WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 10, Issue 3, 368-390. Review Article ISSN 2277– 7105

ADVERSE DRUG REACTION AND PHARMACOVILIANCTIONS OF HERBAL MEDICINE IN INDIA

***[1]Shelke Shivani R. (B. Pharm), [2]R. A. Wandre (M. Pharm), [3]L. D. Hingane (PhD Scholar)**

[1]Student at Aditya Pharmacy College.
[2]Professor at Aditya Pharmacy College.
[3]Principal at Aditya Pharmacy College.
[1]Aditya Pharmacy College Beed India.

Article Received on
24 Dec. 2020,
Revised on 14 Jan. 2021,
Accepted on 04 Feb. 2021
DOI: https://doi.org/10.17605/OSF.IO/2ZVAW

***Corresponding Author**
Shelke Shivani R.
(B. Pharm)
Student at Aditya Pharmacy College.

ABSTRACT

Herbal drugs are essential components of traditional medicine in several countries including China and India. India has a well-established system of medicine known as Ayurveda. Ayurveda utilises plants, animal and minerals for the welfare of human beings. India is also a hot-spot of megabiodiversity. There is an urgent need to rationally The government of India has taken several initiatives to develop technology for the effective conservation and efficient utilisation of medicinal plants, to coordinate research and developmental activities as well as to prepare databases. Priority of the Department of Biotechnology, Government of India and the Indian Council of Agricultural Research This review provides information on Indian herbal drug biodiversity, supply and demand, use of herbal drugs in the pharmaceutical industry and quality control methods required for the modern drug industry.

INTRODUCTION

The study or practice of the medicinal and therapeutic use of plants, herbalism. Herbal medicine (HM) is the fulcrum of complementary and alternative medicine, which in recent times is increasingly gaining widespread popularity all over the world and gradually streaming toward integration into the mainstream healthcare systems. Due to the increasing popularity of HM, stakes in the world markets (local and international) are also rapidly increasing and the annual sale is rapidly approaching US $62 billion.

Herbal medicine includes preparations of biologically active natural products that consist largely of herbs or herbal materials, some recipes may contain materials such as fungal and bee products, as well as minerals (kaolin, bentonite), ash, shells, insects and animal parts, and are used for the maintenance of health and management of various diseases. HMs can elicit numerous benefits just as some can cause adverse effects. The knowledge gap on herbal medicines especially as it relates to their benefits and potential drawbacks by the primary healthcare professionals: doctors, pharmacists, nurses and the public. and development, formulation, regulation, analytical techniques, quality control, economic importance, and so on.

Sr.no	Name of source	Biological source	Family	Uses
1.	Turmeric	Curcuma longa	Zingiberaceae	Anti- inflammatory.
2.	Amla	Emblica officinalis	Euphorbiaceae	Inks,hairoil, shampoo rice source of vit c.
3.	Cinnamon	Cinnamomum zeylanicum	Lauraceae	Carminative, mild astringent.
4.	Garlics	Allium sativum	Liliaceae	Anti- hypertensive, hypoglycemic.
5.	Aloe	Aloe barbadensis miller	Liliaceae	Anti- inflammatory, clear acne, improves digestive health.
6.	Ginger	Zingiber officinale	Zingiberaceae	Aromatic, flavor.

Benefits of herbal medicine

Herbal medicines (HM) include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations and are used especially for the prevention and treatment of diseases.In contemporary times, HM remains a major component of the primary healthcare in many rural African and Asian communities. HMs are prepared often from fresh or dried herbs which are commonly made into infusions, decoctions, poultices, powders to be poured into open wounds or incorporated into native beverages, puddings, and so on.

Conventional commercial HMs products are commonly available as pills, capsules, tablets, powders/granules, creams, ointments, and so on. The presentation of HMs in pharmaceutical dosage forms is expected to enhance accurate dosing, esthetics as well as compliance by enticing usageSafety and efficacy is another important factor overriding the use and commercialization of HMs. The quality of herbal products is essentially dependent on the safety and efficacy of the herbal material in relation to the intrinsic chemical components, type of contaminants production processing.

Poly herbal

In contrast to the pharmaceutical drugs which often consist primarily of single chemical entity (pure compounds), HMs are typically made up of numerous compounds usually in the crude, unpurified state. Many finished herbal products are made from folk recipes often containing more than one herbal material as the active component. The polynomial constitution of most HMs may be the reason for many of their benefits. The constituent polynomial ingredients of many HMs as indicated in many folk recipes are often important for the completeness of the product if desired effects are to be produced.

