

SUSTAINABLE WILD COLLECTION PRACTICES

QUALITY ASSURANCE MANUAL



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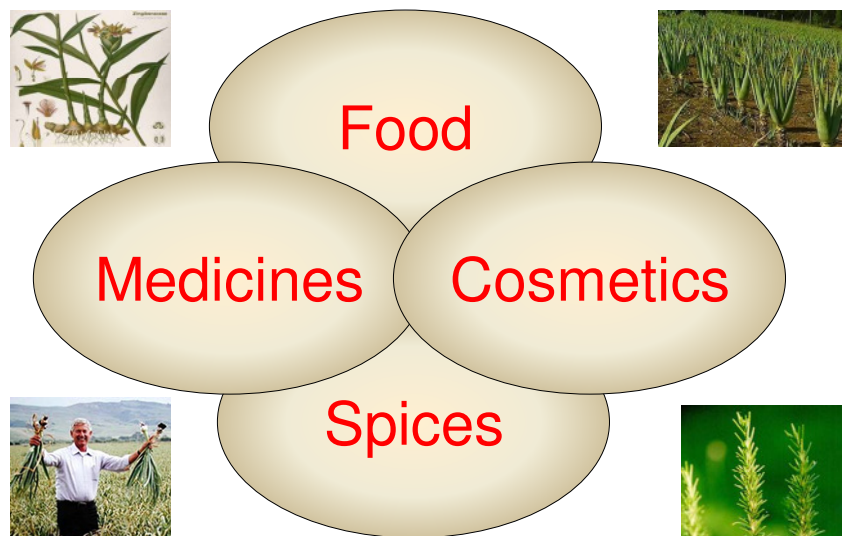
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Part A: Principles for Quality Management

1. Introduction

Uses of Wild Crops



The Quality Manual documents quality system of Company to demonstrate the company's ability to consistently provide product that meet customer and regulatory requirements.

The main problems of the quality system on all industry sectors, the possible ways of development and the main activities in quality systems and the ways of improving education related to Quality Management issues. However significant development can be noted in the field of knowledge circulation of quality management during the past years, there is a great lagging behind, since several leaders and experts of middle and big sized companies have high-level knowledge of quality management, this is not general in the case of the whole staff of companies or small sized companies. Therefore, quality management is not efficient enough, since the majority of the employees should have sufficient knowledge—at their level. This lack of knowledge decreases the possibilities for ensuring the implementation of safety related specifications of quality, including safety. The result is that the quality assurance of the products and services is far below the suitable level – especially in the aspect of knowledge. These consist of the basis for the development of quality management and competitiveness. Without these basics, the system quality cannot be suitable.

The given Quality Manual can be used in the Companies that like to implement/improve their Quality Management System implementing control system of the following topics: HACCP and GMP (including Personnel, Buildings and Facilities, Sanitary operations, Sanitary Facilities and Controls.); Identification/authentication of the plants (incl. Botanical identity, Site selection, Climatic, Soil conditions); Climatic, Soil conditions; Harvest; Procurement of plant raw material; Plant raw material acceptance procedure; Initial processing /assortment; Drying raw material (incl. Natural and artificial drying of raw material) ; Bringing raw material into standard state; Storage; Packaging; Principles for Packing Areas; Marking / Labeling; Transportation; Traceability; Cleaning and Disinfection; Preparation works; Employees Training; Plant pests and ways of pest control; Sampling; Equipment and Supplies and Protection of Nature

1.1 Policy & Objectives

Improvement of products and processes is of great importance, fostering competitive demands for innovation - improvement and reduction of costs. The trilogy: planning, control and improvement is the key for progress in this area. The following steps should be taken by Company for continues improvement:

Quality planning is the continuous process of product development or services, which meet customer demands. For this purpose we have registration journal to write down all demands and requirements of our customers, including internal customer.

Quality control includes actions undertaken which achieve the objectives that involves evaluation of actual quality performance in comparison with quality objectives and action to annulate the differences. In this purpose we draw the procedure of Nonconformity Control.

Quality improvement is stimulated by the need for change. It implies that the companies learn to facilitate, communicate, set up procedures and reward systems on identifying changes in internal and external business environment aimed at avoiding routine and rigid structures.

An important base for quality improvement is an approach with both management and employee involvement. Management should initiate the driving force for this process; because improvement alters routine structures. In many cases within firms, routine structures exist, that cause rigidity. They hamper the improvement and will only be accepted if there is sufficient commitment.

Quality improvement is a systematic approach for improving a system. It involves documentation, measurement and analysis. Typical goals of quality improvement include increasing customer satisfaction, achieving higher quality levels, reducing cost, increasing productivity and accelerating the process.

This level of quality is achieved through adoption of a system of procedures that reflect the competence of the Company to existing customers, potential customers, and independent auditing authorities.

Achievement of this policy involves all staff, who are individually responsible for the quality of their work, resulting in a continually improving working environment for all. This policy is provided and explained to each employee by the Managing Director or Quality Manager.

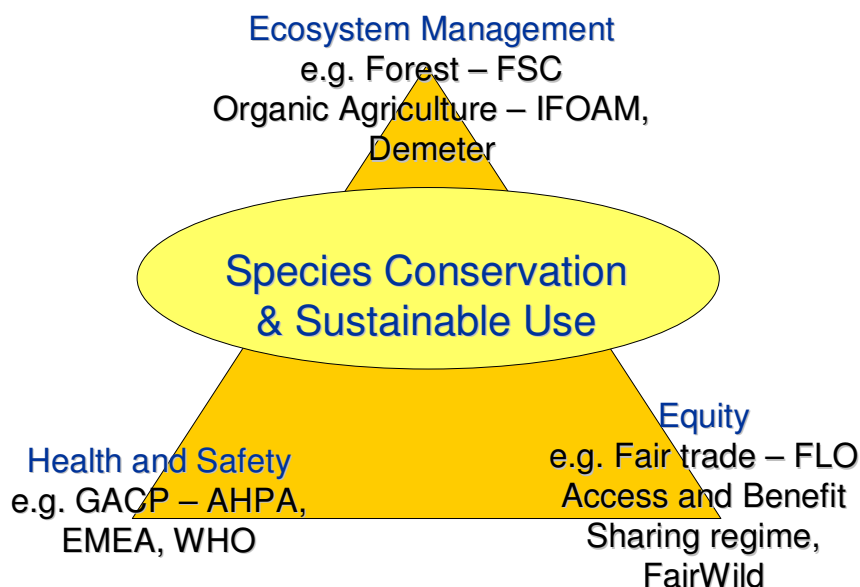
To achieve and maintain the required level of assurance the Managing Director retains responsibility for the Quality System with routine operation controlled by the Quality Manager.

1.2 Quality System

A quality system refers to activities a business uses to promote quality within the organization. It is often called a quality management system (QMS). This system includes the business's activities, plans, policies and procedures used in producing quality goods and services.

The purpose of a quality system is to meet customer's expectations and increase profitability. Companies purchase QMS software to assist in this. With a quality system, a company focuses on the quality of goods and services produced.

Existing Frameworks & Gaps



A quality system consists of planning, documenting and controlling all business processes. It requires constant review to implement changes and improvements to increase customer satisfaction and demand. A quality system focuses on continuously measuring the company's performance to make improvements to the system leading to increased profitability.

Quality systems focus on eight principles: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making and mutual beneficial supplier relationships. These eight components work together and allow companies to increase the quality in their products.

The Quality Assurance System focused especially on practical aspects of quality. In the WHO Good Manufacturing Practices guidelines and other guidelines, only general terms are given. That is why we elaborated given guideline to give concrete information about specific exemplary plants.

Our Quality Manual applies to all activities of the Company, and has been developed in accordance with International Standards. The Company has established, documented, implemented and maintains a Quality Management System in accordance with the requirements of ISO 9001: 2008. The company continually improves the effectiveness of its QMS. The Quality Assurance System is fully documented and structured in 4 levels:



Quality Manual - A quality manual documents an organization's quality management system. It can be a paper manual or an electronic manual. Quality manual should:

- ✚ Define the scope of your QMS.
- ✚ Explain reductions in the scope of your QMS.
- ✚ Justify all exclusions (reductions in scope).
- ✚ Describe how your QMS processes interact.
- ✚ Document your quality procedures or refer to them.

Methodological Instructions – methodological instructions, unlike method (which systematically details a given procedure or process), does not describe specific methods despite the attention given to the nature and kinds of processes to be followed in a given procedure or in attaining an objective. When proper to a study of methodology, such processes constitute a constructive generic framework; thus they may be broken down in sub-processes, combined, or their sequence changed. As such, methodology may entail a description of generic process or, metaphorically, may be extended to explications of philosophically coherent concepts or theories as they relate to a particular discipline or field of inquiry. By similar reasoning methodology refers to the rationale and/or the philosophical assumptions that underlie a particular study or a particular methodology (for example, the scientific method). In scholarly literature a section on the methodology of the researchers is typically de rigueur.

Job Descriptions - A job description is a list that a person might use for general tasks, or functions, and responsibilities of a position. It may often include to whom the position reports, specifications such as the qualifications or skills needed by the person in the job, or a salary range. Job descriptions are usually narrative, but some may instead comprise a simple list of competencies; for instance, strategic human resource planning methodologies may be used to develop a competency architecture for an organization, from which job descriptions are built as a shortlist of competencies. A job description is usually developed by conducting a job analysis, which includes examining the tasks and sequences of tasks necessary to perform the job. The analysis considers the areas of knowledge and skills needed for the job. A job usually includes several roles. The job description might be broadened to form a person specification or may be known as Terms of Reference.

Quality Records - A record is a type of document. Records provide evidence that activities have been performed or results have been achieved. They always document the past. Records can, for example, be used to show that traceability requirements are being met, that verification is being performed, and that preventive and corrective actions are being carried out.

The Company's Quality Management System:

- ✚ identifies the processes needed for its operations and their application throughout the organization
- ✚ determines the sequence and interaction of these primary processes
- ✚ determines criteria and methods needed to ensure that both the operation and management of these processes are effective
- ✚ ensures the availability of resources and information necessary to support the operation and monitoring of these processes
- ✚ ensures monitoring, measurement and analyses of these processes and
- ✚ ensures implementation of actions necessary to achieve planned results and continual improvement of these processes.

1.3 Authority & responsibilities

Authority

How can people be influenced to make commitments to the goals of the organization? In part, this question can be answered by how managers define and use power, influence, and authority. Deciding what type of authority system to create is part of the managerial responsibility of organizing. Compare, for example, two managers. One accepts or rejects all ideas generated at lower levels. The other gives the authority for making some decisions to employees at the level where these decisions will most likely affect those employees. How managers use their power, influence, and authority can determine their effectiveness in meeting the goals of the organization.

Company should share the authority and responsibility of identifying noncompliance or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence.

Responsibilities

Responsibility is the obligation to accomplish the goals related to the position and the organization. Managers, at no matter what level of the organization, typically have the same basic responsibilities when it comes to managing the work force: Direct employees toward objectives, oversee the work effort of employees, deal with immediate problems, and report on the progress of work to their superiors. Managers' primary responsibilities are to examine tasks, problems, or opportunities in relationship to the company's short-and long-range goals. They must be quick to identify areas of potential problems, continually search for solutions, and be alert to new opportunities and ways to take advantage of the best ones.

Managing Director

- ✚ Approval of the Quality Assurance System
- ✚ Management Review
- ✚ Supplier Selection & Purchasing
- ✚ Contract Management & Control
- ✚ Planning & organization

- ✚ New Product Identification & Evaluation
- ✚ Training

Quality Manager

- ✚ Internal Audit
- ✚ Resolution of Quality Assurance System Discrepancies
- ✚ Control & Maintenance of the Quality Assurance System
- ✚ Documentation & Change Control (Quality System Documents)

Accountant/Financial Manager

- ✚ Control of Finance, Accounts and Warehouse Operations
- ✚ Training
- ✚ Supplier Selection and Purchasing

Warehouse

- ✚ Control of Stock
- ✚ Replenishment Recommendation
- ✚ Protection and Preservation of Stock
- ✚ Receiving Inspection
- ✚ Packaging and Despatch

1.4 Management Review and Internal Audit

Management review of the suitability and effectiveness of the Quality System takes place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system.

The objectives of Management Review are:

- ✚ To establish that the Quality (Management) System is achieving the expected results and meeting the Company's requirements, continuing to conform to the Standard, continuing to satisfy the customer's needs and expectations, and functioning in accordance with the established Operating Procedures.
- ✚ To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.
- ✚ To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.
- ✚ To review any complaints received, identify the cause and recommend corrective action if required.
- ✚ To review the finding of internal/ external audits and identify any areas of recurring problems or potential improvements.
- ✚ To review the reports of nonconforming items and trend information to identify possible improvements.

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Programme is compiled at least a year in advance however, should particular needs be identified, the frequency of audit may be increased at the discretion of the Quality Manager.

Audits are undertaken by auditors who are trained in auditing and not directly responsible for the functions being audited within that Company. Nonconformance observed is brought to the attention of the person responsible, and is recorded, documented and subject to timely corrective action to ensure full rectification.

All productive work is planned and undertaken in accordance with the company's procedures, and any specific documents agreed for individual contracts (e.g. contract specifications).

Work instructions are provided by the agreed contract specification and any documents referenced therein, alternatively work is performed in accordance with internationally accepted codes of practice.

2. Good Manufacturing Practices

2.1 Personnel

Disease control. Any person who is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination shall be excluded from any operations dealing with food, equipment, or packaging.

Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- ✚ Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food packaging materials.
- ✚ Maintaining adequate personal cleanliness.
- ✚ Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
- ✚ Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand.
- ✚ Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
- ✚ Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
- ✚ Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
- ✚ Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

2.2 Education and training

Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

All employees, including full time, part time and seasonal personnel and supervisors, should have a good working knowledge of basic sanitation and hygiene principles. The level of needed understanding will vary as determined by the type of operation, the task, and the assigned responsibilities.

The main cause of contamination of produce with pathogenic microorganisms is the negligence of workers or managers who have allowed workers to work.

The first main problem is the failure to observe personal hygiene. Particularly problematic is the hand-washing (especially after using the toilet), since inadequate cleaning and disinfecting of hands is the cause of introducing pathogenic organisms in 60-70% of cases. Pathogenic microbes remain on the surface of the hands, gloves, and tools for a very long time if those surfaces are not washed and sanitized. Washing not followed with sanitizing is not enough. For this reason, hands, gloves, equipment and tools should be washed with soap and hot water and then be sanitized. Employees should wash their hands after each visit to the toilet, after contact with field containers or tools, when switching from one product to another, after a meal or going beyond the workplace. The centers should have at least one male and female toilets equipped with hot water taps.

The second major problem is access of sick or infected workers. Pathogens are guaranteed to pass on any surface in contact with those workers, and the surface of fresh agricultural produce is a very favorable medium for the development of pathogenic organisms. Those employees, who are observed or have symptoms of illness or diarrhea, should be reassigned to activities that do not involve crops or crops surface contact. Otherwise they should not be allowed to work. This should be an established policy known to all employees, including supervisors. To do that, managers must evaluate on a daily basis the state of workers health, exclude sick employees contacting with produce, check health confirmation certificate at the recruiting and require a medical examination according to the Armenian Labor Code (for permanent personnel).

Each collection center should develop a sanitation training program for their employees. It may be in a form of formal presentations, one-on-one instruction, or demonstrations (for example, hand washing). Before the start of the season, a training session is mandatory. Depending on the workers' job requirements, periodic refresher or follow-up training sessions may be needed. Part-time, seasonal and field employees, and newly hired employees, or reassigned employees should also be instructed on proper health and hygiene practices.

Training on following topics should be provided to personnel:

✚ The importance of hand washing.

Thorough hand washing before commencing work with produce and after using the toilet is very important. Contaminated hands can transmit up to 70% of microbes.

✚ Proper hand washing techniques.

The workers not necessarily know how to wash their hands properly. Teaching proper hand washing techniques should include the following:

- ▶ Hand washing with water. Warm water is more effective than cold water for washing hands;
- ▶ Use of soap (preferably, liquid soap);
- ▶ Thorough scrubbing (including cleaning under fingernails and between fingers), rinsing, and drying of the hands; and
- ▶ Common, or shared, towels should not be used. It is recommended to install an automatic hand dryer fan.

It is recommended that workers performing sorting, grading and packing operations use gloves. They should be cleaned and disinfected every day.

Sign for hand washing instructions



How to wash hands correctly and reduce infection

1. Rub palm to palm



2. Rub the back of both palms

3. Rub palms again with fingers interlaced



4. Rub backs of interlaced fingers



5. Remember to wash back thumbs



6. Rub both palms with fingertips

7. Wash hands under running water using soap, rinse and dry thoroughly

Managers should periodically inspect areas frequented by unsupervised workers to identify where and if additional training is needed.

2.3 Buildings and Facilities

Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

- ✚ Properly storing equipment, removing litter and waste, and cutting weeds or Herb within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
- ✚ Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- ✚ Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
- ✚ Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

- ✚ Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
- ✚ Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth or other extraneous material. Contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.
- ✚ Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair
- ✚ Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs to protect against food contamination in case of glass breakage.
- ✚ Provide adequate ventilation to minimize contaminating food, food-packaging materials, and food-contact surfaces with odors and noxious fumes
- ✚ Provide, where necessary, adequate screening or other protection against pests.

2.4 Sanitary operations

General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated

Substances used in cleaning and sanitizing. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- ✚ Those required maintaining clean and sanitary conditions;
- ✚ Those necessary for use in laboratory testing procedures;
- ✚ Those necessary for plant and equipment maintenance and operation; and
- ✚ Those necessary for use in the plant's operations.

Storage of toxic materials. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

Pest control. No pests shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests.

Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned with hot water and detergent after each run and sanitized with adequate sanitizing agents before the next run.

Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

2.5 Sanitary Facilities and Controls

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source.

Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant, properly convey sewage and liquid disposable waste from the plant.

Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities away from processing area. Compliance with this requirement may be accomplished by:

- ✚ Maintaining the facilities in a sanitary condition.
- ✚ Keeping the facilities in good repair at all times.
- ✚ Providing self-closing doors.

Hand-washing facilities. Hand washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

- ✚ Hand-washing and, where appropriate hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
- ✚ Effective hand-cleaning and sanitizing preparations.
- ✚ Sanitary towel service or suitable drying devices.
- ✚ Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
- ✚ Readily understandable signs directing employees to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated.
- ✚ Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

Rubbish disposal. Rubbish shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

3. Hazard Analysis Critical Control Point (HACCP)

HACCP management system concentrates prevention strategies on known hazards and the risks of them occurring at specific points in the food chain. It is this specificity which makes HACCP so effective and the approach easily integrates into Total Quality Management or ISO 9000.

Developing HACCP assists companies to comply with legislation, supports due diligence and fulfils customer requirements for a food safety management system. The introduction of common food hygiene rules across the European Community through Directive 93/43/EEC was achieved within the UK in 1995 by the Food Safety (General Food Hygiene) regulations, which legally require the HACCP approach. Industry guides to good hygienic practice are

voluntary guides providing more detailed advice on complying with the regulations as they relate to specific sectors.

Food safety should be given the highest priority, however companies are often short of time and appropriate personnel require training, especially in food safety, which needs to be widely disseminated throughout their company. Food safety management systems are much more likely to be effective if they are owned by all in production and management.

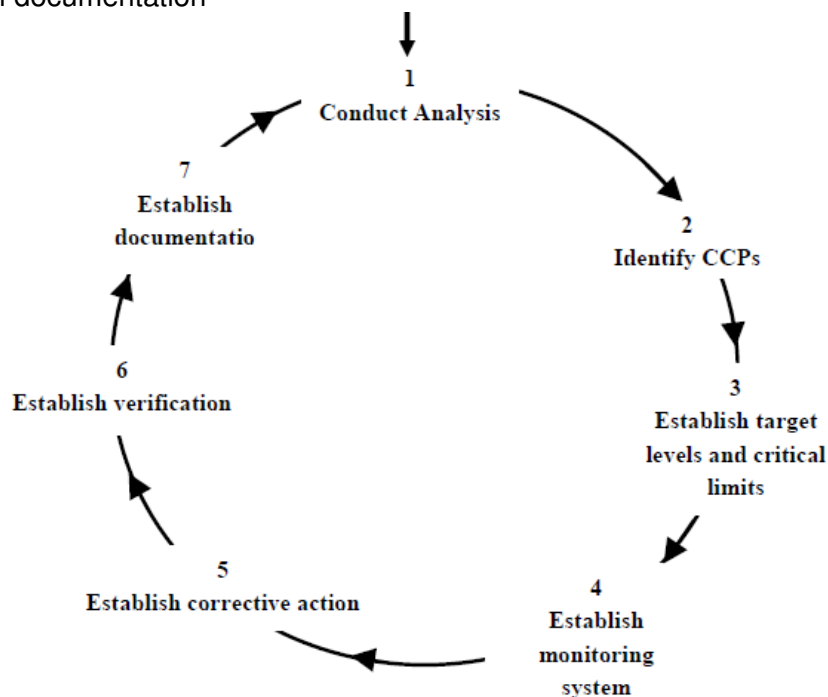
3.1 HACCP principles

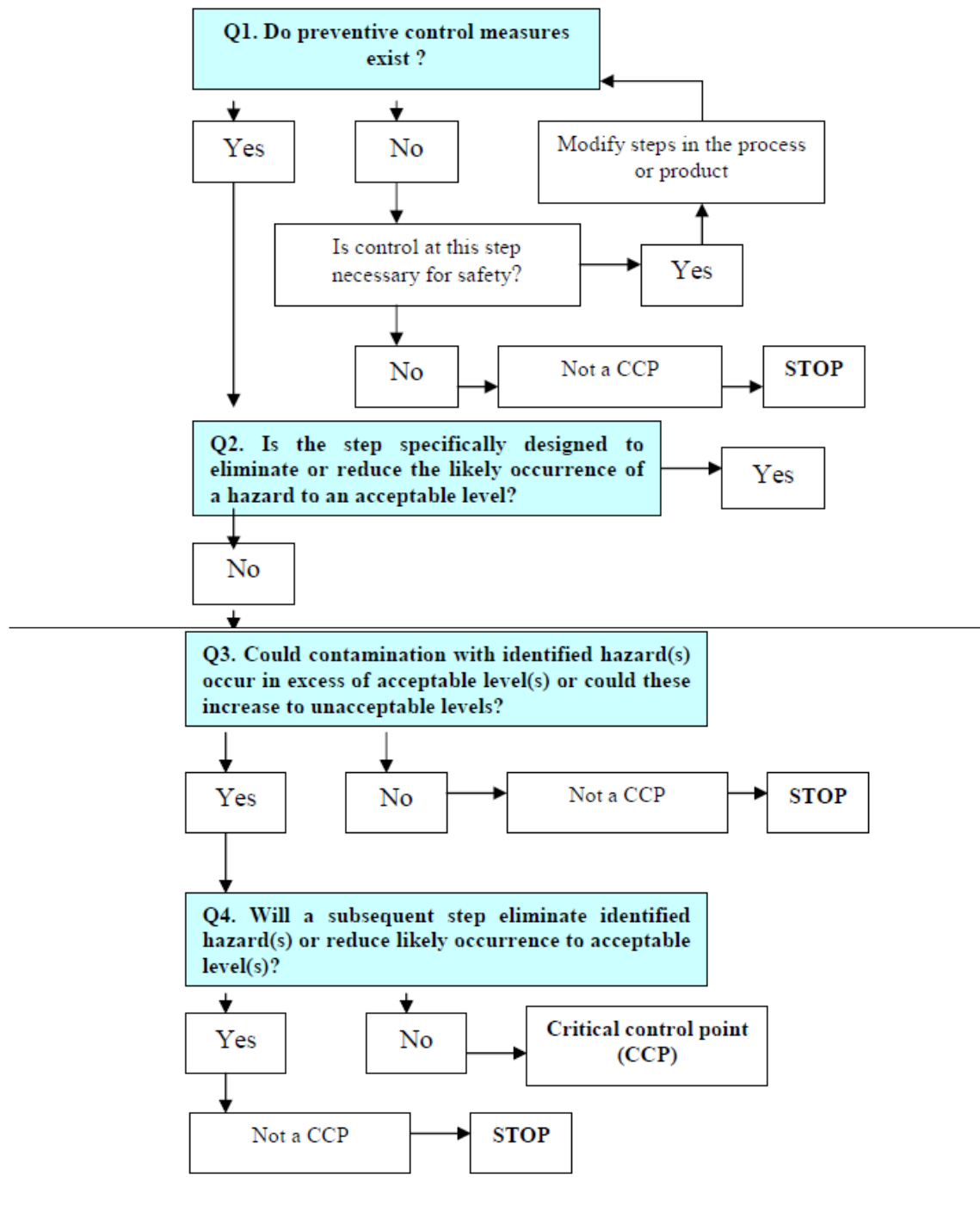
Hazard Assessment of Critical Control Points (HACCP) aims the identification, evaluation and control of steps that are critical to product safety in the food technological chain. HACCP enables the management of a cost-effective, ongoing food safety programme. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than end product testing. For the implementation of a HACCP based approach to food safety, the responsibility involves:

- ✚ Industries involved in food chain
- ✚ Policy makers and managers who can facilitate the adoption of HACCP systems
- ✚ Government authorities, including legislators, regulatory food control officials and health education bodies.

