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STANDARDIZATION OF HERBAL DRUGS: NEED OF THE DAY FOR GLOBAL COMPETITION

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ABSTRACT

Complementary and Alternative Medicine (CAM)/ Traditional Medicine (TM) have grown globally. The world market for botanical medicines including drug products and raw materials has been estimated to have an annual growth rate between 5-15 percent. Total botanical global market is estimated as US$ 62 billion and is expected to grow to the tune of US$ 5 trillion by 2050. Since time immemorial, plants and natural products have provided solutions to many difficult questions the human race has faced. Nature has provided prescriptions for various diseases.

Chemo profiling using HPLC, HPTLC and GC has wide applicability in quality control of herbal medicine. Multi-component botanical formulations can be standardized by using these sophisticated techniques. Spectroscopic analysis has also been suggested by certain pharmacopoeias for analysis of botanicals. Scientifically validated and technologically standardized botanical medicines will play an important role in future advancement in healthcare. Development of parameters for standardization and quality control of botanicals is a challenging task. Various regulatory authorities, research organizations and botanical drug manufactures have contributed in developing guiding principles addressing issues related to their quality, safety and efficacy.

Keywords: *Complimentary medicines; Standardization; Quality control; Regulatory requirements; Marker compound; Herboprint; Herbal Drugs used Clinically*

INTRODUCTION

Practice of Complementary and Alternative Medicine (CAM)/ Traditional Medicine (TM) has grown globally. Almost half of the population of many industrialized countries regularly use some form of CAM[1]. In India, the history of health care goes back to 5000 BCE, when health care needs and diseases were noted in ancient literatures like 'Rig-Veda' and 'Atharva-Veda'[2]. Later, the texts like 'Charak Samhita' and 'Sushruta Samhita' were documented in about 1000 years BCE, where use of plants and polyherbal formulations was highlighted for health care. Evolution of Ayurveda and plant-based remedies for health care through day-to-day life experiences is a part of cultural heritage of India[2]. Use of indigenous drugs from plant origin forms a major part of such therapies. The world market for botanical medicines including drug products and raw materials has been estimated to have an annual growth rate between 5-15 percent. Total botanical global market is estimated as US$ 62 billion and is expected to grow to the tune of US$ 5 trillion by 2050[3]. In the USA alone, use of botanicals has increased by 380 percent between 1990 and 1997. In 2001, USA spent US$ 17.8 billion on dietary supplements, of which US$ 4.2 billion for botanical remedies[4]. Within the European Union, botanical medicines represent an important share of US$ 7 billion[5].

In India, the value of medicinal plant related trade is about US$ 10 billion per annum and this industry is growing at the rate of 7-15 per cent annually with exports of US$ 1.1 billion per year[6]. Although, Ayurveda, the Indian system of medicine is one of the most ancient, (Fig 1) yet living traditions, faces a typical western bias[7]. Global trend leading to increased demand of medicinal plants for pharmaceuticals, phytochemicals, nutraceuticals, cosmetics and other products is an opportunity sector for Indian trade and commerce. Wide spread and growing use of botanicals has created public health challenges globally in terms of quality, safety and efficacy[8,9].

Since time immemorial plants and natural products have provided solutions to many difficult questions the human race has faced. Nature has provided prescriptions for various diseases. The treatments

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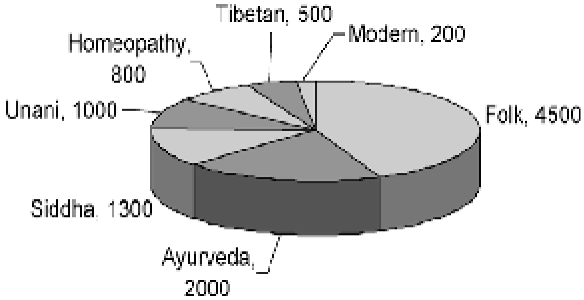

Fig. 1: *Number of plants used in different systems of medicines in India*

developed hundreds of generations ago, passed on to the present generation known as traditional medicine (TRM). The human race is greatly indebted to the countless anonymous authors who compiled treatise of the Chinese, Ayurvedic and other systems of traditional medicine, as well as the untold scribes and knowledgeable shamans who passed on their locally valued information in a more personal manner[10].

According to a WHO estimate, as high as 80% of the population in developing countries depend on traditional and herbal medicines as their primary source of health care[1]. It is likely that the profound knowledge of herbal remedies in traditional cultures developed through trial and error over many centuries, and that the most important cures were carefully passed on verbally from one generation to another[11]. Over the past decade, there has been an increased global interest in traditional systems of medicine and herbal medicinal products. In part, this surge emerged due to the rare or prohibitive access to modern medicines in developing countries as well as the acceptance of herbal medicines by large population in affluent nations. In developed countries, non conventional medical modalities, also designated as CAM, are often used concomitantly with conventional medicine. The popularity of CAM in the USA is reflected in a survey, which showed that its use increased from 34% in 1990 to 42% in 1997 among adults. The same survey showed that American consumers spent $27 billion on alternative treatments and an estimated $5.1 billion on herbal medicines in 1997[12]. In the same year, the global market for herbal products was estimated to be approximately $20 billion[13, 14].

DRUG DISCOVERY FROM NATURAL SOURCE

A recent analysis of natural products as a source of new drugs over the period 1981–2002 shows that 67% of the 877 small molecules, new chemical entities (NCE_S) are formally synthetic, but 16.4% correspond to synthetic molecules containing a pharmacophore derived directly from natural products. Furthermore, 12% are actually modeled on a natural product inhibitor of the molecular target of interest, or mimic the endogenous substrate of the active site, such as ATP. Thus only 39% of the 877 NCE_S can be classified as truly synthetic in origin. In the area of the anti-infectives (anti-bacterial, anti-fungal, parasitic, and viral), close to 70% are naturally derived or inspired, while in the cancer treatment area 67% are in this category[15]. Various important herbal drugs for therapeutic activity like anti-cancer, abortifacients, antidiarrhoeal, drugs used in GIT, antihypertensive, antileprotics, diuretics, antidiabetics etc., included in ayurvedic texts, manufactured in India, are used clinically now a days by ayurvedic practitioner[16] (Table 1).

Table 1: *Herbal Drugs used Clinically in India*[16]