The multi component ingredients may boost benefits by enhancing simultaneously certain important pharmacological activities such as absorption, distribution, metabolism and elimination of bioactive components.

Preparation of medicinal herb

1. Good agricultural/Manufacturing practices and Collection Season of herbs.

A) Quantity control of active compound

The Geographical variations effect on the chemical composition and therapeutic conditions, for example, analysis of the root sample of *Rauwolfia serpentine* collected from different

parts of the country revealed average content of 2.25% of alkaloid content but the yield from the roots obtained from other parts of the country was 1.7%. Also the active chemical constituent's concentrations in the plant are affected by the stage of growth and season at the time of collection.

B) Quality control of active compound

Quality control and the standardization of herbal medicines also involve several other steps like source and quality of raw materials, good agriculturalpractices and good manufacturing practices.

These practices play a pivotal role in guaranteeing the quality and stability of herbal the quality of a plant product is determined by the prevailing conditions during growth, and accepted Good Agricultural Practices (GAP) can control this.

Good agricultural practices include

Seed selection, growth conditions, fertilizers application, harvesting, drying and storage. In fact, GAP procedures are integral part of quality control.

Factors such as the use of fresh plants, age and part of plant collected, period, time and method of collection, temperature of processing, exposure to light, availability of water,

nutrients, drying, packing, transportation of raw material and storage, can greatly affect the quality, and hence the therapeutic value of herbal medicines.

Apart from these criteria, factors such as:

The method of extraction

A. Contamination with microorganisms, heavy metals, and pesticides can alter the quality, safety, and efficacy of herbal drugs.

a) Sometimes, the active principles are destroyed by enzyme processes that continue for long periods from collection to marketing, resulting in a variation of composition. Thus, proper standardization and quality control of both the raw material and the herbal preparations should be conducted.

b) The stage of maturation of the part to be collected is also important.

General introduction to Intraction and Classification

Pharmacokinetic and pharmacodynamic interactions

Pharmacokinetics is currently defined as the study of the time course of drug absorption, distribution, metabolism, and excretion. Clinical pharmacokinetics is the application of pharmacokinetic principles to the safe and effective therapeutic management of drugs in an individual patient. Primary goals of clinical pharmacokinetics include enhancing efficacy and decreasing toxicity of a patient's drug therapy. The development of strong correlations between drug concentrations and their pharmacologic responses has enabled clinicians to apply pharmacokinetic principles to actual patient situations.

Kinetic homogeneity describes the predictable relationship between plasma drug concentration and concentration at the receptor site where a given drug produces its therapeutic effect.

Changes in the plasma drug concentration reflect changes in drug concentrations at the receptor site, as well as in other tissues. As the concentration of drug in plasma increases, the concentration of drug in most tissues will increase proportionally

Examples

Turmeric (Curcumin)

What is turmeric and how does it work?

Is a natural herb that is commonly used as a spice in a wide variety of food. It is a plant that is originally from India. Turmeric is also called curcumin, which is the active ingredient in the spice. When used as a spice in food, turmeric powder is yellow in color. It can also be used as an herbal supplement as follows:

Taken orally, turmeric is used to as a treatment for jaundice, hepatitis, and liver disease, gallbladder complaints, headaches, bronchitis, colds, respiratory infections, fibromyalgia, leprosy, fever, amenorrhea, and cancer. Used topically turmeric is used as an anti-inflammatory treatment for treat skin conditions. It is also used to treat pain in thebody, ringworm, bruising, leech bites, eye infections, inflammation of the oral mucosa, infected wounds, joint pain, and arthritis.

Turmeric is effective in treatment of indigestion (dyspepsia). Studies have shown that turmeric may be effective in lowering the level of cholesterol in the blood, and may be effective at preventing heart disease. Turmeric is also provides an antioxidant benefit, fighting potential damage from free radicals in the body.

Dosages of turmeric should be given as follows

Adult and Pediatric Dosage Forms & Strengths Extract standardized to 95% curcumin

- Indigestion (Dyspepsia)
  - 500 mg taken orally four times a day
  - 200mg/mL (Depo-Turmeric)
- Colorectal Cancer
  - Curcumin extract: 440 to 2200 mg (containing curcumin 36 to 180 mg) once daily for no more than 4 months

Dosage considerations

There are no dosage consideration for turmeric.

- **Effects of drug abuse**

  There are no effects of drug abuse from the use of turmeric.

- **Short-term effects**

  There are no short-term effects from the use of turmeric.

- **Long-term effects**

  There are no long-term effects from the use of turmeric.

Healthy eating: health benefits of turmeric

Fig:- Turmeric.

