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Review Article

REVIEW ON DRUGS STANDARDIZATION OF AYURVEDIC MEDICATION

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ABSTRACT

India is a mother hub for the development of Ayurveda, and different natural herbs based mostly health science (AYUSH). Herbal pharmaceutical business has nice potential and opportunities for development in the future. Standardization of drug suggests that confirmation of its identity, quality and purity throughout all phases of its cycle i.e. shelf-life, storage, distribution. Totally different techniques concerned in the standardization of crude and finished compound medication to this point, for example, large ways, physical ways, chemical ways, biological ways, and macroscopically ways. As we have a tendency to all recognize in our Ayurvedic system of medicines, drug standardization of Ayurvedic formulation may be a massive challenge. Clear cut pointers have not been developed to this point. Book testing protocol is also adopted for drug identification. Drug standardization is needed for the event of Indian system of medicines (namely, Ayurveda) for the identification of drug, purity of drug, safety of drug, strength of drug, effectiveness of drug, and to follow good manufacturing practice (GMP) and good laboratory practice standards as per varied restrictive authorities. The national health authorities (national drug restrictive authorities, drug management committee) got to build sure that each one ASU pharmaceutical product subject to their management square measure in conformity with quality, safety, effectiveness that all premises and practices used the manufacturing and distribution of these product suits GMP standards, therefore on check that the continued conformity of the merchandise with these requirements until such time as they're delivered to the tip user.

Keywords: Drug, Standardization, Ayurveda, Unani, Accumulation, Testing.

INTRODUCTION

India may be a mother hub for the development of Ayurveda, Unani, and Siddha; medical care and different natural herbs based mostly health science (AYUSH). Ayush pharmaceutical business has nice potential and opportunities for the development in future. Primarily in the following seasoning healthful plants and their worth additional merchandise well accepted in domestic and international market, for example, Ayurvedic medicines, Unani medicines, Siddha medicines, Homoeopathic medicines, seasoning nutraceuticals, seasoning cosmeceutical, seasoning health drinks, dietary health supplements, healthful plants/crude medication, seasoning extracts/concentrates, seasoning veterinary medicines, health foods, AYUSH health-care management, and Ayurvedic Panchakarma Centre and Spa. Standardization of drug suggests that confirmation of its identity, quality and purity throughout all phases of its cycle i.e. shelf-life, storage, distribution [1-4]. As we have a tendency to all recognize in our Ayurvedic system of medicines, drug standardization of the Ayurvedic formulation may be a massive challenge. Clear cut pointers have not been developed to this point. Thus, it is necessary to market doctrine producing business individuals for drug standardization work. Ministry of AYUSH, Government of India recently established pharmacopoeial commission of Indian medicines and medical care (PCIM and H) for putting in place drug customary of ASU and H Medicine to grasp drug standardization following aspects ought to be learned and implement in our existing system.

METHOD OF STANDARDIZATION

Their area unit totally different techniques concerned in the standardization of crude/finished compound medication as follows: (1) Macroscopic ways, (2) microscopic ways, (3) physical ways, (4) chemical ways, and (5) biological ways.