Activity for drugs used Clinically	Plant Botanical Name (Hindi Name)	Part Used	Chemical Constituents	Dosage form with Manufacturer	Other activity Reported
Abortifacients	Sapindus trifoliatus (Ritha)	Fruit	Saponins	Menosan (Himalaya Drug Company), Amycordial (Aimil Pharmaceuticals)	Antifertility, purgative, antileptic
	Daucus carota (Gajar)	Roots, seeds and fruits	Carbohydrates, carotene, hydrocarotene, pectin, mailc acid, bisabolene, daucinoxide, terpenolene	Requrin (Himalaya Herbals), Mensonorm capsule (Chirayu Company), Sage carrot facial oil (Sage Hebals), Manoll (Charak Pharma Pvt. Ltd.)	For Piles, carminative
	Ferula asafetida (Heeng)	Resinous exudates of the root	Voatile oil, resins, gum	Madhudoshantak (Jamuna Pharma)	Digestive problems
Spinal chord stimulant	Strychnos nuxvomica (Kajra)	Bark, leaves, seeds	Alkaloids-strychnine, brucine; glycosides	Pain kill oil (Jamuna Pharma), Neo (Charak)	
Tranquillizers	Celastrus paniculatus (Malakanguni)	Seeds, leaves and oil	Tannin, alkaloids, glucoside	One of the ingredients of preparation known as Abana, Geriforte, Himcolin, Mentat (Himalaya Herbals), J.P. Massaj oil, J.P. Pain kill oil (Jamuna pharma), Syrup Learnol Plus (Dalmia industries, Delhi)	Memory improving, digestive
Antidiarrhoeal Drugs	Aegle marmelos (Bel)	Fruits, leaves, rind of the ripe fruit and flower	Tannin, marmalosin, essential oil, alkaloids	One of the ingredients of preparation known as Diakof a cough syrup, Lukol for leucorrhoea; Chyawanprash (Himalaya Drug Company), Isabgol and Bilwadi churna (Baidyanath Company), Madhushantak (Jamuna Pharama), Sage bilwa churn (Sage Herbals)	Anidiabetic, coolant
Anthelminitics	Allium sativum (Lahasun)	Bulb, oil, leaves and seeds	Starch, mucilage, scordinins, volatile oil, allylpropyl disulphide, diallyl disulphide, allicin, Vit.A, B, C	Lasuna (Himalaya Drug Company), Lashunnadi bati (Baidyanath Company)	Antihyperlipidemic, aphrodisiac, antirheumatic
	Chenopodium album (Bathua)	Leaves, seed and whole plant	Essential oil, alkaloids like trigonelline, chenopodine; Steroids like hydroxyecdysone and polypodine B		Digestive, anthelmintic, laxative
	Butea monosperma (Dhak)	Bark, leaves, seeds and gum	Kinotannic and gallic acid, mucilage, resin	Lukol (Himalaya Herbals) for leucorrhoea; J.P. Nikhar oil (Jamuna Pharma, Bhopal) as hair oil	Aphrodisiac, anthelmintic, laxative
	Azadirachta indica (Neem)	Root, Bark, Fruits Seeds, Flower leaves , gum and oil	Bitter principal margosine, catechin, gum, tannin, nimbin, quercetin	Gludibit (Lupin herbal) for Diabetes mellitus; Pilex for Piles, Liv 52, Blood purifier capsules (Himalaya herbals); Neemka tail (Baidyanath company), Amrutyre	Digestive, antidiabetic

				(Aimil Pharmaceuticals) a blood purifier, Pilisecare, Syrup fever end (Chirayu, Bhopal), Neem guard (Good care Pharma Pvt. Ltd.)	
	Cocos nucifera (Nariyal)	Flowers, root,fruit, oil, juice and kernel	Caprylic acid, polyphenols, alkaloids, mannitol, tartaric acid	One of ingredient in preparation Lipbalm, Evecare (Himalaya Herbals)	Dyspepsia, coolant
	Costus speciosus (Keun)	Root and tuber	Dioscin, prosapogenins, protodioscin, gracillin, costusoside		Aphrodisiac, anthelmintic, antidiabetic
	Embelia ribes (Baybiyanga)	Frits, leaves and root bark	Embolic acid, tannins, alkaloid- christembine, embeline	One of the ingredients of preparation known as Gasex, Diakof, Herbolax and Koflet (Himalaya Herbals)	Hepatoprotective
	Tribulus terrestris (Chhota Gokhru)	Whole plant	Glycosides, steroidal saponins and sapogenins	One of the ingredients of preparation known as Bonnisan, Confido, Himplasia, Renalka, Dhatupaushtik churan (Baidyanath Company), Semento (Aimil Pharmaceuticals), Body plus capsule (Jay Pranav Ayurvedic Pharmaceuticals)	Aphrodisiac, digestive
	Aristolochia bracteolate (Kirmar)	Root and leaves	Aristolochic acid, palmitic, oleic and stearic acid		For inflammation, in dysmenorrhoea
	Aconitum ferox (Bachnag)	Tuberous root	Alkaoids- picroacoinine, aconine, Sterids, flavonoids, saponins, phenolics	One of the ingredients of preparation known as Painkill oil (Jamuna Pharm, Bhopal)	Diuretic, antidiabetic, antipyretic
	Aconitum hetrophyllum (Atis)	Dried tuberous roots	Root contain steroids, terpenids and quaternary alkaloids		Antidiarrhoeal
	Crocus sativus (Keshar)	Dried stigmas, styles	Glucoside, proteins, essential oil, glucoside, essential oil	One of the ingredients of preparation known as Tentex forte (increasing sexual vigour and vitality), Speman forte (increases sperm count) (Himalaya Herbals), J.P. Nikhar oil (Sage Herbals) and Amyron (Aimil Pharmaceuticals)	Aphrodisiac
	Allium cepa (Piyaz)	Bulb and seed	Volatile oil, pheolic acid, amino acids, vanillic acid, citric acid		Aphrodisiac, expectorant
Antidiabetics	Momordica charantia (Karela)	Whole plant	Alkaloids, saponin-charantin in fruits and leaves, Momordicin in fruits	Karela pure herbal powder (Himalaya drug Company)	Regulate metabolism
	Ficus benghalensis (Bargad)	Bark, bud, fruits and leaves	Tannins, bengalenoside, flavonoid glycoside, leucocynidin		Improves skin complextion
	Ficus religiosa (Pipal)	Bark, root, fruit and leaves	Tannins, mannose, phenolic glucoside, flacortin	One of the ingredients of preparation known as Kas bati (Baidyanath Company) for cough and cold	Astringent, purgative
	Gymnema sylvestre (Gudmar)	Leaves/whole plant	Bitter and neutral resins, gumnemosides I-VII, gypenoside, gymnemic acid	One of the ingredients of preparation known as Gludibit (Lupin Herbal Laboratory), Madhu Mehari Yog (Baidyanath Company), Diabecon, Ayurslim (Himalay Herbals), Amree plus (Aimil Pharmaceuticals), Madhudoshantak (Jamuna Pharma	Purgative
	Stevia rebaudiana	Leaves	Apegenin-4-o-beta-d-glucoside, stevioside	Stevier (ASR Herbals, Bangalore)	
Antihyperlipidemics	Curcuma amada (Amahaldi)	Rhizome	Essential oil, resin		Antiinflammatory
	Curcuma longa (Haldi)	Rhizomes and tubers	Essential oil, resin, alkaloid- curcumin	One of the ingredients of preparation known as Respinova (Lupin Herbal Laboratory) cough remedy, Diabecon, Purian (Himalaya Herbals), J.P. Nikhar oil and J.P. Kasantak (Jamuna Pharma, Bhopal)	Antiinflammatory, antilipidmic, digestant, antifertility
	Garcinia cambogia (Bitter kola)	Dried fruits	Resin (gambogic acid), hydoxycitric acid, biflavonoids, xanthones and benzophenone	Bioslim (Sunova Pharma Pvt. Ltd)	Reduction in weight and increases lifespan
	Garcinia indica (Dikanali)	Seeds, fruit, bark and young leaves	Garcinol, hydroxycitric acid	Bioslim (Sunova Pharma Pvt. Ltd)	Antiulcer
Antihpertensives	Rauwolfia serpentina (Sarpagandha)	Roots and rhizomes	Indole alkaloids- reserpine, serpentine, azlmalicine, yohimbine	One of the ingredients of preparation known as Confido, Lukol, Serpina (Himalaya Drug Company), Sarpagandhaghan bati (Baidyanath Company)	Anthelmintic
Antiinflammatory drugs	Camella sinensis (Cay)	Leaves	Carotenoids, vitamins, xanthones	Oral Preparation Dilmah	Antiinflammatory, Nervine tonic, diuretic
	Glycyrrhiza glabra (Mulethi)	Peeled root	Saponin glycoside, glycyrrhizin, asparagin, glycyrrhetic acid	Ysasti madhu (Zandu Pharmuticals), Herbolex, Koflet, Regurin (Himalaya Herbals), Eladi bati (Baidyanath Company), Jeevani malt (Chirayu Pharma, Bhopal), Sage fairness lotion (Sage Herbals), Kas Madhu Cough syrup (Tulison Pharma), Madhumehari (Baidyanath Company)	Antiulcer, diuretic
	Cyperus rotundus (Nagarmotha)	Tuber	Essential oil, carbohydrates	Diarex, Himplagin and Abana (Himalaya Herbals), J.P. Massaj oil, J.P. Nikhar oil, Pain kill oil, J.P. Liver syurp (Jamuna Pharma), Fever end syrup (Chirayu Company), Hempushpa (Rajvaidya Shital Prasad and sons)	Remedy for fever
Antileprotics	Pterocarpus marsupium (Vijayasar)	Heart wood, leaves, flower, gum	l-epicatechin, tannins, kintannic acid	One of the ingredients of preparation known as Gludibit (Lupin Herbal Laboratory), Diabecon (Himalaya Drug Company)	Antidiabeic, anthelmintic
Antilithiatics	Bergenia ligulata (Pashanbheda)	Rhizomes	Bergenin, catechin-3-gallate	Cystone and Nephrolex (Himalay Drug Company)	Dissolving kidney stones
	Cissampelos pariera (Padha)	Root, bark and leaves	Cissampeline, pilosine		Antilithiatic, antidiarrhoeal, antileprotic, antipyretic
	Crataeva nurvala (Varuna)	Bark, leaves and root bark	Saponin, lupeol, Flavonoids	One of the ingredients of preparation known as Renalka, Purian and Himplasia (Himalayan Herbals)	Antirheumatic, anthelmintic, purgative
Antimalarials	Artemisia annua	Leaves, Flower, seeds	Artemisinin, abrotamine	E-Mal (Arteether injection, Themis Medicare Ltd.), Falcigo, Malither	Antiseptic, digestive, febrifuge
Antipyretics	Capsicum annum (LalMirch)	Fruits	Phenolic compounds, capsaicinoids, flavonoids, casotenoids	Deepact (Lupin Herbal Laboratory), a topical anti-rheumatic cream, Capsigyl-D (Shalaks)	Improves blood flow
	Averrhoa carambola (Kamarakh)	Leaves and fruits	Quercetin, rutin, lupeol		Antidiarrhoeal, anthelmintic
	Cedrus deodara (Deodar)	Leaves and heart wood	Aloe- resin as kelankatel	One of the ingredients of preparation known as Pmensa (Lupin Herbal) for painful relief in premenstrual syndrome, Rumalaya gel (Himalaya Herbals)	Antiulcer, GIT disorders
	Alstonia scholaris (Saorna)	Leaves, bark and milky juice	Alkaloids mainly ditaine, echitemine, ditamine, resinous substance		Antiulcer, aphrodisiac, febrifuge