A relative of ginger, this vivid yellow-orange spice is common in Indian, Southeast Asian, and Middle Eastern cooking. It's also been used as medicine in places like India for centuries to treat issues such as breathing problems. Lately, turmeric has been touted as a super food that can fight cancer, ease depression, and more. Find out what turmeric do for your health.

Depression

Fig:- Depression.

Several compounds in turmeric may support your health. The most well-known of these is curcumin. Scientists are excited about curcumin's potential to ease depression and help antidepressants work better. But so far, research results have been mixed.

Diabetes

Fig:- Diabetes.

Because curcumin can help fight inflammation and keep blood sugar levels steady, it could be a useful tool to prevent or treat type 2 diabetes. One study followed 240 adults with prediabetes and found that taking a curcumin supplement over 9 months lowered their odds of developing diabetes. Research is ongoing, but a lot of the studies so far have been on animals, not people.

Premenstrual syndrome

Fig:- Premenstrual syndrome

A recent study that followed women for three menstrual cycles in a row found that curcumin supplements helped ease PMS symptoms. A study on muscles from guinea pigs and rats suggests that turmeric could bring relief from menstrual cramps, too.

Alzheimer's disease

Fig:- Alzheimer's disease.

People with Alzheimer's have chronic inflammation, and turmeric seems to have natural anti-inflammatory effects. So does turmeric fight Alzheimer's? Sorry, there's no strong scientific evidence yet that taking turmeric is an effective way to prevent the disease.

Arthritis

Fig:- Arthritis.

Turmeric has shown promise for its ability to ease joint pain, stiffness, and inflammation. However, we need more research before turmeric becomes a go-to arthritis treatment. If you

decide to try it for your joint pain, help your body absorb natural curcumin by eating your turmeric along with black pepper.

Cancer

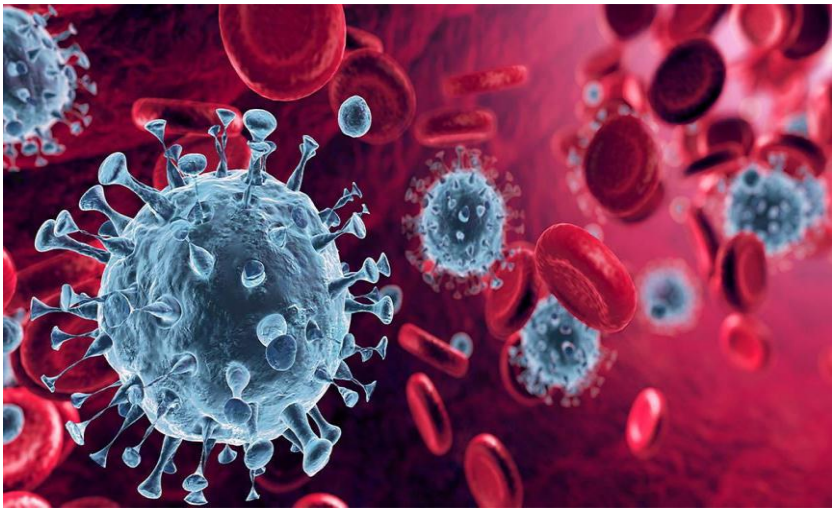

Fig:- Cancer.

In lab and animal studies, turmeric has stopped the growth of tumor cells, helped detoxifying enzymes work better, and more. What these studies can't tell us, though, is what will happen in the human body when a person eats turmeric. Plus, there's a chance that turmeric might interfere with some chemotherapy drugs.

Irritable bowel syndrome

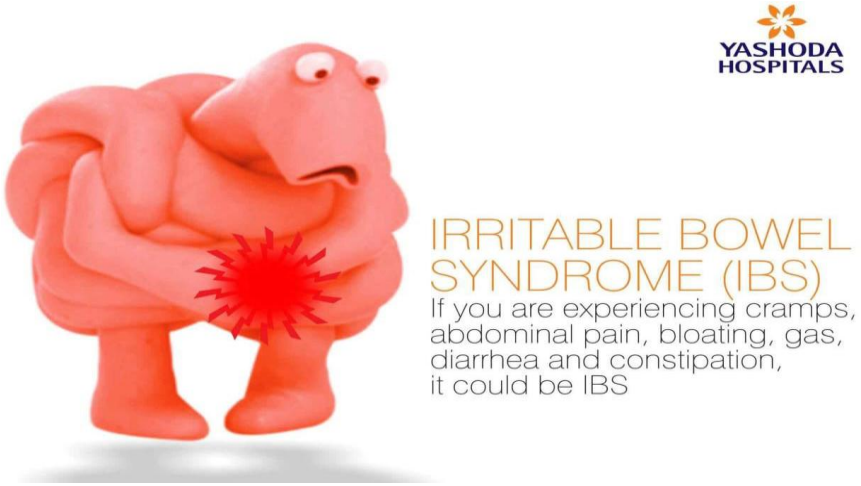

Fig:- Irritable bowel syndrome.

