

QUALITY CONTROL OF HERBS



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III- Safety measures:

Drug adulteration

The **adulteration and substitution** of herbal drugs is the burning problem in herbal industry and it has caused a **major effect** in the commercial use of natural products.

Adulteration in market samples is one of the greatest drawbacks in promotion of herbal products. **Adulteration** it is a practice of substituting the original crude drug partially or fully with other substances which is either free from or inferior in therapeutic and chemical properties or addition of low grade or spoiled drugs or entirely different drug similar to that of original drug substituted with an intention of enhancement of profits. **Or adulteration may be defined as mixing or substituting the original drug material with other spurious, inferior, defective, spoiled, useless other parts of same or different plant or harmful substances or drug which do not confirm with the official standards**

Adulteration may takes place by two ways:

- Direct or intentional adulteration
- Indirect or unintentional adulteration

1- Direct or intentional adulteration

Direct or intentional adulteration is done intentionally which usually includes practices in which an herbal drug is substituted partially or fully with other inferior products. Due to morphological resemblance to the authentic herb, many different inferior commercial varieties are used as adulterants. These may or may not have any chemical or therapeutic potential. Substitution by “exhausted” drugs entails adulteration of the plant material with the same plant material devoid of the active constituents. This practice is most common in the case of volatile oil-containing materials, where the dried exhausted material resembles the original drug but is free of the essential oils. Foreign matter such as other parts of the same plant with no active ingredients, sand and stones, manufactured artifacts, and synthetic inferior principles are used as substitutes.

* With artificially manufactured materials

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

* With inferior quality materials

Inferior quality material may or may not have same chemical or therapeutic value as that of original natural drug due to their morphological resemblance to authentic drug, they are marketed as adulterants e.g. *Belladonna* leaves are substituted with *Ailanthus* leaves, **papaya seeds to adulterate *Piper nigrum***, mother cloves and clove stalks are mixed with clove, **beeswax is substituted by Japan wax.**

*** With exhausted material**

Many drugs extracted on large scale for isolation of active principle, volatile oils etc. the exhausted material may be used entirely or in part as a substituent for the genuine drug e.g. umbelliferous fruits and cloves (without volatile oils) are adulterated with exhausted (without volatile oils) original drugs, exhausted jalap and Indian hemp (without resins) are used as adulterant.

*** With foreign matter**

Sometimes synthetic chemicals are used to enhance the natural character e.g. addition of benzyl benzoate to balsam of Peru, citral to citrus oils like oil of lemon and orange oil etc.

* **With harmful / Fictitious substances**

Sometimes the wastes from market are collected and admixed with authentic drugs particularly for liquids or unorganized drugs e.g. pieces of amber colored glass in colophony, limestone in asafetida, lead shot in opium, white oil in coconut oil, cocoa butter with stearin or paraffin.

* **Adulteration of powders**

Besides entire drug powder form frequently found to be adulterated e.g. powder liquorice or gentian admixed with powder olive stones, under the name of cinchona, *C. calisaya* wedd., *C. officinalis* Linn.f., *C. ledgeriana* and *C. succirubra* are available as mixtures.

2- Indirect or unintentional adulteration

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

* Faulty collection

Some of the herbal adulteration is due to the carelessness of herbal collectors and suppliers. The correct part of genuine plant should be collected. Other less valuable part of the genuine plant should not be collected. Moreover collection should be carried out at a proper season and time when the active constituents reach maximum. *Datura strumarium* leaves should be collected during flowering stage and wild cherry bark in autumn etc. collection from other plant by ignorance, due to similarity in the appearance, color, lack of knowledge may lead to adulteration.

* **Imperfect preparation**

Non removal of associated structures eg. stems are collected with leaves, flowers, fruits. Non-removal of undesirable parts or structures e.g. cork should be removed from ginger rhizome. Proper drying conditions should be adhered. Improper drying may lead to unintentional adulteration e.g. if digitalis leaves are dried above 65°C decomposition of glycosides by enzymatic hydrolysis.

* **Incorrect storage**

Deterioration especially during storage, leading to the loss of the active ingredients, production of metabolites with no activity and, in extreme cases, the production of toxic metabolites. **Physical factors such as air (oxygen), humidity, light, and temperature can bring about deterioration directly or indirectly. These factors, alone or in combination, can lead to the development of organisms such as molds, mites, and bacteria. Oxidation of the constituents of a drug can be brought about by oxygen in the air, causing some products, such as essential oils, to resinify or to become rancid.**

Moisture or humidity and elevated temperatures can accelerate enzymatic activities, leading to changes in the physical appearance and decomposition of the herb. For example volatile oils should be protected from light and stored in well closed containers in cool place. Belladonna leaf should be stored in moisture free containers, which may cause enzymatic action lead to decomposition of medicinally active constituents. Mites, nematode worms, insects/moths, and beetles can also destroy herbal drugs during storage.

