Chapter 10
Herbal Drugs: Their Collection, Preservation, and Preparation; Evaluation, Quality Control, and Standardization of Herbal Drugs

Abstract The WHOs' criteria for good herbal drug preparation include the identity of source plant, optimum time of harvest, post-harvest handling, cooking utensils etc. Natural drug products may be obtained from the wild or through cultivation, fermentation, cell or organ culture, microbial transformation as well as biologics. Right source of drug plant and harvest time are important factors for maximizing the yield of the desired phytochemical content. Collection schedule of different plant parts are different, e.g., roots and rhizomes at the end of the vegetation period, bark in the spring, leaves and herbs at bloom, flowers at anthesis or shortly after opening, and fruits and seeds after maturity or ripe. Hand collection is preferable for wild source. Post-harvest handling including garbling, washing, drying in air, oven drying, milling and re-milling, sieving, storage, labeling with the name of the plant, place and date of collection are important for standard herbal preparation. Collected plant material must be preserved to keep the active compounds unchanged during transport and storage. Drying, freeze-drying or lyophilization, stabilization, fermentation etc. are some of the common methods of preservation. Herbal preparations are made from herbal drugs, such as whole plant, plant parts, algae, fungi, lichen, exudates, in a crude state in dried or fresh form and extracts with the help of different processes such as infusion, decoction, maceration, distillation, expression, fractionation, purification, concentration, fermentation. These herbal preparations include whole plant or parts, comminuted or powdered herbal drugs, tinctures and extracts, fatty oils, essential oils, expressed juices and processed exudates of herbal materials. Herbal preparations are the basis for finished herbal products. Finished herbal products are medicinal products containing exclusively herbal drugs (active substances) and herbal drug preparations. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials and may consist of herbal preparations made from one herb or more herbs (mixed herbal product). They may contain excipients in addition to the active ingredients or may contain natural organic or inorganic active ingredients not of plant origin (e.g., animal materials and mineral materials). Finished products or mixed products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal. Herbal drugs are precisely defined by the botanical

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scientific name according to the binominal system. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products. Storage of crude drugs in dry condition in airtight container placed in dry dark place is very important for stability and quality maintenance. Grinding of crude drugs by hammer-, knife- or tooth mill to a powder of suitable particle size is carried out for isolation of a pure compound or for manufacture of a simple preparation. Cold grinding is preferable for crude drugs containing heat labile compounds. Sifting to ensure particle size (course—2.00 mm to fine—0.18 mm) can be performed following the principles of sieving and blast sifting. Extracts are preparations of crude drugs containing all the constituents soluble in the extracting solvent. Extracts may be dry (when all solvent has been removed), soft or fluid (solvent prepared with mixtures of water and ethanol). Tinctures are prepared by extraction of the crude drug with five to ten parts of ethanol of varying concentration without concentration of the final product. For both extracts and tinctures the ratio drug to solvent should always be stated. The criteria for ideal solvent for a certain pharmacologically active constituent include high selectivity for the compound to be extracted, high capacity for extraction in terms of coefficient of saturation of the compound in the medium, nonreactive with the extracted compound or with other compounds in the plant material, low price, harmless to man and to the environment, completely volatile. Aliphatic alcohols (up to 3C) or mixtures of the alcohols with water, are the solvents with the greatest extractive power for almost all natural substances of low molecular weight such as alkaloids, saponins, and flavonoids. Ethyl alcoholis used for obtaining tinctures and fluid, soft and dry extracts. The ethanol–water mixture induces swelling of the plant particles and increases the porosity of the cell walls and thus facilitates the diffusion of extracted substances. For extraction of barks, roots, woody parts and seeds the ideal alcohol: water ratio is about 7:3 or 8:2. For leaves or aerial green parts the ratio 1:1 is usually preferred in order to avoid extraction of chlorophyll. Herbal internal preparations include infusions, decoctions, tinctures, macerations, percolation, digestion, inhalation of powdered plants, steam inhalation, aromatherapy, dry preparations etc. and washes, compresses, poultices, salves and balms are the main external preparations. Infusions are made with leaves and flowers, while decoctions are made with roots, bark, seeds, and berries. Infusion and decoction are preferred for water soluble chemicals (e.g., anti-inflammatory plant steroids) while tincture for alcohol soluble chemicals (anti-bacterial alkaloids). This may explain why a tea of the plant is used for arthritis while a tincture is traditionally used to treat various bacterial infections. Several problems influence the quality of herbal drugs. Quality control and the standardization of herbal medicines involve several steps. The source and quality of raw materials, good agricultural practices and manufacturing processes are certainly essential steps for the quality control of herbal medicines and play a pivotal role in guaranteeing the quality and stability of herbal preparations. For standard herbal drug production at industrial level, source herbal ingredients should be analyzed in detail in respect of quality, efficacy, performance and safety because drugs in commerce are frequently adulterated and do not comply with the standards prescribed for authentic drug. Quality refers to the status of a drug and is based on

three important pharmacopoeial definitions such as identity, purity, and content of active constituents. Voucher specimens are reliable reference sources. Purity evaluation includes ash values, contaminants, heavy metals, microbial contamination, aflatoxins, radioactivity, and pesticide residues. Analytical methods, such as photometric analysis, TLC, HPLC, GC, MS or GS/MS, can be employed to establish the constant composition of herbal preparations. For content, sometimes markers can be used for control purposes because in most herbal drugs the active constituents are unknown. In other cases, where no active constituent or marker can be defined for the herbal drug, the percentage extractable matter with a solvent may be used as a form of assay. The choice of the extracting solvent depends on the nature of the compounds involved, e.g., hot water for herbal tea, steam distillation is suitable for essential oils. Complex nature of herbal drugs, unknown active principle, unavailability of selective analytical methods or reference compounds, chemical and natural variability in the plant materials as well as in source and quality of the raw material, methods of harvesting, drying, storage, transportation, and processing etc. are some of the problems that influence the quality of herbal drugs. Strict guidelines have to be followed for the successful production of a quality herbal drug. Standardization involves adjusting the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity by adding excipients or by mixing herbal drugs or herbal drug preparations because botanical extracts made directly from crude plant material show substantial variation in composition, quality, and therapeutic effects. Standardized extracts are high-quality extracts containing consistent levels of specified compounds, and they are subjected to rigorous quality controls during all phases of the growing, harvesting, and manufacturing processes. Evaluation of crude drug means confirmation and determination of its identity, quality and purity and it can be done by several methods viz. organoleptic and microscopic evaluation; analytical determination of foreign matter, plant ash, heavy metals, microbial contaminants and aflatoxins, etc. Potentially hazardous contaminants and residues in herbal medicines may be grouped as chemical, biological, agrochemical residues, residual solvents, etc.

Keywords Collection · Preservation · Herbal preparations · Analytical evaluation · Quality control · Standardization of herbal medicines

10.1 Herbal Drugs, Their Collection and Preservation

Drug evaluation includes may the determination of identity, purity, and quality of a drug. Identity of biological source, the quantity of the active constituents and the extent of foreign organic material present in a crude drug determine its quality and standard. Pharmaceutical quality of medicinal product is the basis for ensuring safe and effective medicines. Herbal drugs are mainly whole plant, plant parts (e.g., leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes, or other plant

parts), algae, fungi, lichen in an unprocessed state (crude state), in fresh, dried, entire, fragmented or powdered form. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal drugs. Herbal drugs are precisely defined by the botanical scientific name according to the binominal system. Herbal preparations and finished herbal products are also included in herbal medicines. Herbal drugs are obtained from cultivated and wild sources. Suitable collection, cultivation, harvesting, drying, fragmentation, and storage conditions are essential to guarantee the quality of herbal drugs. Herbal drugs are, as far as possible, should be free from impurities such as soil, dust, dirt, and other contaminants such as fungal, insect, other animal contaminations, and rotten plant parts. Decontaminating treatment, if used, should not affect the active drug constituents and should be free from residual effect. The use of ethylene oxide is prohibited for the decontamination of herbal drugs. In the EU, a complex regulatory framework exists that encompasses specific requirements for herbal medicinal products and for marketing, requires authorization by the competent authorities (Kroes 2014). The basic principles governing the assurance of the quality of medicinal products are defined in the amended Directive 2001/83/EC and Directive 2003/63/EC.

The phytochemical composition of plant is variable because of inherent variability and a plethora of external factors, so the production process of quality herbals needs strict systematic regulation. The source materials need to be correctly authenticated and free of adulterants and contaminants. In addition, proper harvest (season and time, developmental stage, temperature, and humidity) and post-harvest processing (drying and storage) have a strong impact on metabolite production plant and alteration of the phytochemical composition of herbal material, respectively. For extraction, the solvent as well as conditions need to be optimized in order to enrich the bioactive constituents in the extract; quality of finished preparations needs to be determined either on the basis of marker constituents or on the basis of analytical fingerprints by applying different methods ranging from macroscopic, microscopic, and DNA-based authentication methods to spectroscopic methods such as vibrational spectroscopy and chromatographic and hyphenated HPLC, GC–MS, and LC–MS methods (Pferschy-Wenzig and Bauer 2015).

According to WHO (2007), herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures, and fatty oils, expressed juices and processed exudates of herbal materials. They are produced with the aid of extraction, distillation, expression, fractionation, purification, concentration, fermentation, or other physical or biological processes; and also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey or in other materials. The finished herbal products or herbal drug preparations are medicinal products that contain exclusively herbal drugs (active substances), may be made from one herb or more herbs (mixed herbal product) and may contain excipients in addition to the active ingredients. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients, which are not of plant origin (e.g., animal

materials and mineral materials). Finished products or mixed products to which chemically defined active substances have been added, including synthetic compounds and/ or isolated constituents from herbal materials, are not considered to be herbal.

WHO's Guidelines for Quality Drugs

Some guidelines formulated by the World Health Organization (WHO 2007) on the use of medicinal plants (proper identity of the medicinal plants), harvest (right time schedule), post-harvest handling (garbling, washing, drying, milling, storage etc.), pottery or pots as cooking utensils (glass, ceramic pot as cooking utensils; copper and stainless steel pot can also be used but not pots made of aluminum, iron, tin or other metals), etc. related to herbal drug preparation are described in the following paragraphs.

Natural drug products may be obtained through collection (wild), cultivation (commercial), fermentation (recombinant DNA technology or genetically engineered drugs), cell culture techniques, microbial transformation as well as biologics (prepared from the blood of animals). Proper botanical identity of the medicinal plants is necessary for ascertaining the right source of drug. Choice of time suitable for collection in an important factor because the amount of a constituent is usually not constant throughout the life of a plant, the stage at which a plant is collected or harvested is, therefore, very important for maximizing the yield of the desired constituent, and the differences are sometimes not only quantitative but also qualitative.

i. **Collection**

Adherence to good agricultural and collection practices (GACP), good plant authentication and identification practice (GPAIP), good manufacturing practice (GMP) before and during the manufacturing process and good laboratory practice (GLP) in analysis are necessary for quality herbal products and their safety and efficacy (Govindaraghavan and Sucher 2015). Suitable time for collection of herbal materials is important for maximizing plant biomass yield, quantitative and qualitative constituents. The optimum time for collection of a plant or its part is necessary to coincide with its optimal state of development and phytochemical content, e.g., roots and rhizomes—at the end of the vegetation period, bark—in the spring, leaves, and herbs—when plant is about to bloom, flowers—just before or shortly after opening, and fruits and seeds—when fully ripe. Hand collection of medicinal plants is preferable and this is especially true in the case of wild plants. With cultivation on a large scale, it may be possible to use modern agricultural harvesters, but in many cases, e.g., barks, manual collection is unavoidable. Thus, the cost of drug production is largely the cost of the labor involved. Post-harvest handling includes garbling—separation and removal of unwanted materials from plants itself or from dirt and other foreign matters, washing—flushing away of soil and/or other solid particles by a thorough but fast rinse with clean running water quickly (long exposure to water may affect the active constituents), drying air (in shaded under ventilation until crumbly, chopped into small pieces if succulent),

oven drying (with circulating air at temperature at not higher than 60 °C), milling and re-milling (reduction to the required particle size as specified), sieving (for uniformly sized particles), Storage—in plastic containers or bottles, preferably brown colored with tight cover away from sunlight in cool place, added charcoal for maintaining dryness, container labeled properly with the name of the plant, date place and date of collection, well-dried and well-stored plant materials can be used up to 6 months after the collection, not to be used older materials and materials with molds or other signs of decay, etc.