Early research, including a pilot study of 207 adults and another one using rats, has found that turmeric could help improve IBS symptoms such as abdominal pain. Like many things we've

already covered here, more research is needed. Turmeric is also being studied as a treatment for diseases like Crohn's and ulcerative colitis.

Acne

Fig:- Acne.

Some people claim that putting a turmeric mask on their skin or eating turmeric will help fight stubborn pimples -- perhaps because of the spice's reported antibacterial and anti-inflammatory properties. Unfortunately, there's no hard science to back this up.

Amla

Amla berry, known as indian gooseberry or amalaki in Ayurveda, is a fruit that has long revered in india as a nutritive tonic, bool purifier and restorative mucous membrane tonic. One fruit contains as much vitamin c as 20 oranges.Indian gooseberry (phyllantusemblica) fruit grows on a three found wild and cultivated in all parts of india. It is said to possess five of the six taste. Amla berry is one of the three fruit in the ayurvedic preparation triphala, and it forms the base for the rejuvenating formula chyavanprash. The fruits were used as a grneral tonic in the winter, to support healty brain function in the elderly, for constipation, urinary problem and occasional anxiety.

They were used topically and internally to support the integrity of the mucosal membranes of the skin, gums, scalp and gastrointestinal tract.

Indian gooseberry is a tree that grows in India, the Middle East, and some southeast Asian countries. Indian gooseberry has been used in Ayurvedic medicine for thousands of years. Today people still use the fruit of the tree to make medicine.

How does it work

Indian gooseberry seems to work by reducing total cholesterol levels, including the fatty acids called triglycerides, without affecting levels of the "good cholesterol" called high-density lipoprotein (HDL).

Uses & Effectiveness possibly effective for

Abnormal levels of cholesterol or blood fats (dyslipidemia). Research shows that taking a specific brand of Indian gooseberry whole fruit extract (Tri-low, Arjuna Natural Ltd.) for 12 weeks decreases low-density lipoprotein (LDL, or "bad") cholesterol and fats called triglycerides. **Persistent heartburn.** Research in people with persistent heartburn shows that taking Indian gooseberry fruit extract for 4 weeks helps to reduce how often heartburn occurs and how severe it is.

Insufficient Evidence for

- A skin disorder that causes white patches to develop on the skin (vitiligo).
- Aging skin.
- Bloody diarrhea (dysentery).
- Cancer.
- Diabetes.
- Diarrhea

Side Effects & Safety

When taken by mouth: Indian gooseberry is LIKELY SAFE for most people when consumed in amounts found in foods. Indian gooseberry is POSSIBLY SAFE when used as medicine at doses of up to 1,000 mg daily, short-term. Ayurvedic formulations containing Indian gooseberry have been linked to liver damage. But it's not clear if taking Indian gooseberry alone would have this effect.

Special Precautions & Warnings

Bleeding disorders

- Indian gooseberry might increase the risk of bleeding or bruising in some people. If you have a bleeding disorder, use Indian gooseberry with caution. **Diabetes**: Indian gooseberry might decrease blood sugar levels. Your diabetes medications might need to be adjusted by your healthcare provider. **Liver disease**: In theory, taking Indian gooseberry with ginger, Tinosporacordifolia, and Indian frankincense might make liver function worse in people with

liver disease. But it's not known if taking Indian gooseberry alone can have these effects.

Surgery: Indian gooseberry might increase the risk of bleeding during and after surgery. Stop taking Indian gooseberry at least 2 weeks before a scheduled surgery.

By mouth

- **For abnormal levels of cholesterol or blood fats (dyslipidemia)**: A specific product providing 0.5 grams of Indian gooseberry fruit extract has been taken two times daily for 12 weeks.
- **For persistent heartburn**: 1 gram of Indian gooseberry fruit extract has been taken twice daily for 4 weeks.

Cassia cinnamon

- **Other name(S)**
- Bastard Cinnamon, Canela de Cassia, Canela de la China, CanelaMolida, Canelero.

Fig:- Cinnamon.

