

## Title of the manuscript: A Review on Adulteration of Raw Materials used in ASU Drug Manufacturing

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### Abstract

Unani System of Medicine is an important segment of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy). In 20<sup>th</sup> and 21<sup>st</sup> century due to side effects of synthetic drugs, there is an increasing interest in ASU (Ayurveda, Siddha and Unani) 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 and analysis of herbs is largely dependent upon reliable methodologies for correct identification, standardization and quality assurance of ASU drugs. In India normally the contamination/adulteration in food/crude drugs is done either for financial gain or due to carelessness and lack of proper hygienic conditions 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 various factors like confusion in vernacular names, lack of knowledge about authentic plants, non availability of genuine drugs, 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:** ASU drugs, adulteration, adulterants, crude drugs, quality assurance.

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### INTRODUCTION

In India, about 80% of the rural population depends on medicinal herbs and indigenous system of medicine for primary health care. Adulteration and substitution are the common malpractices in herbal raw material trade. Substitution 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. 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 [1]. 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 these factors 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 them but 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 [2]. Medicinal plant dealers have discovered the scientific methods of adulteration that without microscopic and chemical analysis, it is very difficult to trace these adulterants and adulterations. The major problem in the wider acceptability of ASU and their 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

The ASU drug mainly consists of vegetable or animal drugs that have undergone only the processes of collection and drying. They are natural substances having:

- Plant origin: leaves, flowers, seeds and barks. Or vegetable saps, extracts and secretions.
- Animal origin: whole animals, glands or organs, extracts and secretions.
- Minerals: Metals, non metals, Clay and Stone

### Definition of Adulteration

- Adulteration is mixing of other matter of an inferior and sometimes harmful quality with food/drink intended to be sold. As a result of adulteration food or drink becomes impure and unfit for human consumption.
- Adulteration is a practice of substituting original crude drug particularly or whole with other similar looking substances but the letter is either free from or inferior in chemical and therapeutic properties [1, 2].

However Unani classical Book e.g. Al-qanoon-fi-Tib officially recognized this issue as “unavailability of some raw materials” and provided some substitute with similar therapeutic activity for the unavailability of some crude drugs [3]. The concept of substitution (*Abdal-e-Advia*) [4] prevailed ages back and in Unani System of Medicine we can find this in books of *Galen*, *Hunain bin Ishaq* and *Ibn Sina* etc [3]. There is need to analyze these concepts with present trend of adulteration and substitution. So that we can differentiate and adopt the proper. Some legal aspects of adulteration under Drugs & Cosmetics act for provision of ASU drugs:

The Drugs and Cosmetics Act, 1940 is an Act of the Parliament of India which regulates the import, manufacture and distribution of drugs in India [1]. The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards [2]. The related Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule [2, 5]. The Drugs & Cosmetics Act-1940, Drugs and Cosmetics Rules-1945 and the Drugs and Cosmetics (10<sup>th</sup> amendment) Rule, 2003 has provided guidelines related to misbranded, adulterated or substituted and spurious drugs used in any herbal or polyherbal ASU as follows:

### Standards of Quality

- 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].
- 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.

### Misbranded Drugs

For the purposes of this Chapter a drug shall be deemed to be misbranded: (a) if it is so colored, 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 labeled 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.

### Adulterated Drugs

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

- if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
- 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
- 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
- if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or
- if it contains any harmful or toxic substance which may render it injurious to health; or
- if any substance has been mixed therewith so as to reduce its quality or strength.

### Spurious Drugs

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

- If it is imported under a name which belongs to another drug; or
- 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
- 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
- If it has been substituted wholly or in part by another drug or substance; or
- If it purports to be the product of a manufacturer of whom it is not truly a product.

**Types of adulteration:** Adulteration may take place by two ways:

- Direct or intentional adulteration
- Indirect or unintentional adulteration

#### 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.

#### Probable way of adulterating the drugs

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

#### 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 (*strychnosnux-vomica*) are adulterated with *Strychnosnux-blanda* or *Strychnos potatorum* seed.

#### 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).

#### 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.

#### 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.

#### 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.

#### Adulteration of Powders

The drugs which are in the form of powders are frequently adulterated. Examples: powdered bark of drugs adulterated with brick powder [4].

#### 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 [2].

#### Logical possible reasons of adulteration:

- 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, 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).
- Lack of knowledge about authentic source: Nagakesar is one of the important drugs in Ayurveda. The authentic source is *Mesua ferrea*. However, markets samples are adulterated with flowers of *Calophyllum inophyllum* 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.
- Similarity in morphology: *Mucuna pruriensis* 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 formis* 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.
- 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.

- 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 euchromavar*. *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*.

- 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 perforate* and *Parmelia cirrhata*). Sometimes, *Usnea* sp. is also mixed with them [6].

