

# CHAPTER 3

## Adulteration and Evaluation of Drugs

### 3.1. DRUG ADULTERATION

#### 3.1.1. Introduction

Drug degradation by an adulterant (resembling the genuine drug morphologically as well as organoleptically) is termed **adulteration**. However, the adulterant lacks the active constituents of genuine drug. Adulteration disrupts the drug quality.

A drug can be adulterated by **introducing impurities, removing the active constituents** either completely or partially, or by **adding low grade and spoiled drugs** or totally different material which resemble the genuine drug being substituted.

**Adulteration** thus can also be defined as admixture or substitution of genuine drugs with spurious, inferior, defective, useless, or harmful substances.

The corrupt dealers practice adulteration when the supply of drug becomes limited or when the price of drug is high. However, if appropriate conditions of collection, transportation, and identification are not maintained, accidental adulteration can occur, which is termed **undeliberate/unconditional adulteration**.

Adulteration involves:

- 1) **Deterioration:** Impairment in drug quality.
- 2) **Admixture:** Accidental addition of one object into another due to ignorance or carelessness.
- 3) **Sophistication:** Intentional type of adulteration.
- 4) **Substitution:** Addition of an entirely different substance instead of the original drug.
- 5) **Inferiority:** Addition of any substandard drug.
- 6) **Spoilage:** Occurs as a result of microbial attack.

#### 3.1.2. Types of Adulterants

Adulterants or adulteration type can be categorised as follows:

- 1) **Unintentional Adulteration:** The following reasons cause unintentional adulteration:
  - i) **Name Confusion:** Similarity in the names of certain herbs in traditional systems of medicine causes confusion and leads to their interchange or adulteration or substitution; for example, Parpatta in Ayurveda is *Fumaria parviflora* and Parpadagam in Siddha is *Mollugo pentaphylla*. In South India, Siddha medicine is preferred, thus the traders supply *M. pentaphylla* as Parpatta or Parpadagam in these regions; while the north Indian traders supply *F. parviflora*. *M. pentaphylla* and *F. parviflora* can be distinguished as the former has pale yellow to mild brown coloured, thin wiry stems, and small simple leaves, whereas the latter has black to dark brown coloured, and digitate leaves having narrow segments. Other examples of adulterations which occur due to confusing names are *Casuarina equisetifolia* for *Tamarix indica* and *Aerva lanata* for *Bergenia ciliata*.

