

Orphan regulations for orphan drug development in india

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Through this paper an attempt has been made to put forward the challenges faced by rare disease drug development and the current scenario of orphan drugs legislations in India. An orphan drug is a pharmaceutical agent that is used to treat a rare medical condition (viz., Huntington's disease, myoclonus disease, Tourette syndrome etc.). Developed countries like US, EU, Japan; Australia has laid down legal framework for combating rare diseases. A path breaking legislation was formulated by the U.S government way back in 1983, known as 'Orphan Drugs Act (ODA)'. The key purpose of ODA was to incentivize R&D initiatives for such drugs to treat millions of population suffering from 'Orphan Diseases'. Though the percentage of patients suffering from 'Rare Diseases' in India is reportedly higher than the world average, unfortunately even today such cases get little help from our government. By considering the importance of ODA, Indian government should also encourage its domestic pharmaceutical industry to get engaged in research to discover drugs for rare diseases by putting an 'Orphan Drugs Act' in place and extending financial support, and regulatory concessions like smaller and shorter clinical trials, without further delay. Thus India could well demonstrate that the concept of Orphan Drugs for Orphan Diseases is really not Orphan in India.

Biography

I am saikiran reddy pursuing 1st M.Pharm in pharmaceutical regulatory affairs from JSS College of Pharmacy, JSS University, Mysore. I actively took part in various seminars and presented papers in national level symposiums.

Isolation of Heptadecanoic acid and Phytol from the plant of *Dregea volubilis* [Linn.] Leaves

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The present study was undertaken to isolate phytoconstituents of *Dregea volubilis* [Linn.] Benth. Two compounds were isolated from leaves of alcoholic extract of *Dregea volubilis* [Linn.] Benth by continuous hot soxhlet extraction and purification has been done by column chromatography method. The spectral analysis revealed that the isolated compounds are Heptadecanoic acid which is fatty acid and Phytol is diterpenoid moiety. Both compounds showed significance anti hyperlipidemic and anti diabetic activities.

Harmonized GMP Requirements

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The basic rules in any good manufacturing practice (GMP) regulations specify that the pharmaceutical manufacturer must maintain proper documentation and records. Documentation helps to build up a detailed picture of what a manufacturing function has done in the past and what it is doing now and, thus, it provides a basis for planning what it is going to do in the future. Regulatory inspectors, during their inspections of manufacturing sites, often spend much time examining a company's documents and records. GMP is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. GMP is aimed primarily at diminishing the risk inherent in any pharmaceutical production. Effective documentation enhances the visibility of the quality assurance system. In light of above facts, we have made an attempt to harmonize different GMP requirements and prepare comprehensive GMP requirements related to 'documentation and records', followed by a meticulous review of the most influential and frequently referred regulations. Documentation is the key to GMP compliance and ensures traceability of all development, manufacturing, and testing activities. Documentation provides the route for auditors to assess the overall quality of operations within a company and the final product.