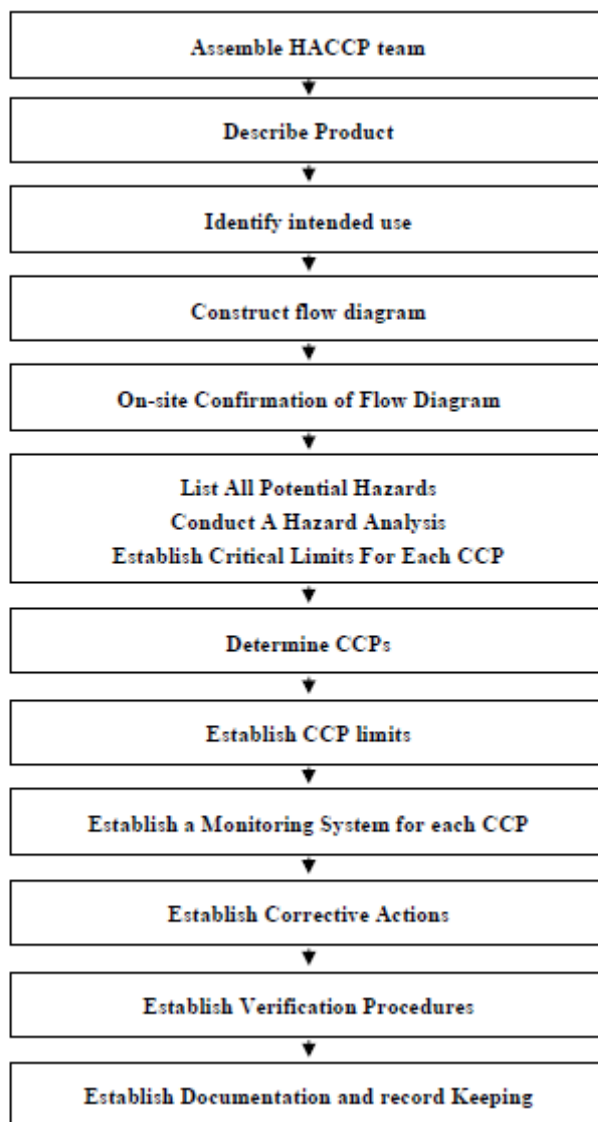
The many activities involved in constructing a HACCP plan will be discussed in detail. The following 7 principles should be used and considered by anyone involved in hazard analysis

1. Conduct Analysis
2. Identify CCPs
3. Establish target levels and critical limits
4. Establish monitoring system
5. Establish corrective action
6. Establish verification
7. Establish documentation





The HACCP plan must be 100 % focused on food safety. The most important HACCP concept is that it relies on prevention rather than inspection. HACCP is an evolving concept that continues to change and improve food quality. The application of HACCP procedure includes 12 steps, in a logic sequence as presented in the following figure:



Step 1: Assembling of an HACCP team

An HACCP study requires multidisciplinary skills and relevant departments involved in food production should be represented. This means individuals with specific knowledge and expertise appropriate to the product and process, but also people directly involved in daily activities, familiar with quality variability and limitations. The HACCP team should, at least, have the following constitution:

- ✚ A quality assurance/quality control specialist, who has knowledge on microbiological and/or chemical hazards and associated risks for particular product group.
- ✚ A production specialist, who is responsible, or is closely involved in the production process.
- ✚ An engineer, who has knowledge on hygienic design and engineering operation of process equipment.
- ✚ Buyers, operators, packaging experts, distribution experts and a hygienic manager.
- ✚ A member of the management to ensure management commitment

Step 2: Description of the product and its distribution

The team should make a full description of the product and its distribution. The description should include:

- ✚ Composition and physical features of final product (aw, pH, etc.)
- ✚ Process information
- ✚ Method of packaging
- ✚ Required shelf life
- ✚ Storage and distribution conditions along the chain
- ✚ Legislative product requirement
- ✚ Instructions for use and storage by consumers

Step 3: Identification of product intended use and consumers

The intended use of the product by consumers should be defined, e.g. the target consumer product group including the effects of potential abuse by consumers.

Step 4: Development of process flow diagrams

Prior to the actual hazard analysis it is necessary to examine a process flow diagram, which provides a simple outline of all steps involved in the process. In the process diagram, sufficient technical data for the study must be provided, typical data that can be included are:

- ✚ All raw materials/ingredients and packaging use
- ✚ Time/temperature history of all raw material, intermediate and final products
- ✚ Process conditions like, flow rate, temperature, time, pH
- ✚ Storage and distribution conditions
- ✚ Product loops for recycling or rework
- ✚ Routes of potential cross-contamination
- ✚ High/low risk area segregation
- ✚ Overview of floors and layout of equipment
- ✚ Features of equipment design
- ✚ Efficacy of cleaning and disinfections procedures
- ✚ Personal hygiene practices
- ✚ Consumer-use instructions

Step 5: On-site verification of flow diagram

The HACCP team should inspect the operation process to verify that each step in the flow diagram is an accurate representation of the actual situation. Inspections of night-and weekend shifts should also be carried out. In case the analyses are applied to a proposed line and verification will not be possible, the team must ensure that the flow diagram represents correctly the processing options.

Step 6: Hazard analysis (Principle 1)

Hazard analysis is one of the most difficult steps in the HACCP procedure because identify all potential hazards and assess their risk. It is a rather complex step and requires much technological knowledge and information. The result of this step is a list of significant hazards, which must be controlled in the process. A hazard identification list, which contains all potential hazards that may cause injury or illness, must be composed.

The HACCP team must review all potential hazards linked to:

- ✚ Raw materials, ingredients and semi-finished products
- ✚ Contamination via equipment, personnel or environment
- ✚ Facility design (adequate separation of raw and processed materials guaranteed)
- ✚ Equipment (appropriate control of functions, time- temperature control, cleaning, etc.)
- ✚ Packaging, characteristics including labeling

Step 7: Determination of Critical Control Points (Principle 2)

A critical control point (CCP) is represented by the specific step at which control can be applied, and where control is essential to prevent or eliminate a food safety hazard or to reduce it to an acceptable level. CCPs are unique for each process. The number of CCPs identified in the flow diagram is not limited. CCPs are determined by applying the CCP decision tree, at each step of the process, for each potential hazard established in hazard analysis.

Step 8: Establishment of critical limits for each CCP (Principle 3)

Each CCP will have one or more preventive measures that must be controlled in order to assure prevention, elimination or reduction of hazards to an acceptable level. For each preventive measure, critical limits must be established. Critical limits can be set by legal and/or other requirements, or can be based on information from hazard analysis or quantitative risk analysis.

Step 9: Establishment of a monitoring system for each CCP (Principle 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. It is required to assess if the CCP is under control and to provide written documentation for verification. The monitoring system and procedure for each CCP need to :

- ✚ detect the loss of control at the critical point
- ✚ inform about many to adjust the process
- ✚ assign a person with relevant knowledge to evaluate and sign the monitoring data

Step 10: Establishment of corrective actions for each CCP (Principle 5)

If monitoring data reveals deviation from critical limits, corrective actions must be taken, for ensure that the CCP has been brought under control. Corrective actions include:

- ✚ determination and correction of the cause of non-compliance (nonconformance)
- ✚ characterization of the non-compliant product (non-conformance product)
- ✚ recording of corrective actions to take

The corrective actions plan must provide information about which actions should be taken when the process exceeds critical limits, and who is responsible for implementation and recording of corrective actions.

Step 11: Verification of the HACCP plan (Principle 6)

Verification is defined as activities (other than monitoring), that determines validity of the HACCP plan and assures that the plan is respected. Verification can include:

- ✚ validation of initial HACCP plan
- ✚ verification if the HACCP plan is applied in practice, if it is correctly applied, if CCPs are monitored and under control, if corrective actions are recorded?
- ✚ validation of process steps by sampling and testing of CCPs
- ✚ calibration of equipment
- ✚ checking of training and knowledge of personnel responsible for monitoring CCPs.

Step 12: Establish record keeping and documentation (Principle 7)

Documentation and record keeping are essential for the HACCP system. The approved HACCP plan and HACCP procedures must be documented, whereas relevant data obtained during operation must be recorded. Examples of documentation are process flow diagrams,

conductance of hazard and CCP analysis. Record include: information about used ingredients, processing data, specifications of packaging materials, temperature records etc.

Part B: Criteria for high quality raw and processed plant material

4. Pre- harvest

4.1 Protection of Nature

The following conservation measures shall be observed during harvesting:

- ✚ To harvest underground parts of perennial plants (trees and bushes) as well as bark and buds, it is necessary to acquire a license from a forestry enterprise.
- ✚ While harvesting underground parts of perennial herbaceous plants 3-5 specimens of well developed plants shall be remained per 1 sq.m (for insemination purposes) and seeds of harvested plants shall be shaken off to the hole.
- ✚ Repeated harvesting of underground parts on this territory shall be made no earlier than 5-8 years.
- ✚ While harvesting aboveground parts of perennial plants (trees and bushes) raw material should be picked no more than 40 % and of herbaceous perennial plants raw material should be picked up to 60%.

Aboveground parts plants shall be harvested without inflicting any damage to other parts of plant, which is not considered to be a raw material.

4.2 Identification/authentication of the plants

Botanical identity. The botanical identity – scientific name (genus, species, subspecies/variety, author, and family) – of each plant should be verified and recorded. If available, the local and English common names should also be recorded.

4.3 Site selection

Plant materials derived from the same species can show significant differences in quality when cultivated at different sites, owing to the influence of soil, climate and other factors. These differences may relate to physical appearance or to variations in their constituents, the biosynthesis of which may be affected by extrinsic environmental conditions, including ecological and geographical variables, and should be taken into consideration.

Risks of contamination as a result of pollution of the soil, air or water by hazardous chemicals should be avoided. The impact of past land/forest uses should be evaluated.

4.4 Climatic, Soil conditions

Climatic conditions, for example, length of day, rainfall (water supply) and field temperature, significantly influence the physical, chemical and biological qualities of plants. The duration of sunlight, average rainfall, average temperature, including daytime and night-time temperature differences, also influence the physiological and biochemical activities of plants, and prior knowledge should be the soil should contain appropriate amounts of nutrients, organic matter and other elements to ensure optimal wild plant growth and quality. Optimal soil conditions, including soil type, drainage, moisture retention, fertility and pH, will be dictated by the selected wild plant species and/or target wild plant part. These conditions should be analyzed by processor/collector before giving primary collectors a collection assignment.

5. Harvest

Wild plants should be harvested during the optimal season or time period to ensure the production of wild plant materials and finished herbal products of the best possible quality. The time of harvest depends on the plant part to be used. Detailed information concerning the appropriate timing of harvest is often available in national pharmacopoeias, published standards, official monographs and major reference books.



However, it is well known that the concentration of biologically active constituents varies with the stage of plant growth and development. This also applies to non-targeted toxic or poisonous indigenous plant ingredients. The best time for harvest (quality peak season/time of day) should be determined according to the quality and quantity of biologically active constituents rather than the total vegetative yield of the targeted wild plant parts. During harvest, care should be taken to ensure that no foreign matter, weeds or toxic plants are mixed with the harvested wild plant materials.

Wild plants should be harvested under the best possible conditions, avoiding dew, rain or exceptionally high humidity. If harvesting occurs in wet conditions, the harvested material should be transported immediately to an indoor drying facility to expedite drying so as to prevent any possible deleterious effects due to increased moisture levels, which promote microbial fermentation and mould.

Cutting devices and other machines should be kept clean and adjusted to reduce damage and contamination from soil and other materials. They should be stored in an uncontaminated, dry place or facility free from insects, rodents, birds and other pests, and inaccessible to livestock and domestic animals.

Contact with soil should be avoided to the extent possible so as to minimize the microbial load of harvested wild plant materials. Where necessary, large drop cloths preferably made of clean muslin, may be used as an interface between the harvested plants and the soil. If the underground parts (such as the roots) are used, any adhering soil should be removed from the wild plant materials as soon as they are harvested.

The harvested raw wild plant materials should be transported promptly in clean, dry conditions. They may be placed in clean baskets, dry sacks, trailers, hoppers or other well-aerated containers and carried to a central point for transport to the processing facility.

All containers used at harvest should be kept clean and free from contamination by previously harvested wild plants and other foreign matter. If plastic containers are used, particular attention should be paid to any possible retention of moisture that could lead to the

growth of mould. When containers are not in use, they should be kept in dry conditions, in an area that is protected from insects, rodents, birds and other pests, and inaccessible to livestock and domestic animals.

Any mechanical damage or compacting of the raw wild plant materials, as a consequence, for example, of overfilling or stacking of sacks or bags that may result in composting or otherwise diminish quality should be avoided. Decomposed wild plant materials should be identified and discarded during harvest, post-harvest inspections and processing, in order to avoid microbial contamination and loss of product quality.

All surfaces and implements that touch crops must be treated as food contact surfaces.

- ✚ Clean all harvest containers/bins prior to use.
- ✚ In the field/forest (at harvest time), containers/bins should be placed so to prevent invasion of birds, mice, insects and their manure to the containers/bins. Containers/bins should not be left under rain.
- ✚ Organize waste disposal in the field, so that it does not stay along with harvested crops.

5.1 Harvesting of wild berries is considered to be a rather delicate process

1. While harvesting wild berries it has to be taken into consideration that overwhelming majority of them will not ripen after picking (during storage period). Thus, it is mandatory to harvest already ripen fruits and berries. Usually harvesting of berries and fruits is carried out by so called “layers” method i.e. harvesting firstly ripen fruits and berries, and then in 2-3 days (depending on the weather) harvesting for the second time. Depending on the type of berry, the number of “layers” may vary from 3 to 10.
2. In the meantime it has to be taken into considerations that overripe berries and fruits are not suitable for transportation. Therefore, berries should be harvested not on the stage of commercial ripening but rather on technical ripening stage (a little bit not ripen). Certainly, it is true, if it is supposed to transport picked berries, in case harvested berries are going to be used locally, this rule is not applicable.

5.2 Implements for picking of berries

Implements like fruit-picker basket, tarpaulin fruit removing bags, with detaching bottom, buckets with soft trimming may be used for harvesting of fruits and berries. Lightweight tables and stairs might be needed as well. The fruits located on the top of crown should be harvested by using fruit-picker tools. Before harvesting packages and implements shall be thoroughly washed and dried under the sun.

5.3 Fruits harvesting technique

Careless attitude to harvesting technique may result in loss of salable condition and fast spoiling during transportation and storage. That is why it is mandatory to prevent damage of fruits and berries during harvesting and initial grading. To avoid accidental damages harvesters have to short cut their nails. Fruits removing techniques is the following – fruit shall be by grappled by hand, so that forefinger comes right on the connection spot of stem and fruit, then push the fruit upward and turn slightly aside. If the fruit is ripen will come off easily. Harvesting shall be started from the lower part of a crown and move gradually

upward, in order to reduce amount of the damaged fruits. Fruits of each sort shall be picked, packed and stored separately, taking into account size and maturity grade.

5.4 Procurement of plant raw material

Harvesting of wild fruit and berries is a delicate process for a variety of reasons.

When harvesting wild fruit and berries it should be considered that their absolute majority does not ripen after harvesting (during storage). Thus, fruit and berries should be harvested ripe. Usually harvesting of fruit and berries is done by «layers» – ripe fruit and berries are harvested first, and in 2-3 days - (depending on weather) harvesting is repeated. There can be from 3 to 10 such «layers» depending on cropper.

Too ripe fruit and berries are bad for transportation. Thus, they should be harvested not at the commercial (consumer) stage of ripeness, but at the stage of technical ripeness (i.e. a little unripe). Certainly, it should be done only if they have to be transported. This is not so significant in case they are for local consumption.

Rotten, moldy, dried, crumbled and damaged berries and fruits should not be harvested for procurement purposes. It is not recommended to wash them by water, since washed berries and fruits proved to be unendurable during storage. High grade production could be obtained only through timely harvesting and properly drying of fruits and berries.

On each plant part of flowerings shall be preserved for insemination purposes, this is especially true for harvesting of flowerings of annual plants and biennial plants. Untimely or belated harvesting of buds, admixture of pedicles, stems, leafs and grinded parts are among most frequent reasons of having inferior quality raw materials. Extraneous organic admixtures, flowerings of other plants similar in appearance, brownish parts, pale flowerings, long remnants of stems and untripped buds shall be removed from harvested raw materials.

Value of collected raw material depends specifically on the time of collection, that is why processors and collectors shall determine (perhaps with involvement of the specialists) optimal terms for raw material harvesting.

Every supplier shall be aware of the followings:

- ✚ what to harvest (type of plant, its signs and what parts)
- ✚ when to harvest (season, time of a day)
- ✚ where to harvest (natural habitat, specially allocated territory)
- ✚ how and by what tools to harvest (harvesting technique)

Processors and collectors shall possess the following basic knowledge:

Buds shall be harvested in wintertime or in early spring, when they are in full bud, yet not started growing. Usually, it takes place in a period of February-March. When buds turn green (birch - *Betula pendula* Roth / *Betula pubescens* Ehrh, cottonwood - *Populus deltoides*) harvesting should be ceased, since blossomed out buds have no value at all. For medical purposes it is used sometimes buds of birch, cottonwood and pine. Starting from February buds of birch tree shall be harvested along with the branches (max 30 cm). Branches shall be cut and bundled into small brooms and dried out on open air, and cleaned out of impurities. If buds are harvested during sap move it should be cut off by hand or thrashed immediately. Buds of black cottonwood and aspen shall be picked by hand, trying not to jam them. Cottonwood's buds shall be harvested from young trees, by cutting them from the top of sprout and picking up buds.

Bark shall be collected from young trunks (no older than 3-4 years), branches, and sprout in early spring, during the period of intense sap move and when trees are in full bud. During

that period bark is rich with healing substances and could be easily taken off, owing to the layer of cambium saturated with water, which separates bark and wood. Harvest only smooth bark. An old, cracked bark contains high portion of suberic substances and a small portion of active substances. Bark collection on living plants often leads to the death of the whole plant.

To take off bark of the trunk it is necessary to make two semicircle cuts on the distance the 30-40 cm. of each other and then connect them with slits. Formed grooves of bark shall be taken off the wood. While collecting bark some parts may be lichen strike, with the remnants of wood and darkened inner side. While harvesting bark special attention should be paid to the specific type of a tree, since bark is harvested on trees without leaves. That is why it is necessary to know all external characteristics of the trees.

Leaves shall be harvested during the period of budding and plant blossoming. Usually it shall be carried out under dry weather condition, taking leaves off manually, from top to down along with petiole, or without thereof. It should be noted that thick and sappy butt slows down leaves drying process. Besides they are rich with healing substances. Usually well developed, low-level and mid-level leaves shall be harvested; whereas marcescent, affected with insects and fungi shall be rejected. Juicy leaves (coltsfoot, foal foot, foxglove purple and others) shall be piled loosely and promptly delivered to the place of drying. While collecting leaves of nettle it is necessary to mow down plants and when leaves are getting wither (losing its pungency) they can be picked off. Herb can be dried out and then leaves can be grinded.

Pale and losing natural color, withered, damaged with pests, worm-eaten, dusty and dirty leaves shall not be harvested as well.

Leaves and sprouts shall be placed in a basket carefully, so that to avoid caking and spontaneous heating. Placing leaves in plastic bags is not desirable, since plants can be steamed.

