### Herbs as Raw Materials, Biodynamic Agriculture, Indian Systems of Medicine

#### Two marks category questions

#### 1. Define herbs?

Herbs include crude leafy green flowering plants, which areshort-lived and do not have a woody stem. It could be either perennial, biennial, or annual in nature. Such plants generally have aromatic properties, are sometimes used as food, and may also possess medicinal properties. Vegetables do not constitute herbs. Any plant part, namely leaves, stems, flowers, fruit, stem, bark, roots, rhizomes, or even the entire plant, preferably in an unprocessed manner, can be called a herb. Example – Tulsi.

#### 2. Define Herbal medicine?

Includes herbs, herbal materials, herbal preparations, and finished herbal products.

#### **3.** Define herbal material?

Whole or fragmented plant parts (leaves, roots, bark, rhizomes, etc.) in an unprocessed state generally in dried form. They include herbs, fresh juices, gums, fixed oils, essential oils, resins, and dry powders of herbs.

#### 4. Define herbal drugs?

Herbal drugs are also known as herbal substances and indicate the part of the plant which is used for therapeutic purposes. Such plant parts can be in the form of a whole plant or any specific part (like leaves, roots, barks, etc.). These parts may be available in cut, fragmented, or even powdered forms obtained from both higher plants (like turmeric, neem) as well as lower plants (like algae, fungi, etc.).

#### 5. Define herbal medicinal products?

Any medicinal product is specifically exhibiting its therapeutic effect due to the presence of single or multiple herbal drugs or various herbal drug preparations or a combination of both herbal drugs and herbal preparations: for example – Brahmi capsules.

#### 6. What do you mean by herbal drug preparation?

Outcome or final end product obtained after subjecting herbal drugs either in crude form or processed form to different extraction methods (like maceration, Soxhlet extraction, distillation, expression, etc.) and other methods such as purification, enrichment, or fermentation. Example- extract obtained after maceration, essential oil obtained after distillation, juices obtained after expression.

#### 7. What do you mean by herbal remedy?

Usage of herbal products for therapeutic purposes is known as a herbal remedy. For example, the use of various herbal products for the management of diabetes and herbal products for the management of COVID-19 infection is a good example of herbal remedy where certain herbal products are used to treat or manage a particular disease. The herbal remedy may also come under the drug regulations in a specific country.

#### 8. What do you mean by herbal teas?

Herbal teas are aqueous decoctions or infusions prepared from a single herbal drug or a mixture of herbal drugs for oral consumption. It is one type of herbal preparation which the enduser prepares just before consumption.

#### 9. Define markers.

Markers indicate chemically defined specific phytoconstituents or any group of phytoconstituents present in a herbal drug and which can be qualitatively and quantitatively used for determining the quality of the drug and finished product as well. The presence of the minimum quantity of the marker is essential for declaring the crude drug or finished product as fit in terms of quality for further use. If the crude drug is found to contain the desired quantity of the marker, then it can be further used for processing of finished products, and if the finished product is found to contain the desired quantity of the marker, it can be considered fit for human use.

- a) Analytical markers such markers do not have therapeutic value, but their quantity determines the quality of the crude drug or finished herbal product. They are used mainly for analytical purposes.
- b) Active markers or bio-markers such markers have biological activity and play a vital role in thestandardization of medicinal plants and herbal products. The presence of a minimum quantity of the desired biomarker ensures the exhibition of the intended biological effect by the crude drug or herbal product. For example – curcumin is the marker for turmeric. So, in order to declare turmeric rhizomes fit for use, they must contain the specified amount of curcumin. If a finished herbal product containing turmeric is to be used, in order to pass the quality test and to ensure that the final product will exhibit the desired medicinal effect, the final product should contain the desired quantity of curcumin.

#### 10. List out the sources of herbs.

The different sources of herbs are,

- a) Plants: Includes both higher plants (angiosperms and gymnosperms) and lower plants like algae, fungi, lichens, and bryophytes (mosses and liverworts). Example Higher plants: leaves (tulsi), flowers (clove bud), fruits (amla), roots (rauwolfia), rhizomes (podophyllum, ginger), lower plants: ergot, algae
- Marine sources: Organisms found in the marine ecosystem b) which serve as excellent drug sources are sponges, tunicates, fishes, soft corals, sea hares, mollusks, echinoderms, bryozoans, shells, prawns, sea slugs, marine microorganisms, and phytoplankton's. Such aquatic living organisms have been screened for antibacterial, cardioactive. immunomodulator, anti-fungal, antiinflammatory, anticancer, antimicrobial, neuroprotective, analgesic, toxins, and antimalarial properties. Examples of clinically approved marine drugs: - Cytarabine (used in

leukemia), Vidarabine (used in recurrent epithelial keratitis caused by HSV), Ziconotide (analgesic), and Trabectedin (used for the treatment of ovarian cancer).

c) Plant tissue culture: It is an artificial method of growing plants (*in-vitro* multiplication of plant cells) in laboratory conditions on a defined solid or liquid medium under aseptic conditions through various biotechnological interventions. Example – production of catharanthine from *Catharanthus roseus*, Diosgenin from *Dioscorea doryphore*, reserpine from *Rauwolfia* species, Ginsenosides from *Panax ginseng* are some good examples of drugs obtained through the tissue culture method.

## 11. What is the basis of the selection of herbal materials for research purposes?

Herbal materials (plant parts) are selected for research purposes based on the following criteria's,

- a) Ethnobotanical data: herbal material can be selected based on their ethnic use or existing use in society. Such herbal materials, if in use among a particular community for several generations, then the drug discovery research from such plant materials is likely to yield sure success.
- b) Chemotaxonomy data: based on chemotaxonomic relations, plants can be selected for research. Plants belonging to a particular family share some common phytoconstituents. Hence, if the plant family is identified by a taxonomist, a judicious decision regarding the probable presence of particular chemical constituents and possible use of the plant can be made. Example – Solanaceae family are rich in tropane alkaloids.
- c) Random selection: plants are selected based on random phytochemical screening and high throughput screening based on *in-vitro* enzyme assay methods. Plants responding positively to the presence of some phytoconstituents through *in-vitro* enzyme-substrate assay methods are further taken up for lab-based research. Chances of success in ending up with a drug-like compound are fewer.

#### Unit I: Herbs as Raw Materials, Biodynamic Agriculture,... | 5

- d) Traditional information-based approach: information obtained from traditional systems of medicine such as Ayurveda, Unani can form the basis of plant selection. Such plants which are extensively used in traditional systems of medicine are likely to yield success in drug discovery research.
- e) Zoo-pharmacognosy approach: close monitoring and observation of grazing and wild animals can provide vital leads in search of herbs for research purposes with special reference to drug discovery.

### 12. Explain the selection criteria of herbal materials for inclusion in WHO monographs

There are two major criteria for the selection of herbal material for its inclusion in WHO monographs which are as follows,

- a) Must be in common use in any two WHO regions
- b) Availability of sufficient scientific data to satisfy monograph data requirements. Example – data on purity tests (microbiological, chemical, heavy metal, radioactive contamination data), chemical assays, and pharmacological activity must be available as per requirement for establishing a monograph.

# 13. What is the significance of proper identification and authentication of herbal materials in herbal drug manufacturing?

Medicinal plants (herbal materials) are the starting material in medicinal plant research or herbal drug manufacturing. Henceforth, a wrong identification or a non-judicious selection of any herbal material is sufficient enough to spoil the latter stages to come, thus compromising the entire objective. Herbal materials are valued because of the medicinal activity of the phytoconstituents present in them, whose quantity determines the quality of the finished product. Proper identification and authentication, which ensures quality, safety, and efficacy of herbal medicine, are important because of the following reasons,

- a) Adulteration: in order to ensure that herbal materials are free from any kind of adulteration (intentional or unintentional).
- b) Correct species: in order to ensure that taxonomically correct species have been selected.
- c) Quality: in order to ensure that substandard herbal materials are not used as starting material. Quality is determined by ensuring that the desired phytoconstituents are present in the right quantity enough for exhibiting the desired pharmacological activity.
- d) To counter variability in the quality of herbal raw material due to geographical differences associated with its cultivation.

### 14. Name the different methods employed in making herbal preparations.

Herbal preparations are made by subjecting the herbal raw materials (either processed or unprocessed), usually in dried form, to methods like maceration, Soxhlet extraction, percolation, infusion, decoction, digestion, distillation (herbal materials are used in fresh form for extraction of essential oil), microwave-assisted extraction, supercritical fluid extraction (for extraction of essential oil) and fractionation techniques for purification purposes. Such herbal preparations can be used directly for therapeutic purposes if prepared under GMP conditions or may be used as intermediates for making the finished herbal medicinal product or various other herbal dosage forms.

# 15. List out and define the constant parameters involved in quantitative microscopy for quality control of herbal raw material.

a) Stomatal Index: Stomatal index is defined as the percentage ratio of the number of stomata to the total number of epidermal cells. The stomatal number may vary with the age of the leaf species, but the stomatal index is relatively constant for a given species.