* **Gross substitution with plant material**

Due to morphological resemblance i.e similarity in appearance, colors etc the genuine crude drugs are substituted with others are very often sold in the market e.g. *Podophyllum peltatum* L. is used as a substitute for *P. hexandrum*, *Belladonna* leaves are substituted with *Ailanthus* leaves, saffron is admixed with dried flowers of *Carthamus tinctorius*, mother cloves and clove stalks are mixed with clove.

* **Substitution with exhausted drugs**

In this type, the same drug is admixed but devoid of any medicinally active constituents as they are already extracted out. This practice is more common in case of volatile oil containing drugs like fennel, clove, coriander, caraway etc. sometime, natural characters of exhausted drugs like color and taste are manipulated by adding other additives and then it is substituted eg. exhausted gentian made bitter with aloes.

Adulteration involves a number of different conditions:

inferiority, spoilage, deterioration, admixture, sophistication and substitution. From the standpoint of present day commerce, inferior, spoiled or deteriorated drug represent the greatest percentage of cases of drug adulteration.

1- Inferiority:

Inferiority refers to any substandard drug or substance. The more restricted definition as applied to **foods, drugs and materials produced** by nature indicates a **naturals substandard condition**.

The dried, ripe seeds of *Strychnos nuxvomica* containing **less than 1.15% of strychnine** would be an inferior or substandard drug. If, on the other hand, this drug had **originally** contained the required **1.15%** of strychnine had been partially abstracted with a solvent, the drug would be considered as adulterated or deteriorated.

Milk, offered for sale at retail, is usually required to contain **not less than 3% of butterfat**. If milk containing **4%** of butterfat has **water** added to it to reduce the butterfat to **3%**, it is considered **adulterated**, but if the same milk has all the butterfat separated from it in the form of cream and then just enough of this cream is restored to the milk to give the required 3% of butterfat, it is **not considered adulterated**.

The standard for **powdered opium** is not **less than 10%** and not **more than 10.5%** of anhydrous **morphine**. Powdered opium containing a higher percentage of alkaloids may be admixed with inferior or exhausted powdered opium to bring the amount of alkaloids in the mixture to the stated percentage. Such an admixture is **not constructed as adulteration**.

The official compendia permit this practice to be followed for powdered extracts and they list the permissible diluents that may be used.

2- Spoilage:

Spoilage refers to a form of substandard drug in which the **quality** or **value** or **usefulness** of the article has been **impaired or destroyed** by the action of **fungi** and **bacteria** as to render the article unfit for human consumption.

Many examples of spoilage are found in the food industry, particularly in fresh fruits, vegetables, meats, fish and seafood.

All drugs which are unfit for human or animal consumption are legally considered as adulterated.

3- Deterioration: فساد

It is applied to any **impairment** of the quality or value of an article by the abstraction or destruction of valuable constituents by **distillation, extraction, aging, moisture, heat, fungi, insects.**

- 1- Whole **cloves** from which part of the volatile oil has been removed by distillation "spent cloves".
- 2- Ground **linseed** from which part of the fixed oil has been expressed "linseed cake".
- 3- **Lard** in which the fats have to some extent decomposed to form fatty acids "rancid lard".
- 4- Powdered **squill** that has hardened through absorption of moisture.
- 5- **Coffee** that has largely lost its caffeine through over roasting.
- 6- **Ergot** that is moldy and **rhubarb** that has become "wormy" are examples of deterioration.

4- Admixture: مزيج

It is the addition of one article to another through **accident, ignorance or carelessness**. If the admixture is done **intentionally to defraud**, it is sophistication. **Buchu** containing a few stem or root with some adhering soil would be classed as admixtures. If, however, an admixture exceeds the established standard, it legally becomes an adulteration.

5- Sophistication:

It is addition of a spurious or inferior material to any article with **intent to defraud**. The addition of **wheat flour** to powdered **ginger**, with enough **capsicum** to restore or enhance the **pungency** and enough **curcuma** to maintain the **color**, would represent a typical example of **sophistication (which is sometimes referred to as true adulteration)**.

6- Substitution:

It is occur when an **entirely different article** is used or sold in place of the one required or requested. A **complete substitution**, even through **intentional** and **fraudulent**, is none of the true article is present. All types of substitution are considered legally as **adulteration**. **Cottonseed oil** sold as **olive oil** and **American saffron** sold as **Spanish saffron** are examples of substitution.

Too often we hear the expression: “**Since herbal products are natural, they are safe**”. Unfortunately, this is **not always true**, due to a many factors including the following:

1- Factual information about many herbs is often **lacking**.

2- **A portion** of the information available about many herbs currently on the market may be **exaggerated** or **misleading**.

This is especially true of some individuals and organizations that are mainly interested in marketing their products **only for profit**, with little regard for the consumer.