Herb is the correct word. Herb refers to green Herb from the lawn. (e.g. on a golf course). Herb refers to fresh or dried aerial plant parts from annual or perennial plants without any woody parts may include the flower, leaf, and the stem of the plant, and occasionally fruits too. The stem must NEVER contain any woody parts. Please integrate this in your description/instruction. If collectors harvest also woody parts then they are cutting too long and the plant is damaged. Also the woody parts are not of the desired quality and need to be sorted out.

Herb i.e. above ground part of the plants, should be cut on the low leaves level. Of some high herbs like (wormwood, St.-John's wort, and motherwort) only foliated and blossoming tops with length of 15-20 cm and side branches shall be cut off. Thick and rough stalks contain less healing substances that is why it is not advisable to collect them. The stem must NEVER contain any woody parts. If harvested plant or herb has many stalks (thyme, origanum and Melilot or Sweet Clover) they should be dried as a whole, and then leaves and stalks shall be thrashed. Woody parts are not of the desired quality and need to be sorted out. While collecting herbs they should not be pulled out with the roots.

Flowers and blossom clusters shall be harvested with an onset of plants blossoming, when they do not have any sign of fading. At that time plants contain many active substances, they withstand drying, preserve coloring and fall off less in storage and processing. Flowers and inflorescences shall be harvested manually, by plucking pedicels, cutting with scissors or pruners from trees. Inflorescences (German chamomile and marigold and others) shall be collected during horizontal location of reed petals and flowers which have only tubular type flowers like (tansy, Matricaria discoidea, commonly known as pineapple weed and others) during the blossoming of flowers. Overripe inflorescences are usually crumbled during harvesting. Inflorescences are the tenderest part of a plant, that is why they should be piled loosely in thin layers and better in woven basket, trying not to jam them and protecting from direct sun light.

Fruits and seeds. Maximal concentration of healing substances takes place in fruits and seeds in the period of full ripening. That is why they should be harvested selectively, as they ripen and process them manually without fruit stem. Plants with fruits located in umbels or in corymbs, inflorescences shall be harvested as a whole, and after drying fruits shall be separated from fruit stem. It is advisable to harvest rosehip along with chalice, cup, which should be removed after drying, thrashing manually rosehip fruit. Ripen seeds will fall off, that is why they should be harvested before full ripening, when they are getting brown. Tops of the stems should be cut along with the fructiferous inflorescences, bind into small bunches and hanged for further drying and ripening in dry and well vented space, whereupon seeds shall be grinded. Sappy berries (black currants, strawberries, currants, stone berry - bird cherry, apple, rowanberry and others) should be harvested only when are ripened and robust. Harvest should be made manually in a rather shallow woven basket, lined inside with fabric. Each layer of berries (app. 3-5 cm) shall be covered with leafs, so that they will not be jammed and will not squeeze each other. Berries should be harvested carefully; even a light pressure could cause formation of dark spots, with the following rotting. It is not recommended to harvest damp berries and wash them in water it can cause quick rotting. Only undamaged and not decayed fruits and seeds shall be harvested. Harvested raw material shall be cleaned of various admixtures like unripe, overripe and damaged fruits and seeds, and (fruits like hawthorn and ash berry) fruit stems shall be removed.

For harvesting and packaging of growing wild fruits and berries use boxes, sieves, baskets and other packing, lined inside with fabric, which shall be filled up to the brims. Nut plants have a great importance as nutritional food and oil plant. Harvesting of pine nuts is very important (seeds of Siberian cedar pine). Usually nuts are harvested in September-October period. Nuts shall be harvested when they reach full ripeness stage. Ripeness of pine nuts can be determined by appearance of a cone. If cone is covered with galipot (sulfur) it means that nuts are ripened. The process of harvesting of pine nuts consists of few procedures: shaking off cones from trees, cleaning, grading and drying. Dried nuts shall be stored in fabric bags in dry well vented space, with relative humidity no higher than 70%.

Mushrooms also have high nutritional value; however, while fresh it is a perishable product. Maximal storage term for mushrooms is 6-8 hours. Mushrooms are grown in forests starting from spring up to late fall. Mushrooms fructify in wave-like and layer-like ways. There are usually 3-4 mushroom layers occur in a season. There are basic rules for mushroom harvesting. Mushrooms should be cut by knife, clean it from stuck soil, moss, branches and leafs. Then mushroom should be placed in boxes, baskets or other air-permeable package. It is recommended to place mushroom with caps down. While harvesting mushrooms for handing to procurement stations, mushrooms shall be graded in accordance with their caps, since size of caps determines its grade. Stalks shall be cleaned from soil and cut to required size. It is not allowed to harvest dirty, frozen, moldy, worm-eaten, having the musty odor, with signs of rot, flabby, faded, wet, washy, and slimy, with the traces of pesticides, mushrooms. Harvested mushrooms shall not contain admixtures of other kind mushrooms, parts of noxious plants and organic admixture of animal origin.

Roots, rhizomes, tubers and bulbs are underground part of the plants. They are harvested usually in fall; when aboveground parts of plants are dying off. At this time maximal quantity of active ingredients are being accumulated in the underground part of plants. It should be observed that while harvesting remnants of aboveground parts shall be preserved, so that not to be mistaken in the specific type of harvested plant. Roots and rhizomes may be harvested in early spring, before nutrients go to the aboveground parts of growing plant. Underground parts of plants shall be taken out by shovels or other tools with the soil. Soil, then has to be shaken off, It is advisable to wash but it depends on the plant and buyer requirements. After washing and cleaning of soil, raw material shall be set on Herb or matting allowing it to dry. Large parts shall be cut into pieces. Then roots and rhizomes shall be cleaned out of the remnants of stems, small rootlets, damaged and rotten parts and undergone final drying. Underground parts of some plants contain slime and saponins

(orchis, cyanosis and others) shall not be washed in water, since slime mucous substances are swelling and grow mouldy. These roots and tubers shall be shacked off the soil; upper peel shall be taken off and set on drying. If underground parts of harvested raw materials are relatively clean of soil, it is not necessary to wash them. However, they should be washed and then dried if: a) they are soiled b) if they shall be stored along with other raw materials; c) if they were taken out of the marshland or highly damp place. Different types of plants shall be harvested separately, to avoid their blending and without weed plant admixtures.

5.5 Plant raw material acceptance procedure

Plant raw material shall be accepted in small and large batches. While carrying out visual inspection, a special attention shall be paid to proper labeling and package integrity (i.e. lack of damp patch, stained spots, breakage, rupture and other damages), affecting quality and preservation integrity of raw material.

It is quite difficult and is almost impossible to check quality of all batch of raw material, accepted by norms and regulations, that is why sampling of a raw material batch is applied. Sampling shall be made of intact samples of raw material, selected from the various places of a batch. Volume of sampling depends much on the size of a lot.

Quality of raw material in damaged packages shall be checked separately. If in selected specimens a non-uniform raw material has been detected, so the whole lot shall be sorted out and to be submitted for acceptance for the second time.

Raw material shall be sorted out in the following cases:

- ✚ Persistent musty odor, not disappearing even after long-term exposure to airing.
- ✚ Presence of extraneous odour, not typical for this type of raw material or absence of odour, typical for this kind of raw material.
- ✚ Presence of mould and rot
- ✚ Presence of noxious plants

Contamination of raw material (admixtures like straw, pebbles, rodents and birds droppings) as well as contamination with foreign plants, in a quantity exceeding allowed norms.

In case inconsistency of raw material quality to requirements of norms and standards has been approved, it should be re-checked. For this purpose sampling shall be made again and results of retesting shall be considered as final.

For full evaluation of provisions and norms of procedures for accepting raw material, harvester/collector can use GOST ГOCT 24027.0 80.

5.6 Non-conforming items, preventive and corrective actions

Once non-conforming items have been noticed they are identified by location, associated documents, or specific markings to prevent their inadvertent use. All non-conforming items and customer complaints are subject to review and rectification by nominated personnel. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated, documented, and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

All employees are encouraged to suggest improvements in methods, materials, suppliers, and sub-contractors. The Company has established procedures for review of all activities in order to identify and evaluate all possible improvements in methods/ materials and its procedures.

5.7 Berries harvesting technique

Berries should be picked with a part of stem. Stem should be detached by shredding by two fingers. In case when berries are clustered and have very short stem they should be cut by scissors or picked, at least, without stems. While shredding or cutting it is not recommended to touch berries by fingers. Berries are tender and being handled carelessly they can be easily jammed. To avoid this it is necessary to do the following: firstly take a sprout by left hand and while supporting it pass your right hand with the palm upward and pick the berries. When stem is pinched, berries fall right on the palm. Some 5-6 berries may be kept, at the same time, in the hollow of the hand. From the hollow hand berries should be carefully placed into the basket. Cutting berries with scissors is much more difficult process. In doing so sprout or tree branch should be supported by left hand, meanwhile pass your left hand palm underneath of the berries and cut berries by right hand; berries fall right on the left hand palm. Berries should be put into the basket very carefully and avoid dropping. During picking fruit stem should have a length of 6-8 mm. Damaged, bruised, picked without stem berries should be placed in a separate basket.

Selecting package for harvesting berries. Wicker fruit-picker baskets and «kuzovok» type baskets with capacity of some 2-3 kg shall be used as a container for harvesting berries. These containers are favourably distinguished from other packages, since they are lightweight, easy to carry and provide well airing. For more convenient harvesting small baskets with capacity of 0,5 – 0,6 kg can be used and strings might be attached to these baskets and wear around the neck. When the baskets got full, berries should be placed carefully to the larger baskets with capacity of 2-3 kg. Bear in mind that during transportation and storage baskets will be stacked on one another, so the baskets should not be filled up to the brims. Pouring berries from one package to another is not allowed.

Storage and transportation of the berries. For temporary storage berries should be placed in a cold and well aired facility. Berries like raspberry and blackberry, could be stored in refrigerators, under subzero temperature condition and relative humidity of 90%, usually for a week. If berries are not going to be transported for remote distance special package is not required during transportation. Baskets with berries filled up lower the brims shall be stacked in few rows, rows should be separated from each other by plywood sheets and covered and fixed with tarpaulin (for protection against rain and dust). The best and healthiest berries, in technical ripening stage (not so juicy), should be selected for transportation. Berries should be placed in 2-4 layers into basket with bearing capacity of 0,5 – 1,0 kg. and placed in refrigerator for cooling. In case berries are ripening, but there is no opportunity for processing, the harvest shall be frozen and stored for further cooking with thermal treatment. For this purpose dry fruits shall be laid in one layer and placed in freezer. Upon freezing berries should be placed in plastic bags and stored in freezer. Mobile freezer chambers become more popular recently (<http://attra.ncat.org/attra-pub/postharvest.html#cooler>), which are operated by petrol or diesel generators and allows freezing in 2-3 hours after harvesting up to 4-6 0 C. Application procedure is as follows: mobile freezing chamber, installed on a trailer or carriage, should be transported closely to the harvesting site (whereas freezing generator shall be turned on) and collectors should start harvesting by moving radial to their harvesting sectors and return every 2-3 hours with the another batch of picked berries.

6. Post- harvest

6.1 Principal causes of postharvest losses and poor quality

The most common causes of postharvest losses in developing countries continue to be rough handling and inadequate cooling and temperature maintenance. The lack of sorting to eliminate defects before storage and the use of inadequate packaging materials further add to the problem. In general, minimizing rough handling, sorting to remove damaged and diseased produce and effective temperature management will help considerably toward maintaining a quality product and reducing storage losses. Storage life will be enhanced if the temperature during the postharvest period is kept as close to the optimum as feasible for a given commodity.

All fruits are living plant parts containing 65 to 95 percent water, and they continue their living processes after harvest. Their post-harvest life depends on the rate at which they use up their stored food reserves and their rate of water loss. When food and water reserves are exhausted, the produce dies and decays. Anything that increases the rate of this process may make the produce inedible before it can be used. The principal causes of loss are discussed below, but in the marketing of fresh produce they all interact, and the effects of all are influenced by external conditions such as temperature and relative humidity.

Physiological deterioration. An increase in the rate of loss because of normal physiological changes is caused by conditions that increase the rate of natural deterioration, such as high temperature, low atmospheric humidity and physical injury. Abnormal physiological deterioration occurs when fresh produce is subjected to extremes of temperature, of atmospheric modification or of contamination. This may cause unpalatable flavours, failure to ripen or other changes in the living processes of the produce, making it unfit for use.

Mechanical damage (physical injury). Careless handling of fruits causes internal bruising, which results in abnormal physiological damage or splitting and skin breaks, thus rapidly increasing water loss and the rate of normal physiological breakdown. Skin breaks also provide sites for infection by disease organisms causing decay.

Diseases and pests. All living material is subject to attack by parasites. Fresh produce can become infected before or after harvest by diseases widespread in the air, soil and water. Some diseases are able to penetrate the unbroken skin of produce; others require an injury in order to cause infection. Damage so produced is probably the major cause of loss of fresh produce.

The influences of all three causes are strongly affected by the various stages of post-harvest operations. Furthermore, they all have great effect on the marketability of the produce and the price paid for it.

Transpiration, or the loss of water. Most fruits contains from 65 to 95 percent water when harvested. Within growing plants there is a constant flow of water. Fresh produce continues to lose water after harvest, but unlike the growing plant it can no longer replace lost water from the soil and so must use up its water content remaining at harvest. This loss of water from fresh produce after harvest is a serious problem, causing shrinkage and loss of weight. When the harvested produce loses 5 or 10 percent of its fresh weight, it begins to wilt and soon becomes unusable. To extend the usable life of produce, its rate of water loss must be as low as possible. To keep water loss from fresh produce as low as possible, it must be kept in a moist atmosphere.

The effect of air movement on water loss. The faster the surrounding air moves over fresh produce the quicker water is lost. Air movement through produce is essential to remove the

heat of respiration, but the rate of movement must be kept as low as possible. Well-designed packaging materials and suitable stacking patterns for crates and boxes can contribute to controlled air flow through produce.

Damage control. The key to damage reduction is simply TLC, “tender loving care”. Keep this in mind as you design and implement postharvest handling facilities and practices. Sound recommendations should include the following:

- ✚ Train harvest labor to handle products gently.
- ✚ Harvest at the proper stage of maturity; harvest dry, if possible.
- ✚ Handle each fruit or vegetable no more than necessary; *field pack if possible*.
- ✚ Trim fingernails, and/or wear cotton gloves. Jewellery to be taken off hands!
- ✚ Use padding in the bottoms of picking containers.
- ✚ Install padding materials on the sides and bottoms of bulk bins.
- ✚ Do not overfill bulk bins.
- ✚ Minimize drop heights when transferring products from picking containers or bulk bins.
- ✚ Put produce out of direct sunlight;

Training for workers. Workers allocated to specialized tasks, such as harvesting, and the post-harvest selection, grading and packing (if applicable) of the wild crops should be given specific training. This will include demonstration and explanation of:

- ✚ the methods of evaluating the readiness of the wild crop for harvest, and the rejection of unsuitable produce at harvest, according to buyer requirements;
- ✚ the actual technique to be employed in harvesting produce, e.g. breaking the stem or plucking, clipping, cutting or digging;
- ✚ the use of harvest containers, and the transfer of produce to field or marketing containers;
- ✚ the selection of marketable produce at the field assembly point and (if applicable) grading for size and quality;

When are weather conditions right for harvesting a crop? The basic rules about weather are:

- ✚ harvest during the coolest part of the day: early morning or late afternoon;
- ✚ do not harvest produce when it is wet from dew or rain. Wet produce will overheat if not well ventilated, and it will be more likely to decay. Some produce may be more subject to damage when wet.
- ✚ protect harvested produce in the forest by putting it under open-sided shade when transport is not immediately available. Produce left exposed to direct sunlight will get very hot.

Post-harvest hauling. A packing house or collecting/processing center carried by trucks may be in palletized field containers, in bulk bins or in hand-loaded sacks or wooden or plastic boxes; where vehicles wait in the sun or rain for long periods before unloading, only the top part of the load should be protected by a covering; grass or leaves are not recommended for this purpose because they restrict ventilation and may be a source of disease; complete enclosing of the load with a tarpaulin is disastrous because it restricts ventilation and the temperature of the produce rises rapidly. This likewise applies for the trunk and cabin of a car!

Pre-cooling. It is important to remove heat from wild crops as quickly as possible after harvest. This reduces their metabolic activity, reduces the growth of micro-organisms and prevents other changes such as wilting, before crops are placed in cold storage. It also

reduces the load on the cold store refrigeration system. A simple method is to pick the crop either early in the morning when it is cool or late in the evening and leave it to cool overnight.

6.2 Initial processing /assortment

The purpose of initial treatment of the raw materials is in elimination of the defects of harvesting, removal of impurities and defective parts of plant and preparation of the raw material for drying.

Quality of raw material depends on the initial processing/assortment. It should be carried out before or after harvesting (at the moment when few harvesters consolidate their harvest), or during accepting in collection center or before drying. Decision on the place and time of initial processing shall be made by processor/collector, taking into consideration type of raw material, way and range of transportation (if transportation distance from place of harvesting to processing place is too large, so initial processing shall be made in place of harvesting), as well as on weather and other conditions. It also provides clear instruction for harvesters regarding place and time of initial processing/assortment.

For initial processing, raw material shall be laid over clean tarpaulin or other fabric, in a place protected from dust, rain, and direct sun light. Raw material shall pass visual inspection, sorting out damaged parts, yellowed leaves, peeled off flowering baskets, pebbles, pieces of soil and others. Underground parts shall be shaken off and in some cases (see above) washed in running water (except sweat-weed (*Althaea officinalis* L), licorice (*Glycyrrhiza*)). Leaves are sorted out to remove the defective ones, as well as extraneous impurities. The blooms (flowers) that lost their due color are removed. Also, unnecessary parts of a flower or inflorescence, as well as extraneous leaves are removed.

6.3 Drying raw material

Drying is a crucial part in procuring raw material. Bear in mind about preservation of organoleptic properties of mushrooms during harvesting. The shorter is the time period between end of harvesting and beginning of drying, the better are preserved nutritional properties of plants. Under the influence of enzymes biochemical processes are taking place in a fresh harvested plants, as a result acting substances are disintegrated and raw material is getting brown, and covered with mold, losing its commercial value. Enzymes and microorganisms are active in presence of proper quantity of moist that is why in order to suppress activities of enzymes it is necessary to remove excessive moist i.e. to dry raw material. Leaves, Herb and flowerings shall not be dried under the direct sun light, since it affects the color of raw material and destroys biologically active matters. Under the impact of direct sun light green pigment, chlorophyll, can be rapidly destroyed, essential oils intensively evaporate, also deteriorates natural aroma, and hence deteriorate healing properties. There are different temperature modes of drying for various types of raw materials. An optimal temperature of drying for medicinal raw material, containing essential oil is 30- 35⁰ C, for fruits and berries enriched with vitamins is 60- 70 ⁰C. For fruits and berries rich with vitamin C, a rapid short-term drying under the temperature of 70-90 ⁰C (it should be short-term in order vitamin C will not interact with air).

While preparing for drying plants shall be pass visual inspection and defective pieces and weed plants shall be removed. Flowers are usually dried separately of leaves and stems. To speed up drying process it would be better to prepare wooden frame covered with fabric or wire mesh also can be used clean paper. Raw material shall be laid with thickness of 5-7 cm and stirred up from time to time.

Continuity is a crucial factor in drying process, so far as pulp of fruits is considered to be favorable environment for reproduction of microorganisms. There are two types of drying processes – natural and artificial drying of plants.

6.4 Natural drying of raw material

Natural drying shall be carried out on open air without any additional heating. Sun drying is a most simple way. It does not require additional expenses associated with equipping facilities, takes place fast, and as a result gives high quality raw material. However, only underground parts, containing alkaloids and tanning agent, of plants can be dried under the sun, (like Scopolia, silverweed, snakeweed, Polygonum bistorta, garden burnet and others), or above ground parts of plants, which are raw material source for factory-based extraction of alkaloids and tanning agents (like Ethedra, Echinochloa, Smoketree, Cotinus and others). Above ground parts of plants, used in pharmaceutical industry, are not allowed to dry under the sun, so far as under the direct sun light raw material become colorless and unattractive. It is not allowed to dry under the sun raw material containing glycosides, vitamins and other acting substances, which can be destroyed under direct sun light. Raw material which cannot withstand sun drying shall be dried open air under the shadow or in well vented facility. For this purpose a special canopy, shed, industrial facility or attics (especially with metal roof) shall be accommodated. Natural drying takes usually few days. Over that period raw material shall be mixed and ensure protection from rain and dew, if drying takes place open air.

6.5 Raw material artificial drying

Artificial (heat) drying in special dryers is much more convenient process. It allows controlling temperature condition and drying duration, and gives high quality raw material in comparatively short time. Juicy berries and fruits, like rosehip, raspberries, blackcurrant, ashberry can be dried in ovens, if there is no special dryer. It is necessary only to keep temperature rate no higher than 70-75^o C, otherwise raw material will loose its healthy chemical composition and could damage appearance. To speed up drying process sappy parts (large roots, rhizomes, bulbs, tuber and others) shall be preliminary thrashed laid in thinner layers. Fruits and seed shall be dried in ovens and dryers, at first dry-cure it under the temperature of 35-40 °C , then finish drying under the temperature of 60-80 °C (in case artificial dryers are available).

Drying is considered finished, when dried stems can be easily broken and leafs easily grinded into powder, and fruits and berries are crumbled when pressing by fingers. Humidity of dried plants shall range from 10-13 %.

It has to be noted that quality of raw materials especially its appearance, depends to large extent on the drying process. The time period between harvesting and drying shall not exceed 24-36 hours.

6.6 Impact of humidity on the fruit quality

Large amount of precipitations in conjunction with high temperature contribute to the growth and fast ripening of the fruits, whereas fruits storage characteristics are deteriorating. In a rainy but cold summer fruits have lower sugar content, higher acidity, have pale colouring, grow mature slowly and stored badly. Fruits grown under conditions of sufficient and even precipitations level, lack of sharp fluctuation in temperature and proper lighting are distinguished with rather good storage characteristics. Fruits should not be harvested immediately after the rain; they should be harvested after, at least, 24-48 hours after the last rain. Otherwise, storage characteristics are deteriorating and fruits are getting more exposed to physiological diseases.

6.7 Bringing raw material into standard state

Following drying, the defective parts are removed from the raw material and it is brought to the level of complete correspondence to the requirements. Simultaneous to bringing the raw material to standard level, a raw material lot, homogeneous by mass and quality, is made.