**Tables-1: Commonly used adulteration in ASU Drugs [5-7]**

S. No	Example of Drugs	Possible Adulterants
1	Amaltas ( <i>Cassia fistula</i> )	Gandh Babool( <i>Vachelia fernaciana</i> )
2	Arjuna ( <i>Terminalia arjuna</i> )	Jarula/Quince’s crap myrtle ( <i>Adamea glabra</i> Lam.)
3	Ashoka ( <i>Saraca asoca</i> )	Debdaru ( <i>Polyalthia longifolia</i> )
4	Baubadang ( <i>Embelia ribes</i> )	Sp. of Baubadang ( <i>Myrsine Africana</i> )
5	Filfil-e-Siyah ( <i>Piper nigrum</i> )	Tukhm-e-Papita ( <i>Carica papaya</i> )
6	Ghee	Vanaspati Ghee, Potato Starch, Vegitable oil
7	Giloe ( <i>Tinospora cordifolia</i> )	Powder or flour of potato, sweet potato.
8	Gum of Guggul ( <i>Commiphora wightii</i> )	cheaper gum exudate like goandkateera, Gond Kundur ( <i>Boswellia serrata</i> ), Goand Babul etc
9	Honey	Invert Sugar
10	Kamela ( <i>Mallotus philipensis</i> )	Burada-e-Surkh Eint (Red brick powder)
11	Kuchala seed ( <i>Strychnos nuxvomica</i> )	Katak seed ( <i>Strychnos potatorum</i> )
12	Leaf of Araluka ( <i>Ailanthus excels</i> )	Leaf of Vasaka ( <i>Adhatoda vesica</i> )
13	Manjeeth ( <i>Rubiocordifolia</i> ) 8.	Kiratikta ( <i>Swertiachirayta</i> )
14	Saunf (Foeniculum vulgare)	Stem of Tukhm-e-Hulba (Trigonella foenu-graecum)
15	Sanda Surkh ( <i>Pterocarpussantalinus</i> )	Bokmo ( <i>Caesalpiniasappan</i> )
16	Pippali ( <i>Piper longum</i> )	Peepal ( <i>Piper retrofactum</i> )
17	Sat-e-Giloe	Maiz Starch with Bhwana of Neem Water
18	Tabasheer	Calcium Oxalate, Calcium Silicate
19	Vidhara ( <i>Argyrea nervosa</i> )	Farid booti ( <i>Cocculus hirsutus</i> )
20	Yastimadhu ( <i>Glycyrrhizaglabra</i> )	Gunjamool ( <i>Abrus precatorius</i> )
21	Zafran (Saffron)	Identical shape & colures thread with saffron mixed to gain high profit
22	Zarnab ( <i>Taxus baccata</i> )	Talishpatra ( <i>Abies webbiana</i> )

### Measures to prevent adulteration in ASU Drug manufacturing

If Technical staff of manufacturing firm are well aware from the type of adulteration and if they found any technical variation in specification /standards of drug then suspected drug may be confirmed for adulteration. Following methods are suggested for testing of ASU drugs. WHO and Pharmacopoeias on ASU drugs have given various methods and guidelines where the drug is evaluated studying its various properties for drug Identity, strengths, safety, efficacy or its adulteration [6, 7]. They are

- (1) Organoleptic evaluation
- (2) Microscopic evaluation
- (3) Physical evaluation

- (4) Chemical evaluation
- (5) Analytical evaluation
- (6) Biological evaluation

### 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. e.g.: (1) Brown color Cinnamon (2) Aromatic odor, umbelliferous fruits (3) Sweet taste Liquorice (4) Fractured surface Cinchona (5) Wavy shape Rauwolifia (Assarol) 6, 7 to 8mm width 25 to 60 mm length (size) Senna leaf.

- **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. Stomata Number
3. Stomata Index
4. Stomata
5. Vein-islet Number
6. Vein-termination Number
7. Trichomes or plant hairs
8. Calcium oxalate crystals

- **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

- **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

- **Instrumental methods:** They make use of various instruments for evaluation like colorimetry, spectrophotometry etc.
- **Chemical tests:** These are like acid value; iodine value and ester value etc are used for the identification of fixed oils and fats.
- **Individual chemical tests:** These are the tests which are used for identifying particular drugs.
- **Micro chemical tests:** These are the tests which are carried out on slides. Example: Eugenol in clove oil is precipitated as potassium eugenate crystals.
- **Analytical evaluation:**
  - (a) TLC- Thin Layer Chromatography
  - (b) HPTLC- High performance Thin Layer chromatography
  - (c) HPLC- High Performance Liquid Chromatography

- (d) GC- Gas Chromatography
- (e) CC- Column Chromatography
- (f) Gel permeation chromatography
- (g) Affinity chromatography
- (h) AAS- Atomic Absorption Spectroscopy
- (i) FES- Flame Emission Spectroscopy
- (j) Gel Electrophoresis

**Biological evaluation:** The method is generally used when

- The drug cannot be evaluated satisfactorily by chemical or physical methods.
- The quantity of the drug /sample is very less
- These methods are performed on living animals, organs, tissues and micro-organisms.

In this method, the response produced by the test drug on a living system is compared with that of the standard preparation. When the chemical nature of the drug is not known but it has a biological action. For example: Cardiac glycosides are evaluated by this method on cats, frogs or pigeons. Sometimes this method is also used when the chemical nature of the drug is not known but it has a biological action. Indication of Biological activity becomes a parameter to check genuine drug. The microbial load in an ASU drug can also be evaluated by this method as it is also a type of unintentional adulteration.