Crude medication standardization crude ASU medication testing involves the following testing protocol/steps 2–15 for drug standardization; medicobotanical survey/identification, habitat, synonyms, regional names, etc., collection and preservation of stuff, testing of medicine as per approved pharmacopoeial testing protocol; identity by pharmacognosy profile, chemical identification, thin-layer chromatography (TLC)/high-performance TLC (HPTLC) fingerprint profile; purity by physicochemical profile, strength by active marker/assay estimation, safety by significant metal identification, microbiological limit take a look at analysis, aflatoxins analysis, and chemical residue analysis, Ayurvedic properties and action – rasa, guna, virya, vipaka, and karma; and important formulation and important therapeutic use, dose, and anupan (vehicle). Pharmacognostical drug analysis has pharmacognostical tool sixteen apply for analysis of crude drug as; macroscopic examination, visual examination as size, colour, surface, characteristics, texture, and completely different examinations like odour, taste, and macroscopic examination involve varied steps as preparation of sample, scrutiny by analysis, scrutiny by colour filter of ground glass, histochemical detection, section study (transverse section/longitudinal section) TLC/HPTLC process, identification/marking for phytochemicals, compound medication, standardization, compound ASU medication testing involve following testing protocol 17–21 for drug standardization; literature survey/drug reference, collection and preservation of stuff, testing of stuff by on prime of testing protocol, definition, formulation composition, technique of preparation (manufacturing customary operative procedures [SOPs]), testing of compound formulation on beneath mentioned pharmacognostical, and chemistry testing protocol (compound medication testing protocol) as; identity by description, microscopic profile if any, chemical identification if any, TLC11/HPTLC process profile, purity physicochemical profile, strength-active marker/assay if any, safety by vital metal identification, microbiological limit take a glance at analysis, Aflatoxins analysis and chemical residue analysis, storage therapeutic use dose and Anupana (vehicle) self-life of drug by stability Study [5-10]. As per Fig. 1. Their area unit varied chemistry testing used for drug identification that is depend on the particular characteristics of drug as per methodology given in Ayurvedic Pharmacopoeia of India 2–8, 17–19, Siddha Pharmacopeia of India, United States Pharmacopoeia, Indian Pharmacopoeia, etc., as determination of foreign matter, determination of ash worth (at 500–8000°C), determination of removable matter, determination of water and volatile matter, determination of wet content (L.O.D. at 1100°C), determination of bitterness worth, determination