The process of brining raw material into standard state consists of three phases: finish drying, sorting and grinding. These operations should be carried out on procurement stations or in warehouses, so far as raw materials are harvested by various suppliers in different times, dried by various ways and hence is not homogeneous and requires thus an additional processing.

Finish drying. Harvested raw material contains a certain portion of humidity. In this condition it can grow mould, get blacken and rotten eventually. In finish drying process raw material shall reach air-dry condition (i.e shrinkage after finish drying shall range from 5 to15 %). In case raw material acquires odor of mould, it should be laid in thin layers in a well vented space or open air and dried until odor disappears. Raw material with unweathered musty odor is not usable. Dried up raw material (which can be easily broken) shall be stored in a facility with a normal humidity for 1-2 days.

Sorting out. If the raw material has not been properly sorted out before drying, this operation is done after drying. Removal of the defects of raw material and impurities is done by cleaning the raw material from erroneously harvested freak parts of producing plant, by removing defective parts of the given raw material (those that have changed their natural color, covered with mould, coarse footstalk (caulis), ligneous parts of roots - althaea, ligneous sprouts – ledum (marsh tea), by eliminating overground parts of the raw material, by cleaning it from extraneous organic and mineral impurities).

Sorting. If raw material before drying has not been thoroughly sorted out, so it has to be done after drying. While doing sorting extraneous plants, accidentally grabbed long peduncles, fruit stems, bared stems, browned parts, mineral and organic admixtures and finely grinded parts shall be removed from raw material. Sorting shall be made manually or by using basic tools. Sorting tables are used to improve raw material manually.

All sorting operations are conducted in premises that have draft ventilation, since the dust formed during the work with dried raw material may irritate the upper air passages. Caution should be taken when working with poisonous and drastic raw material (protection of the eyes from the dust by means of glasses, protection of the nose and mouth from the dust by means of a respirator or a gauze bandage).

Raw material grinding/grading. Intact raw material is less subjected to weather conditions, can be preserved for a long time and can be easily controlled. It is advisable to store intact raw material in a warehouse.

7. Storage

The purpose of storage is to preserve biologically active substances and raw material itself as a material value. Stored and dried raw material is used in case of need, so most of it has to be stored.

In case of inappropriate storage even properly harvested and dried raw material loses its quality or becomes completely unfit.

So far as raw material absorbs moisture, so improper storage could result in its unsuitability. That is why properly dried plant raw material shall be packed immediately and handed over to procurement station.

For better preservation of biologically active substances raw material should be stored no ground, since the surface of biologically active substances contacting the air is smaller.

Harvested raw material shall be packed in boxes either in fabric or paper bags; raw materials containing essential oils shall be stored in tins with ground-in stoppers. A label indicating name of a plant, date and place of harvesting shall be stuck on each package. Berries like strawberry, black currant and raspberry shall be stored in bags under continuous draught; otherwise worms can be developed in bags. It is not recommended to store dried plants for a very long time, especially herbs, flowers and leafs, since they lose healing properties with time.

Noxious plants shall be stored separately from other plants. The package shall have a label indicating name of plant with an inscription that it is noxious. Fragrant plants should be stored separately from non-fragrant ones.

Bark can be stored from 2 up to 4 years, leafs can be stored 1-2 years, Herb from 1 to 2 years, floral raw material up to 2 years, fruits and seeds up to 2,5 years. Roots and rootstocks can be stored up to 2,5 years and sometimes more. During long term of storage plants lose healing features. Optimal temperature in warehouse shall be 10-12^o C. Warehouse shall be dry and well vented with relative humidity no higher than 60-65 %. Being exposed to high temperature raw material dries up and essential oils evaporate, that's why it is necessary to maintain required temperature and humidity. In warehouses raw material shall be stored on racks (according to standard, GOST). Raw material should be visually inspected and put in a new place once in a year. While moving to a new place warehouses and racks shall be disinfected with materials allowed by specific guides and norms. Terms of storage are defined by standards and norms and are specified in each raw material description.

If all rules are observed and strictly followed, raw material can be stored for a very long time. But some types of raw materials even when all rules of storage are strictly followed lose their active substances very fast (like foxglove, ergot, peppermint leaf, cornflower, mullein, Matricaria recutita or German chamomile and others). That is why this type of raw material shall be replaced once in a year by a fresh harvest.

Mushrooms for drying shall be laid in thin layers on trays, tables and clean mats under shadow. It is not allowed to lay mushrooms with thick layers (5-8 cm), so far as mushrooms can easily get warm and could be bruised. During storage and transportation mushrooms shall not be covered with PVC film or other airtight material. For long term storage of mushrooms shall undergo various processing, of which more popular are drying, salting, marinating and freezing.

Also contamination with nicotine and heavy metal is big problem for dried mushrooms. According to investigation, nicotine contamination in wild collected mushrooms can be a result of:

- ✚ Contamination with heavy metal can be result of harvesting mushrooms in improper places and avoiding neglecting FairWild standard requirements.
- ✚ Contamination with heavy metal can be result of harvesting mushrooms in improper places and avoiding neglecting FairWild standard requirements.

To avoid this problem processors/collection managers should keep following rules:

- ✚ In case that tobacco plants are dried and/or processed in surfaces or machines that have contact with mushrooms, the operator has to ensure adequate separation and cleaning of machines and surfaces. Tobacco dust may also lead to residues in mushrooms
- ✚ Collectors who smoke tobacco must avoid smoking during collection and handling of mushrooms and have to wash their hands before touching the mushrooms

- ✚ Areas of processing and drying of mushrooms must be clearly smoke free areas

Vegetative raw materials should be regularly controlled. Herbs, roots, rootstocks, seeds, and fruit that have lost their natural color, fragrance and the required quantity of active substances and are affected with mould and storage pests should be either rejected, or used after processing and control, depending on the scale of affection.

Temporary storages protect raw materials from atmospheric precipitation and ensure safety of the raw materials for a short period of time.

Permanent storages are called storehouses, and they should correspond to special requirements, since raw material is kept there for a long time.

A storehouse should have the following sections (departments):

- ✚ Reception,
- ✚ Sorting/ packing room,
- ✚ An isolator for a temporary storage of raw materials affected by storage pests,
- ✚ A room for temporary storage of nonstandard raw material for further additional work with it,
- ✚ A room for keeping essential oil materials,
- ✚ A room for keeping fleshy fruit,
- ✚ A room for other types of raw materials.

Storehouses should be equipped correspondingly, have a cement or wooden floor without cracks, plastered walls without windows, or else the windows should be painted white. There should be devices for measuring temperature and humidity. There should be shelves (racks) or pallets in a storehouse that will be no less than 25 cm. in height, and the distance between the shelves should be no less than 75 cm.

It's necessary to maintain cleanness and order in the premises of the storehouse. Cleaning in the premises should be done every day. Once per two months more intensive cleaning should be done in all premises. When storing raw material it's necessary to rearrange raw material annually, paying attention to storage pests and to correspondence of the duration of storage to the date of expire, mentioned in a technological normative document. The premises and shelves should be disinfected annually.

Mixed storage and mixed load distribution may transfer contamination from one lot or product to a previously non-contaminated produce item. Measures should be taken to prevent cross-contamination

Dried raw material shall be packed in clean dry and homogeneous package, appropriate for raw material type and ensure protection from unfavorable conditions.

7.1 Packaging

The purpose of packaging is to preserve the quality of raw material when storing and transporting it. The container requirements are as follows: it should be neutral to raw materials, cheap, available, durable, and comfortable. The package should be similar for each lot of raw material.

Unpacked raw material can easily become moist, lose odour and sometimes taste and takes up larger volume. Packing must be clean, without extraneous odours, single-type for each batch of raw material and ensure its integrity during transportation and storage. Standards (GOST) and Food Safety regulations specify specific type of package for each type of raw material.

Single layer and double layer paper bags may be used for raw material packaging (one bag put in another one), paper packs, single and double layer fabric bags, PVC bags, elongated bales and box-shaped packs; piles, and plywood boxes lined inside with fabric. Stacks not lined with fabric are used for packaging of pressed liquorice (Glycyrrhiza). Raw material can be stored for a long time in pressed form.

Bags are usually used for coarser types of raw material (bark, roots, rootstocks, and fruit) that do not crush during transportation. Boxes are used for more delicate raw materials (flowers, leaves, herbs). Before packaging, the boxes are lined with wrapping and sack paper or imitation parchment. Bales are made for packaging bark, roots, rootstocks, leaves, and herbs (except of fine raw material). Usually bales, covered up with cloth, are used. Bales are made by pressing raw material by a mechanical or hand-power press and covering them up with cloth.

Packing list shall be put in each package with indication of harvester/collector, name of raw material, lot number, and name of harvester. Large lots of leafs, Herb and bark shall be packed in bales or pressed in piles. Berries shall be placed in double-layer bags, flowers in boxes, barrels, lined with thick brown paper; roots, seeds, butts shall be stored in frock bags. Each package shall be labeled. Raw material containing essential oils and oil plants, fruits and seeds shall be packed separately in groups and stored in isolated facilities.

The net weight of raw material should not exceed 50 kg if it's in cloth bags or bales, 15 kg - in paper and plastic bags, and 5 kg - in paper packs. The net weight of raw materials in bales should be no more than 200 kg.



For more detailed information refer to GOST 6077-80 – General rules for packaging crude drug plant.

7.2 Principles for Packing Areas

Well-designed and operated packing area may contribute to the reduction of pathogen contamination. Lapses in facility or operations systems may lead to cross-contamination. Since packing area is the last step in produce handling, and problems cannot be corrected after that, it is extremely important to follow the safety rules.



In operating packing areas, these rules should be followed:

- ✚ Design and maintain packing surfaces (tables) and equipment to minimize injury to produce and to ensure accessibility for cleaning.
- ✚ All surfaces should be routinely cleaned and sanitized. It is recommended to have a written schedule indicating cleaning agents, concentrations and application rules.
- ✚ Remove as much dirt as practicable from harvest containers. This should be done outside the packing area and isolated from any water source used for postharvest handling. Harvest containers should never be stored in the packing area.
- ✚ Clean containers, or bins before use.
- ✚ The area should be absolutely free from insects, rats, birds, cats, and other animals.
- ✚ Store unformed or empty containers on pallets (off the floor) and in a way that protects them from contamination.
- ✚ Provide adequate ventilation to prevent odors and noxious fumes.

7.3 Marking / Labeling

Marking is one of the means to express commodity information. It may be as a text, notation conventions or a picture on a package and (or) goods, used to identify goods or their individual properties, provide consumer with information about producers, qualitative and quantitative characteristics of the goods.

The purpose of marking is to observe the arrangements required for the given type of raw material when storing and transporting it (to avoid confusion during transportation and storage, to observe the corresponding conditions and terms of storing raw material, etc.). An insert, a label or a tag, a document asserting the quality (analytical passport) relate to marking.

Depending on where marking is done, maker's mark and trademark are differed. Marking may include three elements: text, picture and information signs. Besides, during final transportation commodity should be accompanied with a document on quality, which will contain all the information about the authenticity and quality of the raw material.

Marking is an inscription on labels, tags or package, made on the stencil by permanent indelible ink. Inscription shall indicate name of harvester/collector, type of raw material, net and gross weight, date of harvesting, year and month as well as region/village. During delivering and transportation each batch shall be accompanied with quality certificate, issued by consignor. Besides it should have also instruction on handling during transportation and temporary storage (like not do drop, do not stack x pieces on each other and others).

7.4 Factors affecting fruit storage characteristics

Fruit storage characteristic is the ability of fruits to retain for certain time its food and nutritional properties. It depends on the type of plant, grade and storing conditions. For instance storing temperature has a crucial impact on the fruit colouring; high temperature leads to the quick degradation of chlorophyll in cells, and thus, to yellowing of fruits; whereas low temperature could lead to colouring deterioration. An optimal storage characteristic could be attained when fruits are harvested properly and stored under conditions complying storage requirements of the given type and grade.

7.5 Impact of fruits' location, grade and age on storage characteristics.

Extremely large pieces of the same type of fruit are stored badly than midsize and small pieces; that is why fruits must be graded. Age of a tree plays an important role in storing fruits. Fruits of young trees are less caking, since they were not exposed to various diseases. The highest quality fruits are those located on the outer, exposed to sunlight side, of the crown. Grading process is intended for storing. Fruits selected for storing SHALL NOT HAVE ANY DAMAGE! Even a small spot or damage on one fruit could damage the whole box of fruits. All fruits selected for storing should have whole fruit stem. Many farmers did not pay attention or are ignorant of the fact, that fruit itself and fruit stem is a one single whole, when one of them is damaged it lead immediately to damage of another piece, in our case when fruit stem is damaged, fruit itself would not remain intact a long while. All fruits should be clean and dry. Fruits shall be placed for storage on no more than two layers (it is easier to detect spoiling fruit and remove it from package). Between lower and upper layers place 2-3 layers of paper. Boxes (packages) intended for storage must be checked before packing, it should not cause any damage to the fruits. To avoid fruit damage bottom and walls of the box should be covered by 2-3 layers of paper.

7.6 Fruits stacking

There are two ways for stacking of fruits: checker wise and diagonal; whereas the last one is more preferred type. Rectangular and headmost ways for stacking, especially for transportation and further storing are not used, since they do not ensure protection from squeezing. Before stacking boxes should be lined with paper. The bottom of the box should be laid with a layer of woodchips, then place fruits with the cup to the side end of the box, and turning peduncle to the right. Fruits of the next level shall be laid between the rows of the previous row. The last row shall be covered by fluffy woodchips, on which the next layer is placed upon. Depending on the size of fruits, some 2 or 4 layers, usually 3 layers, could fit in a box. The upper layer shall be covered by paper, and woodchips and then with lining paper, giving the package a final look.

7.7 Fruit storage places

If a storage facility is a cold one, it is necessary to ensure additional heating; if a facility is a warm one it is necessary to ensure proper ventilation (to place ventilation window or install fan). The higher is a storage temperature, the more loosely should be packing and packages distribution pattern in a storage facility. Usage of plastic films in warm areas prevents formation of wrinkling and reduce consumption of nutrients on breathing.

7.8 Fruit storage

Fruits should be stored in boxes and in containers. Paper, woodchips and peat may be used as packing materials. Boxes with capacity of 10-12 kg may be used for packing of fruits, for more delicate fruits with capacity of 7-10 kg.

7.9 Temperature condition of fruit storage

Upon picking up fruits should be placed promptly in storage facility with low temperature and high relative humidity. Higher temperature can cause fast disintegration of chlorophyll in cells, and low temperature may have a negative impact on fruit preservation. On average wild fruits are stored at the same temperature as a cultivated ones. For instance apples shall be stored under temperature of 0-3 °C and more heat-loving fruits under 6-12 °C. To reduce temperature (in absence of ice and snow) the facility at the night time or cooling period should be thoroughly ventilated. Temperature should be measured by two thermometers. One should be placed closer to the floor where air is vented (close to doors and windows) and another one close to packed fruits.

7.10 Airing storage facility

In a chilly day time all storage facilities should be aired, and would be better to equip it with ventilation system. The more frequently temperature changes, the more carefully storage facilities should be aired, in order to avoid condensation of water vapors on the fruits.

7.11 Harvesting, processing and storage of fruits

Berries should be harvested every other day or two, at that time they are very tender. Berries should not be poured from one container to another one. Harvested berries should not be placed under the sun. Berries should not be allowed to overripe on the bushes, since they loose taste, appearance and could crumble. In a good weather condition berries ripe faster and in rainy and cold weather ripe slowly. Usually at the beginning of fruiting period yields are low, but starting from the second decade when majority of berries ripen fruiting yields are high. At the end of fruiting period, when only small pieces remain on lower parts of bushes, fruiting yields are decreasing. In good weather condition berries should be harvested in a day or two and in a hot and rainy weather every day. At the end of fruiting berries should be harvested in 3-4 days. Berries should not be harvested in early morning, when dew has not dried and immediately after rain. Harvesting of wet berries is allowed only in extreme situations, during long wet weather; whereas berries should be sent immediately to processing. Berries are considered mature for picking when they get proper coloring. Berries, intended for transportation should not be allowed to ripe up to the full maturity. For consumption and on-site technical processing berries should be harvested fully matured. Ripe berries are sweeter, tastier and more aromatic.

8. Transportation

Raw materials should be transported by dry and clean vehicles having no extraneous odor and not contaminated with storage pests. Transportation of poisonous, drastic, and essential oil material should be done separately from other types of raw material.

During transportation and delivery of raw material each lot should be accompanied by documents asserting quality of the raw material, issued by a transmitter.

GOST 6077-80 - Crude drug plant. Packaging, marking, transportation and storage.

9. Traceability

Traceability is one of the key factors to establish long-term relationships with the clients. Traceability is a mechanism enabling tracing origin of produce if requested by customers or legislation.

Collection centers who purchase from collectors need to be able to identify from which places/village a particular batch of raw material comes in order to trace possible problems to their source. This is more difficult for wild crops, where a day's raw materials may come from tens of small collectors.

Traceability contains the following information: where this produce was harvested, who is collector, who purchased and where. Traceability requires to know who transported the produce and where, what kind of produce, and when it was carried. This mechanism envisages documentation which answers all those questions.

From legal point of view, traceability is not yet compulsory in Armenia, but expected to come in near future. In exports, traceability is one of main criteria to obtain access to foreign markets and meet their requirements. It is also very important tool for food safety management. To ensure traceability at the collection center level, produce should be labelled, separately stored, and properly documented from reception, through storage and up to the dispatching point of the collection center.

10. Cleaning and Disinfection

Only treated (hygienic and sanitized) water is to be used for washing or other post harvest operations. Contaminated water adds external pathogens that create major risk for long-term storage.

Only professional food grade washing and disinfection chemicals are allowed for cleaning and disinfection. All works should be carried out wearing durable rubber gloves, rubber boots and aprons. Be sure to use the water temperature suggested by the manufacturer. For caustic soda, soda ash, and acetic acid temperatures between 60 -70 C are most effective for cleaning and safe for employees. If only hard water is available, increase percentage of solution, temperature or use special boosters.

It is very important to disinfect surfaces only after a thorough cleaning, as the organic debris reduces disinfectant's bactericidal action. Disinfection without preliminary washing and vice versa is a waste of chemicals.

Washing and disinfection of all equipment and tools should be carried out immediately after usage, not hours or days after. There are different washing chemicals for different types of contamination. Organic debris (from herbs, crops etc.) should be washed with alkaline solutions.

The following principles should be followed for cleaning and disinfection of surfaces and equipment:

- ✚ First dry clean by sweeping floors and wiping down equipment
- ✚ Pre-rinse
- ✚ Apply cleanser and/or foam, scrub equipment and walls from top downward – do not allow the detergent to dry on the equipment and/or walls
- ✚ Never place equipment on the floor to clean it
- ✚ Rinse from top to bottom equipment and walls
- ✚ Clean floors with appropriate cleanser
- ✚ Sanitize equipment and floors
- ✚ Dry floors
- ✚ Clean and put away sanitation supplies
- ✚ Visually inspect all surfaces to make sure they are properly cleaned.

All cleaning and sanitizing materials should be non-toxic and safe for food, as well as non-aggressive towards metallic and rubber parts of the equipment and tools.

To achieve best results in washing, the following rules should be observed:

- ✚ Select proper washing and disinfecting materials
- ✚ Use right concentration of washing solution
- ✚ Use washing solution at right temperature and right time
- ✚ Let washing and disinfecting solutions stay on equipment, floor and floors surfaces enough time, as prescribed by instruction.

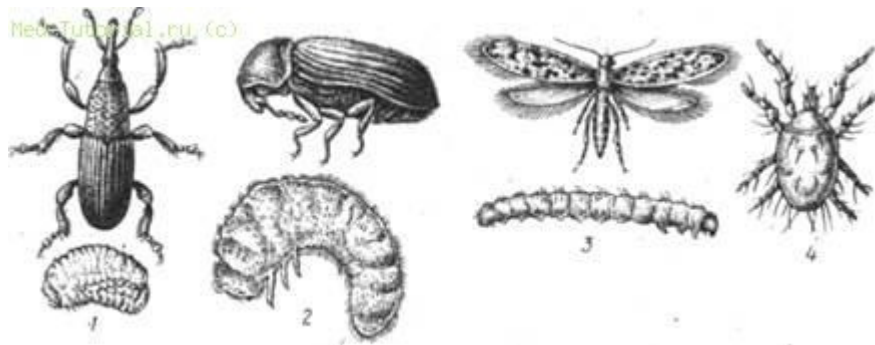
Preparation Works. To ensure quality of the produce to be stored and to prevent losses, it is necessary to properly maintain the collection center facilities year round. Maintenance works can be divided into two major categories: preparation works and current maintenance works. Preparation works should be done before the start of the main operation season and depend on the expected crops and volumes. It may include repair, thorough cleaning, sanitizing of collection center with approved food-grade sanitizers etc. Cleaning and sanitizing should be performed in all premises, including receiving, sorting areas, box storage, supplemental space etc. These sanitizers should be procured only from authorized vendors and application methods strictly followed.

Cooling equipment (if any) should be checked every year by authorized dealers.

Current maintenance works in addition to minor repairs, include cleaning and sanitizing of all areas after each crop. Revolving packaging (boxes etc) should also be regularly sanitized and checked on damages.

11. Plant pests and ways of pest control

Medicinal raw material, containing sugar, starch and other nutritious substances during transportation in contaminated transportation means and improper storage could be inflicted with weevil and corn sawfly, bugs, moths, larva and rodent.



Pic.Storage pests of medicinal raw material: storage weevil and its larva, 2- corn sawfly and its larva. 3- corn and storage moth and its larva, 4-floury tick.

For pest control proper measures have to be undertaken in warehouses. Preventive measures include maintaining clean and well vented facility and maintaining proper climate conditions, temperature (up to +12 °C) and protection from high level of humidity (no higher than 13 %).

Pests shall be exterminated by disinfection, disinfection and disinfestations of facility.

Different crops in the storage, especially for long-term storage, may attract mice and other pests. They may spoil the produce. Also, it is one of requirements towards food safety to ensure strict pest control. The first point is to well insulate all seals and keep the doors always closed. All areas (reception, sorting/grading, dispatching areas,) should be regularly sanitized with approved sanitizers. Only mechanical traps should be used in the collection center to catch mice. They should be inspected at least once a day. No poison is allowed in the entire facility. Cats or dogs should not be allowed to get in at any time! For insects, hanging glue strips or catching lamps should be used.