Stomatal Index =  $S \times 100 \div (E + S)$ 

S = number of stomata in a given area of the leaf surface

E = number of epidermal cell in the same area

- b) Palisade ratio: it is defined as the average number of palisade cells beneath each epidermal cell, using four continuous epidermal cells for the count. It is determined with the help of camera lucida.
- c) Vein-Islet number: the mesophyll tissue of a leaf is divided into small portions of photosynthetic tissues by the branching of veins and veinlets. These small portions so formed midway between midrib and margin of the leaf are known as vein-islet. The number of such vein-islets per sq. mm of the leaf surface is known as the vein-islet number. The value is constant for a leaf species unaffected by the age or size of the leaf. Useful parameter for identifying closely related species.
- d) Vein-Termination number: it is defined as the number of veinlet termination per mm<sup>2</sup> of the leaf surface. The value is constant for a leaf species unaffected by the age or size of the leaf. Useful parameter for identifying closely related species.

The above parameters are constant for a given leaf species, and doesn't change with the age or size of the leaf. Collectively they are known as leaf constants, and such data obtained from test samples can be matched with reference data provided in official books for identification and authentication of the correct plant species. It is a very useful tool for quality control in the case of powdered drugs.

### 16. What do you mean by stomatal number? Mention the functions of stomata.

It is defined as the average number of stomata present per mm<sup>2</sup>of the leaf surface. Stomata help in gaseous exchange (respiration) and transpiration.

#### 17. What do you mean by pest and pest management?

Pests are those species of plants and animals which are undesirable to humans and can potentially reduce the availability, quality, and value of any human resource like agricultural crops.

Pests are natural invaders for any agricultural products and can cause huge damage to crops if not controlled. Pests includes weeds (unwanted invasive plants), certain bacteria, fungi (*Phytophthora nicotianae*) and viruses (Mosaic viruses), rodents (rats), nematodes, mites, and various plant feeding insects (locusts, grasshoppers). Pest management involves all those procedures adopted to reduce the number of pests in any agricultural production to an acceptable threshold by using various biological, chemical, physical, and genetic methods.

#### 18. What do you mean by integrated pest management?

Integrated pest management is a long-term approach that focuses on developing an ecosystem committed towards long-term prevention of damage occurring through pests by achieving effective optimal integration of various methods such as biological control, habitat alteration, changes in agricultural practices, and use of various pest-resistant species.

#### 19. What do you mean by crop rotation? Give its significance.

Crop rotation is the practice of growing different crops sequentially in the same land (plot) in different seasons. It helps in optimizing soil nutrients, improves soil fertility, and helps in eradicating pests and weeds.

#### 20. Name the various disciplines of Ayurveda.

Ayurveda has eight disciplines collectively known as 'Ashtanga Ayurveda'. They are as follows,

- Kayachikitsa (internal medicine)
- Bhootavidya (treating psychological diseases)
- Kaumar Bhritya (pediatric)
- Rasayana (treating geriatric patients)
- Vajikarna (use of aphrodisiacs)
- Shalya (surgery)
- Shalakya (eye and ear)
- Agada tantra (toxins related)

#### 21. Name some ancient Indian medicinal manuscripts.

Rig-Veda, Yajur-Veda, Atharva-Veda, Dhanwantari Nighantu, Charak Samhita and Sushruta Samhita.

22. Name the seven standards of the human body as per the Unani System.

The seven standards of the human body are Mizaj (temperaments), Anza (organs), Quo (resources), Arkan (components), Arawh (spirits), Aklath (humours), and Afal (capacities).

### 23. Differentiate between Ayurveda and Siddha systems of medicine.

	Ayurveda	Siddha
1.	Prevalent throughout India	Prevalent more in Tamil culture
2.	Initially practiced by saints	Initially practiced by Siddhars
3.	Ayurvedic formulations consist of medicinal plants	Formulations mainly consist of metals and minerals
4.	Involves concept of Panchamahabhutas and Triodosha	Apart from Panchamahabhutas and Tridosha also involves concept of Siva and Sakthi
5.	Pancha karma mode of therapy is used	Ashtasthana Pareeksha mode of therapy
6.	Premier institute of Ayurveda = National institute of Ayurveda, Jaipur	Premier institute of Siddha = National institute of Siddha, Chennai
7.	Practioner of Ayurveda is known as Vaidya or Vaidyaraja	Practioner are known as Siddhars
8.	Charaka was one of the principal contributors of Ayurveda	Agasthaya is belived to be the founder father of Siddha

### 24. What are the advantages of the fermentation process used in the preparation of Asavas-Arishtas.

- a) Removes sugars from the plant material and improves bioavailability
- b) Provides better extraction efficiency due to gradually rising alcohol strength during the fermentation process
- c) Yeast cells act as cleansing agents by binding with heavy metals and pesticides
- d) Neutralizes the toxic effects of some phytoconstituents
- e) Fermentation ruptures the plant cells and exposes them to the bacteria and enzymes for necessary transformation.

#### 25. What is the difference between asavas and arishtas.

	Asavas	Arishtas
1.	Fresh or dried crude drug is used	Dried crude drug is used
2.	If fresh crude drug is used – juice is extracted by expression If dried crude drug is used – infusion is prepared	Decoction of the crude drug is the starting material
3.	No heat is used for preparing the starting material which is either juice or infusion	Heat is used for preparation of decoction

#### 26. What do you mean by 'churna'?

Churna is an ayurvedic formulation consisting of a single or mixture of crude drugs in fine free-flowing powder form in a dry state. Desired plants are cleaned, dried, powdered, and passed through sieve#80 to obtain very fine homogenous particles. Lesser is the particle size, greater shall be the surface area resulting in better absorption from GIT. They can be consumed along with water, milk, honey, or ghee. Churna's are also converted into pills or tablets for proper dosing. The efficacy of churna may be influenced by the time of intake, like whether it is consumed before or after a meal. They are mostly used for the treatment of constipation, indigestion, and diabetes. Example – Triphala churna, Trikatu churna, ashwagandha churna, etc.

#### 27. What do you mean by Gutika?

Gutika is an ayurvedic preparation where a single or a mixture of powdered drugs are cooked with jaggery or macerated with honey to achieve a thick consistency and rolled into circularshaped pills. When the same consistency is rolled in the shape of an elongated table like, it is known as Vatika.

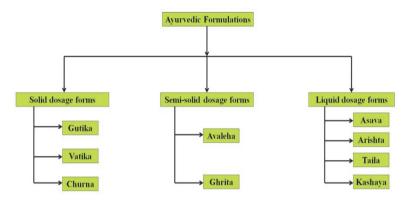
#### 28. Mention the constituents of the final reaction mixture, which is made to undergo fermentation for the preparation of arishta and asava.

For asavas: juice extracted from fresh crude drug or infusion prepared from dried crude drug + jaggery or honey (fermentation medium) + flavouring agent + additional powdered drug (if any) + powdered flower of *Woodfordia fruticosa* (source of yeast to initiate fermentation). For arishta: decoction of crude drug + jaggery or honey (fermentation medium) + flavouring agent + powdered flower of *Woodfordia fruticosa* (source of yeast to initiate fermentation).

#### 29. What is Kashaya?

It is an ayurvedic preparation basically consisting of an aqueous extract of the crude drug.

#### 30. Mention the various types of ayurvedic formulations.



#### **Five marks category questions**

- **31.** List out and explain the different sources of crude drugs. Herbs can be obtained from different sources, which have been explained below,
  - d) **Plant source:** refers to terrestrial plants (both higher and lower plants). Herbs can be obtained from seed-bearing plants such as angiosperms (flowering plants) and gymnosperms (non-flowering plants). Angiosperms are a good source of plants rich in glycosides and essential oils. Gymnosperms predominantly contain constituents such as alkaloids (example –ergot alkaloids in ephedra). Both the typesof plants have profound use in folk and traditional medicine and their different parts such as leaves (senna), flowers (clove buds), seeds (nux-vomica, nutmeg), fruits (amla), bark (cinchona), roots (podophyllum) and rhizomes (turmeric) are frequently used for medicinal purposes. The other type is lower plants, whichincludealgae, fungi, lichens, and bryophytes (mosses and liverworts). Among lower

plants, microscopic and macroscopic algae have been predominantly used as a source for antioxidant, anticancer, and antiviral compounds.

Marine sources: Marine environment provides a unique e) natural habitat, and the living organisms available in the marine environment are totally different from those available in the terrestrial environment. The marine environment is very challenging because of the very drastic conditions prevailing inside the ocean with the continuous threat from changing oceanic environment and various predators. In the process to survive such drastic living conditions, marine organisms continually evolve themselves by producing various biochemicals which help them to adapt to the marine ecosystem. Such chemicals, if scientifically explored, could be beneficial to humans. Organisms found in the marine ecosystem and which serve as excellent drug sources are sponges, tunicates, fishes, soft corals, sea hares, molluscs, echinoderms, bryozoans, prawns, slugs. marine microorganisms, shells. sea and phytoplankton's. Such aquatic living organisms have been basically screened for antibacterial. cardioactive. immunomodulator. anti-fungal. anti-inflammatory, anticancer, antimicrobial, neuroprotective, analgesic, toxins, and antimalarial properties. Example - Zoranol and Iso-Zoranol obtained from marine algae have been used as antimicrobial agents, Simularin obtained from corals has been used as anticancer agents, Cucumechinoside-F obtained from sea cucumber has been used as an antiprotozoal, Eptatretin obtained from sea fish is a potent cardiac stimulant, Laminine obtained from marine algae is a hypotensive agent, Ciguatoxin, Tetrodotoxin& Palytoxin are potent marine toxins with effect on nervous and cardiovascular systems, and Bio-Indol obtained from marine cyanobacterium is a good anti-inflammatory agent.