	Crinum latifolium (Sudarshan)	Leaves and root	Lycorine and its glucoside, stigmasterol		Antitumor antirheumatic, immunomodulatory
Antirheumatics	Sida cordifolia (Bariyar)	Roots, leaves, stem and seed	Alkaloids, resin, resin acids	One of the ingredients of preparation known as Menosan, Reostoen, Tax forte (Himalaya Drug Company	Facial paralysis
	Sida rhombifolia (Bahadai)	Roots, leaves, stem and seed	Ephedrine, quinazolines, phenyletyhlamines		Rheumatism, Diabetes, laxative
Antispasmodics	Cinnamomum cassia (Taj)	Bark and oil	Volatile oil, cinnamic acid, resin, tannin, mannitol	One of the ingredients of preparation known as Diakof, KoflexAbana (Himalaya Drug Company), Shukra Matrika Bati (Baidyanath Company), Madhudoshantak (Jamuna Pharma)	
	Coccinia indica (Kundasu)	Leaves, root, fruit and bark	Alkaoids, lupeol, cycloartenol		Cathartic, antispasmodic, expectorant
Aphrodisiacs	Withania somnifera (Ashwagandha)	Roots and leaves	Steroidal lactones mainly withanolides, alkaloid, flavonoids	Ashwagandha powder (Himalaya Drug Company)	Antioxidant, antitumor antistress and immunomodulatory
	Artocarpus heterophyllus (Kathod)	Fruit, seed, leaves, root and milky juice	Essential amino acids, cycloartenone		Diuretic, laxative
	Dolichos lablab (Sem)	Seeds	Albuminoids, it VA, B.Cand hydocyanic acid	Ingredients of preparation known as Menosi syrup (Aimil Company)	Antioxidant, i immunomodulatory and antihyperlipidemic
	Gossypium arboreum (Kapas)	Bark, seeds, leaves, flower	Resin, albuminoids, gossypetin, phenols	One of the ingredients of preparation known as J.P.Massaj oil	Antidote, laxative
	Prunus amygadalus (Badam)	Kernel, oil	Fixed oil, emulin, amygdallin	One of the ingredients of preparation known as Baidyanath lal tail (Baidyanath Company), Himcolin gel, Mentat, Tex Royal (Himalaya Drug Company), Sage badam roghan (Sage Herbals)	For sexual debility
	Psoralea corylifolia (Bavavci)	Fruits	Psoralen, isopsoralen, crylifolin, psoralidin	One of the ingredients of preparation known as Purim, Erina (Himalaya Drug Company), Purodil (Aimil), Sage somaraji oil (Sage herbals)	Treatment of l eucoderma
	Shorea robusta (Sal)	Bark, leaves, fruit and resin	2-(2-iminoacetic acid) -3- (2H)-benzo-furanone, tannin, amino acids	One of the ingredients of preparation known as Ambimax (Maharishi Ayurved)	Antidiarrhoeal, anthelmintic
	Adenanthera pavonina (Baragunchi)	Bark, leaves, seeds, and heart wood	Fats, steroids, polysaccharides		Rheumatoid arthritis
	Cannabis sativa (Bhang)	Flower, leaves and seeds	Volatile oil, alkaloids, resin and terpenes	One of the ingredients of preparation known as Bilwadi churna (Himalaya Herbals)	Rheumatism, analgesic
Astringent	Acacia arabica (Babul)	Bark, leaves seeds	Gum, tannins	One of the ingredients of preparation known as Evecare (Himalaya Drug Company) as utrine tonic	
	Areca catechu (Supari)	Seeds, root, tuber	Tannins, catechin, gallic acid, alkaloids, glucoside		In treatment of oral infection
	Acacia concima	Fruits	Tannins, catechin, gallic acid, alkaloids, glucoside	One of the ingredients of preparation known as Amla and Shikaki Shampoo (Ayur), Satritha (Denaji), Protein Shampoo (Himalaya Drug Company) for hair growth and remove dandruf	
	Acacia farnesiana (Vat Khadir)	Dried flower, pods	Benzaldihyde, salicylic acid, essential oil		Leaves in gonorrhoea
	Achyranthes aspera (Latjira)	Herb, leaves, seed and root	Alkaloids, saponins, flavonoids	Chief component of Apamarga taila, used for deafness, Cystone (Himalaya Drug Company) for urinary calculi and UTI treatment	Laxative, digestive
	Calophyllum inophyllum (Sultan campa)	Bark, leaves, seeds and oil	Volatile oil, Flavones, glucosides		For internal haemorrhages, dysurea, and constipation
	Saraca indica (Ashoka)	Bark, flower and leaves	Tannins, catechol, sterol	Chief component of preparation known as Pmensa (Lupin Herbal), Asokarishta (Baidyanath), Femiplex (Charak Pharma Pvt. Ltd.)	Complex improver
	Cicer arietinum (Chana)	Seeds and leaves	Polysaccharides, saponin, betaine	One of the ingredients of preparation known as Protein shampoo and Amycon (Himalaya Herbals)	Mild antilipidemic, aphrodisiac
Bioavailability Enhancer	Piper cubeba (Kababacivu)	Dried unripe berries	Cubebin, cubebol and cubebic acid	Chief component of preparation known as Slim fast (Slim care Herbal Products)	Carminative, antimicrobial
	Piper longum (Pipal)	Fruit and root	Piperine, piplarine	One of the ingredients of preparation known as Respinova, Aptikid (Lupin Herbal Laboratory), Bonnisan, Abana, Digyton (Himalaya Drug Company), K.G. Tone (Aimil Pharmaceuticals), Piles care, Memoplus syrup and Fever end syrup (Chirayu Company)	Aphrodisiac, antidiabetic, antirheumatic, digestive, purgative
	Piper nigrum (Kalimirch)	Fruit,	Volatile alkaloid piperine, chavicine, limonene	One of the ingredients of preparation known as Diabecon, Gasex, Tex forte (Himalaya Drug Company), Piles care (Chirayu Company)	Carminative, anthelmintic
Bitter Tonics	Swertia chirata (Chiraayata)	Whole plant	Bitter glycosides	One of the ingredients of preparation known as Diabecon (Himalaya Drug Company), Mehmudgar bati (Baidyanath Company), Sabaigo (Aimil Company), P. Liver syrup (Jamuna Pharma), Fever end syrup (Chirayu Company)	Stomachic, anti-inflammatory
	Andrographis paniculata (Kariyet)	Whole plant	Bitter principles, flavonoids	One of the ingredients of preparation known as Herbohep (Lupin Herbal Laboratory), Pyrim and Acene-n-pimple cream (Himalaya Herbals), Sage liverex (Sage Herbals)	Gastroprotective, Antiulcerogenic
	Picrorhiza kurroa (Kutki)	Dried rhizomes	Glucosides, bitter principle –kutkin, kutkin sterol	One of the ingredients of preparation known as Herbohep (Lupin Herbal Laboratory), Pyrim (Himalaya Drug Company), Madhumehari (Baidyanath Company), Piles care (Chirayu Company)	anti-inflammatory anthelmintic