## RESULT AND DISCUSSION

The drug controlling and Drug regularity affairs in the light of pharmacovigilance aspects is an important and challenging task for ASU System. ASU manufacturer has used blindly misbrand, adulterated or substituted, spurious drugs as intentionally or unintentionally in various types of ASU medicines. Their continuous use by the people causes adverse side effects as they have no medicinal values, as a result instead of showing therapeutic value they have no medicinal value and show various side effects resulting in suffering of the people. It is to be focused here on the basis of scientific observation that all adulterations are intentional malpractice as stated in many authenticated literatures [8-10]. It has been communicated that herbal drugs are adulterated unintentionally also as suppliers, cultivators, collectors and vendors are illiterate and not aware about the spurious drugs or even they do not know about the substitute and thus supply the adulterated products. Major reasons are confusion in names, non-availability and lack of knowledge about authentic plant. Even scientific community and traditional physicians which are attached to or deputed in production sites are unaware of it and use them intentionally or unintentionally. Using only an organoleptic test to identify the raw material in large scale for manufacturing and formulation is a malpractice and has resulted in deterioration of the quality and efficacy as well as decrease in product's shelf life. Today's demand is that the herbal drug industries follow high quality standards using modern

instrumental techniques such as HPTLC, GC-MS, C13 and H1NMR Chromatographic and Spectroscopic techniques respectively to maintain and monitor their quality. Percentage of active ingredients, authenticated standard data's of active phytochemical constituents in formulated classical as well as patent, proprietary ASU drugs should also be investigated. The future research and development requires the Pharmacognostical and Physico-chemical analysis, cross check of active phytochemical constituents and their concentration as the aspects of medicinal potency, purity and safety of the final finished products. Time to time update and modification of the guidelines by Food and Drug Authority (FDA) and Drug Controlling and Regularity authority (DCRA) and World Health Organization (WHO) authorities is necessary for redressal of complaints and control of adulteration, substitution, and spurious drugs in ASU products effectively. Besides this the ASU manufacturing companies should follow cGMP and GLP [5, 11]. 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 taken care of<sup>5</sup>. Suppliers and traders should be educated about the authentic sources and methods of quality control, to improve the quality and reduce the chances of adulteration.

## CONCLUSION

As a result it may be concluded that there is a need to protect critically endangered, rare and costly species to preserve their high medicinal values due to the active phytochemical constituents present in them, especially those growing on high altitude region, endangered and rare species of northern regions of Himalayas, Himachal Pradesh, Jammu & Kashmir and Uttarakhand state. Further to protect critically endangered, rare and costly medicinal plant species innovated techniques like cell culture techniques are required for propagation and conservation. The farming, cultivation and growing of medicinal plants should be motivated so that genuine raw material become available to the manufacturers, as adulteration is mainly related with the profit. Then tested and

authenticated reference standards should be developed. There is also a need to implement the provision of punishment and fine to stop the malpractices of adulteration and preserve our cultural health care heritage.

## REFERENCE

- Poornima B. (2010). Adulteration and Substitution in Herbal drugs a critical analysis. *International Journal of Research in Ayurveda & Pharmacy*, 1(1), 8-12.
- Salman, A., & Mohammad, M. H. (2015). A Concise Review. *World journal of Pharmacy and Pharmaceutical Sciences*, 4(10), 274-283.
- Abdul, L. (2010). *Tauzeehat-e-Kulliyat-e-Adviah*, Ibn Sina Academy of Medieval Medicine & Sciences, Tizara House, Dodhpur, Aligarh, 225-231.
- Abu-Bakr, M., & Bin Zakariyya Al-Razi. (1999). *Kitab Al-Abdal*. English Translation. CCRUM, Ministry of Health and Family Welfare, GOI, New Delhi, 10-16.
- Sagar, P. K. (2014). Adulteration and substitution in endangered, ASU herbal medicinal plants of India, their legal status, scientific screening of active phytochemical constituents. *International Journal of Pharmaceutical Sciences and Research*, 5(9), 4023-4039.
- Neelam, K. N., Dwivedi, K. N., & Ram, B. (2014). Adulteration and substitution of medicinal plant: a burning problem in herbal industry. *International Journal of Pharmaceutical & Biological Archives*, 5(3), 13-18.
- Poonam. (2016). Adulteration of crude drugs burning problem. *International Journal of Applied Research*, 2(2): 99-101.
- Prakash, O., Jyoti, A. K., Kumar, P., & Manna, N. K. (2013). Adulteration and substitution in Indian medicinal plants: an overview. *Journal of medicinal plants studies*, 1(4), 127-132.
- Kuchekar, B. S. (2008). *Pharmaceutical Jurisprudence*. Pragati Books Pvt. Ltd.
- Pillay V. V. (2012). *Modern Medical Toxicology*. Jaypee Brothers Publishers, 30.
- Anonymous. (2006). *The Drug & Cosmetics Act, 1940 & Rule, 1945*. Published by Akalank Kumar Jain, Mori Gate, Delhi.