Examples of clinically approved marine drugs: -Cytarabine (used in leukaemia), Vidarabine (used in recurrent epithelial keratitis caused by HSV), Ziconotide (analgesic), and Trabectedin (used for the treatment of ovarian cancer).

f) **Plant tissue culture**: It is an artificial method of growing plants (in-vitro multiplication of plant cells) in laboratory

conditions on defined solid or liquid medium under aseptic conditions through various biotechnological interventions. Those plants whose production of secondary metabolites is very less can undergo genetic manipulation and can be made to produce 2-3 times more secondary metabolites when such plants are grown in laboratory conditions. Also, through such genetic manipulation pest resistant and frost-resistant plants can be produced. Example – production of catharanthine from *Catharanthus roseus*, Diosgenin from *Dioscorea doryphore*, reserpine from *Rauwolfia* species, Ginsenosides from *Panax ginseng* are some good examples of drugs obtained through the tissue culture method.

- g) Animal source: drugs obtained from the animal source could be either in the form of the whole animal, glandular products like thyroid gland, liver extracts, secretions/fluids of animals, etc. Such products undergo several stages of purification and processing before human consumption. For example -the pancreas of animals is a source for insulin. The sheep thyroid gland is a source for thyroxin, animal blood (horse) is used for the preparation of some vaccines, codliver oil from sharks and honey from bees.
- h) Mineral source: Bothe metallic and non-metallic minerals have been extensively used in traditional medicine since ancient times. Siddha system of medicine extensively uses animal products and minerals of metallic origin in their formulation. Minerals are required in the body in trace quantities to maintain the normal physiology of the body, and their deficiency can lead to various diseases or can complicate pre-existing diseases. For example – iron is used in iron deficiency anaemia, iodine is used in antiseptics, gold salts are used as an anti-inflammatory in the treatment of rheumatoid arthritis.
- Microbial source: microbes are an important source of drugs. Most of the microbes (bacteria) that are used for the production of drugs are obtained from the soil. Microbes continually keep producing certain antibiotics and other biochemicals inside them to gain an advantage over other competitors in the microbial world in the quest for survival. These antibiotics or chemicals are extracted and used for drug development, particularly antibiotics. Microbes can be

effectively used to produce antibiotics, vaccines and various therapeutically important enzymes and proteins which can be used as anti-tumour and immunosuppressants. Currently, genetically engineered microorganisms are used for the production of certain targeted biochemicals, which can be potential drug sources. Example- penicillin produced by Penicillium chrysogenum, streptomycin from Streptomyces Aminoglycosides such gentamicin griseus. as and obtained tobramycin are from streptomyces and micromonosporas.

### **32.** Explain the process of selection of herbal materials for manufacturing herbal preparations.

In the case of organized farming, only those species which are authorized in pharmacopoeia or other government documents should only be used for cultivation. In the case of wild cultivation, genuine herbal materials free from adulteration needs to be selected. The herbal materials are selected at an appropriate vegetative stage when they are fully grown and contain the maximum amount of phytoconstituents. Since the quality of herbal preparations depends on the amount of phytoconstituents present in the finished product, henceforth, it becomes very important that the starting material (herbal materials) must be selected at an appropriate vegetative stage when it contains the maximum phytoconstituents. At the same time, selection of herbal materials should also be made at an appropriate season which favors maximum production of phytoconstituents. Examples,

- Leaves: are collected during the flowering period when the photosynthetic activity is at the maximum. The collection should be made duringdry season because the presence of moisture can cause the degradation of phytoconstituents.
- Flowers: are collected before their full blooming and just before the pollination. It should be collected in dry season because moisture on the petals may cause discolouration during drying.
- Barks: are collected in spring or during early summer when the cambium is active and easily separable. Some barks like those of wild cherry bark are collected in autumn.

• Roots and rhizomes: are collected when they are fully stored with food reserves and before the stoppage of the vegetative process.

## **33.** List out the WHO recommended good processing practices used in making different herbal preparations.

- a) The quality of the raw material should be in accordance with that mentioned in herbal pharmacopeia or other official books of that particular country.
- b) Authentication of the herbal raw material is very important. If organized cultivation was undertaken, authenticated seeds should have been used, and if wild collection is undertaken, taxonomical, microscopical, macroscopical, and chemical authentication should be carried out.
- c) Proper documentation of the herbal raw material should be made as specified in the WHO recommended GMP for herbals.
- d) Requisite primary processing steps must be carried out, followed by drying and size reduction.
- e) Storage time of herbal raw material should be reduced, and processing must take place at the earliest to avoid any contamination or microbe triggered degradation of phytoconstituents.
- f) All operational steps involved in the making of herbal preparations from processed herbal material should be hygienic and as per standard operating procedures.

# 34. Explain the type of documentation involved as per WHO guidelines during the processing of herbal materials into herbal preparations.

During the processing of herbal raw materials, the records regarding the following should be made,

- a) Details of the herbal material used, including its botanical name and plant part used
- b) Stage of vegetative development when harvesting was performed
- c) Cultivation site details
- d) Details of the supplier of raw material
- e) Drying details (if performed)

- f) Details of primary processing performed along with dates of such operations carried out, including the details of the manpower (in-charge) involved in the process
- g) The gross weight of the herbal material before and after processing
- h) Involvement of any special processing
- i) Master formula for the making of the herbal preparation
- j) Details of usage of any animal-derived products or any adjuvants, if used
- k) In-process control records along with records of batch production data
- 1) Records of quality control parameters of the finished product
- m) Storage conditions
- n) Shelf-life.

#### 35. Write a note on organic farming.

Organic farming can be defined as that system of agricultural practice and management that is committed to the preservation of biodiversity, the ecosystem as a whole, and the well-being of humans and animals. It is based on the following principles,

- a) The principle of health: Organic farming is committed to the preservation and enhancement of the health of soil, plant, animal, human, and planet as single system. It means thata healthy ecosystem shall provide healthy soil for the production of the healthy crop, which shall uphold the wellbeing of this planet by keeping humans and animals healthy. The basic role of organic farming is to maintain a healthy ecosystem and to ensure that all organisms in that ecosystem, starting from microbes in the soil to humans, should get high-quality, nutritious food. As a result, organic farming avoids the use of chemical fertilizers, pesticides, insecticides which may be harmful to the ecosystem on the whole.
- b) The principle of ecology: Organic agriculture should achieve ecological balance through the design of farming systems, establishment of habitats and maintenance of genetic and agricultural diversity. Those who produce, process, trade, or consume organic products should protect

and benefit the common environment, including landscapes, climate, habitats, biodiversity, air and water.

- c) The principle of fairness: Organic agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities by ensuring the supply of good food quality and reduction of poverty among farmers
- d) The principle of care: Organic agriculture should be managed in an accountable and responsible manner by not involving genetic engineering products so that the health and well-being of current and future generations and the environment arebeingmaintained.

Some of the good practices under organic farming are,

- a) Non-usage of any synthetic chemicals in the form of fertilizers, or pesticides
- b) Avoidance of concept of genetic engineering
- c) Recycle of waste
- d) Crop rotation for soil regeneration
- e) Use of biopesticide and biological methods for pest control
- f) Ensure suitable ecosystem for soil microorganisms and animals
- g) Protection and maintenance of biodiversity.

Advantages of organic farming,

- a) Produces vegetables with improved nutritive value
- b) Produces medicinal plants with better yield of nutraceuticals and other secondary metabolites
- c) Pesticide and heavy metal contamination is kept under acceptable limits
- d) Lesser chances of inducing cancer risk in the future because of non-usage of synthetic chemicals
- e) Consumption of organic products provide a better healthy life
- f) Beneficial for the ecosystem on the whole as soil fertility and microbial flora of the soil is retained and also improved.

#### 36. Write a short note on Biopesticides.

Biopesticides are those agents which are used to manage agricultural pests by means of specific biological effects rather than as broader chemical pesticides. It is a type of pest controlling product that makes use of biological resources, namely, natural organismsor ingredients obtained from natural materials (such as animals, plants, bacteria,or certain minerals), which also includes their genes or metabolites, for controlling pests.

#### Classification,

- a) Microbial pesticides and other entomopathogens: pesticides that contain microorganisms like bacteria, fungi, or viruses, which attack specific pest species, or entomopathogenic nematodes. Mostly targeted for insect pests, but certain microorganisms are used for the eradication of weed. Examples – The bacterium *Bacillus thuringiensis*is used against caterpillars, and the fungus *Beauveria bassiana* is usedagainst whiteflies, aphids and thrips.
- b) Plant protectants obtained through genetic manipulation: these include pesticidesubstances that are produced in genetically modified plants or organisms.
- c) Biochemicals: these are plant-based extracts containing phytoconstituents which has pesticide properties. This includes insect repellents, pheromones, and plant growth regulators. Examples Azadirachtin (broad-spectrum insecticide), Capsaicin (broad-spectrum insecticide, nematicide and fungicide), Clove, rosemary and peppermint oil (broad-spectrum fungicide).

Advantages,

- less toxic to humans and the environment
- do not leave harmful residues
- pest-specific agents
- capable of replication in target host and persist in the environment resulting in long-term suppression of pest populations even without repeating the application
- the sustainable component in Integrated Pest Management.