Brain tonics	Bacopa monniera (Mandukparni, Brahmi)	Whole plant	Alkaloids, brahmine, betulic acid, saponins, hersaponin	One of the ingredients of preparation known as Iqmen (Lupin Herbal Labortory), Mentat, Anxocare, Mentone (Himalaya Drug Company), Memoplus (Chirayu Company), Brahmi churna (Shantikunj Pharmacy)	Astrigent
	Centella asiatica (Brahmmanduki)	Whole plant	Glycoside-brahmoside, triterpic acid, brahmic acid	One of the ingredients of preparation known as Iqmen (Lupin Herbal Labortory), Mentat, Abana, Geriforte (Himalaya Drug Company)	Cardiotonic, sedative
Diuretics	Cucumis melo (Kharbuja)	Root, pulp, seed	Isomultiflorenol, cycloartenol, lupeol	One of the ingredients of preparation known as Thandai (Haldiram's) used for diuretic and purgative action	Aphrodisiac, purgative
	Dolichos biflorus (Kulti)	Seeds	Albuminoids, rich in urease, starch	One of the ingredients of preparation known as Neeri syrup (Aimil Pharmaceuticals)	Remedy for flatulence
	Raphanus sativus (Muli)	Leaves, root, and seeds	Raphamin, glycosinolates, arabinogalactin		Laxative
	Setania italica (Kanguni)	Stalks and grains	Folic acid, nicotinic acid, proteins, betainealdehyde dehydrogenase		Astringent, source of proteins and vitamins
	Liquidamber orientalis (Silaras)	Balsam	Balsamic acid, cinnamic acid, storesinol		For bronchitis, diarrhea, inflammation
	Cebia pentandra (Saphed simal)	Root and bark	Carbohydrates, lignin, sesquiterpenes		Antipyretic, hepatoprotective
	Cucurbita maxima (Kaddu)	Fruits and seed	Linolenic acid, glycoloipids, proteins	One of the ingredients of preparation known as Roghan Kadu (Hamdard)	Sedative
Drugs acting on GIT System	Punica granatum (Anar)	Seeds and flower	Apigenin, betulinic acid, ellagic acid, polyphenols	One of the ingredients of preparation known as Diarex (Himalaya Drug Company for diarrhea and dysentery, Marichyadi bati (Biadyanath Company)	In chronic bowel complaint, antipyretic, astringent
	Plumbago zeylanica (Citra)	Root	Plumbagin	One of the ingredients of preparation known as J.P. Liver syurp (Jamuna Pharma), Piles care, Mensulate (Chirayu Company), Chitrakaa bati Avaleha (Baidyanath Company)	Flatulence
	Foeniculum vulgare (Saunf)	Whole plant, dried ripe fruits	Volatile oil: methylchavicol, anethole, limonene, ocimene	Amtikid (Lupin Herbal Lab), Abana Shahicool, Anxocare (Himalaya Herbals), Lalifaladi Bati (Baidyanath Company), Hajmola and Janum Gunti (Dabur Company)	Carminative, antimicrobial, anthelmintic activity
	Valeriana wallichi (Tagar)	Roots	Valepotriates, essential oil, valeriosidat, alkaloids	One of the ingredients of preparation known as Mentat, Anxocare (Himalay Drug Company), Saptagun taila (Baidyanath Company)	For anxiety
	Anethum sowa (Somph)	Fruits and whole herb	Volatile and fixed oils, carvone, eugenol	One of the ingredients of preparation known as Bonnisan (Himalaya Drug Company), Vomiteb syrup (Charak Pharma Pvt. Ltd.)	Carminative, Diuretic
	Cinnamomum tamala (Tejpatt)	Leaves	Essential oils	Trijataka	Carminative
	Coriandrum sativum (Dhania)	Fruits and leaves	Essential oil linalool, borneol	One of the ingredients of preparation known as Bilwadi churna (Baidyanth Company), Sage massaj oil (Sgae herbals)	Carminative
	Pinus longifolia (Dhuprarala)	Wood, oil, resin	Oleoresin, turpentine	One of the ingredients of preparation known as Rumalaya gel and Pain balm (Himalaya Drug Company)	Antiseptic, coolant, stimulant
	Saussurea lappa (Kutha)	Roots	Volatile oil, alkaloids, resin, tannins	One of the ingredients of preparation known as Purim, Septilin syrup (Himalaya Drug Company), Pain Kill Oil (Jamuna Pharma)	Carminative, antiseptic
	Carum carvi (Shia-Jira)	Fruits	Volatile oils, Fixed oil, proteins	Chief component of Jirakadya taila for eczema, Gripe water (Himalay Drug Company), Sage baby oil (Sage Herbals)	Carminative, cytoprotectve, mild aphrodisiac
	Linum usitatissimum (Alsi)	Flowers, seed and oil	Linolenic acid, lignans, mucilage	One of the ingredients of preparation known as Canisep and Scavon (Himalaya Drug Company)	Constipation, Dysurea, cardiac debility
	Zingiber officinale (Adrak)	Rhizome	Volatile oil, Sesquiterpenes	Abana, Gasex (Himalaya drug company), Hing Goli (Poddar Company), Hajmola (Dabur), Pileccare, Feverend	Carminative, anthelmintic, anti-inflammatory
	Apium graveolens (Ajamoda)	Roots and seed	Volatile oil, flavonoids, furanocoumarins	One of the ingredients of preparation known as Himcospazm (Himalaya Drug Company)	Carminative, aphrodisiac
	Alpania galanga (Kulanjan)	Rhizome and fruit	Methyl cinnamtae, cineole, pinene	Rumalaya forte (Himalaya Drug Company)	Carminative, Diuretic
	Commiphora myrrha (Harabol)	Gum	Resin, gum	Guggulipid (By CDRI, Lucknow), Yograj guggulu (Baidyanath)	Antihyperlipidemic, anti-inflammatory
	Oroxylum indicum (Sonapatha)	Roots, leaves, fruit and seeds	Flavone colouring matter, oroxlin, alkaloids	Mentat, Anxocare (Himalaya Drug Company)	Digestive, anti-inflammatory
	Oxalis corniculata (Amrul)	Whole plant	Oxalic acid, vitexin and isovitexin, glycolipids	One of the constituent of Chaarngeryaadi Ghrutham (Nagarjuna) for piles and micturation	Diarrhoea, Piles
	Rosa centifolia (Gulab)	Roots, leaves, flowers	Essential oil, quercetin, kampferol	Abana and Opthacare (Himalay Drug Company	For improving colour complextion
	Smilax china (Copacini)	Root	Tannins, resin, cinchonin, saponin, flavonoids	Leucomap (Maharishi Ayurved)	Digestive, purgative, aphrodisiac
	Solanum indicum (Barhanta)	Roots	Alkaloids: solanine, solanidine, good source of cortisone and sex hormone	One of the ingredients of preparation known as J.P. Kasantak (Jamuna Pharma), Kasantaka Avaleha (Baidyanath Company), Tefroliv forte syrup (TTK Health care Pvt. Ltd.)	Cardiac debility, poor digestion and sex debility
	Elettaria cardamomum (Chhoti elaychi)	Ripe seed, oil of fruits	Fixed oils, essential oil	Koflet, Mentat, Anoxocare (Himalaya Drug Company)	Antiafatoxin
	Alocasia indica (Mankanda)	Root, stem	Flavonoids, cyanogenetic glycosides, Steroids		Juice of the petioles is used in Otorrhoea in children
	Amomum subulatum (Badi elaychi)	Seed and oil	Essential oil, rich in cineole, glycosides	One of the ingredients of preparation known as Antiwrinkle cream (Himlaya), Memoplus syrup (Chirayu), Sitopaladi churna (Baidyanath Company), Zymnet syrup (Aimil Pharma)	Diuretic