After collection, the plant material must first be preserved so that the active compounds will remain unchanged during transport and storage. The cells of living plants contain large number of low molecular weight compounds and enzymes, and the cells have many kinds of barriers that keep these constituents apart. When the plant dies the barriers are quickly broken down and the enzymes get the opportunity to promote various chemical changes in the cell constituents (e.g., oxidation, hydrolysis). Different methods of preservation aim at limiting these processes as far as possible.

ii. **Drying**

Drying is the most common method for preserving plant material is drying. Like many other crops, medicinal plants have to be dried before storage. Drying is defined as decreasing moisture content (MC) to preserve the product for extended shelf life. MC is commonly defined either as mass of water *mw* per total mass noted as MC wet basis (wb) in percentage. Microbes such as fungi, yeasts, and bacteria increasingly develop at >70% relative humidity (RH) and since the activity of decomposing enzymes is also enhanced by increasing water activity, a threshold of RH $\leq$ 60% is recommended to preserve the quality of medicinal plants during storage (Müller and Heindl 2006). The final MC to which the material should be dried can be derived from the sorption isotherm as depicted by Heiss and Eichner (1990). Living plant material has high water content: leaves may contain 60–90% water, roots and rhizomes 70–85%, and wood 40–50%. The lowest percentage, often no more than 5–10%, is found in seeds. Enzymatic breakdown takes place in moist condition and rapid removal of the water from the cell will, therefore, largely prevent degradation of the cell constituents. To stop the enzymatic processes, the water content must be brought down to about 10%. Drying also decreases the risk of microbial attack. Drying must be done quickly, in other words at raised temperatures and with rapid and efficient removal of the water vapor. The most efficient drying is achieved in large driers of the tunnel type. The plant material is spread out on shallow trays, which are placed on mobile racks and passed into a tunnel where they meet a stream of warm air. The air temperature is kept at 20–40 °C for thin materials such as leaves, but is often raised to 60–70 °C for plant parts that are harder to dry, e.g., roots and barks. When the crude drug has been collected under primitive conditions, without access to a drier, it must be dried in the open. Even then, the material should be spread out in shallow layers with good ventilation to

Table 10.1 Maximum final moisture content (MCf) for various medicinal plant species as prescribed in the European pharmacopoeia

Species	Drug	Drug MCf, %w.b
Althaea officinalis L.	Roots	10
Arnica montana L.	Flowers	10
Calendula officinalis L.	Flowers	12
Chamomilla recutita [L.] Rauschert	Flowers	12
Coriandrum sativum L.	Seed	10
Foeniculum vulgare Mill.	Seed	8
Hypericum perforatum L.	Herb	10
Levisticum officinale Koch	Leaves	12
Malva sylvestris L.	Leaves, flowers	12
Melissa officinalis L.	Leaves	10
Mentha x *piperita* L.	Leaves	11
Plantago lanceolata L.	Herb	10
Valeriana officinalis L.	Roots	12
Verbascum phlomoides L.	Herb	12

Source: Europäisches Arzneibuch (Ph.Eur. 5.00) (European pharmacopoeia 2005)

facilitate the drying. The choice of sunshine or shade is determined by the sensitivity to light of the constituents. In a dried drug the enzymes are not destroyed but only rendered inactive due to the low water content. As soon as water is added, they become active again. Hence, dried drugs must be protected from moisture during storage. Maximum final moisture content (MCf), % of wb for various medicinal plant species as prescribed in the European pharmacopoeia is shown in Table 10.1.

iii. **Freeze-drying**

Freeze-drying (lyophilization) is a very mild method. Frozen material is placed in an evacuated apparatus which has a cold surface maintained at −60 to −80 °C. Freeze-drying works by freezing the material and then reducing the surrounding pressure to allow the frozen water in the material to sublimate directly from the solid phase to the gas phase i.e., water vapor from the frozen material then passes rapidly to the cold surface. The method requires a relatively complicated apparatus and is much more expensive than hot-air drying. For this reason, it is not used as a routine method, but it is very important for drying heat-sensitive substances, e.g., antibiotics and proteins. Some people consider that freeze-dried herbs are superior to other types, but the existing research indicates that freeze-drying imperfectly preserves important classes of medicinal compounds (such as volatiles, phenolics, and carotenoids). However, there is insufficient information to conclude that freeze-drying has negative effects on the medicinal qualities of plants (Abascal et al. 2005).

iv. **Stabilization**

Stabilization is a process of stabilizing the active principles of the crude drugs. On long storage, enzymatic reactions will slowly destroy the constituents, because the last traces of water can never be removed. In order to avoid this degradation, the enzymes should be destroyed before drying, a process usually called stabilization. The most common method is being a brief exposure (a few minutes only) of the plant material to ethanol vapor under pressure (0.5 atm.). Stabilization may be of value for the isolation of compounds that are very susceptible to enzymatic degradation. Stability is an essential factor of quality, safety, and efficacy of a drug product.

v. **Fermentation**

Fermentation or enzymatic transformation of the original plant constituents is sometimes desirable. The fresh material is then placed in thick layers, sometimes covered and often exposed to raised temperatures (30–40 °C) and humidity, so as to accelerate the enzymatic processes. This treatment is usually called fermentation as followed in tea factory. The fermented product must, of course, be dried afterward to prevent attack by microorganisms, e.g., molds. Fermentation is mostly used to remove bitter or unpleasant-tasting substances or to promote the formation of aromatic compounds with a pleasant smell or taste. It is mainly applied to drugs used as spices or stimulants, e.g., vanilla, tea, and cacao.

vi. **Storage**

Storage of crude drugs is very important for stability as well as quality maintenance. There are great differences in the stability of crude drugs because of slow enzymatic changes in the constituents. Drugs containing glycosides and esters are usually less stable than those containing alkaloids. Drugs with essential oils deteriorate rather quickly through evaporation, oxidation, and polymerization of the substances constituting the essential oil. Tannins, on the other hand, have an almost unlimited durability. In order to keep crude drugs as long as possible it is essential to store them in a dry condition in carefully closed containers, it is also advisable to exclude light, because—even if it does not affect the active constituents—it almost always causes changes in the appearance of the drug, especially loss of color and it is also necessary to protect the drug against insect attack.

vii. **Grinding**

Grinding of crude drugs is carried out for different purposes. Regardless of whether the crude drug is to be used for isolation of a pure compound or for manufacture of a simple preparation, the first operation that must be performed is grinding of the plant material to a powder of suitable particle size. It is important that the particles are of as uniform a size as possible. Excessive dust can clog percolators and result in a turbid extract which is hard to clarify. Large particles take a longer time for complete extraction than small ones and large differences in particle size thus slow down the extraction process. Several types of machines are available for grinding

crude drugs including (i) hammer mill (a common type for grinding crude drugs), (ii) knife mill (useful for production of low-dust powders of leaves, barks and roots for subsequent percolation or maceration), (iii) tooth mill (used for production of very fine powders), etc.

Grinding produces a certain amount of heat which must be observed when grinding crude drugs containing heat-sensitive compounds. Mills cooled with liquid nitrogen are available for such purposes. Cold grinding is also preferable for crude drugs containing volatile oils.

Following grinding, the material must be shifted to ensure the proper particle size. Sifting can be performed according to two different principles: sieving and blast sifting.

viii. **Sieving**

In sieving, the material is passed through a sieve of suitable mesh size (coarse—2.00 mm to fine—0.18 mm) giving two fractions. The fraction passing the sieve consists of particles with a size smaller than or corresponding to the mesh size. The remaining fraction consists of coarser particles which are returned to the mill for continued grinding. In blast sifting the material to be classified is blown with compressed air into an apparatus which allows the particles to sediment according to their weight. Coarse, heavy particles settle fast whereas small, light particles stay for a long time in the air stream.

ix. **Extraction**

Extracts can be defined as preparations of crude drugs which contain all the constituents which are soluble in the solvent used in making the extract. They may be dry, soft or fluid. In dry extracts, all solvent has been removed. Soft extracts and fluidextracts are prepared with mixtures of water and ethanol as solvent. Tinctures are prepared by extraction of the crude drug with five to ten parts of ethanol of varying concentration, without concentration of the final product. For both extracts and tinctures, the ratio drug/solvent should always be stated.

Several factors influence the extraction process. Plant constituents are usually contained inside the cells. Therefore, the solvent used for extraction must diffuse into the cell to dissolve the desired compounds whereupon the solution must pass the cell wall in the opposite direction and mix with the surrounding liquid. Equilibrium is established between the solute inside the cells and the solvent surrounding the fragmented plant tissues. The speed with which this equilibrium is established depends on temperature, pH, particle size and the movement of the solvent.

The criteria for ideal solvent for a certain pharmacologically active constituent should be highly selective for the compound to be extracted, should have a high capacity for extraction in terms of coefficient of saturation of the compound in the medium, should not react with the extracted compound or with other compounds in the plant material, should have a low price, should be harmless to man and to the environment, should be completely volatile.

Aliphatic alcohols (up to three carbon atoms), or mixtures of the alcohols with water, are the solvents with the greatest extractive power for almost all natural substances of low molecular weight such as alkaloids, saponins, and flavonoids. According to the pharmacopoeias, ethyl alcoholis the solvent of choice for obtaining classic extracts such as tinctures and fluid, soft, and dry extracts. The ethanol is usually mixed with water to induce swelling of the plant particles and to increase the porosity of the cell walls which facilitates the diffusion of extracted substances from inside the cells to the surrounding solvent. For extraction of barks, roots, woody parts, and seeds, the ideal alcohol/water ratio is about 7:3 or 8:2. For leaves or aerial green parts the ratio 1:1 is usually preferred in order to avoid extraction of chlorophyll.

10.2 Methods of Preparation of Herbal Remedies

Herbal remedies, in traditional systems, are prepared in several ways depending on the plant type, therapeutic constituents, way and purpose of application, etc. Part of the art of herbal medicine relies on the method as to how to best prepare an herb in order for the medicinal properties of that plant to be best released. Herbs can be used both internally and externally, although usually, they are more effective healing agents used internally. Infusions (hot teas), decoctions (boiled teas), tinctures (alcohol–water extracts), macerations (cold-soaking), percolation, digestion, inhalation of powdered plants (like snuff), steam inhalation and even aromatherapy and dry preparations are the main internal preparations, while washes, compresses, poultices, salves, and balms are the main external preparations. A general rule of thumb is that infusions are made with leaves and flowers, while decoctions are made with roots, bark, seeds, and berries.

The therapeutic activity of a medicinal plant is closely related to different groups of chemicals such as essential oils, alkaloids, acids, steroids, tannins, saponins, glycosides. Some of these chemicals are soluble in cold or hot solvents such as water, alcohol, or other organic solvents, and therefore, each one of these classes of chemicals may have a preferred effective method of extraction which facilitates getting the chemicals out of the plant and into the herbal remedy that is being prepared. For example, infusion and decoction are preferred for water soluble chemicals (e.g., anti-inflammatory plant steroids to treat arthritis) while tincture for alcohol soluble chemicals (anti-bacterial alkaloids). This may explain why a tea of the plant is used for arthritis while a tincture is traditionally used to treat various bacterial infections.

Internal Preparations

These herbal preparations are made for internal use by swallowing or inhalation.

i. **Infusion**

An infusion is the simplest form of herbal preparation. It is an herbal preparation in liquid form obtained through extraction of chemical compounds or flavors by

suspending the fresh or dry herbal material for a stipulated period of time (for steeping) in a solvent such as hot water (up to boiling). Water is brought just to a boil and then poured over an herb (or combination of herbs) contained in a container; it is covered and allowed 10–15 min or so for steeping. Infusion is distinct from decoction, which involves boiling the herbal material, or percolation, in which the water passes through the material (as in a coffeemaker). Delicate herbs, tender stem, soft parts of plants such as flowers, leaves, and other plant parts are used for this preparation. It can be prepared in the drinking cup (by just pouring the heated water over the herb in the cup) or by dropping the herb into the pot (ceramic, not metal pot) in which water was heated. Stirring is helpful while steeping, especially with cut herbs. Keeping the infusion covered while steeping is generally recommended. The ratio of herb to water can vary depending on the remedy, the plant, and whether cut herb or powdered herb is used. Generally using 1 teaspoonful of powdered herb or 2 teaspoonful of more bulky cut herb in a 6–8 oz cup (one teacup) of water is sufficient. Infusions are best prepared as needed and taken the same day it was prepared and can be taken hot, warm, or cold.

Method

Preparing an infusion is much like that of tea. Take a warm teapot or any other pot (glass, ceramic or stainless steel) and put 1–2 teaspoonful of dry-fresh herb per cup, pour required quantity of hot water (up to boil) inside (56 g or 2 oz of fresh herb or half of the wt. if dry and pour on 600 ml or 1 pint of boiling water), cover and leave it for about 10–15 min for steeping, strain for the removal of herb and drink. It is best to drink medicinal infusions as hot as possible. The dose is one cupful (6–8 oz) usually three times daily for chronic conditions, or hourly for acute conditions. Preparations should not be kept for more than 24 h. The entire day's dosage can be prepared in the morning. The exceptions are the more aromatic plants with active essential oils. These are best prepared in single dosages (by the cupful) as needed and taken immediately (and while still hot/warm).