#### Disadvantages,

- since they are pest-specific, hence, cannot control a large species of pest
- have reduced shelf life because they contain living organisms
- efficacy is often variable due to the influence of various biotic and abiotic factors
- well informed manpower is required for usage of such products
- thorough knowledge regarding the target pest is required so that optimization regarding application time, field rates, and application intervals can be done
- biopesticides often are developed by research institutions rather than by the traditional pesticide industry. Hence large-scale commercial availability of such products can be an issue
- it is challenging to design an appropriate formulation for efficient field application.

#### 37. Explain the basic principle of Ayurveda.

Avurveda means'The Science of life'. It is made of combination of two Sanskrit words' Ayur' which means life and "Veda" which means knowledge. The fundamental doctrine principle of Ayurveda is based on the belief that the universe is composed of five basic elements, namely, Prithvi (earth), Vayu (air), Jala (water), Aakash (space) and Teja (fire). These five elements are known as Panchabhutas, which exists in the human body in the form of "Doshas', namely, Vata, Pitta and Kapha, collectively known as Tridosha (humour), which regulate the basic physiological functions of the body. In addition to this, the principle of Ayurveda also states the existence of seven basic elements known as 'Sapta dhatus' which are represented by Rasa (tissue fluids), Rakta (blood), Mamsa (muscle), Meda (fat & connective tissue), Asthi (bone), Majja (marrow), Shukra (semen) and Mala(such as faeces, urine and sweat). Vata dosha cellular electrolyte takes care of transport, balance andelimination ofwaste products. Pitta dosha maintains body temperature, regulates optic nerve coordination along with

hunger and thirst. Kapha is believed to maintain lubrication between joints. Vata is responsible for catabolism, Pitta for metabolism and Kapha for anabolism of the body. To maintain a healthy state of living, an optimal balance of the Doshas and other Sapta dhatus are required. Any imbalance shall give rise to a diseased condition. Apart from Doshas and Dhatus, Tri-Malas (urine faeces, sweat) also plays a vital role in maintaining healthy living as their routine excretion is very important to eliminate the toxins generated inside the body. A holistic approach is adopted in Ayurveda for the diagnosis of the disease where the patient as a whole is examined and not only just the symptoms. Ayurveda uses the 'PanchaKarma' mode of therapy, which is based on rejuvenation, cleansing of the body and increasing its longevity. This mode of therapy is composed of five karmas, namely, Virechan (purgation using decoctions), Vaman (forced emesis), Basti (enemas made from essential oil), Rakta moksha (removing toxins from the blood) and Nasya (administering drugs in suitable forms through nasal route). Pancha Karma consists of three steps namely, Poorvakarma (preparing the patient and medications to be used for treatment), Pradhan karma (the stage where the drug is actually administered) and Paschata karma (indicates post-treatment procedures).

#### 38. Explain the basic principle of Siddha.

The word Siddha is derived from the 'Siddhi',which means achieving excellence, and this excellence in medicine was achieved by a group of eighteen saints known as 'Siddhars' who later spread the knowledge. Siddha is more prevalent in the Tamilian culture. The philosophy of Siddha is also similar to Ayurveda and follows the concept of Panchamahabhutas and Doshas. Matter and energy, which are also known as Siva and Sakthi, are believed to be the two most powerful components of the universe according to Siddha philosophy and plays a vital role in maintaining body's healthy condition. Apart from the balance of Doshas, according to the Siddha system, the wellbeing of the body is also regulated by 96 other factors, namely pulse, perception, speech etc. Diagnosis in the siddha system is carried out through 'Ashtasthana Pareeksha'which indicates the examination of eight sites of the body, namely pulse, eyes, voice, colour, tongue etc.Siddha system predominantly uses various metals (gold, silver, copper) and mineral-based preparations. Usage of herbs is less when compared to Ayurveda.

#### **39.** Explain the basic principle of Unani.

Unani system of medicine originated in Greece by Hippocrates and later on further developed by Galen and Aristotle. This system was introduced in India by Arabs and incorporated into the Indian mainstream of medicine by the Mughal emperors. Unani philosophy is based on four conditions of living represented as hot, sodden, frosty, and dry. It is also based on four senses of humour (namely-blood, yellow bile, dark bile, and mucus) as proposed by Hippocrates, whose balance is essential for body's healthy condition. Hippocrates also stated that balance among basic elements, humour and temperament are the minimum requirements for a healthy soul. The proper balance of these senses of humour is maintained by an intrinsic power of the body known as *Quwut-e-Modabira*. Weakening of this power will lead to an imbalance among the humor leading to the diseased condition. Asbabe-Sita-Zarooriya indicates six essential features required for the prevention of diseases, namely, air, food, drinks, body response, sleep, excretion and retention. Treatment protocol under Unani comprises of three basic strategies,

- Ilajbit-ghiza diet therapy
- Ilajbit-tadbeer regimental therapy
- Ilajbit-dawa pharmacotherapy

#### 40. Explain the basic principle of Homeopathy.

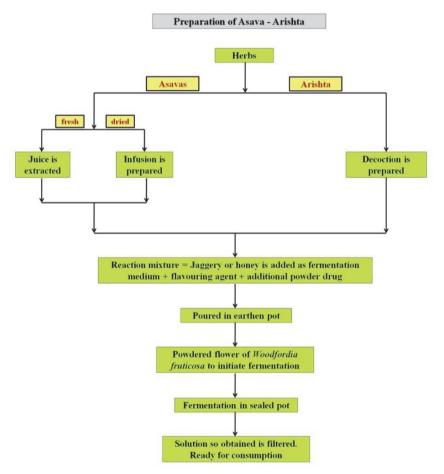
The word homeopathy has been derived from two Greek words, 'homeos' which means similar and 'pathos'which means suffering. Even though the concept originated in Greece by Hippocrates, modern-day homeopathy was developed by a German Physician Dr. Samuel Hahnemann. The principle of homeopathy is based on the similarity in terms of body's response to the drug and the disease. It uses medicines that produces similar symptoms to that of the disease, resulting in initial aggravation of the disease and then finally treating it. Two basic methodologies are involved,

- a) *Like cures Like*: if a drug (tincture) administered to a healthy person produces certain symptoms in the human body, then the same drug would be used for the treatment of those diseases which produced similar symptoms to that of the drug when given to a healthy person. Symptoms produced by the drugs in a healthy person = symptoms produced by a particular disease. In such a situation, both can neutralize the effects of each other. For example extract of cinchona bark produces malaria-like symptoms when given to a healthy individual. Hence it was decided that such extract could be useful for the treatment of malaria.
- b) *Infinite dilution*: the therapeutic activity is enhanced upon successive dilutions, even if the dilution goes beyond the Avogadro's number.

#### 41. Write a note on Arishta and Asava.

Asava-arishta is hydro-alcoholic ayurvedic formulation products generated through the traditional fermentation process. They are basically prepared by subjecting herbal juices or herbal decoctions to fermentation with the addition of sugar or jaggery. This particular dosage form results in neutralizing the toxic effects of various phytoconstituents or converting them into a more potent form apart from offering a better degree of bioabsorption. Moreover, the alcohol content also serves as an extraction solvent for dissolving out the phytoconstituents from the starting material and also act as a preservative. The process of making Asavas and Arishtas is known as 'Sandhana kalpana' in Ayurveda. General methods used in the extraction of medicinal plants in asava and arishta are infusion and decoction. Decoctions are the starting material for the preparation of Arishta, and fresh herbal juices are the starting material for Asavas. Flavouring agents may be added to alter the taste of the finished product. The medicinal plants used for such preparationare cleaned and pulverized. For Asavas, the juice is collected from a fresh plant using mechanical pressure, and if the dried crude drug is used, an infusion is prepared. For Arishta, a decoction is produced. Old jaggery or honey is then added and dissolved, which provides a medium for fermentation. Earthen pots whose internal surface is smeared with 'ghee' are used as

fermentation containers. 'Ghee' blocks the natural perforation present in the earthen pot so that the inner contents are not exposed to outside air, which otherwise could affect the fermentation process. The reaction mixture (juices/infusion for Asavas or decoctions for Arishtas + honey or jaggery + flavouring agent + additional powdered drugs) is poured into the earthen pots upto three-fourth capacity so that during fermentation, increase in volume due to frothing and other gasses can be accommodated in the earthen pot. Yeasts are required as inoculum for initiating the fermentation. Hence, dhataki flowers (*Woodfordia fruticosa*) or mahua flowers are added.



Finally, the vessel is sealed with clay smeared cloth. The vessel is to be kept in the dark place without much air circulation. It can be kept in a grain store or buried in a pit. The time to complete the fermentation depends on the season, summer season requires lesser time (6-7 days) and winter season requires maximum time (10-14 days). The fermentation vessel is generally left undisturbed for a month before opening and then filtered to separate the sediment. The filtrate serves as the finished product. Example – Ashokarishta (used in painful menstruation, relieves inflammation, and increases appetite) and Kanakasava(used in asthma and blood disorders).

#### 42. Write a detailed note on Bhasmas.

Bhasmas are ayurvedic preparation obtained by the process of calcination (heating metals at high temperatures for conversion into their respective oxides) of metals (gold, silver, copper etc.) or minerals (calcium, magnesium, aluminium, zinc etc.) or animal products treated with herbal extracts.

Characteristics of Bhasma,

- A typical specified colour occurs for each bhasma preparation
- Should be lusterless (should not glow or appear shiny)
- Bhasma should be in powder form, light enough to float on still water surface
- Should not cause irritation to the mucous membrane
- Should not revert to its original metallic form
- It should be tasteless.