	Cuminum cyminum (Jira)	Fruit, seeds	Resin, mucilage, gum, protein	One of the ingredients of preparation known as Lukol (Himalaya), Hajmola (Dabur), K.G. Tone (Aimil Pharma), M2-tone syrup (Charak Pharma)	Carminativre, aphrodisiac, task enhancer
	Berberis aristata (Daruhaldi)	Fruit, root, bark	Alkalods berberine, resins	J.P. Nikhar oil (Jamuna Pharma), Eye drop (Ozone Ayurvedics)	Antidiarrhoeal, antipyretic, hepatoprotective, purgative
	Tamarindus indica (Imli)	Roots, leaves. Fruit and seeds	Organic acids, tartaric acid, citric acid	Chief component of preparation known as Pankajakashuri (Pankaja Kashturi Herbals Ltd.), Fair & Lovely (Natural Herbals)	Immunomodulatory activity
Drugs used in treatment of Insomnia	Erythrina variegata (Badap)	Bark and leaves	Alkaloids, saponin	Basant Kusumakar Ras (Baidyanath), Vasant Kusumkar (Sastry & Sons)	Antidiabetic, antirheumatic, digestive
Drugs used in treatment of Piles	Euphorbia prostrata (Red caustic weed)	Whole plant	Flavonoids	Thank God Rlief Capsules, Thank God, Anytime cream (Panacea Biotech)	
	Pterocarpus santalinus (Lalchandan)	Heratwood	Santalin, desoxysantalin, isoflavone	One of the ingredients of preparation known as J.P. Nikhar oil (Jamuna Pharma), Sandalwood talcum powder	Antipyretic, aphrodisiac
Expectorants	Cinnamomum camphora (Kapur)	Deposits in the oil cells	Terpenoids,, bicyclic monoterpene, ketone	One of the ingredients of preparation known as Ophthacare, Pilex, Rumalaya (Himalaya Drug Company), Dabur balm (Dabur)	Counterirrtant
	Ocimum basilicum (Basil)	Whole plant	Essential oil, phenols, carvacol	Sage kuf-kure syrup (Sage Herbals), Decuf (J.B.Chemicals and Pharmaceticals), Skin cliniq nil (Gufic Biosciences)	
	Ocimum sanctum	Leaves, seed and root	Essential oil	One of the ingredients of preparation known as Abana, Diabecon, Diakof, Koflet, Tulsi Pure Herb (Himalay Drug Company), Amylcure (Aimil Pharmaceuticals), Amarks (Nyle Herbals), Qualin (Hamdard), Kofol syrup (Charak Pharma Ltd.)	In cough
	Datura metel (Dhatura)	Whole plant, leaves, seeds, root and fruits	Trpane alkaloids: hyoscyamine, hyoscine, atropine	One of the ingredients of preparation known as Jatifaladi Bati, Jatyadi tail (Baidyanath Company), J.P. Massaj oil, Pain kill oil, J.P. Grace oil (Jamuna Pharma)	Antispasmodic, digestive, antileprotic
	Citrus limon (Jambirinibu)	Fruit	Citric acid, pectin, carotene, vit.c	One of the ingredients of preparation known as Protein shampoo (Himalaya), Panch Nimba Churna (Zaipa Pharmaceuticals), Ultra doux conditioner (Garnier)	Carminative, anthelmintic
	Citrus medica (Kagaji Nibu)	Rind, Juice and oil	Essential oils	Hingoli (Dabur)	Antioxidant
	Cirus reticulata (Santara)	Fruit	Citric acid, essential oil, flavonoids, carotenoids	Fairness Cream (Forever and Fair & lovely)	Antioxidant
Galactogogues/Emmenagogues	Asparagus adscendens (Safed musli)	Tubers, rhizome and roots	Asparagin, proteins, saponins	Geriforte (Himalaya) for antistress, Jeevani mal (Chirayu, Bhopal)	Aphrodisiac, demulcent
	Asparagus racemosus (Satawar)	Root and leaves	Saponins: shatavarin, flavonoids, queecetin	K.G. Tone (Aimil Pharma), Xenosan, Diabecon, Galactin, Abana (Himalaya), Dhatupoushtik churna, Rhuma oil, Brahmi rasayan, Mahanarayan tel (Baidyanath), J.P. Massaj oil, Pain kill oil (Jamuna Pharma), Hemoplus, Jeevani mal (Chirayu), Satavari kalp and Satavarex granules (Zandu, Bombay)	Antidiarrhoeal
	Boswellia serrata (Salai)	Gum, Resin and oil	Essential oil, resin , tannins, volatile oil	Chief component of preparation known as Deepact (Lupin Herbal), Shallaki (Himalya and Gufic Company)	Sedative, analgesic
Hepatoprotective	Eclipta alba (Bhangra)	Root, leaves, whole plant	Alkaloids	One of the ingredients of preparation known as Pilex, Abana (Himalaya), Madhudoshantak, J.P. Liver syrup (Jamuna Pharma), Bhringarajasava, Mahabhringraj tail (Baidyanath), Neeleebringadikeram and Sage livere (Sgae Herbals)	Antidote, Stimulates hair growth
	Boerrhavia diffusa (Punarnava)	Whole plant and root	Alkaloid: punarnavine	Chief component of preparation known as Deepact (Lupin Herbal), Abana, Diabecon (Himalaya), Punarnawadi, Guggulu (Baidyanath), Amylcure, Sobigol (Aimil Pharma), Pain kill oil, J.P. Liver syrup (Jamuna Pharma), Punarnavarista (Baidyanath)	Stomachic, diuretic, laxative
	Emblica officinalis (Amla)	Dried fruits, seeds, leaves, bark, flower	Vitamin c, niacin, embellic acid, pyrogalloltannins	Jeevani mal (Chirayu), Anwala churna	Anaemia, jaundice, dyspepsia
	Phyllanthus amarus (Bhaumla)	Whole plant	Lignans, phyllanthin, flavonoids	Livosin, Liv 52 (Himalaya), Herboheb (Lupin), Chyawanprash (Dabur)	Antihyperlipidemic, hypoglycemic
Laxative/Purgative	Aloe barbadensis (Gawarpatha)	Dried juice of leaves	Aloectin-B, tannins, anthracene derivative	Aloe vera gel, Forever Bright tooth gel, Forever lite Nutritional diet, Aloe Jojoba Shampoo, Aloe liquid soap or Shower gel, AL-sun protection cream, Diabecon, Evecare (Himalaya), Mensonorm (Chirayu), Kumari Asava (Baidyanath) as liver tonic and astringent	Burn and wood injury Purgative
	Argemone mexicana (Kanteila)	Seed, fresh root and milky juice	Alkaloids mainly		Sedative and analgesic
	Cassia angustifolia (Sanaya)	Leaves	Cathartin, emodin, senna-picrin, chrysophenol	One of the ingredients of preparation known as Constivac (Lupin herbal), Softovac (Lupin Ltd.)	
	Cassia fistula (Amulthus)	Pulp, root, bark, roots, flowers, leaves	Sennosides A, B, Volatile oil	One of the ingredients of preparation known as Constivac (Lupin herbal), Pilex, Purian (Himalaya Drug Company)	Febrifuge and tonic
	Cassia occidentalis (Kasondi)	Leaves, seed and root	Resin, anthracene derivative	One of the ingredients of preparation known as Bonnisan, Geriforte, Herbolax and Liv 52 (Himalay Herbals)	Hepatoprotectective, anthelmintic, aphrodisiac
	Cassia tora (Cakunda)	Seeds	Anthraquinone glycosides, emodin, chrysophenol		
	Operculina turpethum (Nisath)	Dried root, stem, root-bark	Glucoside, starch, turpethin, resin, lignin	Ingredients of preparation known as Herbolax (Himalaya Herbals)	
	Pandanus odoratissimus (Kevda)	Root, leaves and flowers	Methylether of phenylethylalcohol, linalool	Chief component of preparation known as Keora Water (Dabur)	Treatment of epilepsy

