VOLUNTARY CERTIFICATION SCHEME FOR MEDICINAL PLANT PRODUCE
CERTIFICATION PROCESS

1. OBJECTIVE

To ensure an objective assessment and certification of the medicinal plant produce at from the farm or collected in the wild and promote uniformity in the operation of the certification scheme and the interaction between the Certification Bodies (CBs) and the producers/collectors seeking certification.

2. SCOPE

This document covers the certification process of medicinal plants based on Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) in the wild or intermediate entity like a trader. Producers/collectors/traders can achieve certification under any one of the four options described under 3 below.

3. CERTIFICATION OPTIONS FOR GAP CERTIFICATION/INSPECTION

3.1 The following options shall be available for certification:

Level 1 Compliance to Good Agriculture Practices (GAP) for producers as per Annex A and Good Field Collection Practices (GFCP) for collectors as per Annex B with identification of species by TLC profiling, wherever needed, and testing for contaminants as listed in Annex D

Level 2 Compliance to the requirements for Level 1and requirements for medicinal plants as per API/UPI/HPI etc as applicable

a) **Option 1 -** Individual producer/collector applies for certification and gets certification for his/her produce.

b) **Option 2 -** A producer/collector group applies for group certification and the producer/collector group, as a legal entity, gets certification.

c) **Option 3 -** The individual farmer may opt for lot wise certification model based on GAP where he/she gets certificate of conformity of the lot of produce submitted to approved certification body for inspection

d) **Option 4** – An intermediate entity like a trader applies for certification of the certified medicinal plant produce for proper storage for supplies in the market or to manufacturer/processor of Ayush Products

3.2 The Scheme is open to all individual or organizations engaged in GAP and GFCP of medicinal plant produce who are legal persons/entities in India.

3.3 The information on how to obtain certification for medicinal plant produce is also available on the website of NMPB (http://nmpb.nic.in/) as well as QCI (www.qcin.org).

3.4 The certification shall be carried out by the Certification Bodies (CBs) duly accredited for the certification scheme as per ISO/IEC 17065 by NABCB and/or recommended by QCI. To

operate under the Scheme, the CBs will require an extension of scope within the accreditation for ISO/IEC 17065

4. CERTIFICATION PROCESS - OPTION 1 FOR INDIVIDUAL FARMER/ COLLECTOR

4.1 Application for certification of individual farmer/collector

4.1.1 Any producer/collector who is a legal person can apply for certification to an approved Certification Body.

4.1.2 The application shall be made before sowing of the crops/collection.

4.1.3 All relevant information concerning producers/collectors applying for certification shall be recorded for the producer/collector 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.

4.1.4 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) Name of producer/collector to be certified,
ii) Annual Area under production/collection,
iii) Medicinal produce to be covered,
iv) First harvest or further harvest details/collection timings.

4.1.5 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.

4.1.6 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.

4.1.7 The prospective applicant shall apply to the Certification Body on the Application form prescribed by the CB, and provide as a minimum information on:

a) the name and address of applicant with contact details,
b) proof of legal entity,
c) location and total land held at location,

d) weather land is held under ownership or lease.
e) produce being handled,
f) relevant certification criteria GAP/GFCP against which certification is sought,
g) Produce handling area,
h) number and competence of manpower,
i) annual area under cultivation/collection and
j) covered medicinal produces area wise within the annual area.
k) Since when the area is under cultivation of Medicinal Plants
l) Any registration with Govt. Deptt (Like State Medicinal Plant Board, etc)

4.1.8 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.

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

4.1.10 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.

4.1.11 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.

4.1.12 Antecedents of applications shall be verified. If punished under the law, the application from the same person will not be entertained during the period of punishment and in any case for at least one year from the date of punishment.

4.1.13 Applications from farmers/collectors who have earlier either misused the Certification/ certification mark, or whose earlier certificate was cancelled because of violation of terms and conditions/misuse of certification mark shall not be entertained within one year of cancellation of the certificate by any CB.

4.1.14 Applications from farmer/collector found to be misusing the Certification/certification Mark while their application is being processed for grant of certificate, shall not be processed any further, and rejected after giving a due notice of 15 days. Fresh applications from them shall be treated as per clause 4.1.13 given above.

4.1.15 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.

4.1.16 Certification Bodies shall reject or close an application under the following conditions;

a) If Initial Evaluation is not carried out within six months of registration of application,
b) if more than 20% of samples drawn fail on testing during the Initial Evaluation

c) If the follow up evaluation carried out after organization has confirmed necessary corrective actions is not satisfactory
d) Lack of competent personnel for production/collection and handling,
e) If farmer/collector shows no progress towards completion of corrective actions within three months of Initial Evaluation and six months of Registration of application,
f) Misuse of Certification/certification mark,
g) Evidence of malpractice and
h) Voluntary withdrawal of application.

4.1.17 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.

4.2 Certification process for individual farmer/collector

4.2.1 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.

4.2.2 Pre-assessment

4.2.2.1 The applicant may seek a pre-assessment, which is not mandatory, during which the certification body shall check the applicant's state of preparedness for the evaluation, and availability of competent personnel and adequate records of producers collectors on CCCC.

4.2.2.2 Deficiencies observed with respect to the certification criteria during the pre-assessment shall be informed in writing to the applicant.

4.2.2.3 There shall be only one pre-assessment.

4.2.3 Initial evaluation

4.2.3.1 A single stage Initial evaluation shall be carried out by a competent evaluation team.

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

4.2.3.3 The certification body shall communicate the composition of the team 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.

4.2.3.4 Timings and date of Initial Evaluation shall be decided in consultation with the applicant ensuring that processes such as harvesting/collection representative of normal operations are 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 evaluation of all

control criteria shall be during harvest time when sufficient records/evidence is available, especially to facilitate verification of the control points related to harvest.

ii) Alternative timing options may be followed where evaluation 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 evaluation 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 different harvest timings of medicinal plants is given in Annex F of GFCP standard
ii) Where the medicinal plant produce to be included in the certification scope are concurrent, i.e. harvested at the same time, then the first evaluation will be timed so that at least one crop can be evaluated at harvest, making an assumption that the other crops getting ready for harvest 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 evaluation 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

4.2.4 Evaluation process

4.2.4.1 The team shall witness the processes covering as many CCCC as possible during evaluation of the applicant. Any nonconformity observed during 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.

4.2.4.2 A representative sample shall 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. The specified criteria shall be clearly mentioned and communicated to the testing laboratory. The samples(s) shall be duly coded and as far as possible, the identity of the manufacturer shall be hidden. The sample(s) shall be so despatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained the testing laboratory shall test contaminants as given in Annex D and conduct TLC profiling, if needed. There may be additional tests needed for Level 2 certification.

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4.2.5 Compliance levels for certification

4.2.5.1 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

4.2.5.2 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 evaluation. It is, however, obligatory to give evidence /comments for all the critical and major compliance criteria inspected in all external evaluation, self-assessments, and internal evaluation.