- ii) **Lack of Knowledge about Authentic Source:** Nagakesar (a famous drug in Ayurveda) is obtained from *Mesua ferrea*. Its available market samples are adulterated as they are found to be mixed with flowers of *Calophyllum inophyllum*. The suppliers of Nagakesar are unacquainted of the fact that *Mesua ferrea* grows widely throughout the Western Ghats and also in parts of the Himalayas. Restrictions in collection of this plant from forests are another factor for adulteration. So, *C. inophyllum* (growing in the plains) is sold by the name of Nagakesar, which can be easily distinguished as the authentic flowers have a two-celled ovary, while the spurious flowers have a single celled ovary.
- iii) **Similarity in Morphology:** An example for unknown authentic plant is *Mucuna pruriens*, which being morphologically similar to papilionaceae seeds, is often adulterated. Popular adulterants are *M. utilis* (white variety) and *M. deeringiana* (bigger variety). *M. cochinchinensis*, *Canavalia virosa*, and *C. ensiformis* are also the adulterated forms of *Mucuna pruriens* available in Indian markets. These species can be distinguished as the authentic seeds are 1cm long, and their surface has a shining black and brown mosaic pattern; while *M. deeringiana* and *M. utilis* are 1.5-2cm long (bigger in size), and dull black and white or buff coloured respectively.
- iv) **Lack of Authentic Plant:** In Europe, *Hypericum perforatum* is cultivated and sold in markets. In India, this species is very less available. The Indo-Nepal species, *H. patulum* is sold in India under the name of *H. perforatum*. Market sample comprising of whole plant with flowers can be identified taxonomically. Anatomical study of T.S. of *H. perforatum* stem shows compressed thin phloem, hollow pith, and no calcium oxalate crystals; whereas the T.S. of *H. patulum* shows a broader phloem, partially hollow pith, and calcium oxalate crystals.
- v) **Similarity in Colour:** It is evident that drug materials gets interchanged or substituted with other plants species; an example is Ratanjot. Few suppliers and Non-Timer Forest Product (NTEP) contractors revealed that earlier the roots of *Ventilago madraspatana* were collected from Western Ghats since it was the only source of Ratanjot. However, this is not the scene today as the current source of Ratanjot is *Arnebia euchroma* var *euchroma*. *V. madraspatana* is substituted with a red dye, *A. euchroma*. It is unnecessary to understand the distinguishing features of these two for identification, since *V. madraspatana* is not available in the markets; thus Ratanjot in the market is the one obtained from *A. euchroma*.
- vi) **Careless Collections:** Several herbal adulterations are caused by mishandling of the herbs by the collectors and suppliers. The Ayurveda, Unani, and Siddha medicine utilise *Parmelia perlata*, which is a household grocery item also. Market samples are admixed with other species (*P. perforate* and *P. cirrhata*), and sometimes with *Usnea* sp. Authentic plants can be distinguished from the spurious ones by their thallus nature.
- vii) **Unknown Reasons:** Vidari is another unknown authentic Ayurvedic plant used widely. It is obtained from *Pueraria tuberosa*, which is substituted by *Ipomoea digitata*. It is to be noted that the market samples of Vidari are not obtained from the above two species; instead an endangered gymnosperm *Cycas circinalis* (originated from Kerala) is sold as Vidari. The authentic plant of Vidari as well as its substitute is abundantly available in India; still the reason for *C. circinalis* becoming a major source is not known. *P. tuberosa* can be distinguished as it has papery flake-like tubers, *I. digitata* has concentric rings of vascular bundles, and their adulterant *C. circinalis* has scars on its leaf and no vessel elements.

- 2) **Intentional Adulteration:** The following reasons cause intentional adulteration:
- i) **Adulteration Using Manufactured Substances:** In this adulteration type, the original substances are adulterated with artificially manufactured materials. The materials are prepared to resemble the appearance and form of various drugs. **For example**, cargo of ergot from Portugal was adulterated using small masses of flour dough moulded into required size and shape, and then dyed using red ink, and then using writing ink; bass-wood is shaped as nutmegs and used for adulteration; compressed chicory is used for adulterating coffee berries; paraffin wax is given yellow colour and used to substitute beeswax; and artificial invert sugar is used for honey.
  - ii) **Substitution Using Inferior Commercial Varieties:** In this adulteration type, the original drugs are substituted with inferior ones having similar morphology, chemical constituents, or therapeutic activity. **For example**, hog gum or hog tragacanth is used as a substitute for tragacanth gum; mangosteen fruits are used for bael fruits; Arabian senna, obovate senna and Provence senna are used for senna; cochineal, African and Japanese ginger are used for adulterating ginger; and *Capsicum annuum* fruits and Japanese chillies are mixed with fruits of *C. minimum*.
  - iii) **Substitution Using Exhausted Drugs:** This substitution is associated with the extraction of the active constituents of the drugs and re-using them. This is suited for the commodities that maintain its shape and appearance after extraction also; the appearance and taste can be reframed by adding colouring or flavouring agents. This technique is employed for volatile oil-containing drugs, e.g., clove, fennel, etc. Saffron and red rose petals are re-coloured with artificial dyes after extraction; balsam of Tolu having no cinnamic acid; and the bitter taste of exhausted gentian is restored with the addition of aloes.
  - iv) **Substitution of Superficially Similar Inferior Natural Substances:** In this adulteration type, the substituents resemble the drug morphologically but do not contain the same active constituents or therapeutic activity. **For example**, ailanthus leaves are used as a substitute for belladonna, senna, etc.; saffron is adulterated with saff flower; peach kernels and apricot kernels are admixed with almonds; clove stalks and mother cloves are added in cloves; peach kernel oil is used for olive oil; hamamelis leaves is substituted with chestnut leaves; and Japan wax is used instead of beeswax.
  - v) **Adulteration Using the Vegetative Part of the Same Plant:** In this adulteration type, the vegetative parts of the same plant are admixed in excess amount with the drug. **For example**, epiphytes like mosses, liverworts, and lichens growing on barks are reported to be present in large amounts with cascara or cinchona; and presence of excessive stems in lobelia, stramonium, hamamelis leaves, etc.
  - vi) **Addition of Toxic Materials:** In this adulteration type, toxic materials are used for adulteration. **For example**, a big stone present in the bale of liquorice root; limestone pieces admixed with asafoetida; opium adulterated with lead shot; amber-coloured glass pieces added to colophony; barium sulphate mixed with silver grain cochineal; and manganese dioxide added into black grain cochineal.
  - vii) **Adulteration of Powders:** Powdered drugs are often adulterated using powdered waste products having a suitable colour and density. **For example**, powdered olive stones are used for powdered drugs (like gentian, liquorice, or pepper); brick powder is mixed with barks; red sanders wood is added to chillies; and dextrin is used for powdered ipecacuanha.

