INTRODUCTION:
Herbal medicines are in great demand in the developed as well as developing countries for primary health care because of their wide range of biological activities, higher safety margins and lesser costs. Public, academic and government interest in herbal medicines is growing exponentially due to increased incidence of the adverse drug reactions and economic burden of the modern system of medicine. Herbal therapy is one of the best practices to overcome the illness. These herbal based medicines are formulated from cultivated as well as wild plants (Saurabh parmar et al. 2011).
Herbal medicine, a form of complementary and alternative medicine, is becoming increasingly popular in both developing and developed countries. A World Health Organization (WHO) survey indicates that about 70-80% of the world population particularly in the developing countries rely on non-conventional medicines mainly of herbal sources in their primary healthcare (WHO guidelines 1998 and Akerele, O. 1993). WHO has described traditional medicine as one of the surest means to achieve total health care coverage of the world's population (Ogbonnia S. O. et al. 2010).
The use of herbal medicines by the traditional practitioners for treatment of diseases remains the main stay of health care system and is gaining increasing popularity especially among the rural populace in the developing countries. Its rising popularity could be attributed to its advantages of being efficacious and also a cheap source of medical care. There is also growing disillusion with modern medicine coupled with the misconception that herbal products being natural may be devoid of adverse and toxic effects associated with convectional and allopathic medicines. Herbal preparations assumed to be safe could be contaminated with microbial and foreign materials such as heavy metals, pesticide residues or even aflatoxins due to the unhygienic way many are produced. The presence of any of the possible contaminants is a potential health risk to a vast population that depends on herbal medicine for their health care need. Increased morbidity and mortality associated with the use of herbs or the so called traditional medicines has raised universal attention in the last few years (Bandaranayake, 2006). Upon exposure, the clinical toxicity may vary from mild to severe and even life threatening making the safety and toxicity evaluations of these preparations imperative.
Although the World Health Organization (WHO) has advocated for the integration of herbal medicinal products into the primary health care system of developing countries (WHO, 1978, 1989), safety issues related to herbal drugs continue to be ignored by herbalists whose method of concocting herbal preparations for the public use are usually unhygienic leading to microbiological hazards (Esimone et al., 2007). These herbal remedies are often perceived as being natural and therefore safe, but they are not free from adverse effects, which may be due to factors such as adulteration, substitution, contamination, misidentification, lack of standardization, incorrect preparation and/or dosage, inappropriate labeling and or advertisement (Lau et al., 2003).

Certain bacterial species occur frequently in all forms of wound infections which may have occurred as a result of the skin normal flora becoming opportunistic pathogens. These infecting bacteria include: *Staphylococcus aureus*, *Staphylococcus epidermides*, *Streptococcus pyogenes*, Diphtheroids sp, *E. coli*, Klebsiella sp, some anaerobic gram negative rods like *Pseudomonas aeruginosa* and some fungi species.

WHO has also developed the technical guidelines for the assessment of microbial quality of herbal medicines. The quality assessment of herbal formulations is very important in order to justify their acceptance in modern system of medicines. It is thus mandatory that the microbiological limit tests of herbal medicinal preparations be done to ensure that the product is free from risk. In India many such formulations are handmade or made by physicians directly (Chitrarekha Kulkarni et al. 2010).

These formulations are not subjected to aseptic conditions during various stages of preparation, packaging, storage, transport etc. as required by regulatory norms. Also plant materials carry a huge number of bacteria and fungi, mainly originating in soil. Aerobic sporulating bacteria frequently predominate in this to which additional contamination and microbial growth occur during harvesting, handling and production. As the use of herbal preparations by patients is increasing, there is an urgent need for pharmacists and physicians to have knowledge about the safety of these preparations.

In Nigeria, there appears to be an overwhelming increase in the public awareness and usage of herbal medical products in the treatments and or prevention of diseases (Okunola et al., 2007) with this increased usage, the safety, efficacy and quality of these medicines have been an important concern for health authorities and health professionals.

The drug plants and their part used as such on commercial scale for drug formulation are called crude drugs or raw material. The herbal drugs are commonly used as single drug or as ingredient of herbal formulations. The raw materials used in the preparations of medicine
have direct impact on the efficacy of the drug. In fact, plants produce a diverse range of bioactive molecules, making them a rich source of different types of medicines.