4.2.5.3 The level of compliance shall be established based on the following:

a) Critical- 100% compliance of all applicable critical control points
b) Major- 90% compliance of all major control points is compulsory
c) Minor-75% of compliance of all applicable minor control points is compulsory.
d) Compliance to contaminants (See Annex D)
e) TLC profiling, if needed.
f) Testing as per API/HPI etc for Level 2 certification as needed

4.2.5.4 Certification Body shall maintain records of all certification activities- application registration, documents provided by applicant, on site evaluation report, test reports of sample(s) sent for independent testing, and evaluation and review of reports for grant of certification.

4.2.6 Internal self-assessment quality assurance

The individual producer/collector shall carry out an internal self-assessment at least once a year. This self-assessment shall 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 shall be available on site for review by the evaluator during the CB evaluation.

4.3 Grant of Certification

4.3.1 The certification Body shall grant certification after ensuring:

a) complete compliance to the Certification Criteria (GAP/GFCP) based on evaluation reports (See 4.2.4 and 4.2.5),
b) certification scheme requirements,
c) Compliance to limits of contaminants as specified in Annex D
d) TLC profiling, wherever needed ,
e) conformance to product requirements after testing as per API/HPI etc for Level 2 certification as needed and

f) satisfactory resolution of nonconformities raised.

There shall be no conditional grant of certification.

4.3.2 On grant of certification, the Certification body shall inform the farmer/collector and issue a Certificate, uniquely identified, to the farmer/collector 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 farmer /collector site where certified as a minimum.

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

4.3.4 The effective date of certification shall not be before the date of decision to grant the certification to the farmer/collector.

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

4.3.6 Scope of certification

4.3.6.1 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 locations certified must be declared by the certificate holder.

4.3.6.2 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.

4.4 Surveillance Evaluation

4.4.1 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. The surveillance should be timed around harvest time of some crop under certification.

4.4.2 The full checklist and verification process shall be completed by the evaluator 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.

4.4.3 The certification body shall ensure coverage of all the CCCC checklist (Annexes A & B) as applicable so 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 4.2.24).

4.4.3 In case where the farmer/collector 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.

4.4.4 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 self assessment reports,
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.

4.4.5 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.

4.4.6 The CB may increase the frequency of surveillances with duly recorded justification for reasons like investigation of complaints, any doubts about continuing adherence to standards prescribed etc.

4.4.7 If the surveillance evaluation results in an infructuous 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.

4.5 Market samples

4.5.1 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.

4.5.2 The certification body shall draw a minimum of one sample for each crop certified during the certification cycle from market as well as onsite - 50% samples should be from market. In case market samples are not available, they could be taken from collector/producers end but it should be resorted to in exceptional situations like exports with recorded justification.

4.5.3 In case where the farmer/collector 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.

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

4.5.5 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.

4.5.6 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 producer/collector shall be informed of the decision taken.

4.5.7 When there is repetitive failure of the sample, the CB shall suspend the certification, till adequate and effective corrective actions are taken (See 4.6).

4.6 Suspension of certification

4.6.1 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.

4.6.2 A Suspension is issued when:

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

4.6.3 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.

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

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

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

4.6.7 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.

4.7 Cancellation of certification

4.7.1 A Cancellation shall be issued when:

a) A producer cannot show sufficient corrective action after 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) Major contractual nonconformities are detected.
d) Certified client 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

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

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

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

4.7.5 Certification body shall cancel the certification at the request of the certified client, if the operation(s) in the certified client's premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, or closure of operations etc.

4.8 Recertification

4.8.1 The certificate shall be revalidated at the end of every year (See 4.8.5) depending on the performance of operation of certification but recertification shall be at the end of 3 years

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

4.8.3 The certified farmer/collector 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.

4.8.4 The certification body shall review the performance of the certified client who has sought recertification, with respect to compliance to certification criteria during the certification cycle prior to a decision on the recertification.

4.8.5 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.

4.8.6 Recertification shall be based on the satisfactory performance of the certified client.

4.8.7 There shall be no conditional recertification.

4.8.7 When performance of the certified client is not satisfactory, the certification body shall withhold the recertification clearly stating the reasons and give time for effecting corrective

actions. The verification and decision on recertification shall be taken within 3 months of the expiry date.

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

4.8.9 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.

4.8.10 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.

4.9 Change of Ownership/Name

4.9.1 In the event of change of Ownership, the new owner farmer/collector shall submit proof of change of ownership. He shall also submit acceptance to the agreement for Certification with the CB regarding the operation and payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in ownership. Such changes shall not call for a visit to the site.

4.9.2 In case of change of name, the applicant/certified client shall inform the change in the name to the CB supported with documentary evidence, and if satisfied the CB shall endorse the new name in the application/certificate.

4.10 Extension of scope

4.10.1 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 client has requisite resources required for the new produce/variety and technical skills as evaluated at harvest of that particular produce and samples(s) from new varieties to be included are on independent testing found conforming to requirements of the Criteria.

4.10.2 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.

4.11 Certificate

4.11.1 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

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

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

4.12 Fee

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

4.12.2 The CB's fee structure shall be publicly accessible and also be provided on request.

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

5. CERTIFICATION PROCESS - OPTION 2 GROUP PRODUCER

5.1 Concept of group certification

5.1.1 The group shall be registered as a legal entity as Producers Association. This legal entity shall have ultimate responsibility over the production, handling and ownership of the products, thus it is responsible for the compliance with the standard. The legal entity shall enter into a contractual relationship and will have Certification Agreement with approved CB, and becomes the sole holder of the certificate.

5.1.2 The administrative structure of the producer group shall be documented and clearly identify the relationship between the producers and the legal entity. There shall be written signed contracts between each producer and the producer group. The contracts shall include the following elements:

i) Name or fiscal identification of the producer,
ii) Contact address,
iii) Details of the individual production locations,
iv) Commitment to comply with the requirements of the standard,
v) Agreement to comply with the group's documented procedures, policies and
vi) any other internal requirements not being met.

5.1.3 The producer group shall maintain a register of all member producers, and of all the applicable sites used for production in accordance with the standard. All these member producers in the producer register must be registered individually enter into contract with the producer group. The register shall at least contain the following information for each producer:

i) Name of producer,
ii) Name of contact person,
iii) Full address (physical and postal),
iv) Contact data (telephone number and e-mail and/or fax number),
v) Other ID (GST, AADHAAR VAT Number, PAN, etc),
vi) Produce registered
vii) Growing/Production area and/or quantity for each registered produce
viii) Internal audit date
ix) Since when the producer is associated with the group.
x) Any sanction earlier placed and withdrawn
xi) Producer registration with any Govt. Dept.(The State Medicinal Plant Board etc)

5.2 Quality Management System of group facility

5.2.1 Management and Organisation

The producer group shall have a management structure and sufficient suitably trained resources to effectively ensure that the registered producers meet the requirements of GAP on their production locations. The organisational structure of the group shall be documented and shall include:

i) GAP management representative - person responsible for managing the implementation of GAP in the group.
ii) Internal inspector(s)–person(s) responsible for the internal inspections of each producer
iii) member of the group- complying with the GAP requirements set for an internal group inspector.
iv) Internal auditor(s)- person(s) responsible for the internal audit of the Quality Management System, complying with the GAP requirements set for an internal group auditor
v) Agricultural technical person – person(s) responsible for technical advice to the group.
vi) Quality Systems Management (QMS) persons – person(s) responsible for managing the QMS.