viii) **Addition of Synthetic Principles:** Synthetic pharmaceutical actives having therapeutic value are marketed. For example, citral is added in lemon oil and benzyl benzoate is added to balsam of Peru. The herbal products claiming to improve sexual activity in men were found to be containing sildenafil traces when analysed. Brand names like Actra-Rx, Yilishen, Hua Fo, Vinarol and Vasx, Sleeping Buddha containing estazolam, Diabetes Angel containing glyburide and phenfromin.

## 3.2. DRUG EVALUATION

### 3.2.1. Introduction

A drug is evaluated for identifying it, determining its quality and purity, and detecting the adulteration type. Crude drug evaluation is required for studying:

- 1) Biochemical variation a drug undergoes,
- 2) Deterioration while being treated and during storage, and
- 3) Substitution and adulteration due to carelessness, ignorance, or fraud.

A drug can be evaluated by the following 6 methods:

- 1) Organoleptic evaluation,
- 2) Microscopic evaluation,
- 3) Physical evaluation,
- 4) Chemical evaluation, and
- 5) Biological evaluation.

### 3.2.2. Organoleptic Evaluation

Organoleptic evaluation of a drug involves determining its colour, odour, taste, size, shape, touch, texture, etc. It is a qualitative evaluation type in which the morphological and sensory characters of drugs are studied.

Study of a drug's macroscopy involves its visual appearance to the naked eye. This study depends on the plant part from which the drug is derived. A specific systematic examination is performed for specific morphological group.

The organised drugs of the following morphological groups are classified as:

- 1) **Barks:** The woody stem tissues present on the outer surface of inter-fascicular cambium form the bark drugs, e.g., cinnamon, cinchona, quillaia, ashoka, kurchi bark, etc. Barks are collected as narrow strips by stripping them from the trunk or branches of the desired trees. After collection the barks are dried during which they attain different shapes (**figure 3.1**) by undergoing unequal contractions.