When used woody parts, such as bark, seeds, nuts, after breaking up by crushing or chopping add 56 g of fresh herb or 28 g if dry to 600 ml of cold water (i.e., two teaspoonful of fresh or one of dry herb to one cup water). Place in a non-aluminum pan, bring to the boil, cover and simmer for 10–15 min. Strain and allow to cool before drink. If the volume decreases during simmering, make up the volume by adding hot water to the original. The usual dose is one cupful three times daily or hourly for acute conditions. Preparations should not be kept for more than 24 h.

Infusion with Honey

It is a more palatable way to take whole herbs. Use finely chopped fresh, or powdered dry herb. Cover with honey, leave to infuse for a few minutes, and then take on a spoon. This method can be used for essential oils, one drop to a teaspoonful of honey.

ii. **Decoction**

A decoction is a liquid extract made by boiling hard fibrous or woody stem, roots, rhizomes, non-aromatic seeds and barks in water for a longer period of time to

soften the harder material and release its active constituents. It involves first mashing or simmering and then boiling in water to extract chemical substances. Unlike infusions (steeping it in hot water), the plant material is boiled, decoctions are boiled because simple infusion is unable to extract the full medicinal properties of the hard herbal material. Therefore, decoctions and infusions produce liquids with differing chemical properties. Root/ rhizome tea from Angelica (*Angelica archangelica*), Ashwagandha (*Withania somnifera*), Astragalus (*Astragalus membranaceus*), Ginger (*Zingiber officinale*), etc., are some examples of decoctions. Although this method of extraction differs from infusion and percolation, the resultant liquids are often functionally similar.

Method To prepare a decoction, select a saucepan (ceramic, enamel or stainless steel but never aluminum) with a snug fitting lid, measure the amount of herb needed (1 teaspoonful powdered herb or 2 teaspoonful of cut herb per 8 oz or 1 cup of water; 56 g of fresh herb or 28 g if dry, to 600 ml of cold water) into the pot and add the proper amount of cold water depending on how many cups of the decoction to be prepared. Turn on the heat to medium high and bring to a roiling boil. Once it reaches boiling point, cover the pot tightly (valuable essential oils escape through loose lid), turn the heat down to medium or medium-low so that the mixture stays at a good simmer for 20 min. After 20 min, remove from heat and cool slightly. For stronger decoctions using larger woody pieces of bark, longer boiling time (up to 2 h or more to break down, soften, and extract the larger pieces) is required but from smaller woody pieces, the decoction is prepared as usual (boiling 20 min), then it is allowed to sit overnight before straining out the herb. If using cut herbs, strain the mixture through a tea strainer into a teacup and drink while still hot. When straining, make sure to press on the cut herb pieces in the strainer to get as much decoction out of the herb pieces as possible. If using powdered herb, allow the powder to settle to the bottom of the pot and then pour off the decoction from the top into a teacup. Standard dosages for decoction are generally one-half to one cup, two or three times daily. The entire day's dosage can be prepared in the morning (2–3 cups at one time).

iii. **Tincture**

A tincture is an alcoholic herbal extract. Alcoholic solvent is used when plant's active chemicals are not very soluble in water or heat and when a larger quantity is prepared for longer storage. Plant material (dry powder or cut) is soaked in alcohol in an appropriate plant: solvent ratio (usually 1:4) in a concealed vessel (dark colored glass bottle or jar with tight fitting lid or cork), left for 2–6 weeks and strained before use. Alcoholic tinctures are made with various ethanol concentrations, 25% being the most common. The percentage of alcohol and water is unique to the herbs and determines its shelf life; higher percentage of alcohol increases the shelf life of the extract. Many properly prepared plant tinctures stored in the dark bottle out of the sunlight can last several years or more without losing potency. To prepare a tincture with a shelf life of at least one year, it is suggested to use a minimum of 40% alcohol (or 80 US proof vodka or rum without adding any water).

Besides ethanol, other solvents used in herbal tincture preparation include vinegar, glycerol, ether and propylene glycol. Some of these preparations cannot be used for internal consumption. Ethanol has the advantage of being an excellent solvent for both acidic and basic (alkaline) constituents. Glycerin is generally a poor solvent while vinegar, being acidic, is a better solvent for obtaining alkaloids but a poor for acidic components. Non-alcoholic glycerites (extract made using glycerin) offer an alternative for preparations for those who avoid alcohol. Tincture of benzoin (alcoholic solution of benzoin resin, a balsamic resin obtained from the bark of several species of trees in the genus *Styrax*, Styracaceae), Cannabis (an alcoholic extract of flowers, leaves, or stems of *Cannabis sativa*), cantharides (from Spanish fly, *Lytta vesicatoria*), castoreum (exudate from the castor sacs of the mature beaver—*Castor canadensis*, *C. fiber*), opium (laudanum) (contains almost all of the opium alkaloids, including morphine and codeine), pennyroyal (*Mentha pulegium*), spirit of camphor (solution of alcohol and camphor, *Cinnamomum camphora*) are some related examples of tincture. It can be used for poisonous bites, inflammation, blood poisoning, burns and more. St. John's Wort can be used as a tincture to produce beneficial results for depression and anxiety.

Method Herbal tinctures are prepared from raw, dry powder or cut (coarse cut 4 mm, medium cut 2.8 mm fine cut 2 mm) herbal materials and soaked in alcohol to extract the active properties from herbs that will not dissolve in water or in the presence of heat. When working with dried plants, use 2 oz of plant material (cut or powder) for every 8 oz (1 cup) of liquid in the ratio 1:4 or the ratio be 1:5 (200 g or 7 oz dry herb per 1 L or 2.2 pints vodka); measure the amount of cut herb by weight and not volume since many cut herbs can be bulky. Put the herb (powder or cut) in a container containing 40% alcohol (ethanol, 80 US proof vodka, rum, etc.) and leave for 2–6 weeks, strain and use. In the Amazon, a sugar-cane alcohol resembling rum and called aguardiente (alcoholic beverages) is often used to prepare plant tinctures and it is 40–50% alcohol (or 80–100 US proofs). A standard 4:1 tincture usually means 1 part herb to 4 parts liquid (1 oz herb to 4 oz of liquid). To prepare approximately 1 cup of tincture place 2 oz of the herb (powder or cut) into your clean glass container. Pour ½ cup (4 oz) of distilled water and ½ cup (4 oz) of 180 proof alcohols into the container (or 1 cup of 80 proof vodka without water). Seal the container and keep at room temperature away from direct sunlight for at least 2 weeks to soak (larger woody cut pieces need 4 weeks) and shake the container (bottle/jar) periodically, at least once daily. At the end of 2 or 4 weeks, strain the tincture through a muslin cloth or fine mesh strainer. Squeeze out the excess liquid from the herb matter. Discard the plant matter and bottle the tincture in a dark glass bottle and seal.

Since this method uses a higher ratio of plant to liquid and helps concentrate the chemicals through the use of alcohol, dosages needed for tinctures are usually much less than infusions and decoctions. Average dosages for tinctures are about 1–2 milliliters (about 30–60 drops) two to three times daily. The tincture can be placed directly in the mouth for immediate absorption, or placed in a small amount of water or juice. Addition of about 1–2 oz of very hot water in the alcoholic dosage

may help to evaporate alcohol in the hot water in a minute, then cool and drink alcohol-free tincture. Store the tincture at room temperature and away from direct sunlight.

iv. **Maceration**

Macerations can be made out of a wide variety of different plant matter. Any plant matter (herbs or spices) suspended in a liquid (oils, alcohol, vinegar, plain water, honey etc.) and left for a long amount of time to imbue its inherent essences into the suspension can be considered maceration. It is the easiest and most basic method of creating herbal remedies. Maceration process involves a slow steeping of plant matter in any type of liquid, usually (but not limited to), oils. Maceration is a type of cold infusion, a slower time-consuming one that generally does not involve the use of heat. During maceration, plant matter is suspended in a liquid and left for few weeks to few months depending on the desired potency or eventual purpose of the maceration. It is good for the extraction of delicate or highly volatile herbal essences. At its most basic, all macerations are literally cold infusions or very subtle heat infusions.

There are several types of macerations, e.g., herb or spice-infused oil macerations, herb or spice-infused vinegar macerations, herb or spice-infused liquor macerations, herb or spice-infused honey macerations, and plain water-infused cold macerations. Some maceration may be used as massage oils or hair oils, while others may be employed as antiseptics or salves to facilitate wound healing. Still, others may be used a medicine (especially tinctures), that are either drunk straight or (more often than not) diluted with water or some other palatable liquid. With regards to oils, vinegars, and waters, the maceration process renders the suspending liquid quite strong, but not quite as potent as tinctures or essential oils, thereby making them perfectly usable sans any dilution (with a few rare exceptions). Still, one must always try them out for possible adverse reactions prior to use.

Method

This method of preparation is certainly the easiest. The fresh or dried plant material is simply covered in cool water and soaked overnight. The herb is strained out and the liquid is taken. Normally this is used for very tender plants and/or fresh plants, or those with delicate chemicals that might be harmed by heating or which might be degraded in strong alcohol. This is also the easiest to adapt to western methods, since tablets or capsules can be used instead. Alternatively, just stir the ground plant powder into juice, water or smoothies and drink. Maceration can be made by mixing any liquid substance with dry plant matter because moisture in the fresh sample oftentimes causes bacteria and other microbes to multiply and therefore fresh herbs and spices not suggested for macerations. To hasten the process, shake the maceration regularly throughout its sitting or infusing phase, or otherwise gently heat (not simmer or boil, mind you, but simply heat). Another method of quickening the maceration process is to place the suspension in a warm sunny place, preferably under direct sunlight during the whole of the sitting phase. Always use perfectly sterilized and thoroughly dry containers to prevent the possibility of

bacterial formation, always cover it tightly to prevent contamination and spillage and store in a cool, dark environment. After some weeks to some months, strain the decoction through a fine mesh sieve topped by doubled or tripled muslin or cheesecloth into dark-hued mason jars for storage.

v. **Percolation**

Percolation differs slightly from maceration. The powdered drug is dampened with the menstruum (it is an old word meaning solvent, and in herbal circles it refers to the substance, usually liquid, used to extract certain properties from herbs, thus making a medicine), left for 4 h then packed into a percolator. Sufficient menstruum/solvent is added to cover the drug and left for 24 h. The liquid is then allowed to very slowly drain from the bottom of the percolator (about twenty drops per minute). More menstruum/solvent is added and the process continued until the volume in the collecting flask reaches about three-quarters of the required volume. The marc is pressed, this liquid added to the flask, more menstruum/solvent added to make the specified volume then the whole liquid is clarified.

Methods

Methods of preparation, quantitative presence of the active drug constituents in the preparation as well as its mode of use are important for a desired therapeutic effect from an herbal preparation. Fresh materials are considered to be the best, but can be dried to ensure a constant supply throughout the year. In case of dry material, half of the quantity of fresh material may serve the purpose. Methods of preparation of herbal remedies depend on the part of the plant, the active ingredient or the mode of administration. In traditional herbal medicine systems, herbal remedies are prepared in several ways. Some of the methods are described below.

vi. **Syrup**

Syrup is a concentrated solution of sugar in water with specific healing properties. A syrup is classic in treating coughs, mucus congestion, bronchial catarrh and sore throats because it may coat the area and keep the herbs in direct contact with the affected area. Syrups are especially helpful for children and those with a sensitive palate. Basil, mint, rosemary, jasmine, and thyme syrups are examples of some of the common herbal syrups.

Method

(i) Syrups may be made by adding about two ounces of herbs to a quart of water and cautiously boiled down to one pint. While the blend is still warm, two ounces of honey and/or glycerin is added to produce the thickened substance. Licorice and wild cherry bark are popular flavors and therapeutic agents in making syrups. Other herbs that are commonly used are anise seed, comfrey, fennel seed and Irish moss.

(ii) Prepare a syrup using 125 g of sugar in 60 ml of water; bring to the boil while stirring to dissolve the sugar. Add one part of an herbal tincture to three parts syrup. The mixture will keep for a long time since the sugar acts as a

preservative. With infusions or decoctions add 325 g (¾ lb) sugar to each 600 ml, heat while stirring until the sugar dissolves and the mixture thickens. Cool and store in the fridge, in sterile dark bottles with cork stoppers (pressure can build if fermentation occurs).

vii. **Inhalation**

An inhalation is the use of steam to administer herbs or their essential oils. Steam inhalation is a method of introducing warm, moist air into the lungs via the nose and throat for therapeutic benefit. Essential oils are often added to provide additional relief. Steam containing suitable herbal essential oil is one of the best methods to ease breathing, congestion, and stuffy nose. Moisture from a hot shower with the door closed or saline nasal spray is just as helpful to ease congestion. The steam may help ease congestion by loosening mucus and making it easier to clear by blowing nose. Adding menthol, eucalyptus, camphor, thyme, pine etc. oils to the water may help clear the passageways in the nose. Steam inhalation is not advised for children because of the risk of scalding. Instead, it might help a child if they sit in a hot, steamy bathroom. Ancient Egyptians recognized the good therapeutic effects of inhalation therapy through the use of public baths. Steam inhalation has since become a simple and effective home remedy for various health issues (respiratory benefits, natural expectorant, headaches and migraines, pore cleansing and rejuvenation). Inhalation methods may be portable using 1–2 oz bottle and over the bowl inhalation.