NOTE: A group needs at least one internal auditor, who can cover the functions of internal group inspector and internal auditor (in case only one internal auditor who performs also the inspections, another person, identified in the QMS must approve the producer internal inspections

5.2.2 Responsibility and Duties

The duties and responsibilities of all personnel involved with the compliance of GAP requirements shall be documented, and an individual who holds a position of sufficient seniority and resources to serve as the overall responsible person will be nominated for maintenance of the GAP certification.

5.2.3 Competency and Training of Staff

i) The group shall ensure that all personnel with responsibility for compliance with the GAP standard are adequately trained and meet defined competency requirements. They shall possess degree/diploma in agricultural sciences with suitable training.
ii) The competency requirements, training and qualifications for key staff shall be documented and shall meet any defined competency requirements.
iii) Records of qualifications and training shall be maintained for all key staff (managers, auditors, inspectors, etc.) involved in compliance with GAP requirements to demonstrate competence.
iv) The internal auditor(s) and inspector(s) shall undergo training and evaluation, on the job audits/inspections to ensure consistency in their approach and interpretation of the standard.
Systems shall be in place to demonstrate that key staff is informed and aware of development, issues and legislative changes relevant to the compliance to the GAP standard

Reference- ISO 19011-2011 Guideline for auditing management systems

5.2.4 Quality Manual

5.2.4.1 The group shall have a quality manual containing as a minimum the following:

i) Documented operating and quality management systems related to the GAP standard
ii) Policies and procedures shall be sufficiently detailed to demonstrate the group's control of the principal requirements of the GAP standard.
iii) Relevant procedures and policies available to the producer group registered members and key staff.
iv) Quality Manual shall be reviewed periodically to ensure that it continues to meet the requirements of the GAP standard and those of the producer group.
v) Incorporation of relevant modifications of the GAP standard that come into force within the time period specified.

5.2.5 Document Control

5.2.5.1 Quality Management System (QMS) Documents

All documentation relevant to the operation of the Quality Management System (QMS) for GAP compliance shall be adequately controlled. This documentation shall include:

i) The Quality Manual
ii) GAP operating procedures
iii) Work instructions
iv) Recording forms
v) Relevant documents of external origin.

5.2.5.2 Quality Management System Document Control Requirements

i) There shall be a written procedure defining the control of documents.
ii) All documentation shall be reviewed and approved by authorised personnel before issue and distribution.
iii) All controlled documents shall be identified with an issue number, issue date/review date and be appropriately paged.
iv) Any change in these documents shall be reviewed and approved by authorised personnel prior to its distribution.
v) A copy of all relevant documentation shall be available at any place where the QMS is being controlled.
vi) There shall be a system in place to ensure that documentation is reviewed and that following the issue of new documents, obsolete documents are effectively rescinded.

5.2.6 Records

i) The group shall maintain records to demonstrate effective control of the GAP Quality Management System requirements and compliance with the requirements of GAP standard.
ii) Records from the QMS related to compliance of GAP requirements shall be kept for a minimum of 3 years.
iii) Records shall be genuine, legible, stored and maintained in suitable conditions and shall be accessible for inspection as required.
iv) Records that are kept on-line or electronically are valid. If a signature is required, this can be a password or electronic signature that ensures the unique reference and authorization of the person signing. If a written signature of the responsible person is needed then this must be present. The electronic records must be available during the CB inspections. Back-ups must be available at all times.

5.2.7 Complaint Handling

i) The group shall have a system for effectively managing customer complaints.

ii) There shall be a documented procedure that describes how complaints are received, registered, identified, investigated, followed up and reviewed.

iii) The procedure shall be available to customers as required.

iv) The procedure shall cover both complaints to the group and against individual producers.

Reference- ISO 10002:2004 Quality Management Systems - Guidelines for complaint handling in an organization

5.2.8 Internal Audits and Inspections

Internal audit systems shall be in place both to assess the adequacy and compliance of the documented QMS and to inspect the producers and farms against the GAP standard.

5.2.8.1 Quality Management System Audit

Internal auditor(s), complying with the GAP requirements set for an internal group auditor, shall conduct the internal audit of the QMS.

i) The QMS for the GAP scheme shall be audited at least annually.
ii) Internal auditors shall be suitably trained and independent of the area being audited.
iii) The CB will evaluate the competence of the internal auditor during the external audit
iv) Records of the internal audit plan, audit findings and follow up of corrective actions
v) resulting from an audit shall be maintained and available.

NOTE: It is permitted for the same person to initially develop the QMS within the group, and then undertake the required annual QMS audit, however the person responsible for the day-today ongoing management of the QMS is not allowed to undertake the required subsequent annual internal QMS audits.

5.2.8.2 Producer and Production Location Inspections

Internal inspectors, complying with the GAP requirements set for an internal group inspector will be responsible for carrying out the farm inspections:

i) Inspections shall be carried out at each registered producer and production location at least once a year based on the GAP Checklist (See Annex C). All Critical, Major and Minor control points must be inspected in full.
ii) There shall be a process for the review of the inspection reports and producer status.
iii) New members of the group must always be internally inspected prior to their entering into the GAP registered producers list.
iv) The original inspection reports and notes shall be maintained and available for the CB inspection as required.
v) The inspection report shall contain the following information:

   a) Identification of registered producer and production location(s)
   b) Signature of the registered producer
   c) Date of inspection
   d) Inspector name
   e) Registered products
   f) Evaluation result against each GAP control point
   g) All Critical and major points in the Checklist must include details of what was verified in the comments section of the checklist, in order to enable the audit trail to be reviewed after the event.
   h) Details of any non-compliances identified and time period for corrective action,
   i) GAP status
   j) Harvest windows for the crop inspected
   k) Total extent of land at the location
   l) List of plant protection chemicals used for the present crop
   m) Any sanction earlier imposed on the producer and subsequently withdrawn

n) Produced sold in the 12 months period prior to the date of inspection.

(vii) The internal auditor / audit team will make the decision on whether the producer is compliant with the GAP requirements, based on the inspection reports presented by the internal inspector.

5.2.8.3 Non-conformities and Corrective Action Systems

i) There shall be a procedure to handle non-compliances and corrective actions which may result from internal or external audits and/or inspections, customer complaints or failures of the QMS.
ii) There shall be documented procedures for the identification and evaluation of non-conformities to the QMS by the group or by its members.
iii) Corrective actions following non-compliances shall be evaluated and a timescale defined for action.
iv) Responsibility for implementing and resolving corrective actions shall be defined.