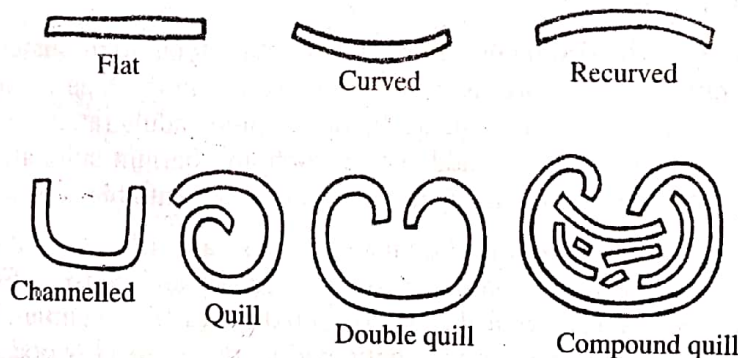
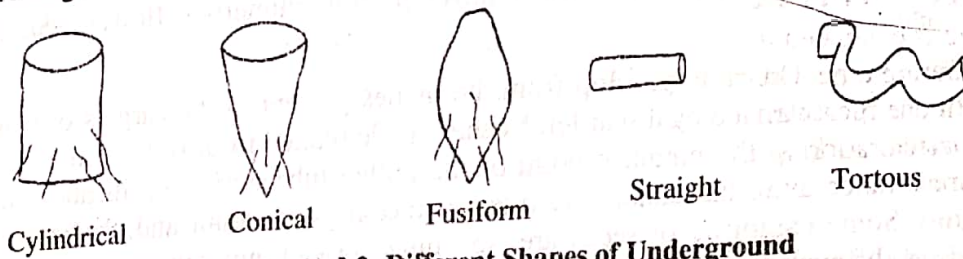


Figure 3.1: Different Shapes of Bark Drugs

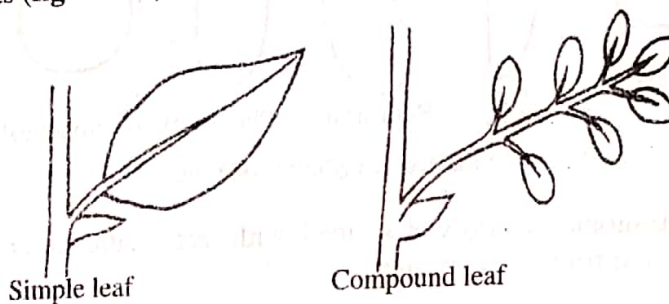
- 2) **Underground Structures:** These structures are of different forms and are used by the plants for storing food. The underground plant parts are mostly swollen, thus are cut into either thin slices or small pieces to ease their drying. The dark coloured cork in some drugs is removed in order to obtain a light coloured product. Some examples of underground plant parts are roots, rhizomes, and stolons.

Roots do not have buds, scale leaves, or leaf scars, but a central core of woody xylem tissue is present (as in podophyllum, liquorice, jatamansi, and rauwolfia). On the other hand, rhizomes and stolons are underground stems in which buds, scale leaves, and leaf scars are present, along with the central pith (as in ginger, turmeric, and dioscorea). Underground roots and rhizomes of various shapes are shown in **figure 3.2**:



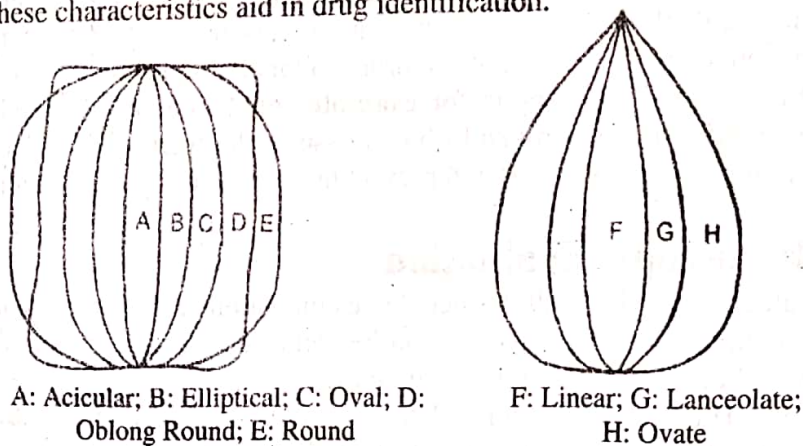
**Figure 3.2: Different Shapes of Underground**

- 3) **Leaves:** These are of different shapes and sizes. A **simple leaf** contains all the photosynthetic organs originating from a node on a stem; while a **compound leaf** has many leaflets (**figure 3.3**).