Method of preparation of Bhasma: it involves two steps, namely,

- a) *Shodhana* (Purification): the basic objective of shodhana is the elimination of toxic properties of metals and minerals, conversion of undesirable characteristics of the drug and improving the overall therapeutic action. There are two types of shodhana,
  - Saamanya shodhana: thin sheets of metals are heated and converted into coarse powder and repeatedly quenched into oil or cow urine
  - Vishesha shodhana: involves certain special treatments like wet grinding of coarsely powdered metals with a

specific liquid preparation – the process is known as *Bhaavana* and dipping of red-hot metal into liquids like oil – a process known as *Nirvaapana*.

b) Marana: the powdered metals obtained after purification is triturated with a specific extract. The contents are transferred to an earthen pot and sealed with clay smeared cloth. The vessel is then placed in a pit which is dug in the ground and surrounded with cow dung cakes which are then ignited to complete the burning (incineration) process. The whole process may be repeated several times. Finally, the bhasma so obtained is powdered and is ready for use. The above method is known as the Putapaka method. Bhasma may also be prepared by the Kupipakwa method, which involves an amalgamation of the purified metal with mercury followed by trituration with purified Sulphur. This preparation is known as Kajjali. Subsequently, the preparation is then subjected to wet grinding with a specified extract/liquid, dried and packed in a glass bottle, sealed and subjected to sand bath for homogenous heating. Finally, the bottle is broken, and bhasma is collected from the bottom and powdered.

Example – Swarna bhasma (analgesic activity, antioxidant), Loha bhasma (used in the treatment of jaundice and anemia) and Tamra bhasma (antioxidant in nature).

#### 43. Write a brief note on *avaleha*.

Avaleha is an ayurvedic preparation obtained by continuous heating of an aqueous extract of a crude drug along with other medicaments and additives.

Basic ingredients of Avaleha = aqueous extract (Kashaya) of a crude drug + substrate (sugar/jaggery) + powdered drug + lipid medium (ghee/oil) + additives (honey).

According to the consistency of the final product, several synonyms are given, such as *Avaleha*, *Leha*, *Lehya*, *Avalehya*, *Rasakriya* etc.

*Method of preparation*: the aqueous extract of the crude drug is prepared, and sweetening agents like jaggery is mixed and heated over a mild fire in a stainless-steel vessel. The contents are

cooled and filtered and heated again to a further thicker consistency. At this stage, ghee or oil is added. At this point, the preparation is known as *Paka lakshana*. Fine powder of other crude drugs is added to the mixture while hot and stirred to obtain a homogenous mixture and allowed to cool. Honey is added at the end, and the product is finally packed in air tight containers.

Example – Chyavanaprasa, Kushmanda Avaleha.

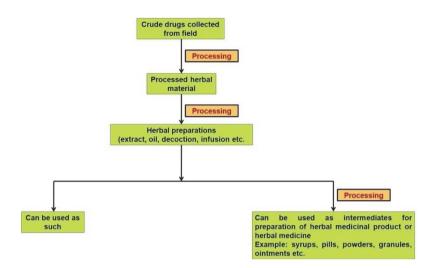
#### Ten marks category questions

### 44. What do you mean by processing of herbal raw material? Explain in detail the different processing stages of herbal raw material.

Processing of herbal raw materials indicates the application of some unique processes through which crude drugs collected from the field in raw form are converted into a suitable state so that they can be further used for,

- Storage for longer duration and transportation to distant places
- Making of herbal preparations followed by making of different herbal formulations or dosage forms
- Different industrial processing in accordance with GMP required for preparing herbal finished products
- Neutralizing the toxicity or enhancing the therapeutic activity of the drug
- Reduction of microbial contamination through the removal of moisture
- Convenience in packaging.

Thus, herbal processing means all those processes involved in the making of processed herbal materials to finished herbal products with the goal to assure quality at every stage. Processing involved in different stages starting from herbal raw materials to finished product (herbal medicine) is presented below,



#### Processing of herbs at different stages,

*Processing of raw materials (crude drugs) into herbal materials*: this indicates the conversion of the raw form of the crude drug as obtained from nature into a form suitable for therapeutic application or further processing into herbal preparations. Various processing steps involved in this stage are,

Primary processing:

- a) Harvesting: good harvesting practices should be adopted. Harvesting of plants should be done at the appropriate vegetative stage when the plant contains maximum phytoconstituents. Trained manpower and specific instruments should be used for harvesting to avoid any damage to the plant material during the process of harvesting.
- b) Garbling: this is the first step after harvesting, where the plant material is cleaned, and all unwanted things like dirt, sand, soil, unwanted non-medicinal parts are removed and sorted. Sorting can be done using mechanical means (machines) or by hand through trained manpower.
- c) Washing: washing with water (running tap water or chlorinated water) is recommended for cleaning additional dirt and soil adhering to the surface of the raw

material. Herbal raw materials should not be soaked in water for a long period of time for the purpose of cleaning.

- d) Blanching: herbal raw material dipped in boiling water for a short time period to facilitate removal of the seed coat of almonds, gelatinizing starch content etc. Such process improves the storage life of the raw material, reduces chances of mould or insect contamination and also deactivates certain enzymes whose activation otherwise could have degraded certain phytoconstituents.
- e) Drying: this step is an essential component of the processing of herbal raw material. Mostly herbal raw materials are subjected to drying unless instructed to use fresh , particularly in case of extraction of essential oil, juices, resins and other exudates. Advantages of drying are,
  - Removes moisture content, and thus microbial growth can be avoided
  - Prevents tissue deterioration
  - Prevents phytochemical alteration likely to be caused by activation of enzymes triggered by the presence of moisture
  - Helps in size reduction so that the raw material can be subjected to further extraction process.

Major aspects of drying are,

- Temperature control
- Humidity
- Air flow
- Cleanliness of air
- Tissue structure and chemical constituents present and their sensitization towards drying
- The appearance of the final form post drying.

Based on the above-mentioned aspects, drying type is selected, which are as follows,

• *Sun-drying*: herbal raw materials should be spread out and subjected to natural sun-drying in the open air.

Necessary precautions must be taken to protect the raw material from pollution, dust, rain and other possible sourcesof contamination. The material should be turned upside down frequently to achieve uniform drying. Volatile oil-bearing plants are not subjected to direct sun-drying in the open air. Discolouration of the herbal raw material is very much possible.

- *Shade-drying*: herbal raw material spread in the thin layer can be subjected to shade drying with or without artificial airflow. Such drying process is slow but prevents discolouration or degradation of phytoconstituents.
- Drying by means of artificial heat: the temperature and humidity may be controlled depending upon the physical and chemical nature of the raw material. Temperature preferably may be kept below 50°C. Drying by artificial means can be conducted by Tray drying- drugs (roots and rhizomes) are spread across a tray, and hot air is circulated throughout the closed system, Vacuum drying- expensive method, used for drugs which are sensitive to temperature and humidity as well, Spray drying- liquid extract/exudate is introduced in fine mist form in a heating tower supplied with hot air. Moisture evaporates in a flush and converts the liquid feed into powder. E.g., preparation of powder for capsules and tablets.
  - *Microwave drying:* crude drugs can be dried by exposure to the microwave while moving in a closed system through a conveyer belt. The moisture absorbs the microwave, gets heated and evaporates.
  - *Infrared radiation drier:* crude drugs are subjected to infrared radiation while passing through a closed system, resulting in evaporation of the moisture present in the crude drug.
- e) Storage: processed herbal raw materials should be stored in closed, dry and well-ventilated rooms duly protected from light and with appropriate humidity conditions to avoid any microbial growth. Contamination from other

sources should also be avoided. The storage area should have sufficient capacity for accommodating all types of materials with a quarantine facility for those materials which require the same. Separate receiving and dispatch areas should be maintained.

Secondary processing:

- f) Size reduction: herbal raw material is subjected to size reduction using machineslike a ball mill. Size reduction offers ease of manufacturing, improves extraction yield and ease in packaging and transportation.
- g) Ageing: refers to storing the herbal raw material for a certain time period immediately after collection from the field. Example- cascara should be aged for one year prior to using in herbal preparations, which is necessary for removing the strong irritation effects that may cause vomiting.
- h) Boiling or steaming: herbal raw material may be subjected to boiling water or steam. Prior treatment with wine or vinegar may be carried out before exposure to steam. This is necessary to denature certain enzymes or to thermally degrade certain chemical constituents. Example- boiling rhizomes of *Acorus calamus* in cow urine can enhance its anti-convulsant activity
- i) Stir-frying: raw materials are put in a frying pan and continuously stirred for a certain period. Wine, vinegar, honey may be added during the stirring process. Stirring may continue until the external colour changes. Exampleliquorice roots and rhizomes are often stirred with honey, fresh ginger is often stir-fried with sand.
- j) Fumigation: fumigation by Sulphurdioxide has been often employed for the purpose of preserving the colour, preventing the growth of insects and also applied to herbal raw materials with bright colours to prevent browning.

Special processing

 k) They are mainly done to reduce the toxic effects of certain phytoconstituents. Sometimes also carried out to enhance the therapeutic properties of a drug. For example- aconite and nux-vomica are generally boiled in water/steam to reduce their toxic effects. Fresh ginseng is converted to red ginseng, which has a better pharmacological activity by a series of steaming process.