Cassia cinnamon is a type of cinnamon. It is prepared from the dried inner bark of a certain evergreen tree. It is the most common type of cinnamon sold in NorthAmerica. Cassia cinnamon is most commonly used for diabetes. It is also used for prediabetes, gas (flatulence), obesity and many other conditions, but there is no good scientific evidence to support these uses.

How does it work?

Cassia cinnamon contains hydroxychalcone and similar chemicals. These chemicals seem to improve insulin sensitivity. Cassia cinnamon also contains chemicals that may activate blood proteins that increase blood sugar uptake. These effects may improve blood sugar control in

patients with diabetes. Cassia cinnamon also contains cinnamaldehyde. This chemical might have activity against bacteria and fungi. It also seems to stop the growth of some types of solid tumor cells.

Uses & Effectiveness insufficient evidence for

- Absence of menstrual periods (amenorrhea).
- Cancer.
- Chest pain (angina).
- Common cold.
- Erectile dysfunction (ED).
- High blood pressure.
- Joint pain.
- Long-term kidney disease (chronic kidney disease orCKD).
- Muscle cramps.
- Nausea and vomiting.
- Obesity.
- Symptoms of menopause.

➢ **When taken by mouth:** Cassia cinnamon is LIKELY SAFE when taken by mouth short-term. Doses of 1-6 grams of cassia cinnamon have been safely used daily for up to 6 weeks. The lower doses (1-2 grams daily) have been safely used for slightly longer (up to 3 months). Cassia cinnamon is POSSIBLY UNSAFE when taken by mouth in large amounts for a long period of time. Cassia cinnamon contains a chemical called coumarin. Taking large amounts of coumarin can cause liver injury in some people,especially.

➢ **When applied to the skin:** Cassia cinnamon is POSSIBLY SAFE when applied to the skin in the short-term. It might cause skin irritation and allergic skin reactions.

✓ **Special Precautions & Warnings**

- **Diabetes:** Cassia cinnamon can lower blood sugar levels in people with diabetes. Watch for signs of low blood sugar (hypoglycemia) and monitor your blood sugar carefully, if you have diabetes and use cassia cinnamon in amounts larger than the amounts normally found in food.
- Interactions
- Medications for diabetes (Antidiabetes drugs) interacts with CASSIA CINNAMON

Cassia cinnamon might decrease blood sugar. Diabetes medications are also used to lower blood sugar. Taking cassia cinnamon along with diabetes medications might cause your blood sugar to go too low. Monitor your blood sugar closely. The dose of your diabetes medication might need to be changed.

Medications that can harm the liver (Hepatotoxic drugs) interacts with cassia cinnamon

- Taking very large doses of cassia cinnamon might harm the liver, especially in people with existing liver disease. Taking large amounts of cassia cinnamon along with medications that might also harm the liver might increase the risk of liver damage. Do not take large amounts of cassia cinnamon if you are taking a medication that can harm the iver.

Some medications that can harm the liver include acetaminophen (Tylenol and others), amiodarone (Cordarone), carbamazepine (Tegretol), isoniazid (INH), methotrexate (Rheumatrex), methyldopa (Aldomet), fluconazole (Diflucan), itraconazole (Sporanox), erythromycin (Erythrocin, Ilosone, others), phenytoin (Dilantin), lovastatin (Mevacor), pravastatin (Pravachol), simvastatin (Zocor), and many others.

Dosing

The following doses have been studied in scientific research: Adults

- By mouth for diabetes: 120 mg to 6 grams taken daily for up to 4 months for type 2 diabetes.

Garlic

- **Other name(S):** Aged Garlic Extract, Ail, Ail Blanc, Ail Cultive, Ail Rocambole, Ajo, Alho, Allii Sativi Bulbus, Allium.

Fig:-Garlic.

- Garlic is an herb that is grown around the world. It is related to onion, leeks, and chives. It is thought that garlic is native to Siberia, but spread to other parts of. Garlic is most commonly used for conditions related to the heart and blood system. These conditions include high blood pressurehigh levels of cholesterolor other fats lipids in the blood hyper lipidemia, and hardening of the arteriesatherosclerosis. In foods and beverages, fresh garlic, garlic

- **Coronavirus disease 2019 (COVID-19)**

While garlic may have some benefit for preventing the common cold there is no good evidence to support using it for COVID-19. Follow healthy lifestyle choices and proven prevention methods instead.

How does it work?

Garlic produces a chemical called allicin. This is what seems to make garlic work for certain conditions. Allicin also makes garlic smell. Some products are made "odorless" by aging the garlic, but this process can also make the garlic less effective. It's a good idea to look for supplements that are coated (enteric coating) so they will dissolve in the intestine and not in the stomach.