Croton tiglium (Jamalgota)	Seed and oil	Fixed oil containing stearic, palmitic, crotonic acid	Jaborandi component of preparation known as Regulax forte (Charak Pharma)	Treatment of epilepsy
Terminalia arjuna (Anjan)	Bark	Tannins, arjunglucosides, phytosterols	One of the ingredients of preparation known as Abana, Geriforte, Liv 52, Menosan (Himalay Herbals), Arjun Ghrita, Arjun churna (Baidyanath), Madhudoshantak (Jamuna Pharma)	
Terminalia bellerica (Baheda)	Bark and fruits	Tannins, gallic acid, ellagic acid, chebulagic acid	Sage triphla syrup (Sage Herbals)	Hepatoprotective, antidiabetic
Terminalia chebula (Harara)	Mature and immature fruits	Tannins, ellagic acid, gallic acid, oleoresins	One of the ingredients of preparation known as Constivac (Lupin herbal), Pilect (Aimil Pharama), Abana, Bonnisan, Gariforte, Koflet, Menosan (Himalaya company), Jaritakh churna, triphla churna, tentex forte (Baidyanath)	
Cirullus colocynthis (Indrayan)	Fruit, root, pulp	Glucoside mainly colocynthin		Antidiabetic, diuretic
Clitoria ternatea (Aparajita)	Root, bark, seed and leaves	Tannin, resin, fixed oil		Memory improving, diuretic, laxative
Cymbopogum citratus (Gandhatrin)	Essential oil and herb	Volatile oil, flavones, limonene, citral	Chief components of Sage liorbalm (Sage Herbals)	
Cynodon dactylon (Dhub)	Whole herb and root stalk	Saponins, tannins, flavonoids, glycosides	Chief components of Syplon (Himalaya Drug Company)	Antiviral against vaccinia virus, potent hypoglycemic, hypotensive
Gloriosa superba (Kalihari)	Seeds and tubers	Resins, tannins, alkaloids	Regulin forte (SAS Pharmaceuticals)	Anthelmintic, abortifacient
Plantago ovata (Isabgol)	Seeds	Mucilage, fixed oil, proteins	Pregnalax, Naturolax, Fibril	

With tremendous expansion in the use of herbal medicines worldwide, their quality control has been an important concern for both health authorities and the public. It has been widely introduced and accepted by WHO, FDA, British Herbal Medicine Association, Indian Drug Manufacturers' Association and some other official or non official organizations as an strategy for assessment of herbal medicines.

Standardization

Standardization is a method of assuring a minimum level of active ingredients in the extract and is becoming increasingly important as a means of ensuring a consistent supply of high-quality phytopharmaceutical products. It can be defined as the establishment of reproducible pharmaceutical quality by comparing a product with established reference substance and by defining minimum amount of one or several compounds or groups of compounds. In the field of phytomedicines, standardization only applies to extracts. Standards for active ingredients to be used in medicinal products may be found in monographs and/or pharmacopeias.

