessments**				
9.1.1	Do the collectors have a written risk assessment for safe and healthy working conditions?	Major			
9.1.2	Do the collectors have a written health, safety and hygiene policy and procedures?	Major			
9.1.3	Is the health Status of Collectors assessed?	Major			
9.2	**Training on health and safety**				
9.2.1	Have collectors and staff received adequate health and safety training and are they instructed according to the risk assessment?	Major			
9.2.2	Is there always an appropriate number of persons (at least one person) trained in first aid present on each collection centre whenever collection activities are being carried out?	Major			
9.3	**Hazards and First Aid**				
9.3.1	Do accident and emergency procedures exist; are they visually displayed and communicated to all persons associated with the collection activities?	Major			
9.3.2	Are potential hazards clearly identified by warning signs and placed where appropriate?	Minor			
9.4	**Protective Clothing/Equipment**				
	Are collectors provided with suitable protective clothing in accordance with legal requirements and/or label instructions or as authorized by a competent authority?	Major			
10	**Record Keeping and Internal Self-Assessment / Internal Inspection**				
10.1	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			
10.2	Does the manager take responsibility to undertake a minimum of one internal self-assessment per year against the requirements of this standard?	Major			
10.3	Are effective corrective actions taken as a result of non-conformances detected during the internal self-assessment?	Major			