Uses & Effectiveness

- **Possibly Effective for**
- **Diabetes.** Garlic seems to modestly reduce pre-meal blood sugar levels in people with or without diabetes. It seems to work best in people with diabetes, especially if it is taken for at

least 3 months. It's unclear if garlic reduces post- meal blood sugar levels or HbA1c levels.

❖ **High blood pressure.** Taking garlic by mouth seems to reduce systolic blood pressure (the top number) by about 7-9 mmHg and diastolic blood pressure (the bottom number) by about 4-6 mmHg in people with high blood pressure.

Insufficient evidence for

- Corns. Early research suggests that applying certain garlic extracts to corns on the feet twice daily might improve corns.
- Cystic fibrosis. Some early research suggests that taking garlic oil macerate does not improve lung function, symptoms, or the need for antibiotics in children with cystic fibrosis.
- Cancer of the esophagus. It is unclear if eating more garlic can reduce the risk for cancer of the esophagus. Some research suggests that it might, but other research disagrees.
- Muscle soreness caused by exercise. Early evidence suggests that taking allicin, a chemical in garlic, daily for 14 days can reduce muscle soreness after exercise in athletes.
- Inherited tendency towards high cholesterol (familial hypercholesterolemia). In children with high levels of low-density lipoprotein (LDL or "bad") cholesterol, taking garlic powder extract by mouth does not seem to improve cholesterol levels or blood pressure.
- Lead poisoning. Some early research suggests that taking garlic powder might help to reduce levels of lead in the blood. But it doesn't seem to work as well as D-penicillamine.
- When taken by mouth: Garlic is LIKELY SAFE for most people when taken by mouth appropriately. Garlic has been used safely in research for up to 7 years. When taken by mouth, garlic can cause bad breath, a burning sensation in the mouth or stomach, heartburn, gas, nausea, vomiting, body odor, and diarrhea. These side effects are often worse with raw garlic. Garlic may also increase the risk of bleeding. There have been reports of bleeding after surgery in people who have taken garlic. Asthma has been reported in people working with garlic, and other allergic reactions are possible.

When applied to the skin: Garlic products are Possibly safe when applied to the skin. Gels, pastes, and mouthwashes containing garlic have been used for up to 3 months. However, when applied to the skin, garlic might cause skin damage that is similar to a burn.

- **Interactions**
- **Isoniazid (Nydrazid, INH) interacts with Garlic**

Garlic might reduce how much isoniazid (Nydrazid, INH) the body absorbs. This might

decrease how well isoniazid (Nydrazid, INH) works. Don't take garlic if you take isoniazid (Nydrazid, INH).

Saquinavir (Fortovase, Invirase) interacts with garlic

The body breaks down saquinavir (Fortovase, Invirase) to get rid of it. Garlic might increase how quickly the body breaks down saquinavir. Taking garlic along with saquinavir (Fortovase, Invirase) might decrease the effectiveness of saquinavir (Fortovase, Invirase).

Moderate Interaction

- **Birth control pills (Contraceptive drugs) interacts with GARLIC**

Some birth control pills contain estrogen. The body breaks down the estrogen in birth control pills to get rid of it. Garlic might increase the breakdown of estrogen. Taking garlic along with birth control pills might decrease the effectiveness of birth control pills. If you take birth control pills along with garlic, use an additional form of birthcontrol such as a condom.

Some birth control pills include ethinyl estradiol and levonorgestrel (Triphasil), ethinyl estradiol and norethindrone.

- **Cyclosporine (Neoral, Sandimmune) interacts with garlic**

The body breaks down cyclosporine (Neoral, Sandimmune) to get rid of it. Garlic might increase how quickly the body breaks down cyclosporine (Neoral, Sandimmune). Taking garlic along with cyclosporine (Neoral, Sandimmune) might decrease the effectiveness of cyclosporine (Neoral, Sandimmune). Do not take garlic if you are taking cyclosporine (Neoral, Sandimmune).

- **Warfarin (Coumadin) interacts with GARLIC**

Warfarin (Coumadin) is used to slow blood clotting. Garlic might increase the effectiveness of warfarin (Coumadin). Taking garlic along with warfarin (Coumadin) might increase the chances of bruising and bleeding. Be sure to have your blood checked regularly. The dose of your warfarin (Coumadin) might need to be changed.

- **Dosing**

By mouth

Extract, taken at a dose of four tablets daily for one year, has been used.

- **For diabetes**

Garlic powder 600-1500 mg daily has been used for at least 12 weeks. A 300 mg garlic tablet

(Allicor, INAT-Farma) taken two to three times daily with medications called metformin or sulfonylurea, for 4 to 24 weeks has been used.