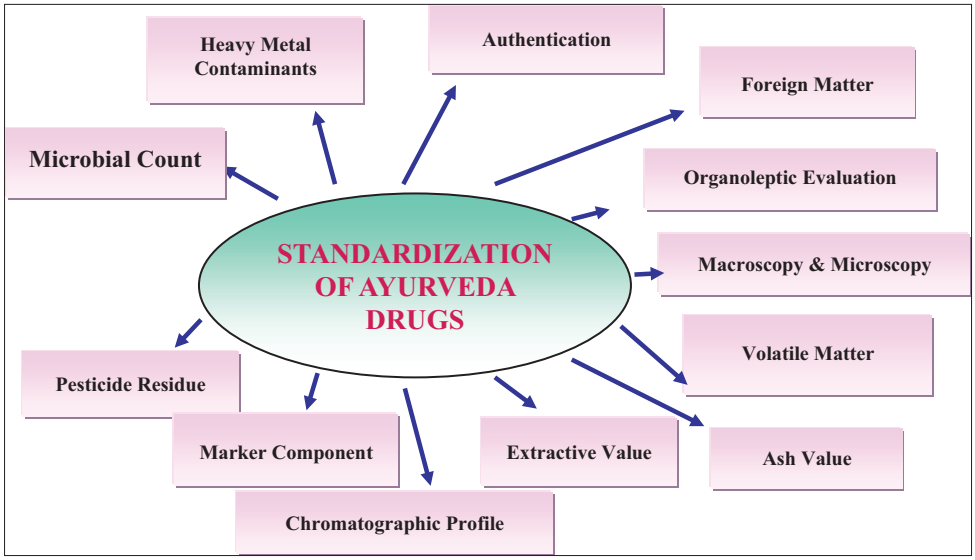

Figure 1: Authentication and standardization of herbal raw material

of hemodynamic activity, determination of tannins, determination of swelling index, determination of foaming index, determination of chemical residue, determination of total Cl and phosphoric, phosphates, determination of arsenic and significant metal, determination of bulk density, determination of radioactive contamination, comparative TLC/high-performance liquid chromatography (HPLC)/HPTLC/gas chromatography–mass spectrometry (GS-MS), and determination of inorganic content by ICP varied take a look at is also administrated for drug standardization. In drug standardization, chemist/technical person ought to acknowledge state of art instrumentation technique, having information of operation qualification, quantitative relation (installation qualification), design qualification, performance qualification, instrument manual and SOPs for instrument handling and maintenance, customary testing procedures, and state (work instruction for various common instrument used within the drug standardization or control method as caution concentration meter, single distillation unit, double distillation unit, Soxhlet assembly, water bath, viscometer, viscometer, bulk density instrumentation, Polari meter, referectometer, microscope, meter analysis unit, hot air household appliance, magnetic stirrer, filtration unit, infrared analysis, wet balance, Karl Fischer apparatus, Muffle chamber, vacuum evaporator, dissolution instrumentation, friability instrumentation, hardness tester, high loading balance, autoclave, B.O.D., incubator, flow, Microbiological colony counter and antibiotic zone reader. In drug standardization work such tons of refined instrument jointly used oftentimes as and once they unit in would really like for application as chromatography setups, natural action instrumentation, double beam photometer, HPTLC unit, HPLC unit, liquid chromatography–MS, GC/MS unit, ICP unit. Microbiological testing conjointly administrated for the estimation of; total aerobic microorganism count, total yeast, and mold count; and presence of pathogens such as enteric bacteria, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus*. Stability study even be administrated for drug customerization work for real-time stability studies (to see the changes within the quality standards at varied intervals is found appropriate for ascertaining the time period of the ASU medicines) in standard storage condition worker: 300±20°C, relative humidity: hour±five you look after # 1/6/12/18/24/30/36 months as per stability study testing protocol. Drug standardization wants and challenges. Drug standardization is needed for the event of Indian system of medicines (namely, Ayurveda) for the following reason; for Ayurvedic MD, to cure unwellness, drug is just tool, drugs would be of fine quality with highest effectiveness and safety, identification of drug, purity of drug, safety of drug, strength of drug, efficacy of drug, and to follow good manufacturing practice (GMP) and good laboratory practice standards given by the WHO. Author reviews current acknowledged doctrine drug-producing business and author found following general difficulties and future challenges for ASU business as; lack of documented validation of merchandise, lack of documented internal control procedures, lack of documented method validation, batch to batch variation in product, toxicity profile – not explained, efficacy – not scientifically evidenced and documented, quality assurance protocol – not properly designed, lack of world category treatment centers, lack of quality enfranchisement, lack of insurance approval, lack of well-trained workforce, and lack of AYUSH technical personnel with scientific knowledge's; there is no Ayurveda pharmacy council in India. Lack of consistency in quality in batch to batch production of merchandise, product effectiveness ought to be of well tested on latest scientific/regulatory demand, product ought to be of highest safety and free from cross-contamination, shortage of raw materials general system of preference, adulteration at intervals the raw materials and substitute issues, life originated product convenience issues, increase in raw materials value lack of written documentary proof on clinical effectiveness, lack of consistency in quality in batch to batch production of merchandise, lack of a well outlined and well organization SOP, lack of scientific validation of the therapeutic claims, lack of scientific validation safety claims customer satisfaction, and confidence would really like assessment to plug exports of Ayurvedic product globally top-quality Ayurvedic medication and cosmetic manufacturers to contend at intervals the international market on current Situations [11-14].

CONCLUSION

Drug standardization and manner forwards for philosophy drug producing business or AYUSH, world as a result of the national health authorities (national drug restrictive authorities, drug management committee) need to check that that every one ASU pharmaceutical product subject to their management unit in conformity with quality, safety, effectiveness that all premises and practices used the producing and distribution of these product accommodates GMP standards thus on check that the continued conformity of the merchandise with These wants until such time as they're delivered to the tip user. Government should be restructuring and strengthen the present drug social control infrastructure development of common stuff sourcing center (Herbal Mandi), development of state medical store for ASU medication, development of quality analysis and development center within the field of seasoning drugs and different merchandise, development of common facility center for quality certification, bench marking, and validation F, development of international selling support centers, development of knowledge center for patent protection intellectual property rights, and development of GMP coaching and technology transfer centers,

common facility center for specialty production, and packaging on contract producing basis for the development of entrepreneurship, soft ability development programmed for hospital Pharma personnel, initiatives, and incentive for quality enfranchisement.

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