Importance of Standardization

It is accepted that concentration or dosages are very important because herbal medicines (in common with conventional medicines) contain biologically active substances that may produce non-trivial side effects when taken in excessive doses. Very low doses, on the other hand, may have no therapeutic value. In practice, plant material is often highly variable, so that a minimum concentration or a concentration range is often used rather than an exact level. An upper limit is necessary with highly active or potentially harmful ingredients, as most plants have a wide therapeutic window. In the case of compounds with a narrow therapeutic window, chemical entities are favoured, as opposed to extracts. These phytodrugs when registered become a medicine that needs to comply with the basic standards required for all drugs. Standardization also allows comparison of the clinical effectiveness, pharmacological effects and side effects of a series of products (e.g. against a placebo). Standardized products provide more security and increase the level of trust in herbal drugs. At the international level, the WHO has developed a strategy to review traditional medicines. Additionally, the European Scientific Cooperative on Phytotherapy (ESCOP) was established in 1989 to advance the scientific status of phytomedicine and to assist with the harmonization of their regulatory status on European level. ESCOP has already published 60 monographs on the medicinal uses of plant drugs that have been submitted to regulatory authorities across Europe and accepted by the Working Party on Herbal Medicinal Products of the European Agency for the Evaluation of Medicinal Products (EMEA) as basis for proposed core-SPCs for European decentralized marketing authorizations. A Pharmacopoeia is a collection of quality standards for medicines and their components. In order to obtain marketing authorization for a medical product, the ingredients or the medicinal product must generally comply with a pharmacopoeial standard. Thus Pharmacopoeial standard may provide guidance on acceptable purity criteria for that ingredient[11].

Scientifically validated and technologically standardized botanical medicines will play an important role in future advancement in healthcare. The development of parameters for standardization and quality control of botanicals is a challenging task. Various regulatory authorities, research organizations and botanical drug manufactures have contributed in developing guiding principles addressing issues related to quality, safety and efficacy[6, 17].

World Health Organization (WHO) on Botanicals

WHO has tried to establish internationally recognizable regulatory guidelines to define basic criteria for the evaluation of quality, safety and efficacy of botanical medicines. WHO assists national regulatory authorities, scientific organizations and manufacturers to undertake an assessment of the documentation/submissions/

dossiers in respect of such products. In 1991, WHO published guidelines for the assessment of herbal medicines. The guidelines also provide details on the preparations of the documentation and data for the assessment of herbal medicines and address the following points:

- Assessment of quality including pharmaceutical assessment, crude plant material, plant preparation, finished products and stability.
- Assessment of safety including toxicological studies and documentation of safety based on experience.
- Assessment of the efficacy including activity, evidence required to indications and combination products.
- Intended use including product information for the consumer and promotion.

The guidelines suggest classification of herbal remedies into two groups; those with well established traditional use and newly developed products. It was recommended that the requirements for assessment of these two groups should be different. As a general rule, traditional experience means long term use, as well as medical, historical and ethnobiological background of the product. Depending on the history of the country, the long-term use may vary but would be of at least several decades[18].

The guidelines suggest that all the necessary approaches should be taken to ensure correct identification of plants. It is noted that when identification of an active principle of herbal medicine is not possible, it should be sufficient to identify a characteristic substance or mixture of substances to ensure consistent quality of herbal medicines. All herbal procedures should be carried out in accordance with Good Manufacturing Practices (GMP). On safety assessment, these guidelines suggest [19]:

- All relevant aspects of the safety assessment of a medicinal product should be covered.
- No specific restrictive regulatory action should be undertaken for a traditionally used product without demonstrated harm unless new evidence demands a revised risk-benefit assessment. Documents submitted should provide evidence on long- term use.
- For drugs used over a long period, chronic toxicological risks may have occurred but may not have been recognized.
- If long-term traditional use cannot be documented, or there are doubts on safety, toxicity data should be submitted.
- If any toxicological studies are available, they should form part of the assessment. A review of relevant literature should be provided with original articles or references to the original articles.

Guidelines for assessing the quality of botanical materials mainly emphasize the need to ensure the quality of medicinal plant products by using modern techniques and applying suitable standards. A series of tests for assessing the quality of medicinal plant materials have been described. Botanical characterization using macroscopic and microscopic methods has been recommended. For physical evaluation, parameters like ash value, extractable matter, volatile matter etc, have been suggested.

Pharmacological evaluation has been recommended for certain norms like bitterness value and haemolytic activity. Detection of pesticidal residue, arsenic and heavy metal content, microbial load and radioactive contaminants has been suggested for safety of the botanical materials (Fig 2).

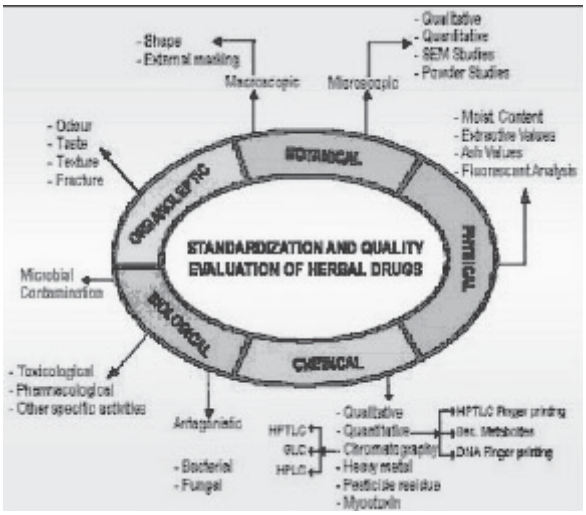

Fig. 2 : *Standardization and quality evaluation of herbal drugs*

In 1997, WHO developed draft guidelines for methodology on research and evaluation of traditional medicines. It mainly focuses on current major debates on safety and efficacy of traditional medicine. It also tries to provide answer for some of the challenging questions concerning evidence base of the traditional knowledge of medicine. These guidelines present some national regulations for the evaluation of botanical medicine, and also recommend new approaches for carrying out clinical research. Specific objectives of these guidelines are to harmonize the use of certain accepted and important terms in TM, summarize key issues for developing methodology for research and evaluation of TM, improve the quality and value of research in TM, and to provide appropriate evaluation methods to facilitate the development of regulation and registration in TM[20].

Under the overall context of quality of botanical medicines, WHO developed the Guidelines on Good Agricultural and Collection Practices (GACP) for

medicinal plants. GACP provides general technical guidance on obtaining medicinal plant materials of good quality for the sustainable production of herbal products classified as medicines. The main objectives of these guidelines are to guide the formulation of national and/or regional GACP guidelines and GACP monographs for medicinal plants and related standard operating procedures and to encourage and support the sustainable cultivation and collection of medicinal plants of good quality.

WHO also has published monographs for selected medicinal plants. It will provide models to assist member states in developing their own monographs or formularies for these and other herbal medicines and facilitate information exchange among member states (Fig 3). WHO recognizes the use of traditional herbal health practioners, pharmacists, manufacturers, research scientists and the general public[21,22]. In 1969 government of Indian established a Central Council for Research on Indian Medicine and Homoeopathy [CCRIMH] to develop scientific research on different systems of medicine: Unani, Ayurveda, Siddha, Yoga, Naturopathy and Homoeopathy. Research activities on these systems continued under the CCRIMH until 1978 when it was split into four separate research councils. Central Council for Research in Ayurveda and Siddha Medicines [CCRAS], Central Council for Research in Unani Medicines [CCRUM], Central Council for Research in Homeopathy [CCRH], Central Council for Research in Yoga and Naturopathy [CCRYN]. These central councils have their own research institutes, laboratories and dispensaries throughout India, which work on the development and propagation of the respective system and the development of lead compounds from the traditional systems for major ailments. In 1995, the Department of Indian System of Medicine and Homeopathy (ISM&H) was established by the Government of India under the Ministry of Health and Family Welfare to control all regulations related to traditional systems of medicine. The manufacture, quality control and sale of all Ayurvedic and other ISM medicines are regulated through the Drug and Cosmetic Act 1940 and various regulations have been made by Government of India for the development of herbal medicines. Quality control and research on traditional systems are further regulated by the Department of Indian System of Medicine and Homeopathy (ISM&H). Pharmacopoeial committees have been established and the ISM & H council has established a separate pharmacopoeial laboratory. A separate drug control for traditional systems of medicines have been created by the department of ISM&H. Government initiatives have come up with separate pharmacopoeias and formularies with the monographs on plants and formulations used in these systems of medicines[2] (Table 2).

