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Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phototherapeutic agents)

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This review highlights the current advances in knowledge about the safety, efficacy, quality control, marketing and regulatory aspects of botanical medicines. Phytotherapeutic agents are standardized herbal preparations consisting of complex mixtures of one or more plants which contain as active ingredients plant parts or plant material in the crude or processed state. A marked growth in the worldwide Phytotherapeutic market has occurred over the last 15 years. For the European and USA markets alone, this will reach about $7 billion and $5 billion per annum, respectively, in 1999, and has thus attracted the interest of most large pharmaceutical companies. Insufficient data exist for most plants to guarantee their quality, efficacy and safety. The idea that herbal drugs are safe and free from side effects is false. Plants contain hundreds of constituents and some of them are very toxic, such as the most cytotoxic anti-cancer plant-derived drugs, digitalis and the pyrrolizidine alkaloids, etc. However, the adverse effects of Phytotherapeutic agents are less frequent compared with synthetic drugs, but well-controlled clinical trials have now confirmed that such effects really exist. Several regulatory models for herbal medicines are currently available including prescription drugs, over-the-counter substances, traditional medicines and dietary supplements. Harmonization and improvement in the processes of regulation is needed, and the general tendency is to perpetuate the German Commission E experience, which combines scientific studies and traditional knowledge (monographs). Finally, the trend in the domestication, production and biotechnological studies and genetic improvement of medicinal plants, instead of the use of plants harvested in the wild, will offer great advantages, since it will be possible to obtain uniform and high quality raw materials which are fundamental to the efficacy and safety of herbal drugs.

Biography

Sachin.J is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B Pharm from JSS College of Pharmacy, Mysore during the year 2011. Presently he is pursuing M Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. He has presented posters at national level and has attended various National and International Conferences. His current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, analytical method development of novel drugs.

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Solubility enhancement of lornoxicam using self microemulsifing drug delivery System

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The prime criterion on which the performance of the drug depends is their solubility. Majority of biopharmaceutical aspect of drug depend on solubility behavior. More than 40% of active pharmaceutical ingredients are fails to reach the formulation stage due to their poor solubility. Lornoxicam is one of the oxicam derivative used to treat various types of pain especially resulting from inflammatory diseases of joints, osteoarthritis, inflammations etc. This API not so popular and routinely used in the formulation because of their weaker water solubility, lower bioavailability and increased cost. The Lornoxicam is made more formulation friendly by amplifying it's solubility by self microemulsifing drug delivery system (SMEDDS) which is the isotropic mixture of oils, surfactants, cosurfactant and drug with unique ability to form fine oil in water emulsion upon mild agitation following dilution with aqueous phase. In the present study solubility of lornoxicam is increased and respective analysis of the formulation parameter is carried out.

Biography

Mr.Sameer Patel has completed their bachelor degree in pharmacy from Shivaji University Kolhapur. Currently Mr.Sameer persuing master degree in Pharmaceutics from Tatyasaheb Kore college of Pharmacy Warananagar. He attended several conferences and have sound knowledge of writing scientific literature.

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