Processing for conversion of processed herbal materials into herbal preparations:

Processed herbal materials may be used as herbal medicine as such or may be further processed to prepare different herbal preparations, which can further be used alone or in combination with processed herbal materials for making finished herbal medicinal products. All procedures adopted should be in accordance with WHO recommended GMP guidelines for herbals. For the making of herbal preparations, different extraction different methods using solvents and extraction conditions are employed to get the optimum yield. The most common herbal preparation is a herbal extract.

Herbal extracts: extracts are of four basic types,

 Liquid extract: it is a liquid preparation of herbal materials commonly using water or alcohol as the solvent. Some examples of the liquid extract are,

Fluidextract - is an alcoholic liquid extract produced by percolation of herbal material,

Decoction - Decoction is a water-based herbal preparation made by boiling herbal materials with water,

Infusion- is a dilute solution made by subjecting the herbal materials in boiling water for a short time only,

Tincture - it is an alcoholic or hydro-alcoholic extract.

- (ii) Soft extract: it is a semi-solid preparation prepared by partial evaporation of the solvent from the main extract.
- (iii) Oleoresin: type of semi-solid product consisting of resin mixed in a solution of essential oil.

(iv) Dry extract: solid extract in powder form obtained by complete evaporation of the extracting solvent using techniques like spray drying.

Processing for conversion of herbal preparations into finished herbal products or herbal dosage forms: Herbal preparations obtained after subjecting the processed herbal materials (botanical material) to processes like extraction can then be used as intermediates for the preparation of finished herbal products or herbal dosage forms. Such dosage forms or finished medicinal products, namely, syrups, ointments, tablets, capsules, creams etc., must be prepared under strict WHO recommended GMP conditions.

45. Explain in detail the methods used for the identification and authentication of herbal materials.

Identification of herbal raw materials indicates correct botanical and taxonomic identification of the plant species free from any possible adulterants. It is highly possible that during wild collection, a wrong plant species or a similar-looking plant may be collected by mistake, which will then badly affect the subsequent steps to follow in the preparation of the final finished herbal product. Identification can be made by a taxonomist by studying the botanical and reproductive features of the plant. Microscopic and phytochemical evaluations can also be done to identify the plant species. Authentication refers to a quality assurance process that validates the identification process carried out for choosing the correct herbal raw material and ensures the quality, safety and efficacy of the herbal material and finished product produced thereafter using the herbal raw material. Official pharmacopoeia of every country provides distinctive quality control procedures for performing identification cum authentication of herbal materials by comparison to standards mentioned in such official books. Such parameters are described below.

a) Organoleptic evaluation (morphological evaluation): refers to colour, odour, taste, arrangement of calcium oxalate crystals, aleurone grains, types of fibres, vessel thickenings, which, reveal vital information regarding the identification and authentication of herbal materials (Example – cinchona contains lignified bast fibres, nuxvomica contains lignified trichomes etc.). On the other hand, quantitative microscopy of drugs mainly includes stomatal index, vein-islet number, vein termination number and palisade ratio, which can be compared with reference value mentioned in official books, helps in differentiating closely similar-looking species, thus helps in avoiding possible adulteration. The abovementioned terms are known as leaf constants, and their value is constant for a particular leaf species irrespective of the age and size of the leaf. Very useful in quality control of powdered drugs.

- b) Foreign organic matter: any other plant parts or any other material other than those specified which does not constitute the desired herbal raw material (crude drug) are considered as foreign matter. Any matter of plant or animal, or mineral origin which is undesirable, constitutes the foreign matter. The collected crude drug should be free from soil, dust, earthy material or any type of animal or insect contamination, including animal excreta.
- c) Ash value: upon incineration (not exceeding 600°C) of crude drugs, they leave inorganic ash which is an indication of the care taken during the processing of crude drugs, especially for underground drugs. There are three different ash values namely,
  - Total ash: indicates the total ash obtained after incineration of the crude drug. It includes 'Physiological ash'which is derived from the burning of plant tissue, and, non-physiological ash'which is obtained by the burning of the extraneous undesirable material adhering to the crude drug surface like soil, sand and earthy material. Percent ash to be calculated with reference to the air-dried drug.
  - Acid-insoluble ash: it is defined as the residue obtained after igniting the insoluble content resulting from boiling the total ash in dilute HCl. The high value of acid-insoluble ash indicates the excess presence of sand.
  - Water-soluble ash: it is defined as the difference in weight between the total ash and the residue obtained after treating the total ash with water.

- d) Extractive values: it refers to the percent chemical constituents (extractable matter) extracted from the crude drug using a specific organic solvent. It provides information regarding the extent of polar, non-polar and medium polarity constituents present in the crude HPTLC/HPLC/GC drug. Since instrumentation provides exact quantification of the active constituents present in the crude drug, henceforth, extractive values are of lesser significance in modern time. But still, it is an inexpensive and quick indicator of the exhaustive and adulterated drug. Alcohol and water extractive value must be determined.
- e) Determination of moisture content: this parameter indicates the moisture content of the crude drug. The moisture content of a crude drug must be within specified limits because excess moisture content may encourage microbial growth leading to the deterioration of active constituents of crude drugs. The test specimen is to be dried at 105° C for 3 hours and then weighed. Drying and weighing are to be continued at half an hour intervals until the difference between two successive weighings corresponds to not more than 0.25%.
- Chromatographic fingerprinting: this is a sure shot f) method for identification and authentication of herbal materials (crude drugs). Chromatographic fingerprint refers to a fixed chromatographic pattern indicating the presence of various active phytoconstituents or classes of phytoconstituents present in that extract obtained through the use of analytical instruments, namely, HPTLC, HPLC, GC-FID. A chromatographic pattern for an extract is usually fixed, and a standard chromatographic pattern for most of the commercial crude drugs are available in standard books. The similarity of the chromatographic pattern for the sample is matched with that of the standard for assessing its quality. A chromatographic fingerprint obtained from HPTLC is represented in the form of bands viewed under UV or fluorescent light, where

each band represents a particular phytoconstituent. The intensity of the bands is matched. In the case of fingerprinting obtained through HPLC or GC, an array of peaks is obtained. A standard set of peaks obtained from a reference sample is considered as a standard chromatogram documented in official books. The set of peaks obtained from the test sample is matched with the chromatogram mentioned in official books. However, this test is a qualitative test where information regarding the quantity of phytoconstituents present in the extract is not reflected. Nevertheless, matching the chromatographic pattern provides evidence regarding the identity conclusive and authentication of the herbal raw material.

- Pesticide residue: Pesticides are defined as anv g) substance which is intended for preventing, destroying, attracting, repelling, or controlling any pest, including unwanted species of plants or animals during distribution production. storage. transport, and processing. Medicinal plants can easily accumulate pesticides through groundwater, soil and direct foliar application. World Health Organization has set maximum residuelimits of pesticides in medicinal plants. Different types of pesticides are dichlorodiphenyltricholoroethane (DDT), benzene hexachloride (BHC), toxaphene, aldrin, carbaryl etc. Extraction and sample enrichment of pesticide from herbal raw materials can be performed using solid-**OuEChERS** method phase extraction, etc. Quantification can be done by using GC, MS, GC-MS or immunochemical methods. Limit for DDT - 1 mg/Kg, aldrin – 0.05 mg/Kg.
- h) Radioactive contamination: A certain amount of exposure to ionizing radiation is unavoidable because many sourcesof radionuclides occur naturally in the ground and the atmosphere. Examples of such radionuclides include long-lived and short-lived fission products, actinides and activation products. In general, the nature and the intensity of these radionuclides may

differ markedly and depends on factors such as the source, which could be a reactor, reprocessing plant, fuel fabrication plant, isotope production unit or other. Instruments used for such detection are Geiger Mueller (GM) Detectors, Alpha Radiation Survey Meter, Dose Rate Meter etc.

- Mycotoxin determination: Mycotoxins are secondary i) metabolic products that are non-volatile, having low molecular weight and are usually secreted onto or into the medicinal plant material. They help in eliminating other microorganisms competing in the same environment and, secondly, help parasitic fungi to invade host tissues. Mycotoxins produced by species of fungi including Aspergillus, Fusarium and Penicillium are the most commonly reported. Mycotoxins are of four major types, namely, aflatoxins, ochratoxins, fumonisins and trichothecenes, all of which have toxic effects. Permissible limit for B1 aflatoxin < 2ppb and for B1+B2+G1+G2 aflatoxin is < 5ppb.
- j) Heavy metal contamination determination: due to environmental pollution and industrialization, it is very likely that medicinal plants may get contaminated with heavy metals like arsenic, cadmium, lead and mercury. For authentication of herbal raw materials, prescribed limits in parts per million should be satisfied. Permissible limits for lead are 10 ppm, arsenic – 3 ppm, cadmium – 0.3 ppm and mercury – 1 ppm. Atomic absorption spectrophotometry and the Indictive Coupled Plasma method can be used for determination of heavy metals.
- k) Microbial contaminants: Herbs and herbal materials generally possess a large number of bacteria and molds which originates from soil or are derived from manure. Poor practices of harvesting, production, transportation and storage may cause additional contamination and microbial growth. Such microbial growth is mainly due to uncontrolled moisture levels in herbal materials. The presence of *Escherichia coli*, *Salmonella* and molds in herbal materials may possibly indicate poor production

and harvesting practices. Microbial contamination may occur during harvest by personnel who are themselves pathogenic bacteria, infected with post-harvest processing and the manufacturing process. Total aerobic count, total fungal count and total Enterobacteriaceae count must be carried out using validated pharmacopoeia methods. The total count of E. coli, Staphylococcus aureus, P. aeruginosa, Shigella species and Salmonella typhimurium must also be determined

## 46. What do you mean by Good Agricultural Practices (GAP)? Explain the WHO guidelines related to GAP in the cultivation of medicinal plants.