5.2.9 Product Traceability and Segregation

i) Product meeting the requirements of the GAP standard and marketed as such shall be traceable and handled in a manner that prevents mixing with non-GAP approved products.
ii) There shall be a documented procedure for the identification of registered produce and to enable traceability of all product, both conforming and non-conforming to the applicable production sites. A mass balance exercise must be carried out to demonstrate compliance within the legal entity.
iii) The produce handling site shall operate procedures which enable registered product to be identifiable and traceable from receipt, through handling, storage and dispatch.
iv) Effective systems and procedures shall be in place to negate any risk of mis-labeling or mixing of GAP certified and non-GAP certified products.

5.2.10 Sanctions and Non-Conformances

i) The group shall operate a system of sanctions and non-conformances with their producers.
ii) Contracts with individual producers shall define the procedure for sanctions including the levels of Warning, Suspension and Cancellation.
iii) The group shall have mechanisms in place to notify the GAP approved Certification Body immediately of Suspensions or Cancellations of registered producers.
iv) Records shall be maintained of all sanctions including evidence of subsequent corrective actions and decision-making processes.

5.2.11 Withdrawal of Certified Product

i) Documented procedures shall be in place to effectively manage the withdrawal of registered product.

ii) Procedures shall identify the types of event which may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of product, the mechanism for notifying customers and the Certification Body; and methods of reconciling stock.
iii) The procedure shall be capable of being operated at any time.
iv) The procedure shall be tested in an appropriate manner at least annually to ensure that it is effective and records of the test retained.

5.2.12 Subcontractors

i) Procedures shall exist to ensure that any services subcontracted to third parties are carried out in accordance with the requirements of the GAP standard.
ii) Records shall be maintained to demonstrate that the competency of any subcontractor is assessed and meets the requirements of the standard.
iii) Subcontractors shall work in accordance with the group's QMS and relevant procedures and this shall be specified in service level agreements or contracts.

5.3 Application for Group certification

5.3.1 A producer group forming a legal entity can apply for certification to an accredited Certification Body. A producer group which enables the application of a Quality Management System across the whole group of the group's registered producer members comply in a uniform manner with the GAP requirements. The producer group registered members must be legally responsible for their respective production locations.

5.3.2 The producers group applying for certification must be recorded for the producer group 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.

5.3.3 **Producer Registration information**

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

i) Produce/ collector
ii) Annual Area under production/collection,
iii) Covered or non-covered produce
iv) First harvest or further harvest/ collection timings

For the registration to be accepted, the producer will have signed the Certification Agreement between the CB and the producer, a Client number, as well as any registration number the CB may assign and agreed to pay the registration fee.

5.3.4 The following information must accompany the application:

a) Quality Manual and other related documents,
b) the name and address of applicant
c) proof of legal entity,

d) location and total number of registered producers,
e) produce being handled at the group facility,
f) relevant certification criteria GAP/GFCP against which certification is sought,
g) Produce handling and storage area,
h) number and competence of manpower, and
i) covered medicinal produces producer wise.

5.3.5 Provisions given under 4.1.7-4.1.16 shall also apply.

5.4 Certification process

5.4.1 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.

5.4.2 The Quality Management Compliance Criteria (QMS)

The quality management Systems (See 5.2) of the Producer shall be evaluated with the QMS Checklist (See Annex C)

Reference- ISO 9001:2015 Quality Management Systems-Requirements

5.4.3 Pre-assessment

5.4.3.1 The applicant may seek a pre-assessment, which is not mandatory, during which the certification body shall check the applicant's state of preparedness for the evaluation, documentation and availability of competent personnel and adequate records of member producers.

5.4.3.2 Deficiencies observed with respect to the certification criteria during the pre-assessment shall be informed in writing to the applicant.

5.4.4 Evaluation process

5.4.4.1 Facility evaluation/audit- The evaluation shall be planned when maximum number of crops in their maturity/zone and they are likely to brought to the group facility for pre-processing and storage. The criteria defined under 4.2.3 and 4.24 shall apply

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

5.4.4.3 **External Quality Management System (QMS) Audit by approved Certification Body-**One announced external audit carried out annually by the approved CB of the registered producer group. The CB shall audit the QMS of the Producer Group facility.

5.4.4.4 **External Producer Inspection by approved Certification Body -** CB shall select producers 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 (√25) must be inspected at this first inspection.

5.4.5 Grant of certificate

5.4.5.1 The certificate compliance shall be issued on conformity with the following requirements:

a) Satisfactory operation of Group facility,
b) complete compliance to the Certification Criteria (GAP/GFCP) based on evaluation report of selected producers
c) Compliance to limits of contaminants as specified in Annex D
d) TLC profiling, wherever needed ,
e) conformance to product requirements after testing as per API/HPI etc for Level 2 certification as needed and
f) Satisfactory resolution of nonconformities raised.

5.4.5.2 On grant of certification, the Certification body shall inform the producer group, the applicant and issue a Certificate, uniquely identified, to the group producer 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 producer group.

5.4.5.3 A list of all the producers and sites to which the certificate relates shall be issued in an annex referred to in the certificate. The CB shall keep this list up to date.

5.4.5.4 The effective date of certification shall not be before the date of decision to grant the certification to the producer group.

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

5.4.6 Surveillance

5.4.6.1 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 evaluation reports /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.

5.4.6.2 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.

5.4.6.3 The certification body may increase or decrease the frequency of surveillance evaluation based on the performance of the organization. During the validity period of a certificate, the CB will carry out an unannounced inspection on a number of producers in the producer group equivalent to 10% of the inspection sample size inspected in the previous announced inspection. Only if the producers inspected externally have no non-conformities raised in that unannounced surveillance inspection, the following regular announced inspection by the CB will be reduced to 10% of the original farmer sample size provided the findings from the Quality Management System audit carried out at the following regular announced inspection are also favourable to this reduction. If there are non-conformities raised in the unannounced inspections, in the following regular announced inspection, justification must be given for inspecting only the minimum (square root) sample size, and not an increased sample size.

5.4.7 Suspension

The provisions of 4.6 will apply except 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.

5.5 Provisions of 4.7 to 4.12 shall apply

6 OPTION 3 – LOT INSPECTION MODEL FOR INDIVIDUAL CERTIFICATION OF PRODUCE FROM GAP

6.1 Application

6.1.1The producer willing to opt for inspection module of shall select an approved certification body to file an application at the time of sowing with following information:

i) Name of producer/collector to be certified,
ii) Registration number of the farm/plot,
iii) Annual Area under production/collection,
iv) Covered Medicinal produce to covered,
v) Harvest timing details
vi) Commitment to follow the GAP standard requirements for crop husbandry practices

6.1.2 CB shall review the application of completeness. If there are any deficiencies further information may be sought.

6.1.3 CB shall get contract signed for certification fee and adherence to the certification requirements

6.2 Evaluation

6.2.1 Constitution of team

6.2.1.1 On getting information, the certification body shall constitute a team of evaluators to visit the applicant site.

