A Review: Standarization & Quality Control of Polyherbal Formulations

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Abstract- *Herbal formulation shall mean a dosage form consisting of one or more herbs or processed herb(s) in specified quantities to provide specific nutritional, cosmetic benefits, and/or other benefits meant for use to diagnose treat, mitigate diseases of human beings or animals and/or to alter the structure or physiology of human beings or animals. Any medicinal product, exclusively containing as active substances one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations. Herbal preparations are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.*

Keywords- Polyherbal formulation, Quality control parameters, Standardization, Physicochemical parameters.

I. INTRODUCTION

Pallab Dasgupta et al, investigate that, in the few decades, there has been exponentionally growth in the field of herbal medicines. Most of the traditional system of medicine are effective but they lack standardization. So there is a need to develop a standardization technique. Standardization of herbal formulation is essential in order to assess the quality, purity, safety and efficacy of the drug. ashwagandha is a reputed drug mentioned in the scientific books of Ayurveda for the treatment of stress, hypertension, sleeping disorders and also as rejuvenative. The present research study deals with the comparagtive standardization of two marketed ashwagandha churna formulation from Dabur and Dhaka Oushodhalay. The standardization of this formulation, the organoleptic characters, physical properties, the various physic-chemical properties such as moisture content, ash values, extractive values were carried out. Thin layer chromatography and heavy metal content study were also carried out to ascertain the quality, purity and safety of this herbal formulation.

Maithani Jyoti et al, investigate that, standardization of herbal formulation is essential in order to assess the quality of drugs. The present paper reports preparation and standardization of a polyherbal formulation which contains Syzgium cumini(bark), Mangifera indica(bark), Ficus bengalensis (bark), Ficus religiosa(bark), Lawsonia inermis (leaves), Juglans nigra (bark), Terminalia bellirica (fruits) and Hibiscusrosa sinensis (bark). This Ayurvedic formulation is used to treat diabetes mellitus. Here we calculate and discussed about Extractive value, Moisture content, Ash value, Carr's index etc. These parameters are required for authentication of any herbal drug and its formulation.

D. Chamundeeswari et al, investigate that, Ayurvedic medicines play an important role in gastro intestinal problems due to safety and efficacy in it. Hence churna meant for digestive property has been formulated by standard procedures and evaluated by physical and analytical methods.The formulation consists of fine powder (sieve 60 size) of dried rhizomes of Zingiber officinale, fruits of Foeniculum vulgarae, barks of Cinnamomum zeylanicum and fruits of Trachyspermum ammi in appropriate proportions (2:2:1:1) and mixed well. Physical parameters viz, total ash, acid insoluble ash, water extractive values, alcohol soluble extractive values and crude fibre content besides heavy metal analysis were carried out.The microbial load of formulation for Escherichia coli was also determined. The efficiency of churna for digestive property is determined by finding the amylolytic activity and lipolytic activity and compared with GASTRAP a marketed formulation for gastritis.

Tekeshwar Kumar et al, investigate that,in the few decades, there has been exponentially growth in the field of herbal remedies. Newer guidelines for standardization, manufacture, quality control and scientifically rigorous research will be necessary for traditional treatments. This traditional knowledge can serve as the powerful search engine that will greatly facilitate drug discovery. Standardization of herbal formulations is essential in order to assess the quality, purity, safety and efficacy of drugs based on the amounts of their active principles. The aim of the present work is to standardize Gokshuradi churna. The churna makes this traditional drug more stable for long term storage and hence, easier to prepare. The "Gokshuradi churna" an Ayurvedic polyherbal formulation used in the treatment of is a polyherbal Ayurvedic medicine used as a diuretic and cardiac tonic. One marketed

and one in- house formulations were used for the study. All the formulations were standardized on the basis of organoleptic characters, physical characteristics and physico-chemical properties. The set parameters were found to be sufficient to evaluate the churna and can be used as reference standards for the quality control/quality assurance purposes. The analysis and quality control of herbal medicines are moving towards an integrative and Comprehensive direction, in order to better address the inherent holistic nature of herbal medicines. It was observed that all ingredients of commercial samples matched exactly with that of authentic standards after performing the standardization as per WHO guideline.