Mechanical and thermal cleaning methods of raw material can also be used, which consists in sifting through the set of sieves and heating up during one hour under the temperature of 50-60 °C. Raw material inflicted by larva shall be heated up during 2-4 hours, then dead larva shall be sifted.

Example of board marking rodent bait station



The extent of infestation depends on quantity of plant pests per 1 kg of raw material. For ticks: first degree - no more than 20 pests per 1 kg of raw material, second degree - more than 20 pests, freely moving on the raw material surface yet not forming solid mass; third degree – pests are too many, they form solid mass and their movement is hampered. For storage moth and corn sawfly: first degree - no more than 5 pests per 1 kg of raw material; second degree- no more than 6-10 pests; third degree -more than 10 pests.

In first degree of infestation a raw material after thorough cleaning can be admitted for further processing. In second degree raw material can be used only for preparation of medicines on specialized pharmaceutical plants (with proper labeling and only within the country); in third degree raw material shall be burned.

12. Sampling

Sampling shall be carried out by processor/collector after drying, after 2, 4, 6 etc. months of storage. On results of sampling processor/collector shall assort raw material on first grade, second grade and third grades. Sampled specimens shall be dissected and by carrying out visual inspection to determine the following: color homogeneity, odour and contamination, presence of rotten parts and mould, persistent extraneous odour, which is not vanished after airing, presence of noxious plants, extraneous admixtures (stones and glasses) and storage pests (by using magnifying glass with magnification factor x5 and x10).

Three spot testing shall be carried out for each piece selected for sampling (for instance better always from top, middle, and bottom. Then mixing and analyzing as described also for seed.): one from the top, another one from middle and third one from a bottom part of plant. Spot testing of seeds and dry fruits shall be taken out by using corn trier; from boxes first spot testing specimens shall be taken out by hand and the second spot testing shall be taken out from the middle part of box and the third spot testing from the bottom of the box. Sampling shall be made carefully, so that not to increase crushing.

To determine extent of infestation by storage pests, a sample specimen with a weight of 500 grams for small types of raw material and a sample specimen with a weight of 1 kg for large

type of raw material shall be allocated from the combined sample. This specimen shall be placed on glass jar with a label put inside.

Equipment and Supplies. To properly operate, the collection point should have necessary equipment and supplies including: weighing scales with capacity 30-500 kg,; sorting tables (min. 2); temperature/RH meters (hygrometers); boxes of various types and sizes; packaging materials, etc.



Figure X . Scales, Design of a sorting table, Temperature/RH Meter

13. Concepts and steps of improvement processes

Three crucial steps in the improvement of processes within a system are established through:

Map the process

- ✚ Collect information about the process, identify each step, determine inputs and outputs, people involved and decisions to take.
- ✚ Document measurement including time, cost, working conditions, employee situation, environment and waste, accidents and/or safety hazards, revenues and/or profits, quality and customer satisfaction, as appropriate.
- ✚ Prepare a flow chart that accurately depicts the process, with key activities and decisions represented inside.

Analyze the process

- ✚ Ask questions about the process: is it logical, are any steps or activities missing, are there any duplications?
- ✚ Ask questions about each step: is the step necessary, could it be eliminated, does the step add value, does any waste occur at this step?

- Analyze for improvement by asking: what causes induced known problems, could they be eliminated, can the process be improved by shortening time or by reducing costs, can the process be improved by providing better conditions for quality?

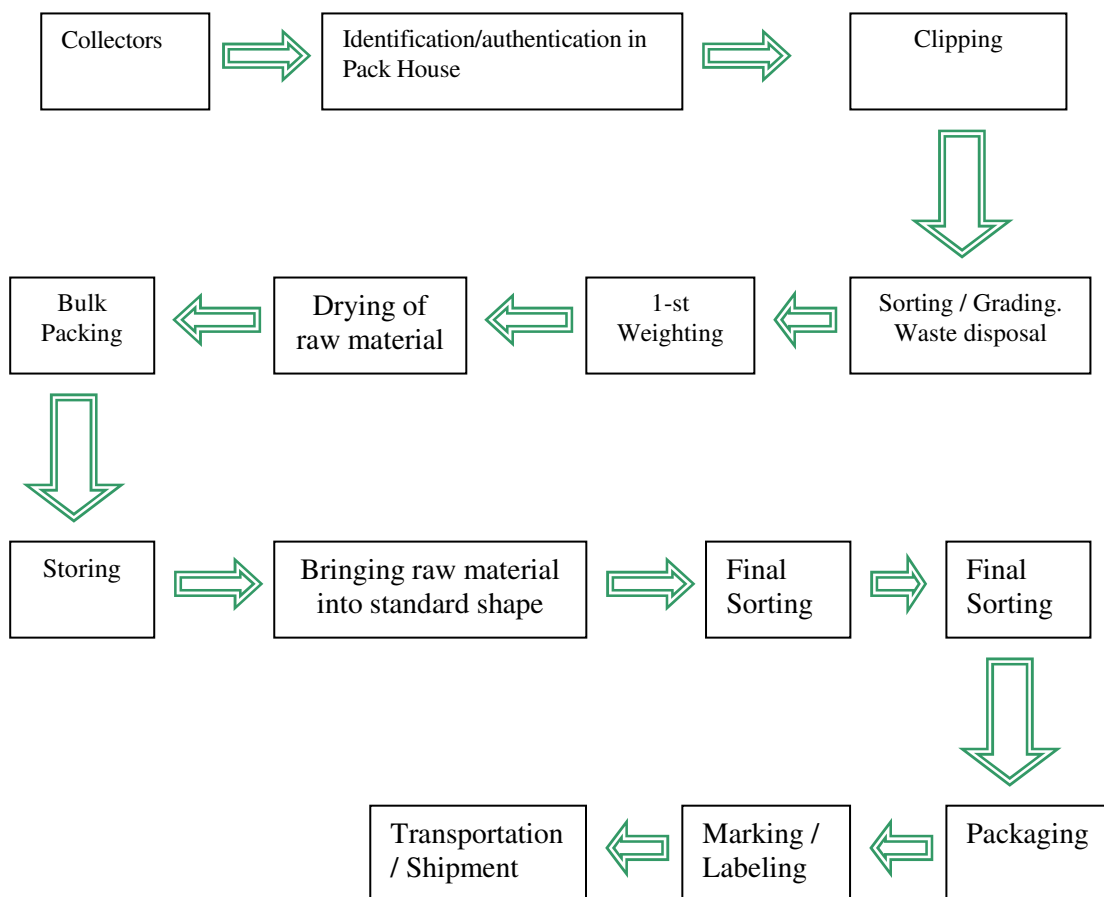
Redesign the process

Use results of analyses to redesign the process. Do documents improve, potential measures such as reductions in time, space, waste, employee turnover, accidents, safety hazards, improvement of working conditions, revenues/profits, quality, for customer satisfaction.

Process control

All productive work is planned and undertaken in accordance with the company's procedures, and any specific documents agreed for individual contracts (e.g. contract specifications).

Work instructions are provided by the agreed contract specification and any documents referenced therein, alternatively work is performed in accordance with internationally accepted codes of practice.



Part C: Annexes

LIST OF ANNEXES

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14. Examples quality requirements for different plant parts

ANNEX 14. 1: Wild Thyme herb GOST 21816-89

WILD THYME

Serpylli herba

DEFINITION

Whole or cut, dried, flowering aerial parts of *Thymus serpyllum* L.s.l.

Content: minimum 3.0 ml/kg of essential oil (dried drug).

CHARACTERS

Macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

A. The stem is much branched, up to about 1.5 mm in diameter, cylindrical or indistinctly quadrangular, green, reddish or purplish, the older stems brown and woody, the younger stems pubescent. The leaves are opposite, 3 mm to 12 mm long and up to 4 mm wide, elliptical to ovate-lanceolate with an obtuse apex, cuneate and shortly petiolate at the base; the margin is entire and markedly ciliate, especially near the base; both surfaces are more or less glabrous but distinctly punctate. The inflorescence is composed of about 6 to 12 flowers in rounded to ovoid, terminal heads. The calyx is tubular, two-lipped with the upper lip dividing to form 3 teeth, the lower lip with 2 teeth, edged with long hairs; inner surfaces strongly pubescent, the hairs forming a closed tube after flowering. The corolla is purplish-violet to red, two-lipped, the lower lip with 3 lobes, upper lip notched, inner surface strongly pubescent; stamens 4, epipetalous, projecting from the corolla tube.

B. Reduce to a powder. The powder is greyish-green to brownish-green. Examine under a microscope using chloral hydrate solution R. The powder shows the following diagnostic characters: fragments of the leaf epidermises with sinuous, slightly thickened anticlinal walls and stomata of the diacytic type; numerous covering trichomes on both epidermises and along the leaf margins, the majority short, conical, unicellular, with thickened and warty walls, fewer long, uniseriate, composed of up to 8 cells, slightly swollen at the joints, with moderately thickened walls; abundant glandular trichomes, mostly multicellular with a small, rounded, unicellular stalk and a large globular head composed of a number of indistinct, radiating cells containing brown secretion, others smaller, capitate, with unicellular stalk and a unicellular, globoid or ovoid head; purplish-violet fragments of the corolla, the outer epidermis with numerous covering and glandular trichomes, inner epidermis papillose; pollen grains spherical to elliptical, 30 µm to 40 µm in diameter, with a finely grained exine and 6 germinal pores.

C. Thin-layer chromatography.

Test solution. To 1.0 g of the powdered drug add 5 ml of methylene chloride R and shake for 3 min. Filter through about 2 g of anhydrous sodium sulphate R.

Reference solution. Dissolve 5 mg of thymol R and 10 µl of carvacrol R in 10 ml of methylene chloride R.

Plate: TLC silica gel F254 plate R.

Mobile phase: methylene chloride R.

Application: 20 µl, as bands.

Development: over a path of 15 cm.

Drying: in air.

Detection A: examine in ultraviolet light at 254 nm.

Results A: see below the sequence of the zones present in the chromatograms obtained with the reference solution and the test solution.

| | |
|--------------------------|----------------------------|
| Top of the plate | |
| | A prominent quenching zone |
| Thymol: a quenching zone | A quenching zone (thymol) |
| _____ | _____ |
| | Quenching zones |
| Reference solution | Test solution |

Detection B: spray with anisaldehyde solution R using 10 ml for a plate 200 mm square and heat at 100-105 °C for 10 min.

Results B: see below the sequence of the zones present in the chromatograms obtained with the reference solution and the test solution. Furthermore, other zones are present in the lower third of the chromatogram obtained with the test solution. The intensity of the zones due to thymol and carvacrol depends upon the sample examined (chemotypes).

| | |
|-------------------------------|--------------------------------|
| Top of the plate | |
| Thymol: a brownish-pink zone | A brownish-pink zone (thymol) |
| Carvacrol: a pale violet zone | A pale violet zone (carvacrol) |
| _____ | _____ |
| | |
| Reference solution | Test solution |

TESTS

Foreign matter: maximum 3 per cent, determined on 30 g.

Foreign matter may also consist of acicular to linear-lanceolate leaves with a strongly bent margin, the adaxial surface showing covering trichomes shaped as pointed teeth with warty walls, the abaxial surface showing many types of warty covering trichomes: unicellular, straight or slightly curved, bicellular or tricellular, often elbow-shaped, and bicellular or tricellular, more or less straight (*Thymus vulgaris*, *Thymus zygis*).

Loss on drying: maximum 10.0 per cent, determined on 1.000 g of the powdered drug by drying in an oven at 100-105 °C for 2 h.

Total ash: maximum 10.0 per cent.

Ash insoluble in hydrochloric acid: maximum 3.0 per cent.

ASSAY

Carry out the determination of essential oils in vegetable drugs. Use 50.0 g of the cut drug, a 1000 ml round-bottomed flask and 500 ml of water R as the distillation liquid. Distil at a rate of 2-3 ml/min for 2 h without xylene R in the graduated tube.

ANNEX 14. 2: Wild Sage leaves

SAGE LEAF (SALVIA OFFICINALIS)

Salviae officinalis folium

DEFINITION

Whole or cut dried leaves of *Salvia officinalis* L.

Content: minimum 15 ml/kg of essential oil for the whole drug and minimum 10 ml/kg of essential oil for the cut drug (anhydrous drug).

CHARACTERS

Sage leaf (*Salvia officinalis*) oil is rich in thujone.

Macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

A. The lamina of whole sage leaf (*Salvia officinalis*) is about 2 cm to 10 cm long and 1 cm to 2 cm wide, oblong-ovate, elliptical. The margin is finely crenate to smooth. The apex is rounded or subacute and the base is shrunk at the petiole and rounded or cordate. The upper surface is greenish-grey and finely granular; the lower surface is white and pubescent and shows a dense network of raised veinlets.

B. Reduce to a powder (355). The powder is light grey to brownish-green. Examine under a microscope using chloral hydrate solution R. The powder shows the following diagnostic characters: very numerous articulated and bent trichomes with narrow elongated cells and a very thick cell at the base as well as fragments of these trichomes; fragments of the upper epidermis with pitted, somewhat polygonal cells; fragments of the lower epidermis with sinuous cells and numerous diacytic stomata; rare single glandular trichomes with a uni- or bicellular head and a stalk consisting of 1 to 4 cells; abundant glandular trichomes with a unicellular stalk and a head composed of 8 radiating cells with a raised common cuticle.

TESTS

Foreign matter: maximum 3 per cent of stems and maximum 2 per cent of other foreign matter.

Water: maximum 100 ml/kg, determined on 20.0 g.

Total ash: maximum 10.0 per cent.

ASSAY

Carry out the determination of essential oils in vegetable drugs. Use 20.0 g of the substance to be examined, cut, if necessary, immediately before the assay, a 500 ml flask, 250 ml of water R as the distillation liquid and 0.5 ml of xylene R in the graduated tube. Distil at a rate of 2-3 ml/min for 2 h.

ANNEX 14.3: Fennel seed GOST 20460-75

FENNEL, BITTER, FOENICULI AMARI FRUCTUS

DEFINITION

Bitter fennel consists of the dry, cremocarps and mericarps of *Foeniculum vulgare* Miller sp. *vulgare* var. *vulgare*. It contains not less than 40 ml/kg of essential oil, calculated with reference to the anhydrous drug. The oil contains not less than 60.0 per cent of anethole and not less than 15.0 per cent of fenchone.

CHARACTERS

Bitter fennel is greenish-brown, brown or green.

It has the macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

A. The fruit of bitter fennel is a cremocarp, of almost cylindrical shape with a rounded base and a narrower summit crowned with a large stylopod. It is generally 3 mm to 12 mm long and 3 mm to 4 mm wide. The mericarps, usually free, are glabrous. Each bears five prominent slightly crenated ridges. When cut transversely, four vittae on the dorsal surface and two on the commissural surface may be seen with a lens.

B. Reduce to a powder. The powder is greyish-brown to greyish-yellow. Examine under a microscope using chloral hydrate solution R. The powder shows the following diagnostic characters: yellow fragments of wide secretory canals, often made up of yellowish-brown-walled polygonal secretory cells, frequently associated with a layer of thin-walled transversely elongated cells 2 µm to 9 µm wide, having a parquetry arrangement; reticulate parenchyma of the mesocarp; numerous fibre bundles from the ridges, often accompanied by narrow spiral vessels; very numerous endosperm fragments containing aleurone grains and very small calcium oxalate microrosette crystals, as well as some fibre bundles from the carpophore.

STORAGE

Store protected from light and moisture.

BOTANICAL PRODUCT SPECIFICATIONS: SWEET FENNEL FRUIT

| | |
|---------------------------|--|
| Botanical name | <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Miller) Thellung (Fam. Apiaceae) |
| Pharmacopoeial name | Foeniculi dulcis fructus |
| Part used | Dried cremocarps and mericarps |
| Cultivated or wild | Cultivated |
| Storage | Store protected from moisture. |
| IDENTIFICATION | |
| Macroscopic | PhEur ID Test A |
| Microscopic | PhEur ID Test B |
| Thin-layer chromatography | PhEur ID Test C |
| TESTS | |
| Foreign matter | NMT 1.5% peduncles and NMT 1.5% other foreign matter (PhEur 2.8.2) |
| Water | NMT 80 ml/kg (PhEur 2.2.13) |
| Total ash | NMT 10.0% (PhEur 2.4.16) |
| Content | NLT 20 ml/kg (anhydrous drug) of essential oil, of which NLT 80% is anethole, NMT 10.0% is estragole, and NMT 7.5% is fenchone |
| CONTAMINATION | |
| Heavy metals | NMT 1.0 ppm cadmium; NMT 5.0 ppm lead; NMT 0.1 ppm mercury |
| Pesticide residues | Meets the requirements PhEur General Chapter 2.8.13 |

ANNEX 14. 4: Fennel, sweet

Foeniculi dulcis fructus

DEFINITION

Sweet fennel consists of the dry, cremocarps and mericarps of *Foeniculum vulgare* Miller sp. *vulgare* var. *dulce* (Miller) Thellung. It contains not less than 20 ml/kg of essential oil, calculated with reference to the anhydrous drug. The oil contains not less than 80.0 per cent of anethole.

CHARACTERS

Sweet fennel is pale green or pale yellowish-brown.

It has the macroscopic and microscopic characters described under identification tests A and B.

IDENTIFICATION

A. The fruit of sweet fennel is a cremocarp of almost cylindrical shape with a rounded base and a narrowed summit crowned with a large stylopod. It is generally 3 mm to 12 mm long and 3 mm to 4 mm wide. The mericarps, usually free, are glabrous. Each bears five prominent slightly crenated ridges. When cut transversely, four vittae on the dorsal surface and two on the commissural surface may be seen with a lens.

B. Reduce to a powder. The powder is greyish-brown to greyish-yellow. Examine under a microscope using chloral hydrate solution R. The powder shows the following diagnostic characters: yellow fragments of wide secretory canals, often made up of yellowish-brown-walled polygonal secretory cells, frequently associated with a layer of thin-walled transversely elongated cells 2 µm to 9 µm wide, having a parquetry arrangement; reticulate parenchyma of the mesocarp; numerous fibre bundles from the ridges, often accompanied by narrow spiral vessels; very numerous endosperm fragments containing aleurone grains and very small calcium oxalate microrosette crystals, as well as some fibre bundles from the carpophore.

Foreign matter. Not more than 1.5 per cent of peduncles and not more than 1.5 per cent of other foreign matter.

Water . Not more than 80 ml/kg, determined by distillation on 20.0 g of the powdered drug.

Total ash. Not more than 10.0 per cent.

ASSAY

STORAGE

Store protected from light and moisture.

| Comparison of Sweet fennel fruit Pharmacopoeial Quality Standards | | | | | | |
|--|-------------|--|--|-------------|-------------|--|
| Identification tests: | Macroscopic | Macroscopic | Macroscopic | Macroscopic | Macroscopic | Macroscopic |
| | Microscopic | Microscopic | Microscopic | Microscopic | Microscopic | Microscopic |
| | TLC | TLC | TLC | TLC | TLC | TLC |
| Water | No standard | No standard | NMT 80 mg/kg | NMT 10.0% | No standard | NMT 8% |
| Foreign matter | NMT 2.0% | NMT 3.0% peduncles and NMT 1.0% other foreign matter | NMT 1.5% peduncles and NMT 1.5% other foreign matter | NMT 4.0% | NMT 2.0% | NMT 1.5% peduncles and NMT 1.5% other foreign matter |
| Total ash | NMT 12.0% | NMT 10.0% | NMT 10.0% | NMT 10.0% | NMT 12.0% | NMT 10% |
| Acid-insoluble ash | NMT 15.0% | NMT 1.5% | No standard | No standard | NMT 15.0% | NMT 1.5% |
| Alcohol-soluble | NLT 4.0% | No standard | No standard | No standard | NLT 4.0% | NMT 11% |

| | | | | | | |
|---------------------------------|----------------|---|--|-----------------|----------------|----------------|
| extractive | | | | | | |
| Water-soluble extractive | NLT 1.0% | No standard | No standard | No standard | NLT 1.0% | NMT 20% |
| Essential oil | NLT 1.4% (v/v) | NLT 0.7 ml from 50 g of pulverized fennel | NLT 20 ml/kg, of which NLT 80% is anethole, NMT 10.0% is estragole, and NMT 7.5% is fenchone | NLT 1.5% (ml/g) | NLT 1.4% (v/w) | NLT 1.4% (v/w) |

ANNEX 14. 5: Nettle (leaf) GOST 12529-67

Specifications

Current standard is applicable for dried leaves of nettle (*Urtica dioica* L.), intended for medicinal-technical use.

1. TECHNICAL REQUIREMENTS

1.1 Nettle leaves must be dried without access of direct sunlight and must meet the requirements specified in the table below:

| Name of indicator | Norm |
|---|---|
| For solid raw material | |
| 1. Appearance | Leaves are oblong, pointed at the edges with sparse hairs, with petioles, which are thin, brittle, have length up to 17 cm, width up to 7 cm. Partially crushed leaves are allowed. |
| 2. Color | Dark green, blackened and brownish leaves are allowed, no more than 5% |
| 3. Smell | Peculiar |
| 4. Taste | Bitter-herbaceous |
| 5. Moisture in %, not more than | 14,0 |
| 6. Mass fraction of nettle pieces (stems, inflorescences and others), in %, not more than | 5,0 |
| 7. Mass fraction of crushed pieces that pass through a sieve with holes of 3 mm diameter, %, not more than | 10,0 |
| 8. Mass fraction of impurities in %, not more than <ul style="list-style-type: none">• Organic (part of the other plants)• Mineral (sand, land, dust, pebbles, etc.) | 2,0 1,0 |

| Name of indicator | Norm |
|--|--|
| For cut raw material | |
| 1. Appearance | Leaves are crushed (cut), the particles of various shapes are ranging in size from 1 to 8mm. |
| 2. Color, smell, taste | Dark green, blackened and brownish leaves are allowed, no more than 5% |
| 3. Moisture in %, not more than | 14,0 |
| 4. Mass fraction of ash, in %, not more than | 20,0 |
| 5. Mass fraction of crushed pieces not more than 8 mm size, in %, not more than | 10,0 |
| 6. Mass fraction of crushed pieces that pass through a sieve with holes of 0,5 mm diameter, %, not more than | 15,0 |
| 7. Mass fraction of impurities in %, not more than | |

| | |
|---|-----------------------|
| <ul style="list-style-type: none"> • Organic (part of the other plants) • Mineral (sand, land, dust, pebbles, etc.) | <p>2,0</p> <p>1,0</p> |
|---|-----------------------|

2. TESTING METHODS

Sampling nettle leaves and determination of their quality should be in accordance with GOST 24027.0-80 and GOST 24027.2-80.