6.2.1.2 This should be planned in such a way that crop produce is ready for evaluation and drawing samples as some of the produce may need pre-preparation such as sorting, cleaning and drying.

6.2.2 Sampling, Packing, Labelling, Coding, Sealing and Signing of Samples

6.2.2.1The samples shall be drawn at random from sufficient quantity of the material which is representative of production lot. The quantity representing one batch is considered adequate. The samples of each type and grade which the applicant wants to be inspected is drawn.

6.2.2.2 It shall be ensured that the size of the sample is adequate for testing the requirements for which it is desired to be tested. Counter samples of identical size shall be drawn and left with the applicant.

6.2.2.3 The inspector shall take every precaution to ensure that the sample is packed in a durable packing material to withstand hazards during handling and transportation. Wherever feasible, all original markings indicating the origin of the product would be removed / defaced from the sample with the objective of concealing the identity of the origin from the testing laboratory.

6.2.2.4 The sample shall be labelled to indicate:

a) name of the product;
b) the relevant Standard against which to test;
c) grade/type/size of the product
d) quantity of sample;
e) batch No./date of production;

6.2.2.5 A code number should be given to the sample/label in the following manner:

a) Initials of the inspector
b) date of drawal of sample

6.2.2.6 The sample shall be properly sealed with official seal and signed by inspector and the representative of applicant so that no substitution or tampering with the contents is possible subsequently. For the purpose of sealing, the inspector should always carry the brass seal or the steel punch.

6.2.2.7 For any sample(s) drawn for testing including counter samples, complaint samples etc. receipt shall be issued by the inspector. The receipt shall be got countersigned by representative of the firm.

6.2.2.8 The samples shall either be brought personally by the inspector or left with applicant with a request to send to the laboratory.

6.3 Issue of certificate

6.3.1 Certificate

A certificate on prescribed format shall be issued after establishing compliance to the requirements. The responsibility of certification body will end after the certificate has been issued.

7. OPTION 4 - CERTIFICATION OF PRODUCE HELD IN POSSESSION OF ANY INTERMEDIATE ENTITY LIKE TRADER FOR PROPER STORAGE PRIOR TO DELIVERY TO FINAL USER

Option 4 – Certification of produce held in possession of any intermediate entity like trader for proper storage prior to delivery to final user

7.1 Implementation of Quality Management System

7.1.1 The entity/trader shall have implemented Quality Management System similar to 5.2 stated above prior to application for certification

7.2 Infrastructure and hygiene

7.2.1 The Structures within establishment of the entity shall be soundly built of durable materials and be easy to maintain and clean:

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect on the produce,
- walls and partitions should have a smooth surface up to a height appropriate to operation
- floors should be constructed to allow adequate drainage and cleaning
- ceilings and overhead fixtures should minimize build up of dirt,
- windows should be easy to clean, be constructed to minimize the build up of dirt,
- doors should have smooth, non-absorbent surfaces, and be easy to clean,
- working surfaces that come into direct contact with produce should be in sound condition, durable and easy to clean and maintain.

7.3 Storage Management

7.3.1 The entity shall provide adequate facilities for storage of produce variety wise. It shall design and construct facilities to:

- permit adequate maintenance and cleaning
- avoid pest access and harbourage
- enable produce to be effectively protected from contamination during storage
- provide environment (temperature and humidity) to avoid deterioration
- provide secure storage facilities for cleaning materials/hazardous substances

7.3.2 Appropriate records of receipt, storage and dispatch shall be retained for a period that exceeds the shelf-life of the produce. Documentation can enhance the credibility and effectiveness of the control system.

7.3.3 Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures
- function as intended, particularly at critical steps
- prevent contamination of produce.

7.3.4 Cleaning programmes should ensure that all parts of establishment are appropriately clean, and should include the cleaning of cleaning equipment.

7.3.5 Pests are threat to safety and suitability of produce. Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Establishments and surrounding areas should be regularly examined for evidence of infestation.

7.4 Application

7.4.1 An entity/trader in the chain of custody shall apply to an approved certification body with the following information:

a) Name of trader/storage agency to be certified,

b) Registration number of the store operation,

c) Medicinal produce to be stored,

d) Licence from authorities to operate the store

7.4.2 CB shall review the application for completeness. If there are any deficiencies further information may be sought.

7.4.3 CB shall get contract signed for certification fee and adherence to the certification requirements

7.4.4 Provisions of 4.1.8 to 4.1.17 shall apply.

7.5 Evaluation

7.5.1 **Constitution of team**

7.5.1.1 On getting information, the certification body shall constitute a team of evaluators to visit the applicant site.

7.5.1.2 This should be planned in such a way that medicinal plant produce is available for evaluation and drawing samples.

7.6 Issue of certificate

7.6.1 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

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

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

7.7 Provisions of 4.6 to 4.10 & 4.12 shall apply

ANNEX A

CHECKLISTS FOR SELF-ASSESSMENT FOR GOOD AGRICULTURAL PRACTICES (GAP) FOR MEDICINAL PLANT PTODUCE

Parameters	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 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	**SOIL CONDITIONS**				
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	Major			

	concentration etc.				
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 MATERIAL**				
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			
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 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			
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 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			
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	Major			

	specific manner so as to provide outlet for excess water?				
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 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			
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	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 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?	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, 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?	Major			
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?	Major			
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 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 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	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. Equipments 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?	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

CHECKLISTS FOR SELF-ASSESSMENT FOR GOOD FIELD COLLECTION PRACTICES FOR MEDICINAL PLANT PRODUCE

Parameters	Control criteria	Level of compliance	Compliance		Remarks
			Yes	Yes	
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	Does the site is 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			
2.1.1	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 India	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	Are 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 Indian Forest Act 1927, The Wildlife (Protection) Act 1972, The Forest (Conservation) Act 1980, The Biological Diversity Act 2002, The Scheduled Tribes &	Critical			

	Other Traditional Forest-Dwellers (Recognition of Forest Rights) Act 2006 followed?				
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 the identity of new medicinal plant species being collected, which does not have any monographs in any of the pharmacopoeias or reference books 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 comes from such associations as in the case of insect galls, agar wood etc?	Major			
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? Is the collection avoided during early hours to avoid dew?	Major 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? When trading is based grades of produce, is parameter of sorting and grading defined objectively?	Major 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? Are collectors vigilant to avoid mixing and cross-contamination with other medicinal plant produce	Major Major			

	being harvested or processed simultaneously?				
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			
2.2.4	**Regeneration of species**: Are medicinal plant species harvested within the limits of their capacity for regeneration?	Major			
3.2.5	**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			
3.2.6	**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			

