ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Review Article

A COMPREHENSIVE REVIEW ON ADULTERATION OF RAW MATERIALS USED IN ASU DRUG MANUFACTURING

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ABSTRACT

Ayurveda is a system of Indian traditional form of alternative medicine. In 20th and 21th century due to side effects of synthetic drugs, there is an increasing interesting ASU medicine. At present the adulteration of the herbal drugs is the burning problem in ASU herbal industry and it has caused a major problem in the research on commercial natural products. The deforestation and extinction of many species and incorrect identification of many plants has resulted in adulteration and substitution of raw drugs. The future development of analysis of herbs is largely depended upon reliable methodologies for correct identification, standardization and quality assurance of Ayurvedic drugs. In India normally the contamination/adulteration in food/crude drugs is done either for financial gain or due to carelessness and lack in proper hygienic condition of processing, storing, transportation and marketing. Medicinal plants constitute an effective source of traditional and modern medicine. Adulteration is considered as an intentional addition of foreign substances to increase the weight of the product or to decrease its cost. It may be due to- Confusion in vernacular names, Lack of knowledge about authentic plants, Non availability, Similarity in morphology, activity, aroma, Careless collection and other unknown reasons. This article throws a light on adulteration, types, common market adulterants in ASU medicines and prescribed Prevention methods.

KEYWORDS: Adulteration, Adulterants, Crude drugs.

INTRODUCTION

In India, about 80% of the rural population depends on medicinal herbs and indigenous system of medicine for primary health care. Adulterants and substitutes are the common malpractices in herbal raw material trade. 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. A adulteration may also 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. A drug shall be deemed to be adulterated if it consists, in whole or in part, of any filthy, putrid or decomposed substance Due to adulteration, faith in ASU drugs has declined. Adulteration in market samples is one of the greatest drawbacks in promotion of herbal products. Many researchers have contributed in checking adulterations and authenticating those it is invariably found that the Adverse Event Reports are not due to the intended herb, but rather due to the presence of an unintended herb. Medicinal plant dealers have discovered the scientific methods in creating adulteration of such a high quality that without microscopic and chemical analysis, it is very difficult

to trace these adulterations. The major problem in the wider acceptability of Ayurveda and its products is the lack of proper standardization techniques of raw materials used in ASU manufacturing. Most of the raw materials come from plant source. These raw materials often adulterated with same herb of low quality or with similar looking different herbs. In general, Adulteration is considered as profit related intentional malpractice.

Types of Drugs:

Vegetable or animal drugs that consist of natural substances that have undergone only the processes of collection and drying.

Natural substances

1- Plant origin: leaves, flowers, seeds and barks. **Or** vegetable saps, extracts and secretions.
2- Animal origin: whole animals, glands or organs, extracts and secretions.

Definition of Adulteration

1. Adulteration is a practice of substituting original crude drug partially or whole with other similar looking substances but the latter is either free from or inferior in chemical and therapeutic properties.
2. Adulteration is broadly defined as admixture or substitution of original or genuine article/ drug with inferior, defective or otherwise useless or harmful substance Adulteration in simple words is the debasement of an article.

Criteria of GMP Rules and act under schedule –T for ASU Drugs[6]

In according to Indian Drugs & Cosmetics Act and Drug regulatory affairs aspects for ASU Drugs as per the Drugs and Cosmetics Rules, 1945, the Drugs and Cosmetics (10th amendment) Rule, 2003 for mandatory controlling rules of Misbranded, Adulterant or substituted, spurious drugs use in any herbal or polyherbal ASU.

A. Standards of quality

(1) for the purposes of this Chapter, the expression "standard quality" means.

(a) In relation to a drug, that the drug complies with the standard set out in [the Second Schedule].

(b) In relation to a cosmetic, that the cosmetic compiles with such standard as may be prescribed].

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend [the Second Schedule], for the purposes of this Chapter, and thereupon the Second Schedule] shall be deemed to be amended accordingly.

B. Misbranded drugs

For the purposes of this Chapter a drug shall be deemed to be misbranded.

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

C. Adulterated drugs

For the purposes of this Chapter, a drug shall be deemed to be adulterated.

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

D. Spurious drugs

For the purposes of this Chapter, a drug shall be deemed to be spurious.

(a) if it is imported under a name which belongs to another drug; or

(b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Types of Adulteration[2]

Adulteration may takes place by two ways:

A. Direct or intentional adulteration

B. Indirect or unintentional adulteration

A) Direct or intentional adulteration

It is done intentionally which usually includes practices in which an herbal drug is substituted partially or fully with other inferior products. Due to morphological resemblances 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 oil.

B. Indirect or unintentional adulteration

Unintentional 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 that influence the quality of the drug.

