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Evaluation of anti-nociceptive activity of aqueous extract of root of ricinus communis linn on albino rats

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Evaluation of Anti-nociceptive activity of aqueous extract of root of Ricinus communis linn on albino rats. The castor oil plant, Ricinus communis, is a species of flowering plant in the spurge family, Euphorbiaceae. It belongs to a monotypic genus, Ricinus, and subtribe, Ricininae. Water extract of root has showed some analgesic activity in rats. It also has anti-inflammatory and anti-histaminic properties. These properties are speculated to the presence of ricinoleic acid, dihydroxystearic, linoleic, oleic, stearic acids, beta-sitosterol, catalase, peroxidase, and reductase. Materials used are, Aqueous extract of root of Ricinus communis (AERRC), Soxhlet's apparatus for extraction, Albino rats, Tail clip, Standard drug: Aspirin. Five groups of albino rats will be taken each consisting of five animals. Group-I will be taken as control to which normal saline will be given, Group-II standard drug will be given, Aspirin, Group III, IV, V test drug will be given AERRC(100mg/kg,200mg/kg,400mg/kg). Results will be discussed at the time of presentation.

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Regulatory strategy for similar biologics in India

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The objective of this paper is to provide guidelines to applicants to enable them to understand and comply with the regulatory requirements for the authorization of similar biologics in India. The CDSCO is the national regulatory authority in India that evaluates safety, efficacy and quality of drugs in the country. The DBT through Review Committee on Genetic Manipulation (RCGM) is responsible for overseeing the development and preclinical evaluation of recombinant biologics. There are several such products under development in India, both regulatory agencies considered the need to publish a clear regulatory pathway outlining the requirements to ensure comparable safety, efficacy and quality of a similar biologic to an authorized reference biologic. A similar biologic may require reduced preclinical and clinical data package as part of submission for market authorization. The similar biologics are regulated as per the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945 (as amended from time to time) and Rules for the manufacture, use, import, export and storage of hazardous microorganisms/genetically engineered organisms or cells, 1989 (Rules, 1989) notified under the Environment (Protection) Act, 1986. Various applicable guidelines are Recombinant DNA safety guidelines, 1990 guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biological, 1999, cdsco guidance for industry.

Competent authorities involved in the approval process are Review committee on genetic manipulation (RCGM) genetic engineering appraisal committee (GEAC) Central Drugs Standard control Organisation (CDSCO). Thus all the global pharmaceutical companies should follow up the guidelines approved for biologics by CDSCO for marketing authorisation in India.

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