3.2.7	**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	**Fair Pricing**: Do the collectors of medicinal plant produce get returns commensurate with their efforts?	Minor			
3.3.3	**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?	Minor			
3.3.4	**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 community and the region in which the activities take place and Due respect given to these values?	Minor			
4	**POST HARVEST MANAGEMENT**				
4.1	**Primary Processing:** Are timely and right processing of medicinal plant produce after it has been harvested takes place to preserve the quality and enhance shelf life of the produce?	Major			
	Are the medicinal plant produce properly dried before packing for shipping or storage?	Major			
4.2	Drying				
4.2.1	Are the harvested produce which is morphologically thick, fleshy or of bigger size, cut	Major			

	or sliced into small/ thin pieces to ensure proper drying of the produce?				
4.2.2	Where the delicate plant parts and aromatic parts constitute the produce, are they dried only under shade?	Major			
4.2.3	In case of open sun or air-drying, is the medicinal plant produce spread out in a thin layer on a drying frame?	Minor			
4.2.4	During drying cycles (sun drying or shade drying), are care taken to move the materials into covered/ partially covered spaces during evening hours?	Minor			
4.2.5	When artificial means of drying like oven or hot air used, is the procedure standardized?	Major			
5	**PACKAGING AND STORAGE**				
5.1	**Packaging**				
5.1.1	Are 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 (like Shankhapushpi, Bhringaraj, Bhumyamlaki etc) by using, manually/ mechanically operated compactors?	Major			
5.1.3	Is each container of medicinal plant produce labeled 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 labeled 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 equipments 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?	Major			
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?	Critical			
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 labeled 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			
8	**DOCUMENTATION**				
8.1	Is the basic information about the plant species, area of collection, and time of collection, regulatory information etc., captured?	Critical			
8.3	Are all processes/events affecting quality of produce maintained?	Major			
8.4	Are documents on different agreements maintained?	Critical			
8.5	Are records of drying conditions and temperature range for artificial drying maintained?	Major			
8.6	Are documents of all permissions taken from authorities maintained?.	Critical			
9	**TRAINING AND MONITORING**				
9.1	Training and capacity building:				
9.1.1	Are proper training imparted to the collectors for ensuring the collection of quality produce without any negative impact on the environment?	Major			
9.1.2	Have the collectors received adequate training on various aspects of medicinal plants?	Major			
9.1.3	Are collectors aware of environmental impact of harvest of medicinal plant produce?	Major			
9.1.4	Are collector given training and awareness on appropriate collection seasons/time of different medicinal plants?	Minor			
9.1.5	Are proper hygiene and safety training provided to collectors and staff?	Major			
9.2	**Baseline Assessment& Monitoring**:				
9.2.1	Is baseline assessment done of availability of medicinal plant produce in the wild?	Major			
9.2.2	Are assessments done on sustainable level of harvest?	Major			

10	**WORKERS HEALTH, SAFETY AND WELFARE**				
10.1	**Risk Assessments**				
10.1.1	Do the collectors have a written risk assessment for safe and healthy working conditions?	Major			
10.1.2	Do the collectors have a written health, safety and hygiene policy and procedures?	Major			
10.1.3	Is the health Status of Collectors assessed?	Major			
10.2	**Training**				
10.2.1	Have collectors and staff received adequate health and safety training and are they instructed according to the risk assessment?	Major			
10.2.2	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			
10.3	**Hazards and First Aid**				
10.3.1	Do accident and emergency procedures exist; are they visually displayed and communicated to all persons associated with the collection activities?	Major			
10.3.2	Are potential hazards clearly identified by warning signs and placed where appropriate?	Minor			
10.4	**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			
11	**RECORD KEEPING & INTERNAL SELF-ASSESSMENT/ INTERNAL INSPECTION**				
11.1	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			

11.2	Does the manager take responsibility to undertake a minimum of one internal self-assessment per year against the requirements of this standard?	Major			
11.3	Are effective corrective actions taken as a result of non-conformances detected during the internal self-assessment?	Major			

ANNEX C

CHECKLIST FOR EVALUATION OF QUALITY MANAGEMENT SYSTEMS FOR GAP

	Control Point	Complies (yes/no)	NA	Justification / Comments
QM 1	WHAT IS A PRODUCER GROUP?			
1	Does the structure of the producer group enable the application of a Quality Management System across the whole group?			
2	Is the Quality Management System (QMS) in place sufficiently robust to ensure (and to demonstrate through audits) that the group's registered producer members/production locations comply in a uniform manner with the GAP standard requirements?			
3	Are producer group registered members legally responsible for their respective production locations?			
4	Is the producer group **not** a multi-site operation where an individual or one organisation owns several production locations or "farms", which in itself are NOT separate legal entities?			
5	Is the entire crop registered for certification?			.
QM 2	ADMINISTRATION AND STRUCTURE			
2.1	**Legality**			
1	Is there documentation, which clearly demonstrates that the applicant producer group is or belongs to a legal entity?			
2	Have the legal entity been granted the legal right to carry out agricultural production and/or trading, and be able to legally contract with and represent the group members?			
3	Does this legal entity have a direct responsibility over the production, handling and ownership of the products, thus it is responsible for the compliance with the GAP standard?			
4	Will the legal entity enter into a contractual relationship with Agreement with an approved CB, and becomes the sole holder of the GAP certificate?			

QM 2.2	**Structure**			
1	Is the administrative structure of the producer group documented and does it clearly identify the relationship between the producers and the legal entity?			
QM 2.3	**Contractual Documentation**			
1	Is there written signed contracts between each producer and the legal entity?			
	Does the contract include the following information:			
2	Name or fiscal identification of the producer ?			
3	Contact address?			
4	Details of the individual production locations?			
5	Commitment to comply with the requirements of the GAP standard?			
6	Agreement to comply with the group's documented procedures, policies and where provided, technical advice?			
7	Violations that may be applied in case of GAP and any other internal requirements not being met?			
2.4	**Producer Register**			
1	Is there a register maintained of all GAP member producers, and of all the applicable sites used for production in accordance with the GAP standard?			
2	Are all these member producers in the producer register, registered individually on the GAP database according to the requirements?			
3	Does the register contain the name of each producer?			
4	Does the register contain the Name of the contact person?			
5	Does the register contain the Full address (physical and postal) of every producer member?			
6	Contact data (telephone number and e-mail and/or fax number)			
7	Doe the register contain any other ID (VAT Number etc) if required for the country of production?			
8	Does the register contain the product registered by each producer member?			
9	Does the register contain information on the growing /production area and/or quantity for each registered product?			
10	Does the register contain information on the Certification Body(ies) if a producer makes use of more than 1 CB?			
11	Does the register contain the Internal inspection date for every producer member?			
12	Does the register log the current of every producer member?			