Methods of Adulterating the Drugs[3]

Adulteration in simple term is debasement of an article. Drugs are generally adulterated or substituted with substandard, inferior or artificial drugs.

A.1 Adulteration with Substandard Commercial Varieties: Adulterants resemble the original crude drug morphologically, chemically, therapeutically but are substandard in nature and cheaper in cost. This is the most common type of adulteration, example is *Nux-vomica* seed (*strychnos nux-vomica*)are adulterated with *Strychnos nux-blanda* or *Strychnos potatorum* seed.

A.2 Adulteration with Superficially Similar but Inferior Drugs: Inferior drugs may or may not have any chemical or therapeutic value. They resemble only morphologically, so due to its resemblance they are used as adulterants. Common example is adulteration of *cloves* by *mother cloves*. *Saffron* with dried flowers of *Carthamus tinctoria(Safflower).*

A.3 Adulteration with Artificially Manufactured Substance: This type of adulteration is observed in case of drugs which are costly. Examples -Paraffin wax is tinged yellow and adulterated with yellow bees wax, while artificial invert sugar is mixed with honey.

A.4 Replacement by Exhausted Drugs: Admixture of the same drug which is devoid of medicinally active substances as it has been extracted already. Mainly volatile oil containing drugs like *clove, coriander, and fennel* are adulterated by this method. As it is devoid of colour and taste due to extraction, natural colour and taste is manipulated with additives.

A.5 Harmful Adulterants: Some harmful materials (adulterants) are collected from market waste materials and admixed with the drug. It is done for the liquid drugs. Example-limestone in asafoetida, lead shot in opium, white oil in coconut oil.

A.6 Adulteration of Powders: The drugs which are in the form of powders are frequently adulterated. Examples: powdered bark of drugs adulterated with brick powder.

Reasons of Adulteration[4]

a. Confusion in Vernacular names

Same vernacular name of different species and different vernacular names of same species creates confusion and invites adulteration (Table-1). In Ayurveda, Parpatta refers to *Fumaria parviflora*. In Siddha, „Parpadagam" refers to *Mollugo pentaphylla*. Owing to the similarity in the names in traditional systems of medicine, these two herbs are often interchanged or adulterated or substituted (Table-1).

b. Lack of knowledge about authentic source

Nagakesar is one of the important drugs in Ayurveda. The authentic source is *Mesua ferrea*. However, market samples are adulterated with flowers of *Calophyll uminophyllum* because suppliers are unaware of it. Authentic flowers can be easily identified by the presence of two-celled ovary whereas in case of spurious flowers they are single celled.

c. Similarity in morphology

*Mucuna pruriens*is adulterated with other similar Papilionaceae seeds having similarity in morphology. *Mucuna utilis* (sold as white variety) and *Mucuna deeringiana* (sold as bigger variety) are popular adulterants. Apart from this *Mucuna cochinchinensis, Canavalia virosa* and *Canavalia ensiformis* are also sold in Indian markets. Authentic seeds are up to 1 cm in length with shining mosaic pattern of black and brown color on their surface. *Mucuna deeringiana* and *Mucuna utilis* are bigger (1.5-2 cm) in size. While *Mucuna deeringiana* is dull black and *Mucuna utilis* is white or buff colored.

d. Lack of authentic plant

Hypericum perforatum is cultivated and sold in European markets. In India, availability of this species is very limited. However, the abundant Indo-Nepal species *Hypericum patulum*, sold in the name of *Hypericum perforatum*. Market sample is a whole plant with flowers and it is easy to identify them taxonomically. Anatomically, transverse section of *Hypericum perforatum* stem has compressed thin

phloem, hollow pith and absence of calcium oxalate crystals. Whereas *Hypericum patulum* as broader phloem, partially hollow pith and presence of calcium oxalate crystals.

e. Similarity in Color

It is well known that with course of time, drug materials get changed to or substituted with other plant species. "Ratanjot" is a recent day example. In the past, roots of *Ventilago madraspatana* were collected from Western Ghats, as the only source of "Ratanjot". However, that has not been practiced now. It is clearly known that *Arnebia euchroma* var. *euchroma*is the present source. Similarity is in yielding a red dye, *Arnebia euchroma* substitutes *Ventilago madraspatana*. Recently *Ventilago madraspatana* is not found in market. Whatever is available in the market, in the name of Ratanjot is originated from *Arnebia euchroma.*

f. Careless Collections

Some of the herbal adulterations are due to the carelessness of herbal collectors and suppliers. *Parmelia perlata* is used in Ayurveda, Unani and Siddha. It is also used as grocery. Market samples showed it to be admixed with other species (*Parmelia perforata* and *Parmelia cirrhata*). Sometimes, *Usnea* sp. is also mixed with them.