- **For high levels of cholesterol or other fats (lipids) in the blood (hyperlipidemia)**:

A dose of 1000-7200 mg of a specific aged garlic extract (Kyolic, Wakanuga) has been used daily in divided doses for 4-6 months. A dose of 600-900 mg of a specific garlic powder tablet (Kwai, Lichtwer Pharma) has been taken daily in two or more divided doses for 6-16 weeks. Also, 300 mg of another specific garlic powder product (Garlex, Bosch Pharmaceuticals) taken twice daily for 12 weeks has been used. Also, 1,200 mg of garlic powder plus 3 grams of fish oil daily for 4 weeks, or 500 mg of garlic oil plus 600 mg of fish oil daily for 60 days, has been used.

Aloe

Fig:- Aloe.

- The botanical name of aloe is Aloe barbadensis miller. The biological source of aloe is dried latex of leaves of it. It is also known as curacao aloe, cape aloe and socotrine aloe. It belongs to the liliaceae family.
- The APG IV system (2016) places the genus in the family Asphodelaceae, subfamily Asphodeloideae. Within the subfamily it may be placed in the tribe Aloeae.

In the past, it has been assigned to the family Aloaceae (now included in the Asphodeloidae) or to a broadly circumscribed family Liliaceae (the lily family). The plant Agave americana, which is sometimes called "American aloe", belongs to the Asparagaceae, a different family.

- The genus is native to tropical and southern Africa, Madagascar, Jordan, the Arabian Peninsula, and various islands in the Indian Ocean (Mauritius, Réunion,

Comoros, etc.). A few species have also become naturalized in other regions (Mediterranean, India, Australia, North and South America, Hawaiian Islands, etc.)

Uses

- Aloe species are frequently cultivated as ornamental plants both in gardens and in pots. Many aloe species are highly decorative and are valued by collectors of succulents. Aloe vera is used both internally and externally on humans as folk or alternative medicine. The Aloe species is known for its medicinal and cosmetic properties. Around 75% of Aloe species are used locally for medicinal uses. The plants can also be made into types of special soaps or used in other skin care products (see natural skin care).
- Numerous cultivars with mixed or uncertain parentage are grown. Of these, Aloe 'Lizard Lips' has gained the Royal Horticultural Society's Award of Garden Merit.
- Aloe variegata has been planted on graves in the superstitious belief that this ensures eternal life.

Pharmacovigilance

Pharmacovigilance also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.

The etymological roots for the word "pharmacovigilance" are: pharmakon (Greek for drug) and vigilare (Latin for to keep watch). As such, pharmacovigilance heavily focuses on adverse drug reaction or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation). Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction.

Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.

- Adverse drug reaction is a side effect (non intended reaction to the drug) occurring with a drug where a positive (direct) causal relationship between the event and the drug is thought, or has been proven, to exist.
- Adverse event (AE) is a side effect occurring with a drug. By definition, the causal relationship between the AE and the drug is unknown.
- Benefits are commonly expressed as the proven therapeutic good of a product but should also include the patient's subjective assessment of its effects.
- Causal relationship is said to exist when a drug is thought to have caused or contributed to the occurrence of an adverse drug reaction.
- Risk is the probability of harm being caused, usually expressed as a percent or ratio of the treated population.
- Risk factor is an attribute of a patient that may predispose, or increase the risk, of that patient developing an event that may or may not be drug-related. For instance, obesity is considered a risk factor for a number of different diseases and, potentially, ADRs. Others would be high blood pressure, diabetes, possessing a specific mutated gene, for example, mutations in the BRCA1 and BRCA2 genes increase propensity to develop breast cancer.

Clinical trial reporting

Also known as AE (adverse event) or SAE (serious AE) reporting from clinical trials, safety information from clinical studies is used to establish a drug's safety profile in humans and is a key component that drug regulatory authorities consider in the decision-making as to whether to grant or deny market authorization (market approval) for a drug. AE reporting occurs when study patients (subjects, participants) experience any kind of "untoward" event during the conducting of clinical trials. Non-serious adverse events are typically captured separately at a level lower than pharmacovigilance.

Risk management

- Increasing, generally, the availability of environmental data on medicinal products;
- Tracking emerging data on environmental exposure, effects and risks after product launch;
- Using Environmental Risk Management Plans (ERMPs) to manage risk throughout a drug's life cycle;
- Following risk identification, promoting further research and environmental monitoring, and

- In general, promoting a global perspective on EPV issues.