Method

Pour boiling or very hot water into a bowl and 3 drops of the essential oil or a few tablespoons of herbs of your choice as per the problem (e.g., use rosemary, eucalyptus, peppermint for clearing nasal passages or lavender, clary sage, vanilla, etc., for calming), place your head about 30 cm above the bowl and cover your head with a towel in such a way that the sides are totally closed and you in actual fact form a tent over the bowl. Do not get the face too close to the hot steam or knock over the bowl, keep your eyes shut and breathe slowly and then deeply through your nose for 1–2 min. If you feel that the treatment is getting too much for you, raise the towel so that fresh air is brought into the area and breathe through your mouth a couple of times and then resume the treatment. Discontinue the treatment when you feel discomfort (at any time). Be careful not to let the steam burn your nose. Use of a humidifier may produce the same effect. When steam and essential oils are combined they form a very potent way to help treat some ailments of the upper respiratory tract, nose, and sinuses. This type of treatment should not be used by anybody suffering from asthma. This is effective against the sufferings due to cold, wheezing chest, sinus discomfort etc., but beyond these discomforts, a licensed medical practitioner should be consulted. When using this treatment with children or elderly people make sure that they do not burn themselves by getting too close to the bowl, or that the steaming water is upset and burns result.

List of some conditions with corresponding herbs (or essential oils) is now available. Same or different herbs or their essential oils may be used in the inhalation therapy to ease difficulties such as breathing (cedar wood, eucalyptus, pine); bronchitis (basil, benzoin, cedar wood, clove, eucalyptus, frankincense, pine, sandalwood, rosemary, tea tree oil, thyme); colds (bay, black pepper, clove, ginger, myrrh, orange, pine, rosemary, tea tree oil); coughing (benzoin, black pepper, cardamom, cedarwood, frankincense, peppermint, rosemary, cypress-a conifer); sinus (basil, rosemary, tea tree oil, eucalyptus, lavender, peppermint, marjoram).

viii. **Bolus (large pill)**

A bolus is a suppository used as an internal poultice in the vaginal or rectal areas. A bolus helps draw toxic poisons to the bolus itself or it is the carrier for healing agents. There are two types of bolus: one that dissolves at body temperature and the other acts as a poultice. The poultice type is made with healing herbs to help draw the poisons and toxins and to help break loose cysts, tumors, and cancerous conditions even as far up as the abdominal area as the bolus has a widespread influence, effecting not only the vagina, but also other organs, such as the bowel and the urinary tract. Boluses are inserted into the rectum for treating ailments such as hemorrhoids and into the vagina for treating vaginal infections and irritations.

Method

The bolus may be made by adding powdered herbs to melted or soft cocoa butter until it forms a compressed and thick consistency. For this, mix one teaspoonful of the powdered herb with a small amount of melted cocoa butter (do not allow it to bubble or burn) and stir a little at a time to have a dough like consistency. If the mixture is too thin, add some turmeric powder and if it is too thick, add some olive or sesame oil. Roll out the mass into a long narrow strip between the palms into a pencil-like form and cut 2.54 cm or 1 in.-long pieces, wrap in wax paper and place in the freezer for 2 h to harden and preserve. Bring the bolus to room temperature before use. Insert the bolus into the vagina or into the rectum. The bolus may be inserted into the vagina to treat infections, irritations or fibroid tumors or into the rectum to treat hemorrhoids or cysts. It is best to use the bolus at night while sleeping when the cocoa butter will melt with the body heat, where the herbs will then be released. Take care to protect clothing and bedding from the melting cocoa butter. Deposits of the bolus should be washed away the following morning.

The herbs used in the bolus are usually astringents. This means that they have a constricting or binding effect. They are able to pull the toxins out of the body. Typical herbs used in a bolus would be white oak or bayberry bark; demulcent herbs will soothe the part or soften the skin to the area applied. Demulcent herbs are comfrey or slippery elm, and antibiotic herbs will inhibit the growth of or destroy microorganisms. Antibiotic herbs are garlic, chaparral or golden seal. Some herbs (all powdered) that are good for bolus, varicosities, hemorrhoids, damaged tissue, softening scar tissue, etc. are: *Hypericum perforatum*, *Hamamelis virginiana*, *Plantago major*, *Capsella bursa-pastoris*, etc.

External Preparations

External or topical remedies are best used for localized skin or muscle complaints, although as the skin is capable of absorbing medicinal constituents, they can be useful for more general complaints as well.

i. **Compresses**

A compress is made by soaking a piece of clean cloth (e.g., linen, cotton, or gauze) folded to form a pad or bandage in a decoction, infusion or tincture and applying it to the affected area, as hot as can be tolerated. When the compress has cooled, it can be soaked again in the reheated liquid and reapplied until the condition has been relieved. Compresses can also be applied cold. A compress is a more concentrated application than a wash, but very useful to accelerate healing of the skin. Compresses are commonly used to treat wounds, eczema, rashes, headaches, muscle aches, fungal skin infections, skin irritation, chest congestion or swelling from an injury. A blend of naturally healing herbs such as calendula flower, black walnut leaf, chaparral leaf, comfrey leaf and root, lobelia, marshmallow root, mullein leaf, skullcap, white oak bark, arnica, plantain, calendula, oats, wild bergamot, chamomile, lavender, rue, and wormwood, traditionally employed as a muscle relaxer, astringent, antiseptic, and vulnerary to heal all manner of connective tissue injuries, are useful in compress.

Method

Make a liter of infusion or decoction (depending on the herbs to be used). Use a clean cloth made of natural fiber such as cotton, linen, or hemp. Soak a pad of the cloth in the hot infusion or decoction (2 cups or 500 ml infusion or decoction, 2 tablespoons or 25 ml tincture in 2 cups or 500 ml water). Wring out the excess liquid and place on the affected area. Before applying, rub a little oil on the affected area to prevent sticking. The heat is an important part of this remedy, so either changes the compress as it cools, or place a hot water bottle on top of the cloth to keep it warm.

Application of hot herbal compresses to restore warmth relieves the pain associated with the initial stage of an injury. Muscles relax, energy and fluid circulation are stimulated (which will normalize inflammation naturally), soothes inflamed membranes, disinfects, draws torn parts together, and proliferates regenerative cell growth. Hot herbal compresses are indicated for sprains, tendonitis, carpal tunnel syndrome, arthritis, bruising, muscle, tendon, ligament, bone, and other connective tissue hurts.

ii. **Poultice**

A poultice is similar to a compress, except that plant parts are used rather than liquid extraction. Poultices are simply moisten herbs applied externally and are commonly used to treat swelling, pain and congestion or be warm crushed fresh or ground powdered herbs that have been applied directly to the skin to relieve abscesses, blood poisoning, bites and eruptions, boils, decrease tissue swelling

(inflammation) and tension, deodorize and disinfect pollutants, soften crusted lesions, encourage the muscles to relax, stimulate healthy skin, and to promote the purging of toxins and healing of the affected area. A poultice may be a hot or moist mass of oil between two pieces of muslin or gauze containing herbs which are applied to the skin to relieve congestion or pain. It may stimulate the absorption of inflammatory toxins produced by the body and to act as a counter-irritant. Antiseptic should be used before applying poultices. Many herbal remedies are applied directly to the skin as poultices—usually on rashes and wounds and as topical pain-relieving remedies. Poultices are prepared in various ways, e.g., from the jungle shaman chewing up fresh leaves or roots and spitting them out onto the skin to mashing up fresh leaves or roots by hand or with a mortar and pestle. Sometimes just enough hot water is poured over dried or fresh plant material to soften them. Then, the wet herbs are placed directly on the skin or between two pieces of cloth and laid on the skin. A light cotton bandage to bind the poultice to the area is generally used or in the outdoor jungle, a nice large flexible leaf is commonly employed and tied with a bit of twine. A poultice is similar to a compress, except that it uses the whole plant matter and not just the liquid extract. Poultices are commonly used for bruises, sprains, inflamed organs, skin complaints and for drawing pus out of infected wounds.

Method

Mash or crush fresh plant parts. Heat them in a pot over boiling water or mix them with a diminutive amount of boiling water. Apply the pulp directly to the skin, as hot as can be tolerated, holding it in place with a gauze bandage. When using dried herb, first powder it and make a paste with 1 tablespoon of powdered herb and a little boiling water or hot organic cider vinegar. The poultice should be a minimum of ¼–½ in. thick. Before applying a poultice, the skin is first covered with oil. It may be held in place with either tape or an elastic bandage and left on for at least 3 h. If the paste is likely to irritate the skin, apply it between two layers of cloth. Poultices can also be left on the body overnight for deep cleansing. Most poultices are applied warm and should not be reheated and then reapplied as toxins have already been absorbed into the poultice pack. When one poultice cools, another may be applied at that time. Use the bruised fresh herbs or powdered dried herbs, which have been mixed to a mush with hot water. It is useful to mix the herb matter with fresh *Aloe vera* gel or castor oil, as this draws the active parts of the plants deep into the skin and underlying tissues. Apply the mix to the affected area and cover with an oiled cloth or plastic wrap to keep the moisture in. Keep it warm with a hot water bottle. Many herbs have a natural drawing power on infections, toxins and foreign bodies embedded in the skin tissue. Plantain and marshmallow are excellent for relieving pain and muscle spasms. Powdered herbs may be moistened with apple cider vinegar, herbal teas, hot water, liniments, or tinctures. A plaster may also be used as a poultice. A potent plaster for drawing out fever may be made by squeezing out water from tofu and mashing the tofu with pastry flour and a large pinch of fresh ginger root.

iii. **Cabbage poultice**

Cabbage poultice improves lymph drainage and helpful in removing toxins.

Method
Finely chop green cabbage sufficient for the area to be treated. Place the cabbage in a blender with just enough water to make a thick paste. Spread the cabbage paste 1 in. thick over a piece of cheesecloth, muslin or a clean tea towel. The size should be sufficient to cover the preferred part of the body. Place the cloth, cabbage-side onto the skin, over the area to be treated. Cover with a clean, dry cloth and wrap the whole area in a thick towel or wool flannel cloth. Leave the poultice in place for 15–60 min depending on the rigorousness of the condition and the reactions of the person. The treated area should get red and warm, but should not get burned. If the person becomes uncomfortable, remove the poultice and wash the area with cool water. Have the person lie down and rest for the duration of the application. After removing the poultice, wash the area with lukewarm water. The cabbage poultice may be repeated two or three times daily as needed, using fresh cabbage each time.

iv. **Compound poultice or plaster**

These are very much like poultices except that the plant materials used are dried and possibly powdered herbs mixed with a carrier or medium such as oatmeal, ground flaxseed, clay, or flour to create a paste when mixed with hot water (e.g., mustard plaster). The hot paste is spread on a piece of cloth and then applied to the affected area. This is covered with another piece of cloth and possibly bound in place by wrapping the area with long strips of cloth. Besides holding the plaster in place for obvious reasons, this also holds in the heat for a bit longer. It may also make this method a little less messy.

v. **Fomentation**

Fomentation (from the Latin word fovimentum means a warm application, to foment means to warm or heat up) is a quaint old term for the application of hot packs or the substance so applied.

Fomentations are used often in natural healing. A fomentation is a special preparation that allows herbs to be absorbed through the skin. A fomentation may be used to treat swellings, pain, colds, and flu.