Tables 1: Commonly used adulteration in ASU Drugs [2]

S. No.	Main drug	Adulterants
1	Gum of *Guggul (Commiphora wightii*)	Gum of *Shallaki* (*Boswellia serrata*)
2	Leaf of *Araluka* (*Ailanthus excels*)	Leaf of *Vasaka* (*Adhatoda vesica*)
3	*Arimeda* (*Acacia fernaciana*)	*Aragvadha* (*Cassia fistula*)
4	*Kuchala* seed (*Strychnos nuxvomica*)	*Katak* seed (*Strychnos potatorum*)
5	*Manjistha* (*Rubia cordifolia)* 8.	*Kiratikta* (*Swertia chirayta*)
6	*Pattanga* (*Caesalpinia sappan*)	*Raktachandan* (*Pterocarpus santalinus*)
7	*Kampillaka* (*Mallotus phillipenensis)*	*Isticachurna* (brick powder)
8	*Yastimadhu* (*Glycyrrhiza glabra*)	*Gunjamool* (*Abrus precatorius*)
9	*Pippali* (*Piper longum*)	*Chavya* (*Piper retrofactum*) and *Tambula* (*Piper betle*)
10	*Guduchisatva* (*Tinospora cordifolia)*	Powder or flour of potato, sweet potato.
11	*Erandkarkati* seed (*Caryca papaya*)	*Maricha* (*Piper nigrum*)
12	*Vidanga* (*Embelia ribes*)	Sp.of *Vidanga* (*Myrsine Africana*)
13	*Arjuna* (*Terminalia arjuna*)	*Jarula* (*Lagerstroemia speciosa*)
14	*Ashoka* (*Saraca asoca*)	*Kasthadaru* (*Polyalthialongifolia*)
15	*Talishpatra* (*Abies webbiana*)	*Sthaunyak* (*Taxusbaccata*)
16	*Vidhara* (*Argyreia nervosa*)	Rivea hypo*crateireformis, cocculushirsutus*
17	Misherya Fruit (*Foeniculum vaulgure*)	Mishreya stem Part (*Foeniculum vaulgare*)
18	Honey	Sugar
19	Ghee	Vanaspati Ghee (Dalda), Potato Starch

Prevention of Adulteration in ASU Manufacturing by Drug Evaluation

Methods of Drug Evaluation

The evaluation of a drug is drug done by studying its various properties. The various properties are:

(1) Organoleptic evaluation
(2) Microscopic evaluation
(3) Physical evaluation
(4) Chemical evaluation
(5) Analytical evaluation
(6) Biological evaluation

(1) Organoleptic (Morphological) Evaluation

This refers to drug evaluation by means of organs of sense and includes other sensory organs like color, odour, taste, size, shape and texture.

Examples

1 Brown colour Cinnamon 2 Aromatic odour Umbelliferous fruits 3 Sweet taste Liquorice 4 Fractured surface Cinchona 5 Wavy shape Rauwolifia 6 7 to 8mm width 25 to 60 mm length (size) Senna leaf.

(2) Microscopic or Anatomical Evaluation

This method allows a more detailed examination of a drug and it can be used to identify organized drugs by their known histological characters.

- Before examination through a microscope the material must be suitably prepared.
- This can be done by powdering, cutting thin sections of the drug or preparing a macerate

1. Palisade Ratio 2. Stomatal Number 3. Stomatal Index 4. Stomata 5. Vein-islet Number 6. Vein-

termination Number 7. Trichomes or plant hairs 8. Calcium oxalate crystals.

Quantitative Microscopy

1. Lycopodium spore method 1. Palisade Ratio 2. Stomatal Number 3. Stomatal Index 4. Stomata 5. Vein-islet Number 6. Vein-termination Number 7. Trichomes or plant hairs 8. Calcium oxalate crystals Quantitative Microscopy 1.Lycopodium spore method

(3) Physical Evaluation

Physical constants are extensively applied to the active principles of drugs, such as alkaloids, volatile oils, fixed oils etc. A few of them are

I. Moisture Content
II. Viscosity
III. Melting point
IV. Solubility
V. Optical Rotation
VI. Refractive Index
VII. Ash values
VIII. Extractive values
IX. Volatile oil Content
X. Foreign organic matter
XI. Swelling factor

(4) Chemical Evaluation

Determination of the active constituent in a drug by chemical tests is referred to as chemical evaluation. The following are various methods of chemical evaluation 1. Instrumental methods 2. Chemical tests 3. Individual constituent chemical tests

1. Instrumental methods: They make use of various instruments for evaluation like colorimetry, spectrophotometer etc.

2. Chemical tests: These are like acid value; iodine value and ester value etc are used for the identification of fixed oils and fats.