A GAP is defined as a well strategized cultivation protocol designed to ensure optimal yield in terms of both quality and quantity of any crop intended for health purposes.

*Objectives of GAP*:

- To improve the quality, safety and efficacy of finished herbal products by ensuring the quality of medicinal plant materials which are used as raw materials in the production of herbal medicine
- Lay down standard operating guidelines for good collection practices of medicinal plants
- To promote sustainable cultivation and collection of medicinal plants
- To support the conservation of medicinal plants and the environment at large

GAP Related to soil & climatic conditions:

- a) Based on metrological data, the best suitable site for cultivation must be selected to ensure an optimal cultivation environment for plant growth both in terms of quality and quantity.
- b) Sites having salinity, acidity factors in the soil, issues related to industrial waste disposal, graveyards, crematoria in close vicinity of cultivation site should be avoided.
- c) The site should be asclose as possible to the source of irrigation.

- d) Soil should be fertile and well-drained with good water holding capacity for providing the proper environment for plant growth. Latest reports on soil nutrients and other physico-chemical properties of the soil must be obtained to decide regarding the fertility status of the soil and take necessary corrective measures to improve fertility.
- e) The quality of water used for irrigation, should be tested for the presence of heavy metals, pesticides and their levels should be within acceptable limits.
- f) Availability of shades across the field, if required, may be ascertained.
- g) Average rainfall, temperature, day & night temperature differences should be considered before cultivation.

GAP Related to seed and propagation material:

- a) Correct identification of the seed/planting material is mandatory
- b) Marker-based analytical projection for the end product is mandatory
- c) Seeds to be used for cultivation must be physically free from pests and other diseases.
- d) Seeds used should be fresh and must have originated from recent harvests
- e) Applicable seed pretreatment procedures, if any, should be carried out well in advance before the planting season
- f) If seedlings are required, they should be produced under nursery conditions as per standard agronomic practices well before the actual field transplantation.

GAP in crop management for cultivation:

- a) Field preparation: includes providing proper physical conditions of the soil, better rhizospheric environment so that a nutritious environment for the plant can be created, which shall include the advantages of beneficial microorganisms also, good soil porosity & texture and eradication of weeds.
- b) Sowing and transplantation:
  - Seedlings per unit area of land shall be as per norms
  - Proper spacing in terms of row-to-row and plant-to-plant
  - Seedlings at the proper growth stage shall be transplanted to the field.

- c) Manures and fertilisers:
  - Organic manure shall be preferred
  - Use of compost, vermicompost, green leafy manure is desirable
  - Use of nitrogen-fixing bacteria
  - Specialized nutritional care for distinct root production or enhancement of leafy bio-mass is desirable
  - Any agrochemicals used to promote the growth of plants should be kept to a minimum level
  - Only approved pesticides and herbicides shall be applied
  - All applications of agrochemicals must be documented. *GAP in irrigation:* 
    - a) Total water requirements of the crop should be estimated, and accordingly, the irrigation cycles should be planned.
    - b) Water harvesting and water conservation methods should be followed.

GAP in harvesting:

- a) Harvesting should take place in optimal season
- b) Time of harvest depends on the plant part used
- c) The best time of harvest should be determined according to the quality and quantity of biologically active constituents and not on the vegetative yield
- d) During harvest, care should be taken to ensure that no foreign matter is mixed with the harvested medicinal plant materials
- e) Harvesting shall be avoided during heavy dew, rain and high humidity conditions
- f) Harvesting instruments and containers must be clean and free from any contamination
- g) Any mechanical damage to harvested plant material during the filling of sacks or bags caused due to overfilling must be avoided.

GAP for personnel:

- a) Personnel involved in cultivation must have thorough knowledge about the medicinal plant being cultivated.
- b) All personnel involved in harvesting must be trained and properly equipped with all appropriate machinery and personnel protective gear required for harvesting.
- c) All personnel involved in harvesting must maintain personnel hygiene.

## 47. Explain in detail the different methods of pest management.

The different methods of pest management are,

- a) *Physical methods*. Such methods do not use any chemicals and include manual removal of pests or installing barriers between the crop and the pests. Generally, applicable for larger pests like rodents. Physical detection of the pests is made, and then various methods are adopted for their eradication like, manual collection of eggs and larvae of insects, trapping of rodents, cutting off branches which gather grasshoppers and other insects etc.
- b) Chemical methods: includes the usage of various insecticides, pesticides and other chemicals mixed with water and sprayed on the leaves. This method is useful for the killing of those pests which generally cannot be seen easily and are difficult to remove by mechanical or physical methods. Pesticides kill pest through various mechanisms such as enzyme inhibition, disruption of signalling system, disruption of cellular components and membrane structures and altering the internal pH & osmotic balance. Such chemicals tend to accumulate in the crop and get potentially transferred to humans through the food chain, causing various neurological and hormonal disorders. Continuous use of the same pesticides can also lead to pesticide-resistant pests.
- c) *Biological methods*: it involves the use of living organisms in the form of predators, pathogens or parasites, which shall provide a competitive environment for the pest and challenge its survival. Thus the abundance of pests in the field can be well regulated. There are three types of biological control (a) importation - the natural enemies of the pest are promoted

through rearing or periodic release into the agricultural field, (b) augmentation – the natural enemy of the pest are bred and reared in large numbers and released into the infected crops to reduce the population of the pest, a process known as augmentation. Conservations refer to maintaining enough soil conditions for conserving the ecosystem of the natural enemies of the pest, (c) Importation - refers to the introduction of a pest's natural enemy to a new habitat where such natural enemies do not occur naturally. Example release of parasitic wasps to control aphids.

- d) *Cultural methods*: includes manipulating agricultural methods to control and avoid pest damage. In this case, pests are not directly killed, but due to adoption of simple agricultural or field practices at suitable times can result in a reduction of the pest population. Simple methods like crop rotation, deep ploughing, good preparation of soil, multiple cropping and intercropping with aromatic herbs are some simple techniques that makes the environment less favourable for pests and more favourable for natural enemies.
- e) *Genetic methods*: there are four strategies through which control over pests can be achieved
  - Sterile insect methods: a large number of sterile insects are released into the wild population as a method of pest control. Insects are made sterile by crosses between hybrid species or different genetic strains or by exposing the insects to ionization radiation to induce lethal mutations resulting in chromosomal damage and thus causing sterility. When such sterile 'insects' mate, the resulting eggs do not hatch because of the damage induced in the genetic material of the parents. Sufficient sterile insects must be released to achieve a significant decrease in the pest population over time. Once the healthy insects complete their life cycle, the future generation of pests shall not develop because of damage induced in their genetic material resulting in the non-hatching of their eggs.
  - Through various biotechnological interventions like gene editing, several genetically modified strains of pest species have been developed with lethality that operates only on females

- Transgenic plants express insecticidal toxins, which act against pests and prevents any pest mediated damage to the plant. Example Bt toxins are expressed in Bt cotton against lepidoptera.
- Producing and release of transgenic male insects (carrying genes that are lethal on females) with severe lethal effects on females.

# 48. Explain the standardization parameters for arishtas and asavas.

The following standardization guidelines have been provided by AYUSH Ministry for standardization of arishtas and asavas,

- a) Description: botanical description of the crude drug, including organoleptic and microscopic examination.
- b) Colour: the final product should display the characteristics colour.
- c) Odour: final product should display the characteristics odour.
- d) pH: can be determined potentiometrically by using a glass electrode, a reference electrode and a pH meter.
- e) Specific gravity: it is defined as the weight of a given volume of a liquid at 25°C compared with the weight of an equal volume of water at the same temperature. Weight is taken by pouring the liquid and water separately in a pycnometer.
- f) Boiling point: the boiling range of a liquid is the range of temperature within which the whole or a specified portion of the liquid starts distilling at normal atmospheric pressure.
- g) Refractive index: The refractive index is measured with reference to the wavelength of the D line of sodium (589.3 nm). Abbe's refractometer is used for the determination of refractive index.
- h) Optical rotation: it is defined as the angle through which the plane of polarised light is rotated when polarised light obtained from sodium or mercury vapour lamp passes through one decimeter thick layer of a liquid or a solution of a substance at a temperature of 25°C. Substances are indicated as dextrorotatory or laevorotatory according to the clockwise or anticlockwise rotation. A polarimeter instrument is used for the determination of optical rotation.