Method
Prepared first a strong infusion, or tea, from the herb parts (usually the leaves, roots, or flowers), soak a soft white towel or clean cloth in the hot infusion or tea. Leave the towel or cloth wet but not dripping. Apply the fomentation to the affected area as hot as the patient can tolerate. To hold in the heat, cover the soaked towel with warm piece of flannel, or another towel or a few cloth diapers around (because they are thick and absorbent). When it cools, the cloth must be wrung out and dipped again to keep it warm. Fomentation should be applied for several hours at a time and perhaps for several days, depending on the condition being treated. Fomentations stimulate circulation, aid in decongestion, draw abscesses, and are

soothing to external tissue and warm stiff joints. They can be used for acute inflammations, local pains and congestion, neuralgia, toothache, and pleurisy. This fomentation works well for major pain but can also help with more common muscle spasms as well. Cramp bark (*Viburnum opulus*) is fabulous for stopping cramps. It works well for muscle cramps, like when you throw out your back, menstrual cramps or even restless legs. Ginger and cayenne fomentations stimulate circulation and reduce inflammation. Mullein and lobelia fomentations relieve mastitis, thyroid malfunction etc.

vi. **Baths and bathing remedies**

Herbal bath is an age old system of hydrotherapy. In China (1100-221 BC), people used Eupatorium in baths to get rid of body odor. This fragrant herb is a common ingredient to relieve summer heat symptoms and to promote appetite. Here, medicinal plants are added to bath water and the patient is soaked in it. It is also known as vapor bath. This method is like some of the currently evolving dermal delivery systems for drug absorption employed in conventional medicine. The skin is a wonderful organ capable of absorbing plant chemicals (and even synthetic chemicals) directly thru the skin, and into the underlying fat tissue, then into the bloodstream. Since fresh plants are generally used for bathing remedies (chopped or crushed first before adding to the bath water), western adaptations are not always possible when only dried plant materials are available here. In the alternative, try 20–30 oz of a strong decoction or infusion added to your bath water and soak in it for at least 10 min. Bathing with all natural botanical products can be a transformative and nourishing experience. Not just for cleansing, bathing in herbal scented water can help reduce stress, soothe the skin and just be a relaxing experience for everyone. The following list of herbs, such as chamomile, basil, eucalyptus, fennel, lavender, lemon balm, rosemary, sage, calendula, yarrow, can be chosen for their therapeutic offerings such as softening, soothing muscles, stimulating circulation, or drawing out infection. In the summer you can treat yourself to fresh lemon balm leaves or calendula flowers from the garden. Relaxing in a steamy, warm herbal baths is my favorite way to get full body skin care. A good bath herb should be tonic to the skin and relaxing/and or stimulating to the mind. Aromatic herbs that contain essential oils fit the bill perfectly.

The purest natural herbs in the form of highly concentrated essential oils interact with the natural healing and soothing powers of water. Essential oils, known as the immune system of the plant, are inhaled from the steam in your bath and absorbed when you soak in your tub. Water has a natural therapeutic effect on the body's systems. The term hydrotherapy has been used to describe the use of water, hot and cold, to provide a profound therapeutic effect. Adding just a cap of Herbal Bath proves to be a transforming and deeply relaxing, bathing experience. The benefits of warm baths have been known since ancient times. Steam baths are the oldest form of relaxation therapies; they promote blood circulation, open air ways, enhance sweating and mucosal secretions and regulate the immune modulating effect. Heat and moisture promote bodily functions, lubricate the body and regulate the internal water metabolism.

Method

Mix an infusion or decoction to fill the bath or use a large gauze bag stuffed with proper herbs (ground) to steep. When taking herbal bath, the water temperature should be between 37 and 42 °C, rub the body surface slightly and soak in the bath no longer than 30 min. After the bath, rinse the body with plain water, rest for half an hour and drink water to replenish lost body liquid. When adding the essential oils to the hot bath, wait until the water has stopped running to avoid evaporation. Dilute the oils in a base oil or honey, or add at a rate of 10–14 drops per bath as a general rule. In case of using fresh herbs, put them in a muslin bag to steep. To soften skin and remove impurities, dissolve 1 cup of Epsom salts ($MgSO_4$) in the bath water. Bath salts (3 parts Epsom salt to 2 parts baking soda equal or 2 cups total or 1½ cup Epsom salt and ½ cup baking soda) base and essential oils (up to 10 drops of essential oil to every 2 cups of your salt) make an everyday bath into a sweet and sensual, delightful hydrotherapy session.

vii. **Ointment**

An ointment is a therapeutic, fatty, soft substance for external application only. It typically has antiseptic, cosmetic or healing properties. Its usual base is petroleum jelly or lanolin to which the herbal preparation is added. Either form is not water soluble; however, some ointments are composed of ingredients which are water soluble. Ointments are preferably used on the skin when the active principles of herbs are needed for longer periods of time which would then accelerate the healing process. This may be in the case of abrasion, contusion, effusion, or injury. Ointments are preferably used on the skin when the active principles of herbs are needed for longer periods of time which would then accelerate the healing process. This may be in the case of abrasion, contusion, effusion, or injury. Lanolin is a purified, fatlike substance that is natural and obtained from the wool of sheep which may be used instead of petroleum products.

Method

(i) To make an ointment, one or two heaping teaspoons of an herb or herbal preparation is brought to boil in the product of choice (petroleum jelly or lanolin). The mixture is then stirred and strained. When the mixture cools, the ointment is put into jars and is ready to use when the time is right.

(ii) It is made with hot or cold infused herbal oil and beeswax. Using a bain-marie (a piece of cooking equipment, a type of heated bath, water bath), melt about 1 cm square (½ in.) of beeswax in 105 ml (3½ lf oz) of the oil while stirring. Pour into an ointment jar while warm and leave to set. This will keep for about a year.

viii. **Liniment (liquid ointment)**

A liniment is usually comprised of herb and a solvent such as alcohol, vinegar, or oil. It is an herbal extraction that is rubbed into the skin. Liniments are used for sore muscles, strains, arthritis, and inflammations of muscles, ligaments and tendons.

Method

To make a liniment for sore muscles, for example, place 4 oz peppermint in a 16-oz jar. Add 4 oz eucalyptus. Add a pint of alcohol or vinegar. Do not use rubbing alcohol; use vodka. Put in a dry place for 14 days and shake twice a day. Use on the affected areas. A few drops of essential oil such as rosemary, peppermint, or eucalyptus may be added. Alternatively, for sore muscles liniment, fill a jar with 1 part arnica flowers (*Arnica montana*) and 1 part fresh St. John's wort flowers (*Hypericum perforatum*). Fill to the top of the jar with brandy, vodka or apple cider vinegar. Allow the mixture to sit for 2–3 weeks, strain and bottle for use. An instant liniment for muscle pain may be made by combining 0.5 cup alcohol with 1 teaspoon peppermint, eucalyptus or rosemary essential oil. First, try using less essential oil and find the amount that works.

ix. **Herbal oil**

Natural herbal oils include ginseng, jojoba oil, walnut seed oil, sage leaf oil, sweet almond oil, carrot seed oil, and much more. To heal dry skin and hair … also for diminishing scars and stretch marks, to prevent premature aging, to correct prior damage to hair or skin, this oil can be used on skin, hair, and body to rejuvenate and moisturize. Herbal oil moisturizes the skin, hydrates dull skin, and diminishes stretch marks and scars.

Method

Apply and gently rub into skin, for hair—squeeze a small amount into palm of your hand and massage into your hair and let it dry. For body massages to stimulate and relax your entire body, massage into stressed areas on body, for the bath, add a few drops to bath water and soak in the bath, after your bath, your skin will be soft and silky.

To make herbal oil, choose an herb. If it is fresh, allow it to wilt in the sun or overnight to release the excess water that can contribute to mold in the oil. Start with a small jar. If recycling an old food jar, scrub it out and sterilize it. Scrubbing and running through a dishwasher will definitely do the trick. Make sure to sterilize the lid so it does not add an odor to the oil. Make sure the herb is dry and the jar is dry. Fill the jars halfway with herb, then cover with oil and continue until an inch or two of oil is on top. Some herbs that are great for herbal oils are *Calendula officinalis*—an anti-inflammatory, antispasmodic that helps heal wounds, useful for bed sores, broken veins, bruises, inflamed gums, varicose veins, Calendula is also effective on rashes and dry, chapped or cracked skin; Comfrey leaf (*Symphytum officinale*) oil is useful for belly massage, promoting elasticity and preventing stretch marks. It can be used on breasts, hips, and thighs. Comfrey leaf oil also can be used as a massage oil for sprains or muscle tears, to strengthen connective tissue in varicose veins and for dry skin and eczema; St. John's Wort (*Hypericum perforatum*). This is my favorite herbal oil. I use it for everything from sunburned skin, sciatica, carpal tunnel pain, sacral pain in labor, back ache, sore necks, varicose veins, hemorrhoids, wounds and bruises; chickweed oil (*Stellaria media*) oil is useful for pruritus and itchy skin, as well as eczema, hemorrhoids, varicose veins, psoriasis and overall skin health.

x. Cream

The cream formulations may be designed by using ethanolic extracts of *Glycyrrhiza glabra*, *Curcuma longa* (roots), seeds of *Psoralea corylifolia*, *Cassia tora*, *Areca catechu*, *Punica granatum*, fruits of *Emblica officinale*, leaves of *Centella asiatica*, dried bark of *Cinnamon zeylanicum* and fresh gel of *Aloe vera* in varied concentrations (0.12–0.9% w/w). The ethanolic extracts of herbs were incorporated in a cream base that may be prepared by a phase inversion emulsification technique. The cream base was prepared by utilizing oil of *Prunus magdalus*, *Sesamum indicum*, honey, cetyl alcohol, stearic acid, polysorbate monoleate, sorbitan monostearate, propylene glycol and glycerin.

Use aqueous cream to incorporate a little of an infusion, decoction or tincture for application two or three times daily or using emulsifying ointment, dried or fresh herbs can be incorporated directly. Melt two tablespoonsful in a bain-marie and add two teaspoonful of the finely chopped herb, stirring until it takes on the color of the herb. Strain while molten, leave to cool and store in a jar. It remains viable up to a year.

xi. Salves or balms

A salve is a medical ointment (astringent) used to soothe the surface of the body. Salves are useful preparations for regular application, as they are in the form of a cream. Ichthyol salve has been traditionally used to treat minor skin problems such as sebaceous cysts, boils, ingrown toenails, and splinters. The main ingredients are often ichthammol (from sulfur-rich sedimentary rock oil shale or kerogen shale), phenyl alcohol, or *Arnica montana*, and may contain herbs such as Echinacea (coneflowers of Asteraceae) or calendula (pot marigold or marigold of Asteraceae). Common herbs that are prepared as salves are camphor and peppermint for aching muscles, calendula for wound healing and fungal infections, and comfrey or arnica for bruises and broken bones. In herbal salves, the healing powers of medicinal herbs are infused into emollient organic oils and blended with organic beeswax. Within minutes, nourishing oils penetrate and bring the healing and soothing properties of the herbs deep into the tissues. Salves are used externally for minor skin irritations, insect bites, cuts, abrasions, sore muscles, chest congestion and stress relief.

Method

Salves are more complicated to make and are best bought. A simple salve is a firm beeswax and oil combination that is intended for external application. Use olive oil or infused oil such as plantain, comfrey, or calendula. For one pint of oil use about 1–1/2 oz of beeswax or for one ounce of oil use about 1/2 teaspoon of beeswax (an ounce of beeswax is equivalent to about five teaspoons). Heat the oil with the beeswax and mix until all of the wax is melted. Then, add herbs and essential oils and pour into containers. If the salve is too hard, re-melt and add more oil; if too soft, re-melt and add more wax (vegetarian wax or coconut oil may be used instead of beeswax).

xii. **Oil**

Oil is a greasy liquid not miscible with water, usually obtained from and classified as mineral, vegetable or animal. According to character, oils are subdivided as fixed or fatty and volatile or essential. Fixed oils of plants and animals are glyceryl esters of fatty acids. These oils serve as food reserves in animals. They are nonvolatile and contain no acid, e.g., castor oil, olive oil, or cold liver oil. Volatile oils have an odor and produce taste sensations which are obtained from certain plants by steam distillation. These oils are used in flavors, perfumes and healing remedies. They are usually complex chemicals that are difficult to purify (e.g., peppermint or rose). Herb oils are useful when ointments or compresses are not practical. It is important that herb oils be stored in brown glass containers.

Method

When the main property of an herb is much the same as its essential oils, an oil extract may be the best way of preparing a concentrate from fresh herbs. Oils are prepared by softening and pounding the fresh, dried herbs. The oil of choice is then added, approximately 2 oz of an herb to one pint of oil. The mixture is then put in a warm place around 4 days. A swifter process is to carefully heat the oil and herbs in a pan for about 1 h. The oil is then strained and bottled. A small amount of vitamin E may be added as a preservative. Oils are typically made from the aromatic herbs such as eucalyptus, lavender, ginger, peppermint, and spearmint.

Dry Preparations

Herbal preparations often require the use of dried herbs. Herbs are tied to a straight rope or other support upside down or spread on paper towel in an open shelf in a hot dry well ventilated place until they are crisp for grinding.

i. **Powder**

A powder is a collection of fine particles of one or more substances that may be passed through fine meshes. Herbal powders are finely milled herbal material such as dry leaves, flowers, roots, barks, and berries. Powder provides the nutritional and healing benefits of herbs. Powdering herbs is a three step process—drying, grinding and sifting. Freeze-drying or slow-drying at low temperatures preserves phyto-chemical profile of the herbs. Grinding-breaking and sifting—removal of lumps or large particles can be done manually using stone or ceramic grinder and a sieve as well as mechanically. An electrical grinding machine witted with a sieve can be used to facilitate the powdering and sifting of large quantities of herbs into different meshes (coarse—between 20 and 50 mesh to fine—between 60 and 100 mesh). By forming a powder, the herb can be taken either by capsule, in water, in herbal teas, or sprinkled onto food. For external use, the powdered herbs, are used with oil, a petroleum jelly, lanolin, water or even *Aloe vera* juice and applied to the skin to treat abrasions, contusions, effusions, inflammatory processes, and wounds. Powders are used to make herbal capsules, in body powders, tooth powders, and for making spices for cooking and baking recipes. This may seem like a lot of work considering that most herbs and spices are widely available for sale already finely

powdered. The problem is powdered herbs lose their potency, flavor, and aroma very quickly—even when properly stored. The quality of freshly powdered herbs makes it is well worth the effort. Powders may be ingested directly (swallowed with some water or tea) or made into a tea by briefly boiling in hot water, and straining out the dregs that sink to the bottom. Powders may be rolled into sticky pills, called honey boluses, or sliced to make tablets. Powders from agnus to castus berry (chasteberry), Agrimony herb, Alfalfa leaf, Angelica root, Aniseed, Artichoke leaf Astragalus root, Barberry bark, Bogbean leaf, Borage herb Buchu leaf are some of the common examples.