13	Are those producers of the legal entity who do not apply for GAP certification listed separately?			
QM3	MANAGEMENT AND ORGANISATION			
3.1	**Structure**			
1	Does the producer group have a management structure and sufficient suitably trained resources to effectively ensure that the registered producers meet the requirements of GAP on their production locations?			
2	Is the organizational structure of the group documented?			
3	Does this include information about the GAP management representative - person or department responsible for managing the implementation of GAP in the group?			
4	Does this include the name(s) of the Internal inspector(s) – person(s) responsible for the internal inspections of each producer member of the group annually; complying with the qualification criteria set for an internal group inspector?			
5	Does this include the name(s) of the Internal auditor(s) – person(s) responsible for the internal audit of the Quality Management System, complying with competence criteria set for an internal group auditor?			
6	Does this include information about the Agricultural or livestock technical person/department – person(s) responsible for technical advice to the group?			
7	Does this include information about the Quality Systems Management (QMS) person/department – person(s) responsible for managing the QMS?			
3.2	**Responsibility and Duties**			
1	Are the duties and responsibilities of all personnel involved with the compliance of GAP requirements documented, and is an individual who holds a position of sufficient seniority and resources to serve as the overall responsible person nominated for maintenance of the GAP certification?			
QM4	**COMPETENCY AND TRAINING OF STAFF**			
1	Does the group ensure that all personnel with responsibility for compliance with the GAP standard are adequately trained and meet defined competency requirements?			
2	Are the competency requirements, training and qualifications for key staff documented and does it meet any defined competency requirements?			
3	Are records of qualifications and training maintained for all key staff (managers, auditors, inspectors, etc.) involved in compliance with GAP requirements to demonstrate competence?			

4	Do the internal auditor(s) and inspector(s) undergo training and evaluationon the job audits, to ensure consistency in their approach and interpretation of the standard?			
	Is there a system in place to demonstrate that key staff is informed and is aware of development, issues and legislative changes relevant to the compliance to theGAP standard?			
Qm5	QUALITY MANUAL			
1	Are the operating and quality management systems related to the GAP standard documented and contained in a Quality Manual(s)?			
2	Are the policies and procedures sufficiently detailed to demonstrate the group's control of the principal requirements of the GAP standard?			
3	Are the relevant procedures and policies available to the producer group registered members and key staff?			
4	Is the contents of the Quality Manual reviewed periodically to ensure that it continues to meet the requirements of the GAP standard and those of the producer group?			
Qm6	DOCUMENT CONTROL			
6.1	**Quality Management System (QMS) Documents**			
1	Do all documentation relevant to the operation of the QMS for GAP compliance exist and are they adequately controlled including:The Quality Manual			
2	Do all documentation relevant to the operation of the QMS for GAP compliance exist and are they adequately controlled including operating procedures			
3	Do all documentation relevant to the operation of the QMS for GAP compliance exist and are they adequately controlled including: Work instructions			
4	Do all documentation relevant to the operation of the QMS for GAP compliance exist and are they adequately controlled including: Recording forms			
5	Relevant external standards, e.g. the current GAP normative documents.			
6.2	**Quality Management System Document Control Requirements**			
1	Is there a written procedure defining the control of documents?			
2	Are all documentation reviewed and approved by authorised personnel before issue and distribution?			
3	Are all controlled documents identified with an issue number, issue date/review date and be appropriately paged?			
4	Is any change in these documents reviewed and approved by authorised personnel prior to its distribution? Wherever possible, is the explanation of			

	the reason and nature of the changes identified?			
5	Is a copy of all relevant documentation available at any place where the QMS is being controlled?			
6	Is there a system in place to ensure that documentation is reviewed and that following the issue of new documents, obsolete documents are effectively rescinded?			
Qm7	RECORDS			
1	Does the group maintain records to demonstrate effective control of the GAP Quality Management System requirements and compliance with the requirements of GAP standard?			
2	Are the records from the QMS related to compliance of GAP requirements kept for a minimum of 3 years?			
3	Are all records genuine, legible, stored and maintained in suitable conditions and accessible for inspection as required?			
4	Are records that are kept on-line or electronically valid? If a signature is required, is there a password or electronic signature that ensures the unique reference and authorization of the person signing? If a written signature of the responsible person is needed, is this present? Are the electronic records available during the CB inspections and are back-ups available at all times?			
Qm8	COMPLAINT HANDLING			
1	Does the group have a system for effectively managing customer complaints?			
2	Is there a documented procedure that describes how complaints are received, registered, identified, investigated, followed up and reviewed?			
3	Is the procedure available to customers as required?			
4	Does the procedure cover both complaints to the group and against individual producers?			
Qm9	INTERNAL AUDITS AND INSPECTIONS			
9.1	**Quality Management System Audit**			
1	Is an internal audit system in place both to assess the adequacy and compliance of the documented QMS and to inspect the producers and farms against the GAP standard?			
2	Do(es) the internal auditor(s), complying with the GAP requirements set for an internal group auditor , do the internal audit of the QMS?			
3	Is the QMS for the GAP scheme audited at least annually?			
4	Are the internal auditors suitably trained and independent of the area being audited?			

5	Does the CB evaluate the competence of the internal auditor during the external audit by checking compliance ?			
6	Are records of the internal audit plan, audit findings and follow up of corrective actions resulting from an audit maintained and available?			
9.2	**Producer and Production Location Inspections**			
1	Is an internal inspection system in place to inspect the producers and farms against the GAP standard?			
2	Are internal inspectors, complying with the GAP requirements set for an internal group inspector responsible for carrying out the farm inspections?			
3	Are inspections carried out at each registered producer and production location at least once per year against the GAP Control Points and Compliance Criteria, based on the GAP Checklist? Have all critical,Major and Minor control points been inspected in full?			
4	Is there a process for the review of the inspection reports and producer status?			
5	Are new members of the group always internally inspected prior to them entering into the GAP registered producers list?			
6	Are the original inspection reports and notes maintained and available for the CB inspection as required?			
7	Does the inspection report contain the Identification of registered producer and production location(s)?			
8	Does the inspection report contain the Signature of the registered producer?			
9	Does the inspection report contain the Date of the inspection?			
10	Does the inspection report contain the Inspector name?			
11	Does the inspection report contain the Registered products?			
12	Does the inspection report contain the Evaluation result against each GAP control point?			
13	Does the checklist include details of what was verified in the comments section of the checklist of All critical in order to enable the audit trail to be reviewed after the event?			
14	Does the inspection report contain the Details of any non-compliances identified and time period for corrective action?			
15	Does the inspection report contain the GAP status of the producer member?			
16	Does the internal auditor team make the decision on whether the producer is compliant with the GAP requirements, based on the inspection reports			