Rakesh S Shivatare et al, investigate that, standardization involves the safe, proper selection and handling of crude materials, ensure efficacy and stability of finished product, and guiding the consumer about the product. With this aim the present study was designed; Narasimha churna an Ayurvedic formulation prepared from various medicinal plants which are commonly used in Cough, deficiency of semen, pain, wrinkles in the skin, graying of hair, alopecia, diabetes and anemia. The present study consists of preparation and standardization of Narasimha churna for parameters like physicochemical properties, phytochemical screening and physical properties of final formulation as per WHO guideline and the results were compared with the marketed formulation. These findings will be useful towards establishing pharmacopoeial standards for crude drugs as well as for formulation which is gaining relevance in research on traditional medicinal system.

Ajay Kr Meena et al, investigate that, ayurvedic medicine, Pancasama Churna known to be effective mainly on gastrointestinal tract (GIT), has been standardized by following modern scientific quality control procedures both for the raw material and the finished product. Pancasama Churna was subjected to macro-microscopic, Physico-chemical, preliminary phytochemical, TLC and HPTLC to fix the quality standards of this drug. This study results a set of diagnostic characters essential for its standardisation. TLC and HPTLC fingerprinting were employed to fix standards. The values obtained after physicochemical parameters study showed that these values should be helpful to develop new pharmacopoeial standards. This will be helpful to overcome batch to batch variations in traditional preparation of Pancasama churna. The physicochemical constituents found to be present in raw material used for the preparation of Pancasama churna possibly facilitate the desirable therapeutic efficacy of the medicinal formulation.

Pamessori Puyam et al, investigate that, standardization of herbal formulation is essential in order to assess the quality of drugs for therapeutic value. According to an estimate of World Health Organization (W.H.O) nearly 80% of populations of developing countries rely on traditional medicines. The World Health Organization (WHO) in 1999 has given a detail protocol for the standardization of herbal drugs comprising of a single content, but very little literature is available for the standardization of poly-herbal formulation. We have developed a simple scheme for standardization and authentification of Shivakshar Pachan Churna. The set parameters were found to be sufficient to standardize the Shivakshar Pachan Churna and can be used as reference standards for the quality control/ quality assurance study mostly on plant drugs for their primary health care needs.

Sangram Keshari Panda et al, investigate that, standardization of herbal formulation is essential in order to asses the quality of drugs for therapeutic value. According to an estimate of World Health Organization (W.H.O) nearly 80% of populations of developing countries rely on traditional medicines. The World Health Organization (WHO) in 1999 has given a detail protocol for the standardization of herbal drugs comprising of a single content, but very little literature is available for the standardization of poly-herbal formulation. We have developed a simple schem for standardization and authentification of sitopaladi Churna. Four marketed preparations and in-house preparations were used for the study. performed The various parameters including organoleptic characteristics and physicochemical . HPTLC was carried out for quantitative analysis of all the formulations.The set parameters were found to be sufficient to standardize the Sitopaladi Churna and can be used as reference standards for the quality control/ quality assurance study mostly on plant drugs for their primary health care needs.

Yogendr Bahuguna et al, investigate that, in the few decades, there has been exponential growth in the field of herbal medicines. Most of the traditional system of medicine is effective but they lack standardization. So there is a need to develop a standardization technique. Standardization of herbal formulation is essential in order to assess the quality, purity, safety and efficacy of the drug. Dabur Triphala Churna is used for immune system stimulation, improvement of digestion, relief of constipation, gastrointestinal tract cleansing, relief of gas, treatment of diabetes and treatment of eye disease. The present research study deals with standardization of Dabur Triphala Churna [i.e. Emblica officinalis (Garetn.) (Amla), Terminalia bellirica (Gaertn.) Roxb. (Baheda) and Terminalia chebula (Retz.) (Harada)]. The standardization of this formulation, the organoleptic characters, physical properties, the various physico-chemical properties such as moisture content, ash values, extractive values were carried out. Heavy metal content studies were also carried out to ascertain the quality, purity and safety of this herbal formulation.