**Figure 3.3: Types of Leaf**

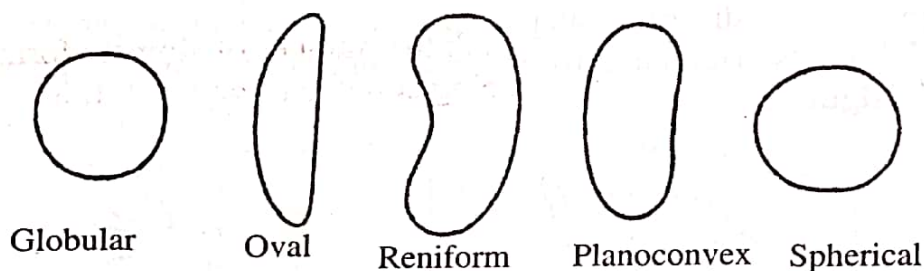
Leaves of various shapes, their margin, base, apex, and venation are given in **figure 3.4**. These characteristics aid in drug identification.



**Figure 3.4: Different Shapes of Leaves**

- 4) **Flowers:** These are the reproductive plant parts found in a variety of forms and also grow on the plant in different manners. The 4 parts of a flower are **calyx**, **corolla**, **androecium**, and **gynoecium**. Some plants consisting of flowering structures further consist of individual flowers, thus forming an **inflorescence**.

- 5) **Fruits:** These globular-, oblong-, or ellipsoidal-shaped plant parts having seeds are often specialised to help in seed dispersal. Fruits mainly develop from the ovary and sometimes from other flower parts. Some **examples** of fruits are cardamom, colocynth, bael, etc. Fruits are of the following **types**:
- i) **Simple Fruits:** These fruits develop from a single carpel or from syncarpous gynoecium. Simple fruits are categorised into **dry** and **fleshy fruits** based on whether the mesocarp is dry or fleshy. Dry fruits are further sub-categorised into **dehiscent** and **indehiscent fruits**.
  - ii) **Aggregate Fruits:** These fruits develop from more than one carpels or apocarpous gynoecium.
  - iii) **Compound Fruits:** These fruits develop from numerous flowers combined together.
- 6) **Seeds:** These plant parts develop from the ovules present in the carpels of flowers. Seeds are characterised by a scar left by the funicle (called **hilum**), by a small hole in the ovule marking the entrance point of the pollen tube during fertilisation (called **micropyl**), or by a vascular tissue ridge connecting the hilum and chalaza (called **raphe**). Some **examples** of seeds are ispaghula, linseed, nux-vomica, psoralea, etc. Seeds of different shapes and types are given in **figure 3.5**:



**Figure 3.5: Different Shapes of Seeds**

- 7) **Herbs:** A herb should be fully described with systematic description of stems, leaves, flowers, and fruits present in it.
- 8) **Sensory Characters:** These include colour, smell, taste, and texture of the drug being evaluated. Drugs containing volatile oil (e.g., cardamom, clove, or cinnamon) have a characteristic **odour** which will not be present if the drugs lose their volatile oil content. The **taste** of drugs may be pungent (e.g., capsicum and ginger), bitter (e.g., gentian and chirata), and sweet (e.g., glycyrrhiza). A drug's **texture** is observed by breaking a piece of it. A drug's **fracture** depends on the nature of tissues and the method of drying it; **for example**, the fracture of glycyrrhiza is hard and fibrous as they have woody and fibrous tissues; the fracture of aconite dried at high temperature is horny as the starch present in it undergoes gelatinisation.