3. Individual chemical tests: These are the tests which are used for identifying particular drugs. 4. Microchemical tests: These are the tests which are carried on slides. Example: Euginol in clove oil is precipitated as potassium euginate crystals.

(5) Analytical evaluation

Chromatographic techniques

a) TLC-Thin layer chromatography
b) HPTLC-High performance thin layer chromatography
c) HPLC-High performance/pressure liquid chromatography
d) GLC-Gas chromatography
e) CC-column chromatography
f) Gel permeation chromatography
g) Affinity chromatography

(6) Biological evaluation

It is employed when the drug cannot be evaluated satisfactorily by chemical and physical methods¬Biological Evaluation Such an activity is represented in units as International Units (I.U). Dose is termed as International units IU. In this method, the response produced by the test drug on a living system is compared with that of the stranded preparation. When the chemical nature of the drug is not known but is has a biological action. Example: Cardiac glycosides are evaluated by this method on cats, frogs or pigeons. Indication of Biological Evaluation Drugs which have different chemical composition but same biological activity. When the quantity of the drug is small and so it cannot be evaluated chemically. When the chemical nature of the drug is not known but is has a biological action. Indication of Biological Evaluation.

SIGNIFICANCE

1. The method is generally used when standardization is not done satisfactory by chemical or physical methods.
2. When the quantity of the drug /sample are very less than the drugs are evaluated by biological methods.
3. These methods are performed on living animals, isolating living organ and tissue, animal preparation, and micro-organism.

RESULT AND DISCUSSION

In the challenging task of Drug controlling and Drug regularity affaires and pharmacovigilance aspects for used Misbrand, Adulterated or Substituted, Spurious drugs in ASU. ASU manufacturer has used blindly Misbrand, Adulterated or Substituted, Spurious drugs as intentionally or unintentionally in our various types of ASU medicines. It is find out focus point on the aspects of conclusive view or scientific observation that all adulterations are intentional malpractice as stated in many authenticated literatures. It's communicated that herbal drugs are adulterated unintentionally also. Suppliers and cultivators, vendors are illiterate and not aware about their spurious as well as collection of substitute, adulterations supply. Major reasons are name confusion, non-availability and lack of knowledge about authentic plant. Now today's demand herbal drug industries follow, high quality standards using modern techniques and instruments such as Auto-UPLC,HPTLC,GC-MS.,C13 and H1NMR Chromatography and Spectroscopy techniques to maintained and monitored their standard quality and determine sophisticated extracts, separated and fractionated ,isolated investigation drugs research data's concussively investigate purity percentage of active ingredients, and developed extensive

authenticated standard data's of active phytochemical constituents in consumed formulated classical as well as patent, proprietary ASU. The future research and development require of the Pharmacognostical and Physico-chemical analysis, cross check of active phytochemical constituents concentration as the aspects of evolution medicinal potency, purity, safety of the final finished goods products. Provide or issue rule and act, time to time update and modify guideline by Food Drug regularity authority (FDA) and Director Drug Controlling and Regularity authority (DCRA), World Health Organization (WHO) authorities for effectively redressial complaints and control of using adulteration, substitution, and spurious drugs in ASU products. World Health Organization in its publication on quality standards for medicinal plant materials recommends rejecting any batch of raw material, which has more than 5% of any other plant part of the same plant even though they derived from the authentic plant. Based on these standards, adulteration whether, intentional or unintentional, should be rejected. Suppliers and traders should be educated about the authentic sources.

As the resulted conclusion and existing scientific observation, it's also must be need to considering high ethno botanical as well as industrial, commercial values and the endangered status of the species for conservation and sustainable utilization of critically endangered, rare costly species having preserve of high medicinal values of active phytochemical constituents and climatically cultivated, officially protected for harvesting and conservation of high altitude region based growing endangered and rare species of northern region of Himachal Pradesh, Jammu & Kashmir and Uttarakhand state, northern Himalayas region. As the scientific ethno botanical and innovated demand of protect critically endangered, rare and costly medicinal plant species. It should be very important need to using cell culture techniques development, propagation and conservation ,cultivation, motivate forming and growing of these endangered, rare species. Also need to be tested and standardized, developed authenticated reference standard, increase and protect for large scale forming, conservation, cultivation and sustainable utilization in climatically low temperature, high altitude growing endangered medicinal species that's a today needful demand for the aspect of preserve our cultural health care heritage.[1]

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Cite this article as:
Kurele Rajeev kumar, KS Rohit, Pawar Gajana, abdulah, Singh JP, B Srinivasulu. A Comprehensive Review on Adulteration of Raw Materials Used in Asu Drug Manufacturing. International Journal of Ayurveda and Pharma Research. 2018;6(3):66-71.

Conflict of interest: None Declared

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