3. PACKAGING, LABELING, TRANSPORTATION AND STORAGE

- 3.1 The packaging and labelling of nettle should be in accordance with GOST 6077-80.
- 3.2 Whole nettle leaves are packed in bales of 50kg capacity, and the cut leaves - in bags of 20kg (GOST 8516 -78).
- 3.3 Nettles should be kept on the shelves in dry, well ventilated areas, without access to direct sunlight.
- 3.4 Transportation and storage of nettle leaves must be carried out under conditions ensuring their complete safety in accordance with instructions approved by the All-Union "Lekrasprom" USSR Ministry of Health in coordination with Centrosoyuz.

ANNEX 14. 6: Fruits of bilberry GOST 3322-69

Specifications

Current standard is applicable for dried, fully ripe fruits of wild growing *Vaccinum myrtillus* from family Ericaceae, intended for medicinal raw material use.

TECHNICAL REQUIREMENTS

The indicators of raw material should be in accordance with the data in the following table.

| Name of indicator | Norm |
|--|--|
| 9. Appearance | The size of fruits of the berry have from 3 to 6 mm in diameter, shapeless, greatly shrunken, have globular shape in soaked condition. At the top of the fruit the rest of the cup is seen in form of small circular rim, surrounding the blistering disc with the remainder of the column in the center or with slight indentation after its mortality. In the pulp of the fruit there are numerous small seeds of ovoid form. At the base of the fruit there is sometimes a short stalk. |
| 10. Color of surface | Black with reddish tinge, matt or slightly shining |
| • Pulp | Red-violet |
| • Seeds | Red-storm |
| 11. Smell | Peculiar, faint |
| 12. Taste | Sour-sweet, slightly astringent |
| 13. Mass fraction of moisture in %, not more than | 17,0 |
| 14. Mass fraction of ash in %, not more than | 3,0 |
| 15. Mass fraction of ash, insoluble in 10% hydrochloric acid solution by GOST 3118-70, in %, not more than | 0,8 |
| 16. Mass fraction of leaves and parts of the stems of blueberry in %, not more than | 0,25 |
| 17. Mass fraction of noon immature, hard and burnt fruits in %, not more than | 1,0 |
| 18. Mass fraction of impurities in %, not more than | |
| • Mineral (land, sand, pebbles) | 0,5 |
| • Organic (part of the other non-poisonous plants) | 2,0 |
| 19. Presence of mold and rot | Prohibited |
| 20. Presence of sustainable foreign smell, which does not disappear with ventilation | The same |

1.2 Collectors and suppliers of raw materials must ensure the conformance of raw material with this standard

1.3 In case of the mutual supply with National Republic of Bulgaria the requirements for blueberry fruits must comply with the table, while the mass fraction of moisture has to be the base – 14%, restrictive – 17%, the presence of pests and their larvae is not allowed.

TESTING METHODS

2.1 Bilberry fruit sampling and determining of quality is carried out according to GOST 24027.0-80 - GOST 24027.2-80 with additions indicated in point 2.2.

2.2 For establishing the authenticity of raw materials, the following qualitative reactions are used.

The decoction of berries (1:10) has a dark purple color.

When adding to it several drops of a solution of sodium hydroxide (caustic soda) according to GOST 4328-77, olive-green coloration appears.

When adding to it several drops of a solution of basic lead carbonate according to GOST 11840-76, amorphous blue precipitate is formed, partially soluble in acids, and at the same time the solution takes a pink or red color.

When adding to the broth a few drops of a solution of iron- ammonium alum, black-green staining appears.

PACKAGING, LABELING, TRANSPORTATION AND STORAGE

Bilberry fruits are packed in sacks in accordance with GOST 6077-80 by 35-50kg netto.

Labelling is done according to GOST 6077-80.

The storage and transportation of bilberry fruits must be carried out in accordance with the instruction approved by the Ministry of Medical Industry of the USSR.

Warranty period of storage is 2 years starting from the production.

ANNEX 14. 7: Coltsfoot leaves GOST 13382-67

Specifications

The current standard applies to dried leaves of wild growing herbaceous plant coltsfoot (*Tussilago fadara* L.) from family of Asteraceae (Compositae), intended for use as medical raw material.

1. TECHNICAL REQUIREMENTS

The leaves of coltsfoot should be collected in the first half of summer and be in accordance with the norms of below table:

| Name of indicator | Norm |
|---|--|
| For solid raw material | |
| 21. Appearance | Leaves have a form of round-heart, emarginate on the edges and unevenly rare and finely toothed, glabrous above, below from the abundance of messy long hair. Petioles are slender, fluted on top, often with preserved tomentose pubescence. The length of the leaf blade is usually 8-15 cm, in width about 10 cm, length of stem is about 5cm. Leaves should not be too young, i.e. should not have dense pubescence on the upper side. |
| 22. Color of top side • Bottom side | Green Whitish-gray |
| 23. Smell | Absent |
| 24. Taste | Weak-bitter with feeling of mucus |
| 25. Moisture in %, not more than | 13,0 |
| 26. Mass fraction of ash, in %, not more than | 20,0 |
| 27. Mass fraction of brownish leaves and brown spots of rust in %, not more than | 8,0 |
| 8, 9. Deleted (see Modification N1) | |
| 10. Mass fraction of impurities in %, not more than • Organic (parts of other non-poisonous plants) • Mineral (soil, sand, pebbles) | 2,0 2,0 |

| Name of indicator | Norm |
|----------------------------------|--|
| For cut raw material | |
| 8. Appearance | Pieces of leaves of different forms, that pass through a sieve by TY 23.2.2068--89 with holes of 7 mm diameter |
| 9. Color | Grayish-green |
| 10. Smell | Absent |
| 11. Taste | Weak-bitter with feeling of mucus |
| 12. Moisture in %, not more than | 13,0 |

| | |
|--|------------|
| 13. Mass fraction of ash, in %, not more than | 20,0 |
| 14. Mass fraction of crushed pieces that do not pass through a sieve by TY 23.2.2068 with holes of 7 mm diameter, %, not more than | 20,0 |
| 15. Mass fraction of crushed pieces that pass through a sieve by TY 23.2.2068 with holes of 0,5 mm diameter, %, not more than | 5,0 |
| 16. Mass fraction of impurities in %, not more than <ul style="list-style-type: none"> • Organic (parts of other non-poisonous plants) • Mineral (soil, sand, pebbles) | 2,0 1,0 |

(Revised edition, Modification N1)

1.2 Collectors and suppliers of raw materials must ensure the conformance of raw material with this standard.

1.3 The presence of mold and rot, resistant foreign smell, which does not vanish when ventilating, is not allowed

1.4 In case of the mutual supply with National Republic of Bulgaria the requirements for coltsfoot leaves must comply with the table; herewith the mass fraction of organic impurities (parts of other non-poisonous plants) has to be not more than 1,5%.

1.3 and 1.4 are introduced additionally

2. TESTING METHODS

2.1 sampling of leaves and determination of their quality is performed according to GOST 24027.0- GOST 24027.2.

3. PACKAGING, LABELING, STORAGE AND TRANSPORTATION

Coltsfoot leaves are packed in bags and bales in accordance with GOST 6077.

Whole and cut coltsfoot leaves, packed in bags, should be not more than 20kg, bags of 50kg. Labelling is done according to GOST 6077.

The storage and transportation of coltsfoot leaves must be carried out in accordance with the instruction approved by the Ministry of Medical Industry of the USSR.

Warranty period of storage is 3 years starting from the production.

(Applied additionally, Modification N1)

ANNEX 14.8: Common Coltsfoot flowers Gost 21568-76

Specifications

The current standard applies to baskets of dried flowers of wild growing perennial herbaceous plant coltsfoot (*Tussilago fadara* L.) from family of Asteraceae (Compositae), intended for export.

4. TECHNICAL REQUIREMENTS

- a. The flowers of common coltsfoot should be collected in the beginning of flowering (in March-April).
- b. By the indicators the quality the common coltsfoot flowers should conform to the requirements and norms of the following table:

| Name of indicator | Norm |
|--|---|
| 28. Appearance | Floral baskets with no stems or with the remainder of peduncle with no longer than 1 cm length. Each basket consists of several rows of edge ligulate pistillate flowers and a few medial tubular-campanulates, with pyatilopastnye edge of bisexual flowers. Dried baskets across have length of 10-15mm. Flowers are arranged on a flat naked receptacle and are surrounded by a common uniform wrapper of linear leaves. All the flowers on the top of the ovary have a tuft of thread-like white hairs. |
| 29. Color of: <ul style="list-style-type: none"> • leaves of wrapper • ligulate and tubular flower stems | Green, purple on the edges and in the middle. Yellow, Green. |
| 30. Smell | Peculiar, weak |
| 31. Taste | Bitter, with feeling of mucus |
| 32. Moisture in %, not more than | 15 |
| 33. Mass fraction of the baskets with the remainder stems longer than 1 cm, in %, not more than | 4 |
| 34. Mass fraction of disbanded and faded baskets, %, not more than | 3 |
| 35. Mass fraction of shredded pieces which pass through a sieve by TY 23.2.2068-89 with holes of 2 mm diameter, %, not more than | 2 |
| 36. Mass fraction of impurities in %, not more than <ul style="list-style-type: none"> • Organic (parts of other non-poisonous plants) • Mineral (soil, sand, pebbles) | 0,5 1 |
| 37. Presence of poisonous plants, | Not allowed |
| 38. Presence of mold and rot | The same |
| 39. Presence of resistant foreign smell, which does not vanish when ventilating | The same |

1.3 Contamination of raw material with granary pests of 2nd and 3rd degrees is not allowed.

5. ACCEPTANCE RULES

- a. Acceptance rules are according to GOST 24027.0- 80.

6. TESTING METHODS

- a. Methods for quality determination in accordance with GOST 24027.0-80, GOST 24027.2-80 with the following addition: for determining the content of the baskets with reminders of peduncle with length from 1,0 to 2 cm from the analytical sample, designed to determine the infestation by pests, manually choose baskets peduncle with length ranging from 0.5 to 2 cm, weigh them individually to the nearest tenth of a gram and calculate their content in percentages. From the same sample plants are selected manually with faded and loose baskets, weigh them individually to the nearest tenth of a gram and calculate their content in percentages.

7. PACKAGING, LABELING, TRANSPORTATION AND STORAGE

- a. The flowers of common coltsfoot are packed in accordance with GOST 6077-80 in plywood boxes, lined from inside with wrapping paper of mark B in accordance to GOST 8273-75, with density 40-50g/sm³ or with sack paper in accordance with GOST 2228-81 or with parchment in accordance with GOST 1760-86, with mass not more than 25 kg.
- b. The labeling of flowers – by GOST 6077-80, the labelling of shipping container – by GOST 14192-77,
- c. Transportation and storage – by GOST 6077-80.

8. WARRANTY OF THE PROVIDER

- a. The supplier shall ensure the compliance of raw materials with the requirements of this standard, subject to consumer storage conditions specified by the standard.
- b. Guaranteed shelf life of common coltsfoot flowers is 2 years after billet.

ANNEX 14.9: Raspberry fruits GOST 3525-75

Specifications

Current standard is applicable for dried fruits of wild or cultivated raspberry bushes from ordinary family Rosaceae, intended for medicinal use.

4. TECHNICAL REQUIREMENTS

4.1 Raspberry fruits should be harvested at maturity, be released from the peduncles and the cone-shaped receptacles and should conform to the requirements of quality indicators of the following table:

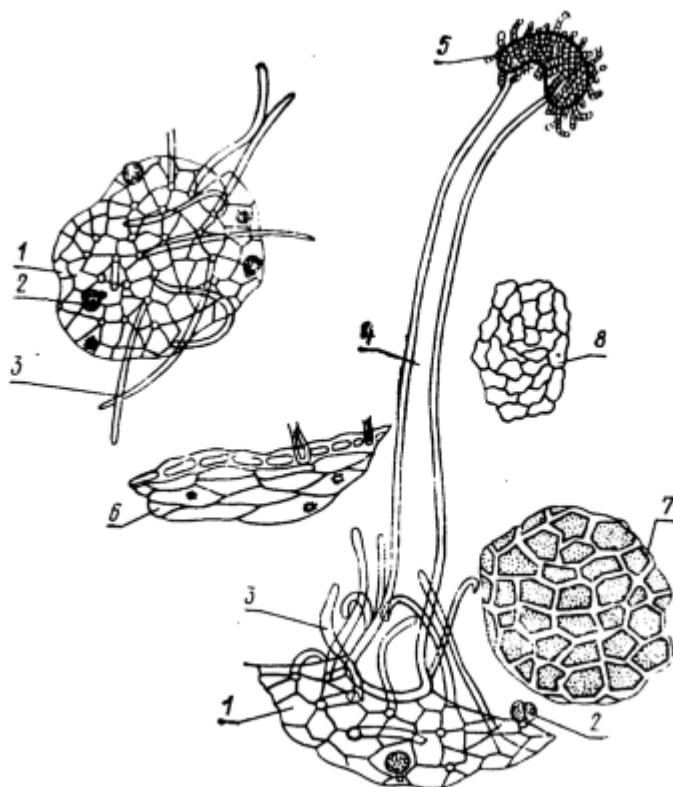
| Name of indicator | Norm |
|---|--|
| 40. Appearance, size and structure | The fruits are in groups - complex drupes of round or cone-shaped appearance, not stuck together in clumps. Consist of a large number (30-60) of separate, fused together stone-fruits. The dimensions of the fetus from 7.5 to 12 mm. Individual drupes are small, spherical or elliptical, with a bone inside, which has a pitted surface. |
| 41. Color of <ul style="list-style-type: none">• surface• pulp• seeds | grayish-raspberry pinkish dark yellow |
| 42. Smell | Specific, pleasant |
| 43. Taste | Sour- sweet |
| 44. Mass fraction of moisture in %, not more than | 15,0 |
| 45. Mass fraction of ash in %, not more than | 3,5 |
| 46. Mass fraction of blackened fruit, %, not more than | 0,8 |
| 47. Mass fraction of fruit stuck in clumps, %, not more than | 4,0 |
| 48. Mass fraction of fetuses with non-separable pedicels and receptacles, %, not more than | 2,0 |
| 49. Mass fraction of ground particles of fruit passing through the sieve in accordance with GOST 214-70 with a hole diameter of 2 mm, %, not more than | 4,0 |
| 50. Mass fraction of leaves and parts of the stems of raspberry in %, not more than | 0,5 |
| 51. Mass fraction of impurities: <ul style="list-style-type: none">• Organic (part of the other non-poisonous plants), %, not more than• Mineral (land, sand, pebbles), %, not more than | 0,5 0,5 |
| 52. The presence of poisonous plants | Prohibited |

| | |
|--|------------|
| and their parts | |
| 53. Presence of mold and rot | Prohibited |
| 54. Presence of sustainable foreign smell, which does not disappear with ventilation | Prohibited |

The anatomy of the fruit of raspberries (see the picture) should match the following description.

When considering a drupe fruit under the microscope, polygonal epidermal cells with very thin walls are visible from the surface. Glandular hair is found on all surfaces. They have a short leg of unicellular and two-celled oval, rarely spherical unicellular head, the content of which is coloured in orange by solution of Sudan III. Numerous simple unicellular, very thin hairs, are bound to the small round cells of the skin. Entire stigma, often with broken pestles, are met.

Parenchyma cells of the pulp are large, thin-walled, contain small Druze calcium oxalate. Mechanical tissue of the pericarp is composed of a drupe of seeds, which are located in layers



5. ACCEPTANCE RULES

Acceptance rules, set in accordance with GOST 6076-74, with the following addition: The ash content and anatomical structure of raspberry fruit determines the consumer.

6. TESTING METHODS

Testing methods are in accordance with GOST 6076-74.

7. PACKAGING, LABELING, TRANSPORTATION AND STORAGE

- 7.1 Raspberry fruits are packed in accordance with GOST 6077-74 with the following addition: raspberry fruit is packed in bags according to GOST 19317 -73 and GOST 18225 -72, by 30-40kg net weight.
- 7.2 Marking of transport packages - by GOST 14192 -71, marking materials - according to GOST 6077 -74.
- 7.3 Transportation and storage of fruits of raspberry by GOST 6077-74.

8. WARRANTY OF THE PROVIDER

- 8.1 The Supplier shall ensure the compliance of raw materials with the requirements of this standard, subject to consumer storage conditions specified by the standard.
- 8.2 Guaranteed shelf life of raspberry fruits is 2 years after processing.

ANNEX 14.10 Persian Walnuts GOST 16832-71

Specifications

This standard applies to walnuts, harvested and purchased by procurement and trading companies, sold in shops and used for processing.

9. TECHNICAL REQUIREMENTS

- 9.1 Depending on quality, walnuts on the fall into three product classes: extra, first and second, corresponding to the standards and characteristics specified in the table.

| Name of indicator | Norm and characterization of the product class | | |
|---|---|--|---|
| | Extra | First | Second |
| 1. Appearance | Nuts whole, it is fully developed, peeled pericarp | | |
| Shell colour | Uniform light-gray to light brown colour | | From light gray to dark brown |
| 2. Shell quality | The shell is thin, the walnut is easily cracked | | Nuts with difficult to split shells are admitted |
| 3. The size of a nut to the largest cross- diameter, mm, not less | 28,0 | 25,0 | 20,0 (not uniform in size) |
| | (uniform in size) | | |
| 4. The surface of the nut | Smooth, with inconspicuous edges | Smooth or slightly rough, edges slightly stand above the surface | Rough, ribbed |
| 5. Exit the kernel, %, not less | 50,0 | 45,0 | 35,0 |
| 6. Severability of kernel from the shell | The kernel can be easily separated as a whole, halves, quarters | | The kernel is removed with difficulty – pieces of different sizes, but not less than 1/8 part |

| | | | |
|--|--|------|---|
| 7. The color and quality of the kernel | Nucleus with a thin skin of golden-yellow until light brown, white with a yellow tinge on the fracture | | Kernel from light brown to brown, on fracture white with yellow shade |
| 8. Taste and smell of the kernel | Peculiar to walnut, without foreign taste and odor | | |
| 9. Humidity kernel, %, not more | 10,0 | 10,0 | 10,0 |
| 10. The presence of impurities nutshell, % (by weight), not more | Prohibited | 0,1 | |
| 11. The presence of nuts with a stubborn skin, % (by weight), not more | Prohibited | 1,0 | 0,3 |
| 12. The presence of damage by pests, rancid, immature kernels, % (by weight), not more | 1,0 | 5,0 | 3,0 Area of stubborn skin is not more than half of the surface of the walnut |
| 13. The presence of live pests (insects or their larvae) inside walnut | Prohibited | | |

1.2. (Deleted, Modification N1).

1.3. The content of toxic elements, aflatoxin B1 and pesticides in the nuts should not exceed permissible levels, established by biomedical requirements and sanitation norms of Quality of raw materials and food products of MOH of the USSR.

(Introduced in addition, Modification N1).

10. ACCEPTANCE RULES

2.1. Walnuts are accepted in batches. Any number of products of one commodity of the same class, which is packed and labelled identically, intended for simultaneous acceptance and decorated by one identity and certificates on "toxicant content in crop products and compliance regulations of pesticide application" approved in installed order, is considered as one batch.

(Revised edition, Modification N1).

2.2. Batch of nuts intended for shipment is checked for compliance in accordance with this standard.

2.3. When accepting, each batch should be inspected for determining the quality of walnuts, their homogeneity, correct packaging and labelling in accordance with the requirements of this standard.

2.4. For quality control of walnuts, standard walnuts from different batches are selected in order to meet the requirements of this standard: below 50 packaging units - at least 5 packing units; over 50 - one packaging unit in addition for each subsequent 20-packed gauge units.

2.3 and 2.4. (Revised edition, Modification N1).

2.5. The control of toxic elements, aflatoxin B¹ and pesticides is carried out in prescribed manner.

2.6. The results of the audit cover the whole batch.

2.7. When accepting a batch of walnuts, it is allowed:

In the batch of extra grade not more than 5% of 1st commercial grade walnuts.

If the batch of extra grade contains more than 5% of 1st commercial grade, the entire batch is transferred to 1st commercial grade;

In the batch of 1st commercial grade there are no more than 10% of nuts 2nd commercial grade.

If the batch of 1st commercial grade contains more than 10% of 2nd commercial grade, the entire batch is transferred to 2nd commercial grade;

In the batch 2nd commercial grade contains no more than 15% of walnuts that do not meet the requirements of these varieties, but is suitable for consumption.

If the batch 2nd commercial grade contains more than 15% of walnuts that do not meet the requirements of 2nd commercial grade, then the whole batch is deemed not to comply with the requirements of this standard.

2.8. After checking the quality, the walnuts selected from the batch, are attached to the controlled batch.

2.5 -2.8. **(Introduced additionally, Modification N1).**

11. TESTING METHODS

3.1. Sample weighing not less than 500 g are extracted from the top, middle and bottom of each selected package unit. All the samples of the batch are thoroughly mixed, flat in a thin layer as square and share in two parts by diagonal, one of which will be an average sample. The weight of walnuts in average sample should be not less 8 kg.

(Revised edition, Modification N1).

3.2. The average sample is divided into two equal parts. One part (test sample) is placed in hermetically-closed container, is sealed and kept longer than one month in the organization, host the batch. Another part (analyzed sample) is checked on all Indicators of this standard. All samples are taken and sealed in the presence of the representative of provider-organization.

3.3. Test portion is weighed with an error not exceeding 5g.

Then the walnuts are poured on a flat surface and separated from the impurities, debris shell, nuts with stubborn skin, are weighted and calculate the percentage of the total mass of the sample.

(Revised edition, Modification N1).

3.4. The appearance and colour of the shell is determined organoleptically.

3.5. To establish the size, 100 walnuts are randomly taken and the caliper size in mm to the largest transverse diameter is determined.

Then the walnuts are chopped and the percentage of damage by pests, underdeveloped, the presence of live insects and their larvae is determined.