CONCLUSION

Even in the light of increased sophistication of modern healthcare as enriched by science and technology, the use of herbal medicine will continue to thrive in both poor and rich societies for many and probably different reasons. It is important for stakeholders: governments, farmers, scientists, healthcare providers (physicians, pharmacists and nurses) and biotechnical engineers to give enough attention to herbal medicines and its challenges in a deliberate effort to create for it appropriate niche that will ensure that it develops alongside with conventional medicine. The application of science and technology especially in area of information resources, conservation and cultivation, production, analytical techniques and quality control, clinical trials and regulation should be promoted.

These efforts will boost benefits, confidence and safety in the use of HMs and its possible induction into the mainstream healthcare. Though, there are several literatures on HM, this book nevertheless has stooped to collate in a simple, unambiguous and readable manner a wide and indebt information that will be useful to all who have a stake in HM: scientist, healthcare professionals, engineers and the general public.

Herbal-based traditional medicine has become popular in developed countries in recent years and its use is likely to be increased in the coming years. This system has advantages over the allopathic system, being prophylactic. This increased utilisation of herbs has direct repercussions on the collection of raw materials and consequently requires sustainable utilisation of these plants along with methods of conservation, and studies of reproductive biology, phytochemistry and pharmacological validation. Standardisation of chemical fingerprinting (TLC, HPLC) towards quality control is another major requirement in developing countries. Although herbal drugs have been used in the Indian system of medicine for last several hundred years, and they are prepared by a procedure prescribed in Ayurvedic text, their toxicity/safety must be evaluated on modern models for universal acceptance. Most of the herbal industries.

REFERENCES

1. Bent S. Herbal medicine in the United States: Review of efficacy, safety, and regulation. Journal of General Internal Medicine, 2008; 23(6): 854-859.
2. Kessler RC, Davis RB, Foster DF, Van Rompay MI, Walters EE, Wilkey SA, Kaptchuk

TJ, Eisenberg DM. Long-term trends in the use of complementary and alternative medical therapies in the United States. Annals of Internal Medicine, 2001; 135(4): 262-268.

3. Bodeker G, Burford G. Traditional, complementary and alternative medicine: Policy and public health perspectives. Bulletin of the World Health Organization, 2007; 86(1): 77-78.
4. Fasinu PS, Bouic PJ, Rosenkranz B. An overview of the evidence and mechanisms of herb– drug interactions. Frontiers in Pharmacology, 2012; 3: 69. DOI: 10.3389/fphar.2012.00069
5. Bensoussan A, Myers SP, Wu S, O'Connor K. Naturopathic and western herbal medicine practice in Australia: A workforce survey. Complementary Therapies in Medicine, 2004; 12(1): 17-27.
6. Urizar NL, Liverman AB, Dodds DT, Silva FV, Ordentlich P, Yan Y, Gonzalez FZ, Heyman RA, Mangelsdorf DF, Moore DD Science, 2002; 269: 1703.
7. Cui J, Huang L, Zhao A, Lew JL, Yu J, Sahoo S, Meinke PT, Royo I, Pelaz F, Wright ST J BiolChem, 2003; 278: 10214.
8. Wang X, Greilberger J, Ledinski G, Kager G, Paigen B, Jurgens G Atherosclerosis, 2004; 172: 239.
9. Dev S Environ Health Persp, 1999; 107: 783.
10. Dahanukar SA, Kulkarni RA, Rege NN 9 Indian J Pharmacol, 2000; 32: 81.
11. Patwardhan B (2000) Indian Drugs 37:213 Handa SS, Kaul MK Supplement to Cultivation and Utilization of Medicinal Plants. CSIR, RRL, Jammu-Tawi, 1996; 64.
12. Wang Z-G, Ren J Trend PharmacolSci Rawat RBS (2002) Medicinal plants sector in India with reference to traditional knowledge and IPR issues (online). Paper presented at the International Seminar for the, 2002; 23: 347.
13. Fabbri LM, Saetta M, Picotti G, and Mapp CE. Late asthmatic reactions, airway inflammation and chronic asthma in toluene-diisocyanate-sensitized subjects. Respiration, 1991; 58(1): 18–21.
14. Stevens RJ, Douglas KMJ, Saratzis AN, and Kitas GD. Inflammation and atherosclerosis in rheumatoid arthritis. Expert Reviews in Molecular Medicine, 2005; 7(7): 1–24.
15. Dhar ML, Dhar MM, Dhawan BN, Mehrotra BN, Ray C. Screening of Indian plants for biological activity: I. Indian J Exp Biol, 1968; 6: 232–247.