3-**The lack of adequate quality control** present in some herbal product companies around the world leads to **variability** in the **quantity and quality** of the products' content. Added to this is the **practice of mislabeling** some herbal supplements, making the use of these products confusing, risky, or simply ineffective.

4- Fortunately, situation is now changing, as some herbal organizations that include competent technical staff are now establishing good manufacturing practices (GMP).

5- Some of the multilevel marketing schemes involving herbal products and other supplements tend to foster self-diagnosis, as well as self-medication, both of which can be potentially dangerous to the consumer.

6- Some herbal products which are new to the Western market, originating in Asia, Africa or South America, for example, have not been adequately tested for purity, safety or efficacy, prior to their introduction into the United States.

7- Some plants have not been adequately studied with respect to their use by special populations, including pregnant or lactating women, small children and the elderly, for example.

8- Interactions between herbal products and conventional medications can sometimes be serious. Much still needs to be learned about this important topic.



What are the risks of using natural herbs during pregnancy?

Although herbs are natural, not all herbs are safe to take during pregnancy. **The FDA urges pregnant women** not to take any herbal products without talking to doctors first and to consult a trained and experienced herbalist if they want to take herbs during their pregnancies.

Herbs may contain substances that can cause: miscarriage, premature birth, uterine contractions, or injury to the fetus.

Herbs to avoid during pregnancy

Rosemary is considered **Likely Safe** when used orally in amounts typically found in foods. (Rosemary has a Generally Recognized as Safe (GRAS) status in the US.) **But** in pregnancy, Rosemary is considered Possibly UnSafe when used orally in medicinal amounts. Rosemary might have **uterine and menstrual flow stimulant effects**. avoid using.

Garlic, Sage, Ginger and Tumeric, All of these herbs could be contraindicated in pregnancy when used in large or concentrated doses, but are considered safe when used in amounts found in food.

Saw Palmetto - when used orally, has hormonal activity

Goldenseal - when used orally, may cross the placenta

Dong Quai - when used orally, due to uterine stimulant and relaxant effects

Blue Cohosh - when used orally; uterine stimulant and can induce labor

Roman Chamomile - when used orally in medicinal amounts

Are there any herbs that are recommended in pregnancy?

Choosing to use herbs during pregnancy is a personal choice, but to ensure the best outcome for you and your baby, you should be well educated on

- 1- the types of herbs,
- 2- parts of the herb (root, leaf, etc...) and
- 3- the way that they could be used (caplet, tonic, tea).

The herbs that are considered safe to use during pregnancy are often **food** or **tonic herbs**. These often will be found in either tablet form, tea, or infusion form.

Herbs used in Pregnancy

The following herbs have been rated **Likely Safe** or **Possibly Safe** for use during pregnancy:

1- Red Raspberry Leaf - Rich in iron, this herb has

- helped tone the uterus,
- increase milk production,
- decrease nausea,
- ease labor pains.

Some studies have even reported that using **red raspberry leaf** during pregnancy can **reduce complications** during birth.

Pregnancy teas that are made from **red raspberry leaf** to help **promote uterine health during pregnancy**.

There is some controversy about whether this should be used throughout pregnancy or just in the second and third trimester, so many health care providers remain cautious and **only** recommend using it **after the first trimester**.

2- Peppermint Leaf - Helpful in relieving nausea/morning sickness and flatulence.

3- Ginger root - Helps relieve nausea and vomiting

4-Slippery Elm Bark - (when the inner bark is used orally in amounts used in foods) Used to help relieve nausea, heartburn, and vaginal irritations

5-Oats & Oat Straw - Rich in calcium and magnesium; helps relieve anxiety, restlessness, and irritated skin

6-Garlic - when used orally in amounts commonly found in foods

7-Capsicum (hot pepper) - when used topically and appropriately.

The following herbs have been rated as having Insufficient Reliable Information Available by the Natural Medicines Database, although many are recommended by homeopathic physicians, herbalists, and midwives who treat pregnant women.

1- Dandelion - Rich in Vitamin A, calcium, and iron; dandelion root and leaf can also help relieve mild edema and nourish the liver.

2-Chamomile (German) - High in calcium and magnesium; also helps with sleeplessness and inflammation of joints

3-Nettles (Stinging Nettles) - High in vitamins A, C, k , calcium, potassium, and iron. Used in many pregnancy teas because it is a great all around pregnancy tonic.

references

Natural Medicines Database <http://www.naturaldatabase.com/>

Women's Health Series: Herbs of Special Interest to Women. *J Am Pharm Assoc* 40(2):234-242, 2000.

Raspberry leaf in pregnancy: its safety and efficacy in labor. *J Midwifery Womens Health*. 2001 Mar-Apr;46(2):51-9. PMID: 11370690

Belew, C Herbs and the childbearing woman: guidelines for Midwives. *J Nurse-Midwifery* 1999;44:231-252