3.6. Severability and exit of the kernel is determined by the selection of a test sample of 100 nuts.

Nuts are weighted and split and after separation and new weighting the percentage of released kernel and the degree of crashing of the walnuts is calculated. Simultaneously the number of rancid nuclei and quality of kernel is determined organoleptically (colour, taste smell). The results are expressed in percentage to the mass of 100 nuts.

3.7. For determining the moisture of the kernels 100 full-cores are taken, crush them up to a value

particles in the bulk of about 1-2 mm. Two parallel samples of 5 g (with an accuracy not worse than

0.0001 g) is poured into sample bottle with a diameter (40 ± 2) mm, place in a heated drying cabinet with temperature up to 135-140 °C and dry at temperature (130 ± 2) °C for 40 min.

After drying, sample bottles with samples are covered with not tight lids, put in desiccator with chloride calcium and strong sulfuric acid for 25-30 minutes until getting totally cooled, then tightly seal and weight.

The amount of moisture (W) in percentages is calculated by the following formula:

$$W=(m_1-m_2/m_1-m_0)*100$$

Where m_1 : Mass of sample bottle with a hitch before drying, g;

m_2 : Mass of sample bottle with a hitch, after drying, g;

m_0 : Mass of empty sample bottle,

Computation is carried out to the second decimal number rounding the result to the first ten-mean-square sign. Permissible discrepancies between parallel determinations should not exceed 3%.

(Revised edition, Modification N1).

3.8. The results of the analysis apply to the entire batch.

3.9. In case of non-conformity of the quality of walnuts to this standard, an iterated test of twice the average of the sample is carried out.

3.10. **(Deleted, Modification N1).**

3.11. The content of toxic elements is determined according to GOST 26927, GOST 26930 - GOST 26934, aflatoxin B₁ and pesticides - a method approved by the USSR Ministry of Health.

(Introduced additionally, Modification N1).

12. PACKAGING, LABELING, TRANSPORTATION AND STORAGE

4.1. Walnuts are tightly packed in cloth bags (not below the third category) with weight up to 50kg in accordance with GOST 30090.

4.2. Containers should be sound, whole, dry, not damaged by pests, clean, without odour. Bags made of cloth are sewn securely, leaving the edges of "ears" for the convenience while carrying.

Kernels may be packed in paper bags of GOST 2226 weighing up to 30 kg;

a) 4-layer: for shipment in cars;

b) 3-layer: when shipped in containers.

4.3. On each unit package with the help of a stencil or label clear marking should be affixed with indelible and odourless paint showing:

the names and addresses of the sending organization;

product names;

commercial grade;

crop year;

gross and net weight;

date of packing;

number of the certificate of quality.

4.4. Each batch of walnuts should be accompanied by a certificate as to the indication of: identity card number and its date of issue;

names and addresses of the sending organization;

name and address of the recipient organization;

product names;

commercial grade;

number of seats, gross and net weight in kg;

date of packing and shipping;

number of the vehicle;

family responsible for quality;

date of last treatment with pesticides and their names;

designations of this standard.

4.3 , 4.4. **(Revised edition, Modification N1).**

4.5. Walnuts should be stored in clean, dry indoors not infected by pests and not having foreign odour at a temperature of minus 15 to plus 20 °C (without sharp fluctuations) and relative humidity of 70%. Shelf life is no more than one year.

4.6. Bags of walnuts are placed on racks or stacked on the board. The distance between racks (board) and the wall, as well as between individual piles shall be not less than 0,7m, the distance from the water pipes, heaters, stoves and chimney - not less than 1m.

4.7. Nuts are transported in compliance with the relevant requirements in clean, dry, not infected by pests wagons, cars. In the carriage of vehicular transport, bags with walnuts

should be protected from the weather.

ANNEX 14.11: Dandelion Root

Botanical: *Taraxacum officinale*

Family: *Compositae* (daisy) - *Asteraceae* (aster)

Other common names: Bitterwort, Pissabed, Lion's Tooth, Priest's Crown, Telltime, Puffball, Cankerwort, Blow Ball, Swine Snout, White Endive, Wild Endive, Irish Daisy, Doonheadclock, Yellow Gowan, Clock Flower, Fortuneteller

History and Uses:

Dandelion is more than just a common lawn weed; it is one of the planet's most famous and useful weeds, containing vital nutrients, minerals and vitamins A, B, C and D. It has been used for centuries as a primary herb that purifies the blood and flushes toxins out of the body, via the liver and kidneys. The genus name, *Taraxacum*, is derived from the Greek words, *taraxos*, meaning "disorder," and *akos*, meaning "remedy" and is said to be one of the bitter herbs in the Passover tradition. Today, Dandelion is commonly found in salads, wines and multi-herbal combinations. Dandelions were brought from Europe by the early colonists and were used to help "clear the body of old emotions, such as anger and fear, that can be stored in the body's liver and kidneys." The principal constituents responsible for Dandelion's effect on the digestive system and liver are the bitter principles. Previously referred to as taraxacin, these constituents are sesquiterpene lactones of the eudesmanolide and germacranolide type, and are unique to Dandelion. Rich in calcium, iron, potassium, phosphorus and sodium, Dandelion is ideal for treating high blood pressure and poor digestion by stimulating the circulation of blood to the entire body. Dandelion's anti-inflammatory properties help alleviate inflammation and muscle spasms, plus it acts as a mild laxative relieving constipation. Dandelion, unlike some chemical diet supplements, will not deplete the body of potassium when used for water weight loss. Dandelion Leaf contains approximately forty-percent inulin, a fiber widely distributed in fruits, vegetables and other plants. Inulin is classified as a food ingredient (not as an additive) and is considered safe to eat. In fact, inulin is a significant part of the daily diet of most of the world's population.

Ingredients: 100% Dandelion Root 4:1 Botanical Extract - Our products contain 100% pure plant-based/natural materials using no fillers, grains, yeast, sugars, binders, excipients, starches, or synthetic materials.

Recommended Dosage:

Take two (2) capsules, two (2) to three (3) times each day with water at mealtimes.

Contraindications:

Pregnant and nursing women should not use Dandelion. It is not recommended for people with gallstones or biliary tract (bile duct) obstruction without first consulting a physician. In cases of stomach ulcers, gastritis or irritable bowel, Dandelion should be used cautiously, as it may cause over production of stomach acid. Those who are allergic to daisies or asters should not use Dandelion. Do not take Dandelion without talking to your doctor first if you are taking certain medicines used to treat infection (antibiotics such as Cipro, Tequin, Levaquin, etc., as it may lower efficacy of drug); Potassium supplements for health condition (too much may be harmful); Blood thinning medicine (Coumadin, Plavix, aspirin, etc.).

| BOTANICAL PRODUCT SPECIFICATIONS DANDELION ROOT Product of Eastern European Countries PRODUCT | Radix Taraxaci ÖAB4 |
|--|--|
| Botanical name | <i>Taraxacum officinale</i> (Weber s.l.) (Asteraceae) |
| Pharmacopoeial name | Taraxaci radix ÖAB |
| Plant part used | Dried root harvested in autumn |
| Cultivated or wild | Wild harvested |
| Storage | Store in well sealed containers protected from light and insect damage |

| | |
|--------------------------------|--|
| IDENTIFICATION | |
| Macroscopic | As per ÖAB monograph |
| Macroscopic | As per ÖAB monograph |
| Organoleptic | Color: grey-brown to blackish brown; Odour: slight; Taste: slightly bitter |
| TESTS | |
| Bitter Value | NLT 100 (ÖAB.: XII, 5) |
| Total ash | NMT 9.0% (ÖAB.: IX, 2, b)) |
| MICROBIOLOGICAL TESTS | |
| Total viable aerobic count | NMT 107 bacteria and NMT 105 fungi per gram or per milliliter |
| <i>Escherichia coli</i> | NMT 102 cfu/g or cfu/ml |
| AVERAGE SINGLE DOSE | |
| | 1.5 g per 1 cup of tea prepared as an infusion or decoction |
| FORMULATIONS | |
| | As a component Species cholagogue (Cholagogue Tea) |
| ACTIONS AND INDICATIONS | |
| | Actions: cholagogue, diuretic, appetite stimulant; Indications: Disturbances in bile flow, stimulation of diuresis, loss of appetite, and dyspepsia. |

ANNEX 15: Checklist Manufacturing Facilities

| Checkup Criteria | | | |
|------------------|--|-----|----|
| N | Manufacturing facilities | Yes | No |
| 1 | Are there any nests, birdhouses and clusters of insects, birds, rodents and other animals in production shops, auxiliary facilities and open-air areas? | | |
| 3 | Has enough clearing space been allocated for installation of equipment, for product storage and for production technology cycle? | | |
| 4 | Are the floors, walls and ceilings built with easy cleaning materials and maintained clean and repaired? | | |
| 5 | Are the final products (vegetable raw material and others) and other contacting surfaces properly protected from contamination, resulting from the pipeworks and other surfaces located above in facility? | | |
| 6 | Are the products (vegetable raw material and others) drying, conservation, packaging and other shops properly isolated from other facilities (like barn, poultry yard, chemical storage, food, spare parts, and fuel storage facilities) and other activities (construction, repair works, machineries/equipment repair work etc.) which could contaminate products (vegetable raw material and others). | | |
| 7 | Are the products (vegetable raw material and others) properly protected from broken fragments of bulbs and other glass materials? | | |
| 8 | Is the air and ventilation system properly protected from dust and air-born contamination substances? | | |
| 9 | Are the doors, windows and other openings protected from intrusion of insects, birds, rodents and other animals? | | |
| 10 | Whether production facilities are used in a way, so that ready products are protected from sewage water and metal cuttings? | | |
| 11 | Whether there are properly equipped, clean and repaired lavatories, available for workers. | | |
| 12 | Whether lavatories, washstand (in some cases disinfection equipment) are available in all necessary places. | | |
| 13 | Whether wastes are being collected, stored and disposed, so that not to attract insects, birds, rodents and other animals? | | |
| 14 | Whether cleaning of production shops and equipment is made with consideration of products (and vegetable raw materials and others) contamination prevention measures. | | |
| 15 | Whether cleaning supplies, powders, liquids, disinfection liquids, dangerous and other auxiliary materials are stored in proper factory packing and are stored isolated from raw material. | | |
| 16 | Whether insects and rodents extermination materials are used and stored with consideration of products and (vegetable raw material) contamination prevention. | | |
| 17 | Whether person in charge of sanitary condition of collection center has been appointed? | | |
| 18 | Are the packaging process and materials clean enough? | | |
| 19 | Whether only food-grade packaging materials and other component materials are used. | | |
| 20 | Whether final products (vegetable raw material and others) are codified, which allows determining production batch with its detailed information, and whether records are made and kept during expiration date and some time after? | | |
| 21 | Whether weighing and measuring conform with the indicated data. | | |

| | | | |
|----|--|--|--|
| 22 | Whether ready products are stored and transported in conditions conforming to sanitary norms. | | |
| 23 | Whether workers suffering from infectious diseases or hurts are not allowed contacting with products and (vegetable raw material). | | |
| 24 | Whether workers contacting with the products and (vegetable raw materials) wear uniform, appropriate head-dress and wear no decorations. | | |
| 25 | Whether worker wash their hands properly. | | |
| 26 | Whether workers eat, drink and smoke outside of production area and keep sanitary norms while working with the products and (vegetable raw materials). | | |

Standard Sanitation Operation Procedures

ANNEX 16: SSOP for washing facilities SSOP (Standard Sanitation Operation Procedures) for washing facilities

The following 5 steps have to be implemented.

1. To remove large pieces of crumbs and trash.
2. To make preliminary rinsing. During preliminary rinsing some 90 % of soluble substances are washed away. During this operation firmly adhered contamination pieces are being released; on the next step disinfecting soluble acts more profoundly.
3. Using cleaning supplies. This step can be facilitated by proper selection of cleaning tools and materials. Prevention of contamination piling is also very important. Rinsing and washing by cleaning supplies at minimal temperature and in the shortest possible time are the factors conducing to contamination prevention and buildup.
4. Rinsing after washing by cleaning supplies. At this stage contamination is being removed. Rinsing also prevents adhering of cleaning supplies to walls, floors and equipment; it also prevents recurring buildup of contamination on the cleaned surfaces.
5. Checkup. This step is highly important to make sure that the given area and equipment are cleaned. Any oversight occurred in previous steps shall be eliminated at this step.

ANNEX 17: SSOP for washing of warehouses

Standard procedure for washing of warehouses, areas of drying, sorting and packaging shall be carried out in the following cases.

1. Before wild collection season.
2. Between acceptance of various plants/crops, for instance after harvesting and drying of one type of plant and before harvesting and collection of another type of plant.
3. Before packaging, if packaging is envisaged.
4. At the end of harvesting season.

ANNEX 18: SSOP Washing and Disinfection of Boxes and Containers

Washing and Disinfection of Boxes and Containers

1. Rinse the container with one of the following solutions:
 - 3-5% hot solution of soda ash, or
 - 10% solution of hydrogen peroxide, or
 - 5-7% hot (60-70 C) solution of sodium hydroxide (caustic soda).
2. Repeat washing with an hour break at the rate of 0.5 liters of solution per 1 square meter of containerⁱ.
3. An hour after the last treatment, rinse with abundant clean warm water and dry.

ⁱ The wooden box 60x40x20 cm has surface of approximately 1 sq. m (from both sides)

Part D: Links to Quality Manuals and Descriptions

The following list contains information to specific plants, obtained from these sources:

BS: British Standards

DAC: Deutscher Arzneimittel Codex (German Pharmaceutical Codex)

EMA: European Medicines Medicine

GOST: gosudarstvennyy standart

ISO: International Standard Organization

MNS: Market News Service: <http://mnsonline.org/>

PhEur: European Pharmacopoeia

PPRC: State Pharmacopoeia of the People's Republic of China

USP: United States Pharmacopoeia

| Plant | Source of information |
|---|---|
| Achillea: Yarrow herb Essential Oil | MNS 11 – June 2004 |
| Althaea: Marshmallow flower and root | MNS 29 – December 2008, PhEur |
| Arctostaphylos uva ursi leaf | MNS 2 – March 2002 , PhEur |
| Arnica flower SE | MNS 1 – September 2001, PhEur |
| Aronia fruit juice concentrate | MNS 25 – December 2007 |
| Artemisia: Sweet wormwood herb EO | MNS 14 – March 2005 |
| Artemisia Essential Oil | MNS 14 – March 2005, PhEur |
| Betula: Birch leaf | MNS 21 – December 2006 PhEur |
| Calendula tincture | MNS 23 – June 2007 |
| Cetraria: Iceland moss | MNS 20 – September 2006, PhEur |
| Coriander fruit | MNS 34 – March 2010 |
| Crataegus: Hawthorn flower and fruit | GOST Standard 3852 93; MNS 1: Sept 2001 / MNS 16: Sept 2005; PhEur |
| Equisetum dried herb | EMA monograph July 2008 PhEur |
| Filipendula: Meadowsweet herb | MNS 13 – December 2004 |
| Glycyrrhiza: Licorice root | MNS 30 – March 2009 PhEur; PPRC, USP |
| Hedera: Ivy leaf PE | MNS 13 – December 2004 |
| Hippophae rhamnoides: Seabuckthorn fruit and pulp extract | MNS 7 – June 2003, MNS 25- December 2007. PPRC, WHO |
| Hypericum: St. John"s wort herb | MNS 10 – March 2004, MNS 31 – June 2009, GOST Standard 15161 93, EMA 2009, PhEur, PPRC, USP |

| | |
|---------------------------------------|--|
| Juniper fruit Essential Oil | MNS 10 – March 2004 |
| Juglans: Walnut fruit | GOST Standard 16832 71 |
| Lavender flower Essen Oil | MNS 12 – September 2004 |
| Malus: Apple (wild) dried fruit | ISO 7701 |
| Matricaria: Chamomile flower | MNS 31 – June 2009 |
| Mint dried leaves | BS 7087-10 |
| Nettle root PE | MNS 4 – September 2002 |
| Oregano dried leaves | ISO 7925, PhEur |
| Pomegranate fruit PE | MNS 14 – March 2005 |
| Primula flowers and roots | PhEur, PhFr, DAC, StZul. |
| Rubus: Blackberry leaf and fruit | DAC, StZul, PhEur |
| Rubus idaeus: Raspberry | GOST Standard 3525 |
| Rosa: Rosehip dried fruit | ISO 23391, PhEur |
| Sage leaf | MNS 8 – September 2003 ISO 11165, PhEur |
| Salix: Willow bark | MNS 5 – December 2002, MNS 19 – June 2006 |
| Sylibum: Milk thistle fruit PE | MNS 1: September 2001 / MNS 7: June 2003 |
| Taraxacum: Dandelion root | MNS 30 – March 2009, PhEur |
| Thyme herb | MNS 26 – March 2008 ISO 6754, PhEur |
| Tussilago : Coltsfoot leaves | GOST Standard 13382 67 and 21568 76, PhEur |
| Urtica: Stinging nettle leaf and root | MNS 15 – June 2005, MNS 33 – December 2009, GOST Standard 12529 67, PhEur, PPRC, USP |
| Vaccinium: Bilberry fruit | MNS 16 – September 2005 GOST Standard 3322-69, PhEur |
| Valerian root | MNS 3 – June 2002, MNS 4 – September 2002 |

ANNEX 19: Other useful information: MNS Reports

| | |
|---|---|
| BOTANICAL PRODUCT SPECIFICATIONS Artichoke Leaf a product of Morocco PRODUCT | Artichoke Leaf PhEur1 |
| Botanical name | <i>Cynara scolymus</i> L. (Asteraceae) |
| Pharmacopoeial name | Cynarae folium PhEur |
| Plant part used | Whole or cut, dried leaf |
| Cultivated or wild | Cultivated |
| IDENTIFICATION | |
| Macroscopic | As per PhEur monograph description |
| Microscopic | As per PhEur monograph description |
| Thin-layer Chromatography | As per PhEur monograph method |
| TESTS | |
| Total ash | NMT 20.0% (PhEur 2.4.16) |
| Loss on drying | NMT 12.0% (PhEur 2.2.32) |
| Chlorogenic acid | NLT 0.8% as determined HPLC |
| MICROBIOLOGICAL TESTS | |
| Total viable aerobic count | NMT 107 bacteria and NMT 105 fungi per gram or per milliliter |
| <i>Escherichia coli</i> | NMT 102 cfu/g or cfu/ml |
| ACTIONS & INDICATIONS | Actions: Choleric (increases excretion of bile by the liver); Indications: Dyspeptic disorders ² |

| | |
|--|---|
| BOTANICAL PRODUCT SPECIFICATIONS Southern Schisandra Fruit A product of China PRODUCT | Nanwuweizi PPRC3 |
| Botanical name | <i>Schisandra sphenanthera</i> Rehder & E.H. Wilson (Fam. Schisandraceae) |
| Pharmacopoeial name | Fructus Schisandrae Sphenantherae PPRC |
| Part used | Dried ripe fruit collected in autumn when ripe, dried in the sun, removed from stalk and foreign matter |
| Cultivated or wild | Wild harvested |
| Storage | Preserve in a ventilated and dry place, protected from mould |
| IDENTIFICATION | |
| Macroscopic | As per PPRC monograph description |
| Thin-layer chromatography | As per PPRC monograph method |
| Color | Brownish-red to dark brown |
| Odor | Odour of pulp, slight |
| Taste | Slightly sour |
| TESTS | |
| Foreign matter | NMT 1% (Appendix IX A) |
| Schisantherin A | NLT 0.12% with reference to the dried drug as determined by HPLC (Appendix VI D) |
| Dosage | 1.5—6.0 g |

| | |
|--|---|
| BOTANICAL PRODUCT SPECIFICATIONS LICORICE ROOT A product of Afghanistan, Azerbaijan, Iran, Kazakhstan, Pakistan, Syria, Turkmenistan, and Uzbekistan Botanical name | <i>Glycyrrhiza glabra</i> L. (Fam. Fabaceae) |
| Pharmacopoeial name | Liquiritiae radix |
| Unani name | ASL-US-SOOS |
| Part used | Dried, unpeeled, stolon and root |
| Cultivated or wild | Wild harvested |
| IDENTIFICATION | |
| Macroscopic | As per UPI I 2007 monograph |
| Microscopic | As per UPI I 2007 monograph |
| Color | Yellowish-brown to dark brown |
| Odor | Faint |
| Taste | Sweetish |
| TESTS | |
| Total ash | NMT 10% |
| Acid-insoluble ash | NMT 2.5% |
| Alcohol soluble extractive | NLT 10% |
| Water soluble extractive | NLT 20% |
| INDICATIONS FOR USE | Traditionally used in Unani System of Medicine for treatment of Sual (cough), Khushunat-e-Halaq (sore throat), Bohat-us-Saut Haad (acute hoarseness), Zeequn Nafas (bronchial asthma), Hirqat-ul-Baul (burning micturation).6 |

| | |
|---|---|
| BOTANICAL PRODUCT SPECIFICATIONS OREGON GRAPE ROOT Product of Canada and of the United States of America PRODUCT | Berberis NF7 / Berberis Aquifolium BHP8 |
| Botanical name | <i>Mahonia aquifolium</i> (Pursh.) Nutt. (Fam.: Berberidaceae) |
| Pharmacopoeial name | Berberis NF or Berberis Aquifolium BHP |
| Plant part used | Dried rhizome and root |
| Cultivated or wild | Wild harvested; Oregon Grape Root Good Wildcrafting Practices are available at (see pages 42-29):9 http://cntr.royalroads.ca/files-cntr/Good%20Wildcrafting%20Practices.pdf |
| Storage | Store in tight containers, protected from light, moisture, and heat. |
| Labeling | The label states the Latin binomial and, following the official name, the parts of the plant contained in the article |
| IDENTIFICATION | |
| Macroscopic | As per NF or BHP monograph |
| Macroscopic | As per NF or BHP monograph |

| | |
|--------------------------------|---|
| Organoleptic | Color: externally light yellowish brown to pale olive; colors the saliva yellow when chewed Odor: slight Taste: distinctive, very bitter |
| Thin Layer Chromatography | As per BHP monograph |
| TESTS | |
| Acid-insoluble ash | NMT 2% |
| Foreign matter | NMT 5% of attached overground stems and not more than 2% of other foreign matter. Reject pieces of the rhizome or root over 45 mm in diameter or with the bark removed. |
| AVERAGE SINGLE DOSE | 1-2 g or by aqueous decoction. Liquid extract (1:1) in 25% alcohol: 1-2 ml. |
| PREPARATION | Fluidextractum Berberidis NF |
| ACTIONS AND INDICATIONS | Actions: bitter stomachic, mild cholagogue and laxative, antiemetic Indications: cholecystitis |

| | | | |
|--|------------------|---------------------------|--|
| Comparison of Boldo Leaf Pharmacopoeial Quality Standards | | | |
| Identification Tests: | Macroscopic | Macroscopic | Macroscopic ID Test A. |
| Microscopic | Microscopic | Microscopic ID Test B | |
| Organoleptic | Organoleptic | Characters (organoleptic) | |
| TLC test | TLC test | TLC ID Test C | |
| Loss on drying | NMT 5% | NMT 12.0% | No standard |
| Water | No standard | No standard | NMT 100 ml/kg |
| Foreign matter | NMT 3% | NMT 2.0% | NMT 4% of twigs and NMT 2% other foreign matter |
| Total ash | NMT 10% | NMT 10.0% | NMT 13.0% |
| Ash insoluble in hydrochloric acid | NMT 6% | No standard | No standard |
| Essential oil | NLT 1.5% | NLT 2.0% | NMT 40 ml/kg |
| Total alkaloids (as boldine) | NLT 0.2% by HPLC | NLT 0.2% by HPLC | NLT 0.1% by HPLC |
| Heavy Metals | No standard | No standard | NMT 1.0 ppm cadmium NMT 5.0 ppm lead NMT 0.1 ppm mercury |

| | |
|---|--|
| BOTANICAL PRODUCT SPECIFICATIONS Boldo Leaf A product of Chile PRODUCT | Boldo, Hoja FHEUM10 |
| Botanical name | <i>Peumus boldus</i> Molina (Fam. Monimiaceae) |
| Pharmacopoeial name | Boldi folium |
| Part used | Dried leaf |

| | |
|----------------------------|---|
| Cultivated or wild | Wild collected |
| Storage | Store in well closed containers protected from moisture |
| IDENTIFICATION | |
| Macroscopic | As per FHEUM 2001 monograph |
| Microscopic | As per FHEUM 2001 monograph |
| Thin-layer chromatography | As per FHEUM 2001 monograph |
| Color | Greyish-green |
| Odor | Characteristic aromatic odor; intensifies when rubbed between fingers |
| Taste | Aromatic, sharp, slightly bitter |
| TESTS | |
| Essential oil | NLT 2.0% essential oil (MGA-FH 0090) |
| Total alkaloids | NLT 0.2% total alkaloids, expressed as boldine (anhydrous drug) |
| Foreign matter | NMT 2.0% (MGA-FH 0030) |
| Water | NMT 12% (MGA-FH 0080) |
| Total ash | NMT 10% (MGA-FH 0060) |
| INDICATIONS FOR USE | Traditionally used in herbal medicine to treat digestive disturbances (dyspepsia) and to stimulate digestion. ¹¹ |