***Fig. 3**: More and more countries are regulating Herbal Medicines (Source: WHO Traditional Medicine Strategy 2002–2005, pg-16)*

***Table 2:** Government institutes involved in research and development of traditional systems of medicines in India*

Name of the council	Different centres of the council	Research activities
Central Council for Research in Ayurveda and Siddha	8 regional research institutes 12 research centres 60 units and dispensaries	Medico-botanical survey and development of Ayurvedic and Siddha medicine based on folklore uses and their scientific validation and implication
Central Council for Research in Unani Medicines	1 central research institute 8 regional research institutes 11 clinical research units 5 drugs standardisation units	Developing independent and multidimensional research into various fundamental and applied aspects of Unani system of medicine
Central Council for Research in Homeopathy	51 research centres around the country	Screening of homeopathic medicines for treating different ailments and development of standardisation parameters
Central Council for Research in Yoga and Naturopathy	Headquarter and central unit at New Delhi, India	Development and propagation of research on yoga and related aspects of yoga and naturopathy
Council for Scientific and Industrial Research and regional laboratories	Regional research laboratory, Jammu Central drug research institute, Lucknow Central institute of medicinal and aromatic plants, Lucknow	Cultivation of medicinal plants, quality control and investigation of medicinal plants and pharmacognosy, including development of agro-biotechnological aspects

Integration of herbal medicine can only be accomplished through scientific research, which must take into account the interrelated issues of quality, efficacy and safety? Quality is a paramount and complex issue when dealing with botanicals. One of the most difficult challenges for any company in the herbal industry is being able to consistently formulate a product, which will deliver the promised physiological effect. One of the most popular practices followed by herbal industry for standardization is to identify and standardize a particular “marker compound” which is believed to be responsible for the physiological effect to an acceptable percentage[23]. However, when it comes to the percentage of the markers, different companies have different yardsticks. The percentage of a particular marker for a particular herb varies from product to product in some cases batch to batch from the same company.

A number of intrinsic as well as extrinsic influences which greatly affect botanical quality have been analyzed to date: species differences, organ specificity, diurnal and seasonal variation, environment, field collection and cultivation methods, contamination, substitution, adulteration, and processing and manufacturing practices[10]. In order to achieve a quality product consistently one has to address all the above issues.

STANDARDIZATION OF HERBAL DRUGS

Quality Aspects

The importance of quality control and standardization of botanical products is of utmost concern for global acceptability. Purity and quality of botanicals is a critical determinant of safety. The first stage of assuring quality, safety and efficacy of botanical medicines is identification and selection of the correct plant species[24]. The information required for authentic botanical includes the currently accepted Latin binomial names and synonyms, vernacular names, the parts of plants used for each preparation and detailed instruction for agricultural production and collection conditions according to each country's good agricultural practices. Regulatory authorities for control of raw material have suggested various methods. Most of the guidelines suggest macroscopic and microscopic evaluation and chemical profiling of the botanicals[18,25,26]. Characterization using sensory parameters like color, taste and surface characteristics are studied in macroscopic evaluation Size and shape of the plant part used is also taken into consideration. However, these characteristics are judged subjectively and substitutes and adulterants may closely resemble the genuine material, it is often necessary to substantiate the findings by microscopy and/or physicochemical analysis. An examination by microscopy alone cannot always provide complete identification, though when used in association with other analytical methods it can frequently supply supporting evidence[19].

Chemo profiling using HPLC, HPTLC and GC has wide applicability in quality control of herbal medicines. Multicomponent botanicals formulations can be standardized by using these sophisticated techniques. Spectroscopic analysis has also been suggested by certain pharmacopoeias for analysis of botanicals. European pharmacopoeia gives assay of quinine type alkaloids and cinchonine type alkaloids in cinchona bark using UV spectroscopy and United States Pharmacopoeia (USP) includes an UV absorption test for the absence of foreign oils in oils of lemon and orange. UV spectroscopic analysis has been used for quantitative and qualitative detection of marker compounds from the herbal material. Infrared spectroscopy; NMR and mass spectroscopy have been used for structure elucidation of marker or active components from plants[27].

By nature, botanicals may be highly variable in their chemical composition. The variability in the flavor, aroma, physical characteristics of wine and coffee from year to year and region to region provide a good analogy. There are numerous factors that may affect the ultimate chemical profile of a botanical and the content of a specific marker, including intrinsic factors such as genetic and extrinsic factors such as growing, harvesting, drying and storage conditions.

The use of chromatographic techniques and marker compound to standardize botanical preparation has its own limitations. Analysis of secondary metabolite is restricted to those plants that produce a suitable range of metabolites which can be easily analyzed and which can distinguish between varieties. Also, the metabolites being used as marker should ideally be neutral to environment effect and management practices[28]. Establishing the presence of a marker compound in an herb is not sufficient to determine the desired quality, since the marker compound may not necessarily be responsible for the biological activity that is attributed to the whole herb[29]. In view of these limitations of the currently used methods there is a need for new approaches that can complement or serve as an alternative for the existing methods. Some of the newly emerging techniques for ensuring quality are Herboprint[30], capillary electrophoresis and DNA analysis. Herboprint evaluates Ayurvedic medicines on the basis of HPLC fingerprint. The capillary electrophoresis is based upon the simple phenomenon of electrophoresis, which is the movement of electrically charged particles or molecules in a conductive liquid medium under the influence of electric field[31]. DNA based molecular markers have acted as versatile tool in plant genome analysis and are specifically important in differentiating different plant species and their varieties. Being environmentally stable and specific, DNA markers could gain wide popularity in quality control and standardization of medicinal plant materials[32].

The quality of finished formulation will depend upon quality of raw material, uniformity of manufacturing processes and standard operating procedures and testing procedures. Proper control over these will ultimately result in quality botanical medicine[33]. In India there are 9000 licensed firms manufacturing TMs with or without proper standardization of the botanicals. As there is lack of standard norms for quality production of botanical medicines, the Indian manufacturers generally follow WHO standards. India needs to design its own parameters and standard set of guidelines for quality control of Ayurvedic medicines[34].

CONCLUSION

Herbal based traditional medicines as potential source of therapeutic aids have attained a significant position in health systems all over the world for both humans and animals has become popular in developed countries in recent years and its use is likely to be increased in the coming years. More than 70% of threatened medicinal plants of India are used in active trade. Standardization of chemical fingerprinting (TLC, HPLC) towards quality control is another major requirement in developing countries like India. To establish the potential of Ayurvedic medicine, research needs to be conducted on the following aspects [2, 35]:

STANDARDIZATION OF HERBAL DRUGS

- To standardize materials, methods and measures for preparation, preservation, presentation and administration of Ayurvedic drugs.
- To provide proper scientific validation and significance to the fundamental principles of the system to the extent possible, so that they can be accepted within a scientific framework.
- To rationalize the utility of positive and judicious use of modern scientific methods that pertains to the development of Ayurvedic and traditional medicines.

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 the Ayurvedic texts, their toxicity/safety must be evaluated on modern lines for universal acceptance.

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