Method
Take necessary fresh plant material such as leaves, flowers, roots, barks, and other useful parts or whole herbs, dry the plant parts as per requirement (freeze-drying or slow-drying at low temperatures preserves phytochemical profile), mash in an electrical grinding machine fitted to a sieve to facilitate the powdering and then sifting into desired meshes (coarse—between 20 and 50 mesh or fine—between 60 and 100 mesh).

ii. **Capsule**

Many herbal medicines are available in capsule or pill form. The herb is ground into a powder and packed in a capsule. This is a convenient method for herbs that are difficult to administer or have an unpleasant taste. Herbs such as *Coptis chinensis*, *Scutellaria baicalensis*, *Phellodendron amourense*, *Gardenia jasminoides*, *Radix Glycyrrhizae*, and *Atractylodes japonica* are bitter tasting but have beneficial medicinal properties. These, among many more herbal medicines, are available in capsules or tablets as it is a much more palatable form. Capsules have the advantage of being easy and convenient, especially for bitter-tasting herbs. The disadvantage of capsules is that the herbs inside them are much harder to assimilate into the body than preparations made with hot water or alcohol.

Method
To take herbs as capsules, you must first buy empty vege-caps, and fill them with the herb. To do this, cover a plate with the powdered herb and take the halves of the capsule apart. Move the halves of the capsule toward each other through the herb powder, filling them in the process. Push the halves of the capsules together to close. Generally speaking, 4 caps need to be taken together to equal 1 teaspoon of herb matter.

10.3 Evaluation, Quality Control and Standardization of Herbal Drugs

Factors that influence the quality of herbal drugs may be enumerated as (i) herbal drugs are usually mixtures of many constituents; (ii) the active principle(s) is (are), in most cases unknown; (iii) selective analytical methods or reference compounds

may not be available commercially; (iv) plant materials are chemically and naturally variable; (v) the source and quality of the raw material are variable; and (vi) the methods of harvesting, drying, storage, transportation, and processing (e.g., mode of extraction and polarity of the extracting solvent, instability of constituents) have an effect.

For standard herbal drug production at industrial level, source herbal ingredients should be analyzed in detail in respect of quality, efficacy, performance, and safety because drugs in commerce are frequently adulterated and do not comply with the standards prescribed for authentic drug. World Health Organization (WHO 2002) puts emphasis on the research and evaluation traditional medicine considering its application since antiquity, popularity and extensive use during the last few decades (owing to natural origin and lesser side effects) as well on the development of appropriate research methodology for evaluating traditional medicine's quality, safety, efficacy, etc.

Quality control for efficacy and safety of herbal drugs and cosmetics is of paramount importance. Quality can be defined as the status of a drug that is determined by identity, purity, content, and other chemical, physical, or biological properties, or by the manufacturing processes. Quality control is a term that refers to processes involved in maintaining the quality and validity of a manufactured product. In general, all preparations, medicines or cosmetics of plant origin, should fulfill the basic requirements of being efficacious and safe, and this can be achieved by suitable practical trials.

Quality control is based on three important pharmacopoeial definitions such as (a) identity (botanical identity); (b) purity: (contaminants free); and (c) content or assay (presence of active constituents at optimum level). For a quality herbal drug production, (i) proper botanical identification; (ii) phytochemical screening; and (iii) standardization are suggested essential steps to be followed strictly.

To prove identity and purity, criteria such as source, type of preparation, physical constants, adulteration, contaminants, moisture, ash content, and solvent residues have to be checked. In most herbal drugs the active constituents are unknown and so the assessment of content is difficult. However, markers can be used for control purposes, but the marker may be independent of any therapeutic activity.

(a) **Identity**: It can be achieved by macro- and microscopical examinations. Voucher specimens are reliable reference sources. Outbreaks of diseases among plants may result in changes to the physical appearance of the plant and lead to incorrect identification. At times an incorrect botanical quality with respect to the labeling can be a problem. For example, in the 1990s, a South American product labeled as 'Paraguay Tea' was associated with an outbreak of anti-cholinergic poisoning in New York. Subsequent chemical analysis revealed the presence of a class of constituents that was different from the metabolites normally found in the plant from which Paraguay tea is made.

(b) **Purity**: It is closely linked with the safe use of drugs and deals with factors such as ash values, contaminants (e.g., foreign matter in the form of other

herbs), and heavy metals. However, due to the application of improved analytical methods, modern purity evaluation also includes microbial contamination, aflatoxins, radioactivity, and pesticide residues. Analytical methods such as photometric analysis, thin layer chromatography (TLC), high-performance liquid chromatography (HPLC), gas chromatography (GC) combined with mass spectrometry (MS), and nuclear magnetic resonance (NMR) can be employed in order to establish the constant composition of herbal preparations. By means of these methods also new insights into the variety of secondary plant metabolites may be obtained.

(c) **Content or assay**: It is the most difficult area of quality control to perform, since in most herbal drugs the active constituents are not known. Sometimes markers can be used. In all other cases, where no active constituent or marker can be defined for the herbal drug, the percentage extractable matter with a solvent may be used as a form of assay, an approach often seen in pharmacopeias. The choice of the extracting solvent depends on the nature of the compounds involved and might be deduced from the traditional uses. For example, when a herbal drug is used to make a tea, the hot water extractable matter, expressed as milligrams per gram of air-dried material, may serve this purpose. A special form of assay is the determination of essential oils by steam distillation. When the active constituents (e.g., sennosides in Senna) or markers (e.g., alkylamides in Echinacea) are known, a vast array of modern chemical analytical methods such as ultraviolet/visible spectroscopy (UV/VIS), TLC, HPLC, GC, MS, or a combination of GC and MS, can be employed.

Botanical extracts made directly from crude plant material show substantial variation in composition, quality, and therapeutic effects. Standardization involves adjusting the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity by adding excipients or by mixing herbal drugs or herbal drug preparations. Standardized extracts are high-quality extracts containing consistent levels of specified compounds, and they are subjected to rigorous quality controls during all phases of the growing, harvesting, and manufacturing processes. However, no regulatory definition exists for standardization of dietary supplements. As a result, the term ‘standardization’ may mean many different things. Some manufacturers use the term standardization incorrectly to refer to uniform manufacturing practices; following a recipe is not sufficient for a product to be called standardized. Therefore, the presence of the word ‘standardized’ on a supplement label does not necessarily indicate product quality. When the active principles are unknown, marker substance(s) should be established for analytical purposes and standardization. Marker substances are chemically defined constituents of an herbal drug that is important for the quality of the finished product. Ideally, the chemical markers chosen would also be the compounds that are responsible for the botanical’s effects in the body.

There are two types of standardization. (i) True standardization indicates that a definite phytochemical or group of constituents is known to have activity, e.g., Ginkgo products containing 26% flavones and 6% terpenes. These products are

highly concentrated and no longer represent the whole herb, and are now considered as phytopharmaceuticals. In many cases, they are vastly more effective than the whole herb. (ii) This type of standardization is based on manufacturers guaranteeing the presence of a certain percentage of marker compounds; these are not indicators of therapeutic activity or quality of the herb.

Methods of Evaluation of Crude Drugs
For quality control of herbal drugs and cosmetics, different procedures for examination and evaluation are followed such as:

i. Organoleptic evaluation
ii. Microscopic evaluation
iii. Physical evaluation
iv. Chemical evaluation
v. Analytical evaluation
vi. Biological evaluation

10.3.1 Organoleptic Evaluation

Organoleptic evaluation of drugs refers to the evaluation of a drug by color, odor, size, shape, taste and special features including touch, texture, etc. Since the majority of information on the identity, purity, and quality of the material can be drawn from these observations, they are of primary importance before any further testing can be carried out. For this purpose authentic specimen of the material under study and samples of pharmacopoeial quality should be available to serve as a reference. This evaluation procedure provides the simplest and quickest means to establish the identity and purity and thereby ensures quality of a particular sample. If it is found to be devoid of or significantly different from the specified sensory characters such as color, consistency, odor, it is considered as not fulfilling the requirements. Judgment based on the sensory characteristics such as odor, taste, however, may vary from person to person and time to time based on individual's nature. So the description of these features is very difficult so that often the characteristic such as odor and taste can only be described as 'characteristic' and reference made to the analyst's memory. No preliminary treatment is necessary for evaluating the sample in this manner except the softening and stretching of the wrinkled and contracted leaves and flowers, etc.

10.3.2 Microscopic Evaluation

Microscopic evaluation is indispensable in the initial identification of herbs, as well as in identifying small fragments of crude or powdered herbs, and detection of

foreign matter and adulterants. A primary visual evaluation, which seldom needs more than a simple magnifying lens, can be used to ensure that the plant is of the required species, and that the right part of the plant is being used. At other times, microscopic analysis is needed to determine the correct species and/or that the correct part of the species is present. For instance, pollen morphology may be used in the case of flowers to identify the species, and the presence of certain microscopic structures such as leaf stomata can be used to identify the plant part used. Although this may seem obvious, it is of prime importance, especially when different parts of the same plant are to be used for different treatments. Stinging nettle (*Urtica urens*) is a classic example where the aerial parts are used to treat rheumatism, while the roots are applied for benign prostate hyperplasia.

10.3.3 Physical Evaluation

Physical constants are sometimes taken into consideration to evaluate certain drugs. These include moisture content, specific gravity, optical rotation, refractive index, melting point, viscosity and solubility in different solvents. All these physical properties are useful in identification and detection of constituents present in plant.

10.3.4 Chemical Evaluation

Most of the drugs have definite chemical constituents to which their biological or pharmacological activity is attributed. Qualitative chemical test is used to identify certain drug or to test their purity. The chemical methods of evaluation include isolation, purification, and identification of active constituents. Qualitative chemical tests, such as acid value, saponification value, ester value, are useful in evaluation, e.g., resins (acid value, sulphated ash), balsams (acid value, saponification value and ester values), volatile oils (acetyl and ester values), and gums (methoxy determination and volatile acidity). Preliminary phytochemical screening is a part of chemical evaluation. These qualitative chemical tests are useful in identification of chemical constituents and detection of adulteration.

10.3.5 Analytical Evaluation

In general, quality control is based on three important pharmacopoeias definitions, e.g., identity, purity, content, or assay. Content or assay is the most difficult area of quality control to perform, since in most herbal drugs the active constituents are not known. Sometimes markers can be used. Sometimes markers can be used. In absence of a marker, the percentage extractable matter with a solvent may be used

as a form of assay. The choice of the extracting solvent depends on the nature of the compounds involved and might be deduced from the traditional uses. A special form of assay is the determination of essential oils by steam distillation.

To prove identity and purity, criteria such as type of preparation, sensory properties, physical constants, adulteration, contaminants, moisture, ash content, and solvent residues have to be checked. The correct identity of the crude herbal material, or the botanical quality, is of prime importance in establishing the quality control of herbal drugs. Identity can be achieved by macro- and microscopical examinations. Voucher specimens are reliable reference sources. Purity is closely linked with the safe use of drugs and deals with factors such as ash values, contaminants (e.g., foreign matter in the form of other herbs), and heavy metals. Besides these, modern purity evaluation includes microbial contamination, aflatoxins, radioactivity, and pesticide residues examination. Analytical methods such as spectrophotometric analysis, ultraviolet–visible spectroscopy (UV/VIS), infrared spectroscopy (IR), near infrared spectroscopy (NIR), mass spectrometry (MS), nuclear magnetic resonance spectroscopy (NMR) as well as thin layer chromatography (TLC), high-performance liquid chromatography (HPLC), and gas chromatography (GC) can be employed in order to establish the constant composition of herbal preparations.

10.3.6 Biological Evaluation

Some drugs have specific biological and pharmacological activity which is utilized for their evaluation. Actually, this activity is due to specific type of constituents present in the plant extract. For evaluation, the experiments are carried out on both intact and isolated organs of living animals. With the help of bioassays (testing the drugs on living animals), strength of drug in its preparation can also be evaluated. A few important biological evaluations are antibiotic, antifertility, hypoglycemic and neuropharmacological activities.