The plant material used in herbal drugs preparations are organic in nature, it provide nutrition to microorganisms and facilitates the multiplication of microorganism which lead to contamination, deterioration and variation in composition. This give rise to inferior quality of herbal product with little or no therapeutic efficacy. The quality of herbal drug is also depend on many factors like environment, collection method, cultivation, harvest, post harvest processing, transport and storage practices. Inadvertant contamination by microbial and chemical agent during any of the production stage can also lead to deterioration in safety and quality and can also cause health hazard to consumer inspite to cure the disease. The subject of herbal drug standardization (Archana Gautam et al 2010) is massively wide and deep.

The guidelines set by WHO,

1. Reference to the identity of the drug:
   - Botanical evaluation- sensory characters,
   - foreign organic matter, microscopical, histological,
   - histochemical evaluation,
   - quantitative measurements etc.
2. Reference to the physicochemical character of the drug:
   - Physical and chemical identity,
   - chromatographic fingerprints,
   - ash values,
   - extractive values,
   - moisture content,
   - volatile oil and alkaloidal assays,
   - quantitative estimation protocols etc.
3. Reference to the pharmacological parameters,
   - biological activity profiles,
   - bitterness values,
   - hemolytic index,
   - astringency,
   - swelling factor,
   - foaming index etc.
Toxicity details- pesticide residues, heavy metals, microbial contamination like total viable count, pathogens like E.coli, Salmonalla, P.aeroginosa, S. aureus, Enterobacteria etc.

The concept of Good Manufacturing Practice (GMP) is well known to every pharmaceutical company in the world. Many countries express GMP in regulations, codes, and guidelines. In this era of worldwide herbal drug revolution, there is a need to implement GMP in the production of medicinal products from natural resources (herbal drugs). In addition to the widespread use of phyto-medicine in developing countries for historical and cultural reasons, developed countries have been increasingly using alternative and complementary medicine for their potential therapeutic efficacy. To meet the worldwide demand for herbal drugs, it is essential to maintain GMP. GMP for herbal drugs covers their cultivation in the field to their preparation in different formulations with the crude powder, the extract, or purified components.

The objectives of GMP for herbal drugs are generally stated in terms of desired achievements in several areas of manufacture and control, including cultivation and collection. India has a wide biodiversity and many herbal drugs from different regions constitute a major part of the health care system. GMP for herbal drugs in India is necessary for quality control of the production and development of herbal drugs, which includes primarily specific courses of action or the procedures to be followed in almost all steps of herbal drug production.

Quality of herbal medicines is a great concern to consumers and regulators throughout the world. The quality of herbal medicines mainly depends on regulatory requirements of respective countries. To probe the role of regulatory standards and their harmonization in improving quality, safety, and efficacy, legislation on herbal medicines of different countries was analyzed. Results show that different countries have been changing and upgrading quality requirements over the last few years, and those who have no legislation presently have started framing suitable legislation. Like other countries, India has also adopted prudent measures to improve the quality of herbal medicines. Though there is a general trend to incorporate stringent measures worldwide, there is little initiative to harmonize regulations, which is essential for providing quality herbal medicines globally.

A key point in choosing the appropriate method to guarantee the quality and safety of herbal products is to develop suitable methodology for their standardization with a sufficient degree of specificity in ensuring the desired endpoint. The unique differences in the constituents of herbal drugs create distinct challenges based on their identity, quality, and consistency of
efficacy. The differentiation of conventional medicines and herbal drugs can be minimally considered from regulatory, economic, and technical perspectives. Health risks associated with herbal products are considered in three categories: extrinsic (accidental, deliberate), intrinsic (bioavailability, pharmacokinetic, pharmacodynamic), and consumer-dependent causative factors (therapeutic failure, adverse drug reaction, hypersensitivity).

A change in these categories through regulation using designated approaches can minimize the health risks. Chemical fingerprinting of natural products and their ability to interact with physiological substrates of the human body are the mainstay of their therapeutic efficacy. This requires a multidisciplinary approach, involving analytical techniques and methodologies common to ethnomedicine, botany, pharmacology, pharmacotherapy, toxicology, and pharmacoepidemiology. An attempt has been made through this article to highlight the use of marker profiling of natural products with special reference to Indian herbal.