	presented by the internal inspector?			
9.3	**Non-Compliances and Corrective Action Systems**			
1	Is there a procedure to handle non-compliances and corrective actions which may result from internal or external audits and/or inspections, customer complaints or failures of the QMS?			
2	Are there documented procedures for the identification and evaluation of non-compliances to the QMS by the group or by its members?			
3	Are the corrective actions following non-compliances evaluated and a timescale defined for action?			
4	Is the responsibility for implementing and resolving corrective actions defined?			
qm10	PRODUCT TRACEABILITY AND SEGREGATION			
1	Is the product meeting the requirements of the GAP standard and marketed as such, traceable and handled in a manner that prevents mixing with non-GAP approved products?			
2	Is there a documented procedure for the identification of registered products and to enable traceability of all product, both conforming and non-conforming to the applicable production sites? Has a mass balance exercise been carried out to demonstrate compliance within the legal entity?			
3	Does the produce handling site operate procedures which enable registered product to be identifiable and traceable from receipt, through handling, storage and dispatch?			
4	Are there effective systems and procedures in place to negate any risk of mis-labeling or mixing of GAP certified and non-GAP certified products?			
Qm11	SANCTIONS AND NON-CONFORMANCES			
1	Does the group operate a system of sanctions and non-conformances with their producers?			
2	Do the contracts with individual producers define the procedure for sanctions including the levels of Warning, Suspension and Cancellation?			
3	Does the group have mechanisms in place to notify the GAP approved Certification Body immediately of Suspensions or Cancellations of registered producers?			
4	Are records maintained of all sanctions including evidence of subsequent corrective actions and decision-making processes?			
Qm12	WITHDRAWAL OF CERTIFIED PRODUCT			
1	Are there documented procedures in place to effectively manage the withdrawal of registered products?			

2	Are there procedures that identify the types of event which may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of product, the mechanism for notifying customers and the GAP approved Certification Body and methods of reconciling stock?			
3	Is the procedure capable of being operated at any time?			
4	Is the procedure tested in an appropriate manner at least annually to ensure that it is effective and records of the test retained?			
Qm13	**SUBCONTRACTORS**			
1	Are there procedures to ensure that any services subcontracted to third parties are carried out in accordance with the requirements of the GAP standard ?			
2	Are records maintained to demonstrate that the competency of any subcontractor is assessed and meets the requirements of the standard?			
3	Do subcontractors work in accordance with the group's QMS and relevant procedures and is this specified in service level agreements or contracts?			

ANNEX D

PERMISSIBLE LEVELS OF CONTAMINANTS UNDER GAP AND GFCP

1. Heavy Metals

S.No.	Parameters	Permissible limit
1.	Lead (Pb)	10 ppm
2	Cadmium (Cd)	0.3 ppm
3.	Arsenic (As)	3 ppm
4.	Mercury (Hg)	1 ppm

2. Aflatoxins

S.No	Aflatoxins	Permissible Limit
	B_1	0.5 ppm
2.	G_1	0.5 ppm

3.	B_2	0.1 ppm
4.	G_2	0.1 ppm

3. Pesticide Residues

Substance	Limit (mg/kg)
Alachlor	0.02
Aldrin and Dieldrin (sum of)	0.05
Azinphos-methyl	1.0
Bromopropylate	3.0
Chlordane (sum of cis-, trans - and Oxythlordane)	0.05
Chlorfenvinphos	0.5
Chlorpyrifos	0.2
Chlorpyrifos-methyl	0.1
Cypermethrin (and isomers)	1.0
DDT (sum of p,p-'DDT, o,p-'DDT, p,p-'DDE and p,p-'TDE	1.0
Deltamethrin	0.5
Dichlorvos	1.0
Dithiocarbamates (as CS2)	2.0
Endosulfan (sum of isomers and Endosulfan sulphate)	3.0
Endrin	0.05
Ethion	2.0
Fenitrothion	0.5
Fenvalerate	1.5
Fonofos	0.05
Heptachlor (sum of Heptachlor and Heptachlorepoxide)	0.05
Hexachlorobenzene	0.1
Hexachlorocyclohexane isomers (other than γ)	0.3
Lindane (γ-Hexachlorocyclohexane)	0.6
Malathion	1.0
Methidathion	0.2
Parathion	0.5
Parathion-methyl	0.2
Permethrin	1.0
Phosalone	0.1
Piperonyl butoxide	3.0
Pirimiphos-methyl	4.0
Pyrethrins (sum of)	3.0
Quintozene (sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide)	1.0

4. Microbial Contamination

S.No.	Parameters	Permissible limits

2.	*Salmonella* sp./g .	Absent
3.	*Pseudomonas aeruginosa*/g	Absent
4.	*Escherichia coli*	Absent
5.	Total microbial plate count (TPC)	10^5/g*
6.	Total Yeast & Mould	10^3/g

*For topical use, the limit shall be 10^7/g.

Amendment Record Sheet

Sl No	Date of Amendment	Description of Amendment	Incorporated by	Approved by
1	**11-Nov-16**	**Clause 3, option 3 and option 4 added**	**Sona Sharma(SS)**	**Anil Jauhri (AJ)**
2	11-Nov-16	Clause 4.17 updated with d, K, l requirements added	SS	AJ
3	11-Nov-16	Clause 4.2.4.1 deleted	SS	AJ
4	11-Nov-16	Added: clause 4.4 - The surveillance should be timed around harvest time of some crop under certification.	SS	AJ
5	11-Nov-16	Added: Clause 4.4.3 -coverage of all the CCCC checklist (Annex A & B) as applicable	SS	AJ
6	11-Nov-16	Clause 4.5.2 – Updated: The certification body shall draw a minimum of one two sample for each crop certified during the certification cycle from market as well as onsite -50% samples should be from market. In case market samples are not available, they could be taken from collector/producers end but it should be resorted to in exceptional situations like exports with recorded justification from the market for each produce/product a in a year.	SS	AJ
7	11-Nov-16	Clause 4.5.3 word - farmer/collector added and word unit deleted	SS	AJ
8	11-Nov-16	Clause 5.2.3 added	SS	AJ
9	11-Nov-16	Clause 5.2.5.1 - added "documents of external origin" & Deleted "external standards, e.g. the current GAP normative documents"	SS	AJ

10	11-Nov-16	Clause 5.2.6 updated "ii) Records from the QMS related to compliance of GAP requirements shall be kept for a minimum of 3 years (changed from 2 to 3 year)	SS	AJ
11	11-Nov-16	Clause 5.2.8.2 - Updated	SS	AJ
12	11-Nov-16	Clause 5.2.8.2 -added j-n points	SS	AJ
13	11-Nov-16	Clause 5.4.2 added	SS	AJ
14	11-Nov-16	Clause 5.4.6.3 - sample size changed from 50% to 10% and regular announced inspection by the CB will be reduced to 10% of the original farmer from 5% as earlier specified.	SS	AJ
15	11-Nov-16	Clause 7.3.1 - added "provide secure storage facilities for cleaning materials/hazardous substances".	SS	AJ
16	11-Nov-16	Clause 7.3.2,7.3.3,7.3.4,7.3.5,7.4,7.5,7.6 added	SS	AJ
17	07-Sep-17	Clause 4.2.4.2 updated, para added, para added	SS	AJ
18	07-Sep-17	Clause 5.4.5.1 updated, pointer c, d, e added	SS	AJ