Some bacteria such as *Salmonella typhi*, *Staphylococcus aureus,* and *Escherichia coli* are used to determine the antiseptic value (the degree of antiseptic activity, e.g., phenol coefficient of certain drugs). The activity of antibiotics is also determined by using *Klebsiella pneumonia*, *Micrococcus flavus*, *Sarcira lutea*, etc. Living bacteria, yeast and molds are used to evaluate certain vitamins. Microbiological assays by cylinder-plate method (in solid medium) and turbidimetric method (in liquid medium) are used in the evaluation of antibiotic activity.

Antifertility drugs include contraceptives and abortifacients. Contraceptive drugs are used to prevent pregnancy and abortifacient to terminate pregnancy. Female rats are used for antifertility activity (anti-ovulation and anti-implantation) and male rats are used for anti-spermatogenic activity (inhibition of spermatogenesis) and spermicidal activity (sperm motility) due to herbal drugs. Rabbits, rats or mice are used to test hypoglycemic activity of plant extract. Radioimmuno assay (RIA) or Enzyme linked immunosorbate assay (ELISA) is done for the measurement of insulin levels.

Neuropharmacological activity tests of the herbal drugs include their effects on central (CNA) and autonomic nervous system (ANS). CNS acting drugs such as cocaine (*Erythroxylum coca*), morphine (*Papaver somniferum*), and cannabinol (*Cannabis sativa*) are tested using rodents. For testing the herbal drugs for their effects on ANS guinea pig ileum for antispasmodic activity, rabbit jejunum for adrenergic activity, rat phrenic nerve-diaphragm for muscle relaxant activity, frog rectus for skeletal muscles activity.

10.3.7 Determination of Foreign

Determination of foreign matter ensures that the stated herbal drugs are made from the specific part of the plant and are devoid of other parts of the same plant or other plants. They should be entirely free from molds or insects, including excreta and visible contaminant such as sand and stones, poisonous and harmful foreign matter and chemical residues. Animal matters such as insects and invisible microbial contaminants, which can produce toxins, are also among the potential contaminants of herbal medicines. Macroscopic examination can easily be employed to determine the presence of foreign matter, although microscopy is indispensable in certain special cases (e.g., starch deliberately added to 'dilute' the plant material). Furthermore, when foreign matter consists, for example, of a chemical residue, TLC is often needed to detect the contaminants.

10.3.8 Determination of Ash Content

Determination of ash content the plant material is done by burning it and followed by the residual ash is measurement as total and acid-insoluble ash. Total ash is the measure of the total amount of material left after burning and includes ash derived from the part of the plant itself and acid-insoluble ash. The latter is the residue obtained after boiling the total ash with dilute hydrochloric acid and burning the remaining insoluble matter. The second procedure measures the amount of silica present, especially in the form of sand and siliceous earth.

10.3.9 Determination of Heavy Metal Contamination

Determination of heavy metal contamination i.e., contamination by toxic metals, either accidental or intentional, such as mercury, lead, copper, cadmium, and arsenic in herbal remedies, is important. It can be attributed to many causes, including environmental pollution, and can pose clinically relevant dangers for the health of the user and should therefore be limited. A simple, straightforward

determination of heavy metals can be found in many pharmacopeias and is based on color reactions with special reagents such as thioacetamide or diethyldithiocarbamate, and the amount present is estimated by comparison with a standard. Instrumental analyses have to be employed when the metals are present in trace quantities, in admixture, or when the analyses have to be quantitative. The main methods commonly used are atomic absorption spectrophotometry (AAS), inductively coupled plasma (ICP) and neutron activation analysis (NAA).

10.3.10 Determination of Microbial Contaminants and Aflatoxins

Determination of microbial contaminants and aflatoxins is necessary because medicinal plants may be associated with a broad variety of microbial contaminants, represented by bacteria, fungi, and viruses. Inevitably, this microbiological background depends on several environmental factors and exerts an important impact on the overall quality of herbal products and preparations. Herbal drugs normally carry a number of bacteria and molds, often originating in the soil. Poor methods of harvesting, cleaning, drying, handling, and storage may also cause additional contamination, as may be the case with *Escherichia coli* or *Salmonella* spp. While a large range of bacteria and fungi are from naturally occurring microflora, aerobic spore-forming bacteria frequently predominate. Laboratory procedures investigating microbial contaminations are laid down in the well-known pharmacopeias, as well as in the WHO guidelines. In general, a complete procedure consists of determining the total aerobic microbial count, the total fungal count, and the total Enterobacteriaceae count, together with tests for the presence of *Escherichia coli*, *Staphylococcus aureus*, *Shigella*, and *Pseudomonas aeruginosa* and *Salmonella* spp. The European pharmacopoeia also specifies that *E. coli* and *Salmonella* spp. should be absent from herbal preparations. However, it is not always these two pathogenic bacteria that cause clinical problems. For example, a fatal case of listeriosis was caused by contamination of alfalfa tablets with the Gram positive bacillus *Listeria monocytogenes*.

10.4 Guidelines for Assessing Quality of Herbal Drugs with Reference to Contaminants and Residues (WHO 2007)

Potentially hazardous contaminants and residues in herbal medicines may be grouped as chemical contaminant (toxic metals and nonmetals, persistent organic pollutants, radioactive contamination, mycotoxins and endotoxins, solvents occurring as contaminants), biological contaminants (microbiological contaminants,

parasitic contamination), agrochemical residues (pesticide residues, extraneous pesticide residues), residual solvents, etc. (Table 10.2).

a. **Contaminants**

i. **Chemical Contaminants**

Toxic Metals and Nonmetals

Contamination of herbal materials with toxic substances such as arsenic can be attributed to many causes. These include environmental pollution, soil composition, and fertilizers. This contamination of the herbal material leads to contamination of the products during various stages of the manufacturing process. Pesticides containing arsenic and mercury were widely used until a few years ago and they are still being used in some countries. As toxic substances are likely to be present in many foods, due to their abundance in nature, it is important to note that concomitant ingestion of herbal products would add to the total concentration of toxic metals consumed by people.

Persistent Organic Pollutants

Persistent organic pollutants (POPs) include organic chemicals, such as the synthetic aromatic chlorinated hydrocarbons, which are only slightly soluble in water and are persistent or stable in the presence of sunlight, moisture, air, and heat. The use of persistent pesticides, DDT and benzene hexachloride (BHC), in agriculture has been banned for many years in many countries. However, they are still found in the areas where they were previously used and often contaminate medicinal plants growing nearby. The Stockholm Convention on Persistent Organic Pollutants currently includes DDT and 11 other POPs including dioxin (a potent carcinogen), aldrin, chlordane, dieldrin, endrin, heptachlor, mirex, toxaphene, and hexachlorobenzene.

Radioactive Contamination

A certain amount of exposure to ionizing radiation is unavoidable because many sources, including of radionuclides occur naturally in the ground and the atmosphere.

Dangerous contamination may be the consequence of a nuclear accident or may arise from other sources. The WHO, in close collaboration with several other international organizations, has developed guidelines for use in the event of widespread contamination by radionuclides resulting from a major nuclear accident. These guidelines emphasize that the health risks posed by herbal medicines accidentally contaminated by radionuclides depend on the specific radionuclide, level of contamination as well as on the dose and duration of use of the product consumed.

Mycotoxins and Endotoxins

The presence of mycotoxins in plant material can pose both acute and chronic risks to health. Mycotoxins are usually secondary metabolic products which are nonvolatile, have a relatively low molecular weight, and may be secreted onto or into the medicinal plant material. Mycotoxins comprise four main groups, namely

Table 10.2 Classification of major contaminants and residues in herbal medicines

General classification	Group	Subgroup	Specific examples	Possible sources	Stage of production at which detectable[a]
a. Contaminants					
i. Chemical contaminants	Toxic and hazardous materials	Toxic metals and nonmetals	Lead, cadmium, mercury, chromium (arsenic, nitrite)	Polluted soil and water, during cultivation/growth, manufacturing process	1, 2, 3, 4
		Persistent organic pollutants	Dioxin aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex	Polluted air, soil, and water, during cultivation/growth	1, 2, 3, 4
		Radionuclide	Cs-134, Cs-137	Air, soil, water during cultivation/growth	1, 2, 3, 4
		Biological toxins	Mycotoxins	Post-harvest processing, transportation, and storage	2, 3, 4
			Bacterial endotoxins	Post-harvest processing, transportation, and storage	1, 2, 3, 4
ii. Biological contaminants	Microorganisms	Bacteria	*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella* species, *Shigella* species, *Escherichia coli*	Soil, post-harvest processing, transportation, and storage	1, 2, 3, 4
		Fungi	Yeast, molds	Post-harvest processing, transportation, and storage	1, 2, 3, 4
	Animals	Parasites	Protozoa–amoebae, Helminths–nematoda	Soil, excreta; organic farming/cultivation, manufacturing process	1, 3, 4
		Insects	Cockroach and its parts	Post-harvest processing, transportation, and storage	1, 2, 4
		Others	Mouse excreta, earthworms, acarus	Post-harvest processing, transportation, and storage	1, 2, 4

(continued)

Table 10.2 (continued)

General classification	Group	Subgroup	Specific examples	Possible sources	Stage of production at which detectable[a]
iii. Solvents		Organic solvents	Acetone, methanol, ethanol, butanol	Soil and water, during cultivation/growth, manufacturing process	1, 2, 3, 4
b. Residues					
i. Agrochemical residues	Pesticides	Insecticides	Carbamate, chlorinated hydrocarbons, organophosphorus	Air, soil, water, during cultivation/growth, post-harvest processing	1, 2, 3, 4
		Herbicides	2,4-D, 2,4,5-T	Air, soil, water, during cultivation/growth, post-harvest processing	1, 2, 3, 4
		Fungicides	Dithiocarbamate	Air, soil, water, during cultivation/growth	1, 2, 3, 4
	Fumigants	Chemical agents	Ethylene oxide, phosphine, methyl bromide, sulfur dioxide	Post-harvest processing	2, 3, 4
	Disease control agents	Antiviral agents	Thiamethoxam	During cultivation	1, 2, 3, 4
ii. Residual solvents		Organic solvents	Acetone, methanol, ethanol, butanol	Manufacturing process	3, 4

[a]Stage of production at which detectable: *1* medicinal plants, *2* herbal materials, *3* herbal preparations, *4* finished herbal products

aflatoxins, ochratoxins, fumonisins, and tricothecenes, all of which have toxic effects. Aflatoxins have been extensively studied and are classified as Group 1 human carcinogens by the International Agency for Research on Cancer. Mycotoxins produced by species of fungi including *Aspergillus*, *Fusarium,* and *Penicillium* are the most commonly reported.

Endotoxins are found mainly in the outer membranes of certain Gram-negative bacteria and are released only when the cells are disrupted or destroyed. They are complex lipopolysaccharide molecules that elicit an antigenic response, cause altered resistance to bacterial infections and have other serious effects. Thus, tests for their presence on herbal medicines should be performed in dosage forms for parenteral use, in compliance with the requirements of national, regional or international pharmacopoeias.

Residual Solvents Occurring as Contaminants

A range of organic solvents are used for manufacturing herbal medicines and can be detected as residues of such processing in herbal preparations and finished herbal products. They should be controlled through GMP and quality control. Solvents to be avoided such as benzene (class I), solvents with limited toxic potential such as methanol or hexane (class II), and solvents with low toxic potential such as ethanol (class III). Solvents used in industries other than the manufacturing of herbal medicines are often detected as contaminants in water used in irrigation, for drinking, and for industrial purposes, and thus, they find their way into medicinal plants and herbal materials at various stages of growth and processing.

Agrochemical Residues

The main agrochemical residues in herbal medicines are derived from pesticides (insecticides, fungicides, nematicides, herbicides, ascaricides, molluscicides and rodenticides) and fumigants.

Examples of fumigants include ethylene oxide, ethylene chlorohydrin, methyl bromide and sulfur dioxide. Medicinal plant materials may contain pesticide residues, which accumulate as a result of agricultural practices, such as spraying, treatment of soils during cultivation, and administration of fumigants during storage. The chlorinated hydrocarbons and related pesticides (e.g., HCH) and a few organophosphorus pesticides (e.g., carbophenothion) have a long residual action. It is therefore recommended that every country producing medicinal plant materials should have at least one control laboratory capable of performing the determination of pesticides using a suitable method.

b. **Biological Contaminants**

Microbiological Contaminants

Herbs and herbal materials normally carry a large number of bacteria and molds, often originating in soil or derived from manure. While a large range of bacteria and fungi form the naturally occurring microflora of medicinal plants, aerobic spore-forming bacteria frequently predominate. Current practices of harvesting, production, transportation, and storage may cause additional contamination and

microbial growth. Proliferation of microorganisms may result from failure to control the moisture levels of herbal medicines during transportation and storage, as well as from failure to control the temperatures of liquid forms and finished herbal products. The presence of *Escherichia coli*, *Salmonella* spp. and molds may indicate poor quality of production and harvesting practices. Microbial contamination may also occur through handling by personnel who are infected with pathogenic bacteria during harvest/collection, post-harvest processing, and the manufacturing process. In order to ensure appropriate and consistent quality of medicinal plant/herbal substances and their products free from microbiological contaminants, it is necessary to establish good agricultural and collection practice (GACP) for herbal starting materials as well good manufacturing practice (GMP), while processing, packaging, and storage of active pharmaceutical ingredients (APIs) also applies to medicinal plants/herbal substances.