- i) Viscosity: indicates resistance to flow. Poise is the unit of dynamic viscosity.
- j) Total solids: it is determined by taking 50 mL of asava and arishta in an evaporating dish, evaporated to dryness followed by drying at 105°C for 3 hours. The dish is to be weighed after cooling. The weight of the dried residue should be within prescribed limits as mentioned in specific official monograph.
- k) Alcohol content: ethanol content is defined as the volume of ethanol contained in 100 volumes of the liquid, at 24.9°C – 25.1°C. Value is expressed as 'percent ethanol by volume'. It may also be expressed as gm of ethanol per 100 gm of liquid. Alcohol content can be determined by gas chromatography and the distillation method. In the case of gas chromatography, 5% v/v ethanol and 5% v/v 1-propanol are used as internal standards. From the distillation method, the specific gravity of the collected distillate is calculated and compared with the standard alcoholometric chart to find out the strength of the alcohol obtained from distillation.
- 1) Reducing sugar and non-reducing sugar.
- m) TLC/HPTLC/GC-MS (anyone or all): comparison of the spots or bands in TLC/HPTLC with authenticated fingerprint under 254 nm or 366 nm can be done. Matching of R<sub>f</sub> value with that of the standard mentioned in the monograph and intensity of spots/bands can serve as a semi-quantitative measurement for determining the chemical profile of the crude drug or finished formulation. GC-MS shall reveal peaks that can be identified using MS interface for determining the chemical profile of the herbal materials involved and the final finished product.
- n) Test for methanol: can be determined using gas chromatography using column made of porous polymer beads and nitrogen as the carrier gas. Injection port temperature to be maintained at 170°C. Methanol 0.25% v/v and 1-propanol 0.25% v/v are used as internal standards.
- o) Total acidity: sample is mixed with carbon dioxide-free water and titrated against standard sodium hydroxide solution using phenolphthalein as the indicator till persistence pink colour is observed. Water to be used as blank.

Acidity as formic acid (%) by weight =  $\frac{0.23 \times V}{M}$ 

V = corrected volume of 0.05N NaOH, M= weight in grams of sample taken

- p) Test for heavy metals: the limits prescribed are, lead 10 ppm, cadmium 0.3 ppm, mercury 1 ppm and arsenic 3 ppm. Atomic absorption spectroscopy and Inductive coupled plasma detection may be used for the quantification of heavy metals.
- q) Pesticide residue: presence of organochlorine pesticides, organophosphoras pesticides, and pyrethroids should be within prescribed limits as per ASU pharmacopoeia. A QuEChERS (Quick, Easy, Cheap, Effective, Rugged and Safe) based extraction method with GC-MS detection is one of the commonly used methods for the detection of pesticide residues.
- r) Microbial contamination: limits prescribed in ASU pharmacopoeia are the complete absence of *Staphylococcus aureus, Salmonella species, Pseudomonas aeruginosa, Escherichia coli.* Total microbial plate count (TPC) limits are  $10^{5}/g$  (for herbal extracts) and  $10^{7}/g$  (for topical applications). The total Yeast and Mould plate count limit is  $10^{3}/g$ .
- s) Aflatoxins: they are poisonous and carcinogenic substances produced by certain fungi. The two most closely related species which produces most of the aflatoxins are *Aspergillus flavus* and *Aspergillus parasiticus*. Approximately there are 14 types of aflatoxins, out of which B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub> are the most troublesome to human and animal health as they contaminate most of the crops and food materials. HPLC-MS and ELISA are mostly used for the detection of aflatoxins. Limits prescribed in ASU pharmacopoeia are B<sub>1</sub>< 2ppb and B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub><5 ppb.
- t) Shelf life: shelf life indicates the tenure for which the product is stable in terms of quality and efficacy under changing environments of temperature, humidity and light. It can be estimated by subjecting the finished herbal products of the same batch to standard storage conditions and accelerated storage conditions.

- 49. Explain the standardization parameters for ayurvedic churnas.
  - a) Description
  - b) Colour
  - c) Odour
  - d) Foreign matters: the sample (herbal material or herbal preparation) should be free from any visible signs indicating presence of mold, sliminess, stones, animal excreta, insects or any other undesirable matter. Take 100 g of the sample and spread it as a thin layer in a tray. Perform a careful examination under daylight. Suspected particles can be examined under 10x objective of a compound microscope.
  - e) Powder microscopy: powder sample can be used for performing standard detection tests associated with starch, lignified characters, determination of leaf constants, mucilage etc.
  - f) Loss on drying / Moisture content: it indicates the moisture content of the drug. 10 gm of the powder is taken in a tared petri dish and dried at 105°C in an oven for 5 hours. The sample is cooled for 30 min and weighed; the process is repeated until a constant weight not varying by more than 0.25% is obtained. Excessive moisture can lead to microbial growth, causing degradation of phytoconstituents. Henceforth, the determination of moisture content is an important quality control step.
  - g) Total ash and acid-insoluble ash: ash value indicates the presence of earthy material, dirt and sand along with the drug and must be within specified limits as prescribed in individual monographs. Higher ash value indicates possible adulteration of the drug with the above-said material, which is more frequent for underground plant parts like roots and rhizomes. Acid insoluble ash indicates the presence of sand or siliceous particles. Incinerate 2-3 g of the powder placed in a silica crucible at a temperature not exceeding 450°C until free from carbon. Calculate the weight of the total ash. For acid-insoluble ash, treat the total ash with 25 mL dilute HCl. Filter the mixture through ashless filter paper. Wash the residue on the filter paper with water until the filtrate is neutral. Dry the residue and ignite to a constant weight. Calculate the content of the acid-insoluble ash with reference to the air-dried drug.

- h) pH
- i) Water-soluble and alcohol soluble extractive: indicates the total extractable matter of the drug. Monographs specifieslimits for extractive values for different drugs. Five g of the powder is macerated with 100 mL chloroform water/alcohol in a closed flask for 24 hours with stirring for the first 6 hours. Twenty five mL of the filtrate is evaporated and dried at 105°C to a constant weight. The percent water-soluble extractive or alcohol-soluble extractive is calculated with reference to the air-dried drug.
- j) Bulk density and tap density: The bulk density of a powder is the ratio of the mass of an untapped powder sample and its volume, including the contribution of the inter-particulate void volume. Hence, the bulk density depends onthe density of powder particles and the spatial arrangement of particles in the powder bed. The bulk density is expressed in g/ml and Kg/m<sup>3</sup> (1 g/ml = 1000 kg/m<sup>3</sup>). The tapped density is an increased bulk density achieved after mechanically tapping a container containing the powder sample. The tapped density is obtained by mechanically tapping a graduated measuring cylinder containing the powder sample. After observing the initial powder volume or mass, the measuring cylinder is mechanically tapped, and volume or mass readings are taken.
- k) HPTLC/HPLC with markers: fingerprint comparison should be done, and estimation of marker compounds should be carried out, and their levels must be above the minimum prescribed values mentioned in the individual monographs.
- l) Test for heavy metals
- m) Pesticide residue
- n) Microbial contamination
- o) Test for aflatoxins
- p) Shelf life.

# Brain Teasers (for competitive exams)

1. How many Doshas are mentioned in Ayurveda? Three, Vata, Pitta and Kapha

- 2. Panchakarma mode of therapy is applicable for which system of medicine? Avurveda
- 3. **Practioners of Siddha are known as?** Siddhars
- 4. In which state Siddha is more prevalent? Tamilnadu
- 5. Which country did Unani originate from? Greece
- The importance of *Mijaz* for maintaining a healthy body is explained in which system of medicine? Unani
- 7. Practioners of Unani are known as? Hakim
- 8. Powdered drugs, when made in the shape of tablets, used as ayurvedic formulations are known as? Vatika
- 9. Powdered drugs, when made in the shape of pills used as ayurvedic formulation, are known as? Gutika
- 10. What is the starting material for asavas?

Juice extracted from fresh plant part or infusion prepared from dried crude drug

- 11. What is the starting material for arishta? Decoction prepared from dried crude drug
- 12. The outcome obtained when herbal materials are subjected to various extraction methods is known as?
  - Herbal preparations (extract, decoctions, votalite oil etc.)
- 13. Botanical Survey of India is located in which city? Kolkata
- 14. What is added to asavas and arishtas for initiating the fermentation process?

Fried flowers of Woodfordia fruticose (dhataki flowers)

- 15. Which traditional system of medicine predominantly uses metals and minerals? Siddha
- 16. What metals are frequently used in bhasmas? Gold, silver, copper and iron
- 17. Name the microorganisms whose limits are prescribed in ASU pharmacopoeia?

Staphylococcus aureus, Salmonella species, Pseudomonas aeruginosaand Escherichia coli

18. Name the heavy metals whose limits are prescribed in ASU pharmacopoeia?

Arsenic, cadmium, lead and mercury

- 19. At what temperature loss on drying test is performed? 105°C
- 20. What type of ayurvedic preparation is Chyavanaprasa? Avaleha
- 21. Which method of pest control makes use of ionizing radiation?

Genetic method

22. Which of the following leaf constants does not change with leaf size or age and is constants for a particular species?

Stomatal index, Palisade ration, Vein-islet number and Vein-termination number

23. Which ayurvedic formulation represents a form of nanomedicine?

Bhasma

24. 'Law of Similar'or 'Like cures Like' is associated with which system of traditional medicine?

Homeopathy

25. Name the apparatus used for the determination of volatile matter?

Clevenger apparatus

26. Name the method used for the determination of alcohol content?

Distillation and Gas chromatography

- 27. Which carrier gas is used in gas chromatography for the determination of alcohol content? Nitrogen
- 28. The high value of acid-insoluble ash indicates? Presence of excessive sand (silicious matter) as an adulterant in the crude drug
- 29. Who is the founder father of Siddha? Agasthya
- 30. How many spores are present in each mg of lycopodium powder? 94000
- 31. What is the formula of the stomata index? S.I = S / E+S
- 32. Aflatoxins are mostly produced by? Fungus