Priyabrata Pattanaya et al, investigate that, quality assurance of herbal products may be ensured by proper quality control of the herbal ingredients and by means of good manufacturing practice. We have developed a simple scheme for the standardization and authentification of Sulaharan Yoga a poly herbal formulation using HPTLC. The present study signifies the use of TLC, HPTLC fingerprint profiles for deciding the identity, purity and strength of the polyherbal formulation and also for fixing standards for this Ayurvedic formulation.

Sudani R.J et al, investigate that, Embelia ribes burm f., also known as Vidanga, is one of the oldest herbs in Indian traditional medicine. Embelia ribes have a long history of use in ayurvedic system of medicine in various forms like churna, asava, aristha and taila. It is used mainly as an anthelmintic, carminative and stimulant. A selective, precise and accurate High Performance Thin Layer Chromatography (HPTLC) method has been developed for the simultaneous quantitation of Embelin in Vidanga churna formulations. The method employed TLC aluminium plate (10 cm x 10cm x 250 µm) precoated with silica gel 60 F254 as a stationary phase. The solvent system consists of Chloroform: Ethyl acetate: Formic acid (5:4:1 v/v/v). Densitometric analysis was carried out in the absorbance mode at 291 nm using Camag TLC scanner-III. Developed HPTLC method showed good regression (r2 = 0.9986 ± 0.0020) and the recovery of Embelin was in the range of 99.09 – 102.01%. The limit of detection and limit of quantitation were found to be 61.28ng/spot and 185.71ng/spot respectively. The method was validated for precision, recovery, limit of detection and limit of quantitation. The proposed HPTLC method was found to be simple, precised and accurate and can be used for the quality control of the raw materials as well as formulations.

Sharad Srivastava et al, investigate that, to develop a simple precise and novel method for the identification and quantification of bioactive molecules ferulic acid in Lycopodium clavatum. Methods: Bioactive molecules ferulic acid in Lycopodium clavatum was indentified and estimated by the assay combined separation and quantitative estimation of the analyte on silica gel 60F254 HPTLC plates with visualization under UV and scanning at 320 nm. Results: HPTLC studies showed the separation and determination of ferulic acid (0.443%) in Lycopodium clavatum. The result of recovery ranged in 95%-97% for ferulic acid. Conclusions: This method is simple, sensitive, economic, novel and first time reported from this species. Therefore, ferulic acid might be a useful chemotaxonomic marker for the genus Lycopodium and other lycopods.

Amartya Bose et al,investigate that, Standardization of Ayurvedic formulations is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for production and manufacturing of herbal drugs. WHO specific guidelines for the assessment of the safety, efficacy and quality of herbal medicines as a prerequisite for global harmonization are of utmost importance. An overview covering various techniques employed in extraction and characterization of herbal medicines as well as herbal Nano medicines standardization is reported. In addition, phytosomes increased bioavailability, bhasma as a metal Nano carrier drug delivery system, potential of metabolomics in the development of improved phytotherapeutic agents, DNA based molecular markers in distinguishing adulterants, and SCAR markers for authentication and discrimination of herbs from their adulterants are reported. Processed metals including Mercury, Gold, Silver, Lead, Zinc, Copper etc. were used very frequently by seers of the Indian tradition in different disease conditions with great authority. Recent advances in the study of minerals include petrological studies to analyze the physical and chemical changes in particular.

A.Mohammad et al, investigate that, the standardized thin-layer chromatographic procedures can be used effectively for the screening analysis as well as quality evaluation of the plant or its derived herbal products. New approaches in thin-layer chromatography enable analysts to separate and determine useful natural products in complex mixtures of plant products. Various chromatographic systems useful for the identification; separation and quantification of herbal products are reported in this review.

II. CONCLUSION

For quality assured herbal product, the standardization is required. In standardization the mentioned parameters i.e. authentify,biological parameters,physical parameters,chemical parameters & analytical profiling gives the quality assured herbal product. HPTLC tool is mostly used for identification of herbal products. Other instruments like UV, Mass Spectroscopy etc. used for standardization of herbal products.

ACKNOWLEDGEMENT

Authors are thankful to Rajarshi Shahu College of Pharmacy & Research for providing facilities to complete this work successfully.

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