Parasitic Contamination

Parasites such as protozoa and nematode, and their ova, may be introduced during cultivation and may cause zoonosis, especially if uncomposted animal excreta are used. Contamination with parasites may also arise during processing and manufacturing if the personnel carrying out these processes have not taken appropriate personal hygiene measures.

Chromatography and Chemical Fingerprints of Herbal Medicines for the Purpose of Quality Control of Herbal Medicines

By definition, a chromatographic fingerprint of an herbal drug is a chromatographic pattern of the extract of some common pharmacologically active chemical components. This chromatographic profile should be featured by the fundamental attributions of integrity and fuzziness or sameness and differences so as to chemically represent the herbal drug investigated. It is suggested that with the help of chromatographic fingerprints obtained, the authentication and identification of herbal medicines can be accurately conducted (integrity) even if the amount and/or concentration of the chemically characteristic constituents are not exactly the same for different samples of drug (hence, fuzziness) or, the chromatographic fingerprints could demonstrate both the sameness and differences between various samples successfully.

It is very tough to obtain reliable chromatographic fingerprints that represent pharmacologically active and chemically characteristic components because of the presence of innumerable number of unknown components in herbal drug and its extract, low concentration, and variability, even within the same herbal materials. Under these circumstances, chromatographic technique is useful to separate the complex chemical components in herbal extracts into many relatively simple subfractions. Based on the conception of phytoequivalence, the chromatographic fingerprints of herbal medicines could be utilized for addressing the problem of quality control of herbal medicines. Chemical fingerprints obtained by chromatography, especially by hyphenated chromatography, are strongly recommended for the purpose of quality control of herbal medicines, since they might represent

appropriately the chemical integrities of the herbal medicines and therefore be used for authentication and identification of the herbal products.

In general, the methods for quality control of herbal medicines involve sensory inspection (macroscopic and microscopic examinations) and analytical inspection using instrumental techniques such as thin layer chromatography, high-performance liquid chromatography (HPLC), gas chromatography coupled with mass spectrometry (GC–MS), liquid chromatography coupled with mass spectrometry (LC–MS), near infrared (NIR), and spectrophotometer. TLC was the common method of choice for herbal analysis before instrumental chromatography methods such as GC and HPLC were established. TLC is still frequently used for the analysis of herbal medicines since various pharmacopoeias such as Indian herbal pharmacopoeia, Ayurvedic pharmacopoeia; American Herbal Pharmacopoeia (AHP), Chinese drug monographs and analysis, pharmacopoeia of the People's Republic of China. TLC is a technique in which a solute undergoes distribution between two phases, a stationary phase acting through adsorption and a mobile phase in the form of a liquid. The adsorbent is a relatively thin, uniform layer of dry finely powdered material applied to a glass (most commonly used), plastic or metal plate or sheet. Separation may also be achieved on the basis of partition or a combination of partition and adsorption, depending on the particular type of support, its preparation and its use with different solvent. Identification can be effected by observation of spots of identical Rf value and about equal magnitude obtained, respectively, with an unknown and a reference sample chromatographed on the same plate. A visual comparison of the size and intensity of the spots usually serves for semi-quantitative estimation. TLC is an easier method of initial screening with a semi-quantitative evaluation. HPTLC is one of the sophisticated instrumental techniques based on the full capabilities of TLC. It is most flexible, reliable and cost efficient separation technique. The advantage of automation, scanning, full optimization, selective detection principle, minimum sample preparation, hyphenation, and so on enable it to be powerful analytical tool for chromatographic information of complex mixtures of pharmaceuticals, natural products, clinical samples, food stuffs, and so on. The advantages of using TLC and also HPTLC to construct the fingerprints of herbal medicines are its simplicity, versatility, high velocity, specific sensitivity and simple sample preparation. Thus, it is a convenient method of determining the quality and possible adulteration of herbal products.

The analysis of volatile compounds by high sensitive gas chromatography (GC) is very important in the analysis of herbal medicines. The GC of the volatile oil gives a reasonable fingerprint (in respect of composition and relative concentration) which can be used to identify the plant. The extraction of the volatile oil is relatively straightforward in GC and can be standardized and the components can be readily identified using GC–MS analysis.

HPLC is a popular and easy method and can be used to analyze almost all the compounds (both volatile and stable compounds) in the herbal medicines. Reversed-phase (RP) columns may be the most popular columns used in the analytical separation of herbal medicines. The optimal separation condition for the HPLC involves many factors, such as the different compositions of the mobile

phases, their pH adjustment, pump pressures. Thus, a good experimental design for the optimal separation seems in general necessary. In order to obtain better separation, some new techniques have been recently developed in research field of liquid chromatography, e.g., micellar electrokinetic capillary chromatography (MECC), high-speed counter-current chromatography (HSCCC), low-pressure size-exclusion chromatography (SEC), reversed-phase ion-pairing HPLC (RP-IPC-HPLC), and strong anion-exchange HPLC (SAX-HPLC).

The advantages of HPLC lie in its versatility for the analysis of the chemical compounds in herbal medicines. The single wavelength UV-HPLC used for the chromophoric compounds can be replaced by the HPLC coupled with evaporative light scattering detection (HPLC–ELSD) for the analysis of non-chromophoric compounds. This ELSD aided HPLC is useful for the analysis of many pharmacologically active components in herbal medicines and thus quite suitable for the construction of the fingerprints of the herbal medicines, since the response of ELSD depends only on the size, shape, and number of elute particles. For structure elucidation of the chemical components in herbal medicine, it is necessary to use the hyphenated HPLC (e.g., HPLC–MS, HPLC–NMR), i.e., chromatographic separation system on-line with a spectroscopic detector. For most (trace-level) analytical problems in the research field of herbal medicines, the combination of column liquid chromatography or capillary gas chromatography with a UV–VIS or a mass spectrometer or HPLC coupled with diode array detection (HPLC–DAD), capillary electrophoresis coupled with diode array detection (CE-DAD), gas chromatography coupled with mass spectrometry (GC–MS) and liquid chromatography coupled with mass spectrometry (LC–MS) becomes the preferred approach for the analysis of herbal medicines.

10.5 Adulteration of Crude Drugs

Adulteration is a practice of substituting the original crude drug partially or fully with other substances which are either free from or inferior in therapeutic and chemical properties or addition of low grade or spoiled drugs or entirely different drug similar to that of original drug substituted with an intention of enhancement of profits, or adulteration may be defined as mixing or substituting the original drug material with other spurious, inferior, defective, spoiled, useless other parts of same or different plant or harmful substances or drug which do not confirm to the official standards. The adulteration and substitution of herbal drugs are the burning problem in herbal industry and it has caused a major effect in the commercial use of natural products. Adulteration in market samples is one of the greatest drawbacks in promotion of herbal products. The ways through which adulterations happen may be direct or intentional, and indirect or unintentional.

Direct or Intentional Adulteration

Direct or intentional adulteration occurs with bad intention of the manufacturer or supplier for high benefit. Direct or intentional adulteration is done deliberately and includes practices in which an herbal drug is substituted partially or fully with other inferior products. Trader's preference to low quality cheaper herbal products and reluctance to pay high prices for high-quality herbs ultimately encourages producers and traders in intentional adulteration. Following are some of the ways and means of adulteration of commercial herbal products.

(i) **With artificially manufactured materials**: Substances artificially manufactured being resembled with original drug are used as substitutes. This practice is generally followed for much costlier drug e.g., nutmeg is adulterated with basswood prepared to the required shape and size; the colored paraffin wax is used in place of beeswax.

(ii) **With inferior quality materials**: Morphological resemblance alone may not ensure the therapeutic authenticity or value of the adulterant as that of original natural drug e.g., Belladonna (*Atropa belladonna*) leaves are substituted with Ailanthus (*Ailanthus altissima*) leaves, papaya (*Carica papaya*) seeds to adulterate *Piper nigrum*, mother cloves and clove stalks are mixed with clove, beeswax is substituted by Japan wax.

(iii) **With exhausted material**: In this type, the same drug is admixed but devoid of any medicinally active constituents as they are already extracted out. This practice is more common in case of volatile oil containing drugs such as fennel, clove, coriander, caraway. Sometimes natural characters of exhausted drugs such as color and taste are manipulated by adding other additives and then it is substituted, e.g., exhausted gentian made bitter with aloes. Apiaceae fruits and cloves (*Syzygium aromaticum*) after extraction of volatile oils (after exhaustion) are adulterated with exhausted original drugs, exhausted jalap (tuberous roots of *Ipomoea purga*, *I. jalapa*) and Indian hemp (*Cannabis indica*) after exhaustion of resins are used as adulterant.

(iv) **With foreign matter**: Sometimes synthetic chemicals are used to enhance the natural character e.g., addition of benzyl benzoate to balsam of Peru, citral to citrus oils such as oil of lemon and orange oil.

(v) **With harmful or fictitious substances**: Different parts of the same plant without active ingredients, sand, stones, manufactured artifacts, synthetic inferior principles and other foreign matter are used as adulterants. Sometimes the wastes from market are collected and admixed with authentic drugs particularly for liquids or unorganized drugs e.g., pieces of amber colored glass in colophony, limestone in asafetida, lead shot in opium, white oil in coconut oil, cocoa butter with stearin or paraffin.

(vi) **Adulteration of powders**: Besides entire drug powder form frequently found to be adulterated e.g., powder liquorice or gentian admixed with powder olive stones, under the name of cinchona, *Cinchona calisaya*, *C. officinalis*, *C. ledgeriana* and *C. succirubra* are available as mixtures.

Indirect or Unintentional Adulteration

Unintentional or undeliberate adulteration sometimes occurs without bad intention of the manufacturer or supplier. Sometimes in the absence of proper means of evaluation, an authentic drug partially or fully devoid of the active ingredients may enter the market. Factors such as geographical sources, growing conditions, processing, and storage are all factors that influence the quality of the drug. Some are described in the following paragraphs.

(i) **Faulty collection**: Some of the herbal adulteration is due to the carelessness of herbal collectors and suppliers. The correct part and tot the other less valuable part of the genuine plant should be collected. Moreover, collection should be carried out at a proper season and time when the active constituents reach maximum. *Datura strumarium* leaves should be collected during flowering stage and wild cherry bark in autumn etc. Collection from other plant by ignorance, due to similarity in the appearance, color, lack of knowledge may lead to adulteration, e.g., collection of *Aconitum deinorhizum* in place of *Aconitum napellus*, or *Rhamnus californica* in place of *Rhamnus purshiana* (cascara bark) lead to adulteration. Confusion existing in the common vernacular name of different plants or different vernacular names of the same plant in various places of the country may lead to this type of adulteration. Often in different states, the same plant is known by. This creates confusion which is best illustrated by Punarnava (*Boerhavia diffusa*) and Brahmi (*Bacopa monnieri*).

(ii) **Imperfect preparation**: Non-removal of associated or undesirable parts or structures e.g., stems from leaves, flowers, fruits, cork should be removed from ginger rhizome etc. Proper drying conditions should be adhered, e.g., if digitalis leaves are dried above 65 °C, enzymatic hydrolysis may lead to decomposition of glycosides. Excessive heat is used in separating the cod liver oil from livers, where the proportions of vitamins, odor, color, etc., are adversely affected.

(iii) **Incorrect storage**: Deterioration of herbal drugs due to improper storage condition (air, humidity, light, and temperature) may lead to the development of organisms such as molds, mites, and bacteria and loss of the active ingredients, production of metabolites with no activity or with toxic effects. Oxidation of the constituents of a drug can be brought about by oxygen in the air, causing some products, such as essential oils, to resinify or to become rancid. Moisture or humidity and elevated temperatures by accelerating enzymatic activities deteriorate and decompose the herb, e.g., volatile oils should be protected from light and stored in well-closed containers in cool place, Belladonna leaf should be stored in moisture free containers, otherwise enzymatic decomposition of active constituents will happen. Mites, nematode worms, insects, and beetles can also destroy herbal drugs during storage.

(iv) **Gross substitution**: Gross substitution with plant material due to morphological resemblance i.e., similarity in appearance, colors, etc. the genuine crude drugs are substituted with others are very often sold in the market, e.g.,

Podophyllum peltatum is used as a substitute for *P. hexandrum*, Belladonna leaves are substituted with Ailanthus leaves, saffron is admixed with dried flowers of *Carthamus tinctorius*, mother cloves and clove stalks are mixed with clove.

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