

Standardization of Natural Products and Drugs

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Traditional knowledge extends to an appreciation of both the material and non-material properties of plants and animals. In countries like India and China, traditional health systems are firmly rooted in long-standing cultural and spiritual values [1]. Herbal medicine is largely used for various human illness and the usage of the medication began from the ancient time the medicinal plants are significant source for pharmaceutical production sector. Medicinal plants and herbal drugs represented a huge level of the pharmaceutical market. The conventional drugs are thought to have more adverse effects in the recent time and hence the natural products (NPs) are more wanted by the public. However recent limitation of the herbal drugs is lack of standardization parameters [2]. Natural product standardization is more important for their potential application in biomedical system. World Health Organization (WHO) has stressed the need to guarantee quality control of herbal drugs by utilizing current procedure and by applying appropriate parameters and principles [3]. So as to conquer certain inescapable deficiency of the Pharmacopoeial monograph other quality control estimates must be investigated. standardization of natural products is the way toward recommending a lot of benchmarks or inalienable attributes, steady parameters, conclusive subjective and quantitative qualities that convey an affirmation of value, viability, wellbeing and reproducibility. It is the way toward creating and concurring upon specialized measures. Explicit measures are worked out by experimentation and perceptions, which would prompt the way toward endorsing a lot of qualities displayed by the specific Natural product. Consequently, standardization is a device in the quality control process. Natural products standardization has many default's its own like NPs usually mixtures of several elements, active constituents are mostly unknown; specific analysis protocols and reference for NPs not available conventionally; NPs are naturally and chemically express and react in variably;

cultivation of plants are lesser in numbers; the sours of NPs and quality is variable. The processes of isolating, drying, storage, shipping, and processing also affect NPs quality.

Approval of conventional drugs is based on high quality experimental information, toxicity studies and human clinical trials. However, pharmacopoeial principles on raw material and by-products are poorly established. Good manufacturing practices (GMP) for natural products industry are not well established. The absence of value standards has developed in mild to serious adverse effects ranging from hepatotoxicity to death. Thus, NPS necessitate tools for defining identity, purity and quality and tools have to be technically sufficient, rapid and cost effective with GMP requirements.

As per WHO [4,5], standardization and quality control of herbals is the procedure engaged with the physicochemical assessment of rough medication covering viewpoints, for example, choice and treatment of unrefined material, wellbeing, adequacy and dependability evaluation of completed item, documentation of security and hazard dependent on experience, arrangement of item data to buyer and item advancement. Validation Each and every progression must be confirmed, zone of the gathering, parts of the plant accumulation, the provincial circumstance, as phytomorphology herbal character, minute and histological analysis (characteristic highlights of cell dividers, cell substance, starch grains, calcium oxalate precious stones, hairs, strands, vessels and so on.) Several investigations of the histological parameters are rundown of palisade proportion, vein islet number, vein end, stomatal number, stomatal record, trichomes, stomata, quantitative microscopy, ordered personality, remote issue. Misfortune on drying, swelling record, frothing list, cinder esteems and extractive qualities, Chromatographic

and spectroscopic assessment, Determination of substantial metals, pesticide developments, microbial contamination, radioactive exposures. The parameter strength of natural definitions that incorporates pharmacognostic parameters, physico-concoction parameters, phyto-substance parameters, microbiological test and chromatographic examination It includes TLC, HPLC, HPTLC, GC, UV, IR, FT-IR, AAS, LC-MS, GC-MS, fluorimetry etc.

WHO empowers, proposes and advances conventional and natural cures in national health care programs on the grounds that these NPs drugs are effectively accessible easily, safe and individuals have confidence in them. The WHO gathering in number of goals has underlined the need to guarantee quality control of therapeutic plant items by utilizing present day methods and applying reasonable standard [2]. Unlike conventional commercial drugs, NPs have frequently had a considerable human use before clinical assessment. To benefit from the utilization of these data in conventional system to assess these items, it is critical that the chemistry, assembling, and control of the item to be utilized emulates that for the traditionally-used formulations.

NPs need full fill flowing three attributes viz., Authenticity, Purity and Assay. Authenticity as the name proposes identifies with demonstrating that the material is valid, i.e. it compares to the originality. Authentication in itself includes numerous parameters including gross morphology, microscopy, compound investigation and DNA fingerprinting. Analysis of purity in NPs is there any other unwanted materials rather than useful constitution. Assay part of standardization is chemical and biological profiling which could evaluate the chemical effects and curative values get established. Safety for use could also be reviewed through this parameter. In biological assays, the drug activity is estimated through a pharmacological model. Chemo profiling is a versatile technique and can be made to good use in standardization. Fingerprinting in essence is chemo profiling, which means establishing a characteristic chemical pattern for the plant material or its cut or fraction or extract [6].

NPs technology is used for translating botanical materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important. The routine methods of NPs standardization address quality related issue using botanical and organoleptic constraints of crude drugs, and chemo profiling assisted characterization with spectroscopic techniques, but the new era of NPs standardization includes pharmacogenetic, chemical, biological, biopharmaceutical and molecular approaches.

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