ORGANIC BITTER FENNEL FRUIT — a product of EGYPT

| | |
|--|---|
| Product Name: | Organic Bitter Fennel Fruit |
| Botanical Name: | <i>Foeniculum vulgare</i> MILLER ssp. <i>vulgare</i> var. <i>vulgare</i> [Apiaceae] |
| Grade: | Food grade |
| Common Name: | Bitter Fennel Seed |
| Plant part: | Dry, cremocarps and mericarps |
| Harvest Season: | May-June |
| Supplier Certifications: | ISO 9001, Egyptian Center of Organic Agriculture (ECO), Naturland |
| Storage: | Protected from light and moisture |
| Organoleptic Evaluation: | |
| Colour: | Yellowish green |
| Odour: | Aromatic |
| Taste: | Characteristic aromatic |
| Tests: | |
| Moisture Content: | Not more than 14,0% |
| Total Ash: | Not more than 12,0% |
| Acid Insoluble Ash: | Not more than 1,5% |
| Volatile Oil: | Not less than 1,4% |
| Microbial Analysis: Total Aerobic Count: | Not more than 107 |
| Escherichia coli (in 1 g): | Not more than 10 ² |
| Total Fungi (in 1 g): | Not more than 10 ⁵ |
| Salmonella (in 10 g): | Negative |

RHUBARB ROOT DRY EXTRACT

| | |
|-------------------------------------|---|
| A product of China PRODUCT | Standardized Rhubarb Root Dry Extract 21 |
| Botanical name(s) | <i>Rheum palmatum</i> L, or <i>Rheum officinale</i> Baillon or hybrids of these two species or a mixture |
| Pharmacopoeial name | Rhei extractum siccum normatum |
| Part used | Dried underground parts |
| Cultivated or wild | Mainly wild collected; some cultivation |
| Production | The extract is produced from the finely cut, dried subterranean parts by percolation procedure using ethanol 70% (V/V) |
| Storage | Store in tightly sealed containers protected from humidity (extract is hygroscopic) and light. |
| IDENTIFICATION | |
| Properties | Appearance: Brown powder or mass that can be powdered Odor: Peculiar Taste: Bitter Solubility: Hardly soluble in water, soluble in ethanol 70% Hygroscopic. |
| Thin-layer chromatography (TLC) | As per DAB monograph (PhEur 2.2.27) |
| PURITY TESTS | |
| Absence of <i>Rheum rhaponticum</i> | As per TLC test in DAB monograph |
| Loss on drying | NMT 5.0% (PhEur 2.8.17) |
| Content | 4.0% to 6.0% of hydroxyanthracene derivatives, expressed as rhein as determined by UV/Vis Spectrophotometry |
| MICROBIAL CONTAMINATION | |
| Total aerobic microbial count | Acceptance criterion: 10 ⁴ CFU/g (PhEur 2.6.12) |
| Total combined yeast/moulds count | Acceptance criterion: 10 ² CFU/g (PhEur 2.6.12) |
| <i>Escherichia coli</i> | Absent (PhEur 2.6.13) |
| <i>Salmonella</i> | Absent (PhEur 2.6.13) |
| HEAVY METALS | |
| Cadmium | Maximum 1.0 ppm |
| Lead | Maximum 5.0 ppm |
| Mercury | Maximum 0.1 ppm |

| Comparison of Rhubarb Root Pharmacopoeial Quality Standards | | | | |
|---|------------------------------|--|--|--------------------------|
| Identification Tests: | Macroscopic | Macroscopic | Macroscopic | Macroscopic |
| Microscopic | Microscopic | Microscopic | Microscopic | Microscopic |
| Organoleptic | Organoleptic | Organoleptic | Organoleptic | Organoleptic |
| TLC tests A & B | TLC test | TLC test | TLC | |
| Color reaction test | | Color reaction test | | |
| Adulteration: Absence of <i>Rheum rhaponticum</i> | TLC test for rhaponticin | TLC test for rhaponticin | TLC test for rhaponticin | TLC test for rhaponticin |
| Loss on drying | NMT 12.0% | NMT 13.0% | NMT 12.0% | NMT 15.0% |
| Foreign matter | NMT 2.0% | No standard | NMT 2.0% | No standard |
| Total ash | NMT 12.0% | NMT 13.0% | NMT 12.0% | NMT 10.0% |
| Ash insoluble in hydrochloric acid | NMT 2.0% | No standard | NMT 2.0% | NMT 0.8% |
| Ethanol-soluble extractive | No standard | NLT 30.0% | No standard | No standard |
| Water-soluble extractive | No standard | No standard | No standard | NLT 25.0% |
| Total amount of aloemodin, rhein, emodin, chrysophanol, and physcion | No standard | No standard | No standard | NLT 1.5% (HPLC) |
| Hydroxyanthracene derivatives expressed as rhein | NLT 2.2% (spectrophotometry) | No standard | NLT 2.2% (spectrophotometry) | No standard |
| Sennosides A | No standard | NLT 0.25% (HPLC) | No standard | No standard |
| Heavy Metals | No standard | NMT 10 ppm heavy metals NMT 5 ppm arsenic | NMT 1.0 ppm cadmium; NMT 5.0 ppm lead; NMT 0.1 ppm mercury | |

| Comparison of Coriander fruit Pharmacopoeial Quality Standards | | | |
|---|---------------------------|---------------------------|-------------|
| Identification tests: | Macroscopic | Macroscopic | Macroscopic |
| Microscopic | Microscopic | Microscopic | Microscopic |
| Organoleptic | Thin-layer chromatography | Thin-layer chromatography | |

| | | | |
|-----------------------------------|----------------|--|----------------|
| Foreign matter | NMT 2.0% | NMT 2.0% and none of the cremocarps show perforations due to animals | NMT 2.0% |
| Loss on drying | No standard | NMT 10.0% | No standard |
| Total ash | NMT 6.0% | NMT 8.0% | NMT 6.0% |
| Acid-insoluble ash | NMT 1.5% | No standard | NMT 1.5% |
| Alcohol-soluble extractive | NLT 10.0% | No standard | NLT 10.0% |
| Water-soluble extractive | NLT 19.0% | No standard | NLT 19.0% |
| Essential oil | NLT 0.3% (v/v) | NLT 3 ml/kg | NLT 0.3% (v/w) |

CORIANDER FRUIT

| | |
|--|--|
| A product of the Bulgaria PRODUCT | Coriander Fruit 26 |
| Botanical name | <i>Coriandrum sativum</i> L. (Fam. Apiaceae) |
| Pharmacopoeial name | Coriandri fructus |
| Part used | Dried cremocarps |
| Cultivated or wild | Cultivated |
| Storage | Store protected from moisture. |
| IDENTIFICATION | |
| Macroscopic | PhEur ID Test A |
| Microscopic | PhEur ID Test B |
| Thin-layer chromatography | PhEur ID Test C (2.2.27) |
| TESTS | |
| Foreign matter | Maximum 2.0% (PhEur 2.8.2). None of the cremocarps show perforations due to animals. |
| Loss on drying | Maximum 10.0% (PhEur 2.2.32) |
| Total ash | Maximum 8.0% (PhEur 2.4.16) |
| Content | Minimum 3 ml/kg of essential oil (dried drug) |
| CONTAMINATION | |
| Heavy metals | NMT 1.0 ppm cadmium NMT 5.0 ppm lead NMT 0.1 ppm mercury |
| Pesticide residues | Meets the requirements PhEur General Chapter 2.8.13 |

| Comparison of Senna Leaf Pharmacopoeial Quality Standards | | | | | |
|--|----------------|--------------|----------------|----------------|-------------|
| Identification tests: | Macroscopic | Macroscopic | Macroscopic | Macroscopic | Macroscopic |
| Microscopic | Microscopic | Microscopic | Microscopic | Histology | |
| Organoleptic | Organoleptic | Organoleptic | Organoleptic | Color reaction | |
| Color reaction | Color reaction | | Color reaction | | |
| TLC | TLC | | TLC | | |
| Loss on drying | No standard | NMT 12.0% | NMT 12.0% | NMT 10.0% | NMT 12.0% |

| | | | | | |
|--|-------------|---|---|----------------------|--|
| Foreign matter | NMT 1.0% | NMT 5.0% rachis and fruit and NMT 1.0% other foreign matter | NMT 3% foreign organs and NMT 1% other foreign matter | NMT 6% | NMT 8.0% senna stems and NMT 2.0% senna pods or other foreign matter |
| Total ash | NMT 14.0% | NMT 12.0% | NMT 12.0% | No standard | NMT 12.0% |
| Acid-insoluble ash | NMT 2.0% | NMT 2.0% | NMT 2.5% | No standard | NMT 3.0% |
| Alcohol-soluble extractive | NLT 3% | No standard | No standard | No standard | No standard |
| Water-soluble extractive | NLT 25% | No standard | No standard | No standard | No standard |
| Total sennosides (hydroxyanthracene glycosides) | No standard | NLT 1.0% (by HPLC) | NLT 2.5% (by UV/Vis) | NLT 2.5% (by UV/Vis) | NLT 2.5% (by UV/Vis) |

SENNA LEAF DRY EXTRACT

| | |
|-----------------------------------|--|
| A product of India PRODUCT | Standardized Senna Leaf Dry Extract 37 |
| Botanical name | <i>Cassia angustifolia</i> Vahl [Fam: Fabaceae] |
| Pharmacopoeial name | Sennae folii extractum siccum normatum PhEur |
| Part used | Dried leaflet |
| Cultivated or wild | Cultivated |
| Production | The extract is produced from the dried leaf by a suitable procedure using ethanol (50-80 per cent V/V) |
| Storage | Store in a dry place |
| IDENTIFICATION | |
| Appearance | Brownish or brown powder |
| Thin-layer chromatography | As per PhEur monograph (PhEur 2.2.27) |
| Color reaction test | As per PhEur monograph test |
| TESTS | |
| Loss on drying | NMT 5.0% (PhEur 2.8.17) |
| Content | 5.5% to 8.0% of hydroxyanthracene glycosides, expressed as sennoside B as determined by UV/Vis Spectrophotometry |
| MICROBIAL CONTAMINATION | |
| Total aerobic microbial count | Acceptance criterion: 104 CFU/g (PhEur 2.6.12) |
| Total combined yeast/moulds count | Acceptance criterion: 102 CFU/g (PhEur 2.6.12) |
| <i>Escherichia coli</i> | Absent (PhEur 2.6.13) |
| <i>Salmonella</i> | Absent (PhEur 2.6.13) |
| HEAVY METALS | |
| Cadmium | Maximum 1.0 ppm |
| Lead | Maximum 5.0 ppm |

| | |
|-----------------------|---|
| Mercury | Maximum 0.1 ppm |
| MEDICINAL USES | Stimulant laxative for relief of occasional constipation. |

| Comparison of Cascara Sagrada bark Pharmacopoeial Quality Standards | | |
|--|---|--|
| Identification Tests: | Macroscopic ID Test A. | Macroscopic ID Test |
| Microscopic ID Test B | | Histology ID Test |
| Thin-layer chromatography ID Test C; for other species of <i>Rhamnus</i> ; anthrones | | Organoleptic description |
| Color Reaction ID Test D | | Color Reaction ID Tests A., B., and C. |
| Loss on drying | NMT 10% (PhEur 2.2.32) | No standard |
| Water | No standard | NMT 12.0% (USP Method III <921>) |
| Foreign matter | NMT 1% (PhEur 2.8.2) | NMT 4.0% (USP <561>) |
| Total ash | NMT 7.0% (PhEur 2.4.16) | No standard |
| Content | Minimum 8.0% of hydroxyanthracene glycosides, of which minimum 60% consists of cascariosides, both calculated as cascarioside A | Minimum 7.0% of hydroxyanthracene derivatives, of which minimum 60% consists of cascariosides, both calculated as cascarioside A |
| Heavy Metals | NMT 1.0 ppm cadmium NMT 5.0 ppm lead NMT 0.1 ppm mercury | No standard |

CASCARA SAGRADA DRY EXTRACT

| | |
|-------------------------------------|--|
| A product of the USA PRODUCT | Cascara Sagrada Extract 46 |
| Botanical name | <i>Rhamnus purshiana</i> De Candolle (Fam. Rhamnaceae). |
| Pharmacopoeial name | Rhamni purshianae extractum siccum normatum |
| Part used | Dried bark collected not less than one year prior to use |
| Cultivated or wild | Wild collected |
| Production | The extract is produced from aged and dried Cascara Sagrada USP by percolation procedure using boiling water as the menstruum |
| Storage | Preserve in tight, light-resistant containers, at a temperature not exceeding 30° |
| Organoleptic description | Cascara sagrada has a distinct odor and a bitter and slightly acid taste |
| ASSAY | |
| Content | The extract contains, in each 100 g, not less than 10.0 g and not more than 12.0 g of hydroxyanthracene derivatives, of which not less than 50 percent consists of cascariosides, both calculated as cascarioside A. |
| Residue on evaporation | Not less than 95% of powdered extract specimen remains as residue |
| CONTAMINATION | |
| Total aerobic microbial count | NMT 104 CFU/g |

| | |
|-----------------------------------|---|
| Total combined yeast/moulds count | NMT 103 CFU/g |
| <i>Escherichia coli</i> | Absent in 10 g |
| <i>Salmonella spp.</i> | Absent in 10 g |
| Heavy metals | Maximum 20 µg per g (USP Method II <231> |
| Pesticide residues | Meets the requirements of USP General Chapter <561> |

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BOTANICAL PRODUCT SPECIFICATIONS

FLAXSEED GRANULES — a product of CANADA

Product: Flaxseed Granules (NutriGrad™; branded ingredient of Pizzey's Milling)

Botanical name: *Linum usitatissimum* L. [Linaceae]

Pharmacopoeial name: Lini semen

Plant part used: Dried ripe seeds

Visual Standards

Color: Medium brown
Texture: Free-flowing granules
Bulk density: Approx. 39 lbs/ft³
Bioassay
Trolox Equivalents (TE) 40,000 TE / 100 g

Chemistry

Calories 295 cal. / 100 g
Moisture 11.0%
Protein 7.0%
Dietary fiber 56.0%
Soluble fiber 30.0%
Insoluble fiber 25.0%
Carbohydrate 64.0%
Fat 12.0% (AOAC 996.06)
Polyunsaturates 8.0%
Omega-3 7.0% (Alpha-Linolenic Acid)
Saturates 2.0%
Lignans (SDG, 281 nm) 6.0%

Microbiological

Total Plate Count <10,000 cfu/g
Coliforms <100 cfu / g
E. coli Negative
Salmonella Negative
Listeria Negative
Yeast & Mold <100 cfu/g

SAGE LEAF— a product of Albania and of Bosnia Herzegovina

| | |
|----------------------------|---|
| Product name: | Sage leaf |
| Botanical name: | <i>Salvia officinalis</i> L. [Fam.: Lamiaceae] |
| Pharmacopoeial name: | Salviae officinalis folium Ph. Eur. |
| Plant part used: | Whole or cut dried leaves |
| Quality: | European Pharmacopoeia-Grade (Ph.Eur. IV 2002-2003) |
| Storage: | Store in tightly-closed containers (non-plastic due to volatile oil), protected from light. Sage stores better vacuum-packed than in double-layered paper bags |
| Identification | |
| Macroscopic: | As per Ph.Eur. monograph |
| Microscopic: | As per Ph.Eur. monograph |
| Organoleptic: | |
| Color: | Powdered: light grey to brownish-green |
| Odor: | Intensely spicy and aromatic. |
| Taste: | Spicy, bitter and astringent |
| Thin-layer chromatography: | As per Ph.Eur. monograph |
| TESTS | |
| Foreign matter: | Not more than 3% of stems and maximum 2% of other foreign matter |
| Water: | Not more than 100 mL / kg, determined on 20.0 g |
| Total ash: | Not more than 10.0% |
| ASSAY | |
| Essential oil content: | Not less than 15 mL / kg for the whole dried leaf and minimum 10 mL / kg for the cut dried leaf. The oil is thujone-rich |

[NOTE: Maté leaf raw material is a product of South America]

| | |
|------------------------------|---|
| Manufacturing Data | |
| Product name: | Maté Leaf Powdered Extract |
| Botanical name: | <i>Ilex paraguariensis</i> A. ST.-HIL. |
| Pharmacopoeial name: | Maté folium extractum s. siccum |
| Plant part used: | Dried green leaf (Maté folium viride DAC) |
| Raw material identity: | As per DAC monograph (macroscopic, microscopic, and TLC) |
| Extraction solvent: | 15% (m/m) ethanolum |
| Drug-to-extract ratio range: | 4–6 : 1 (5=1) |
| Preservatives: | None |
| Carriers: | None |
| Additives: | Acidum ascorbicum Ph.Eur. Acidum citricum monohydricum Ph.Eur. |
| Analytical Data | |
| Appearance: | Fine powder |
| Color: | Brown |
| Solubility: | 0.2% (m/m) in water clearly soluble (NTU <5) |
| Loss on drying: | <5.0% (m/m) |
| Bulk density: | 0.30–0.60 g/mL |
| Caffeoylquinic acids | 20.0–40.0% (m/m) as determined by HPLC |
| Caffeine | 2.0–4.0% (m/m) as determined by HPLC |

| | |
|--------------------------------|---|
| Theobromine | 0.30–1.20% (m/m) as determined by HPLC |
| Triterpene saponins | >1.0% (m/m) as determined by HPLC |
| Residues: | |
| Heavy metals: | (Form. FA003) Ph.Eur. 2.4.27. Pb, Cd, Hg [AAS] |
| Pesticide residues: | (Form. FA002) Ph.Eur. 2.8.13. resp. RHmV [DFG S-19] |
| Radioactivity: | (Cs134 + Cs137) <370 Bq/kg [Scintillation] |
| Residual solvent ethanol: | <0.5% (m/m) (GC:Ph; ICH/283/95, Class 3) |
| Microbiological Load | |
| Total Viable Aerobic Count: | Not more than 10,000 cfu / g |
| Fungi: | Not more than 100 / g |
| Enterobacteria: | Not more than 100 / g |
| Salmonella (in 50 g): | None detected |
| Escherichia coli (in 1 g): | None detected |
| Staphylococcus aureus (in 1 g) | None detected |

| | |
|---|---|
| BOTANICAL EXTRACT SPECIFICATIONS | |
| GARLIC BULB EXTRACT, 1% Allicin — a product of CHINA | |
| Product: | Garlic Bulb Powdered Extract, 1% Allicin |
| Botanical name: | <i>Allium sativum</i> L. [Fam.: Liliaceae] |
| Pharmacopoeial name: | Allii sativi extractum |
| Plant part used: | Dried bulb |
| Extraction solvent: | Water |
| Physical | |
| Appearance: | Fine powder |
| Color: | Light yellow |
| Odor: | Characteristic |
| Particle Size: | 100% through 80 mesh |
| Bulk Density: | 45-55 g / 100 ml |
| Analysis | |
| Allicin: | 1% as determined by HPLC |
| Loss on Drying: | < 5.0% |
| Residue on Ignition: | <4.0% |
| Heavy Metals: | <20 ppm |
| Arsenic | <2 ppm |
| Pesticide Residues: | None detectable |
| Microbiological | |
| Total Plate Count: | < 1,000 cfu/g |
| Yeast & Mold: | < 100 cfu/g |
| <i>E. coli</i> : | Negative |
| <i>Salmonella</i> : | Negative |
| Storage | |
| Packaging: | 25 kg drum |
| Conditions: | In a cool and dry place. Keep away from direct strong light. |
| Shelf life: | Maximum 24 month when stored unopened provided proper storage conditions are maintained |
| POTENTIAL INDICATIONS FOR USE: | |
| Reducing elevated levels of cholesterol in the blood | |