

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.

Biography

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Antioxidant effect and polyphenol content of *Syringodium filiforme* (Cymodoceaceae)

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The marine phanerogam *Syringodium filiforme*, known as “manatee grass”, is a common species that grows in coastal areas associated to *Thalassia testudinum*. With the aim to describe some of its possible chemical characteristics, this study was performed with a sample of 1.2kg, collected in March 2009, in Guanabo beach, Havana, Cuba. The sample was dried (less than 12% humidity) and a total extract prepared; other three extracts were prepared with the use of solvents of increasing polarity. The phytochemical screening and analytical determinations of each fraction were undertaken Total polyphenol content was determined using pyrogallol as reference's standard; chlorophyll a and b and anthocyanin content were also quantified. Total extract and fractions antioxidant activity were evaluated by using the free radical scavenging activity assay with 1,1-Diphenyl-2-Picrylhydrazyl reactive (knowing as DPPH's method). The phytochemical screening of the different extracts detected the presence of high concentrations of flavonoids, phenols, terpenes, antocyaninns, reducing sugars and alkaloids. The total extract and methanol fraction showed significant free radical scavenging properties, while the petroleum ether fraction showed moderate activity, and the chloroform fraction and the aqueous soluble precipitate (residual salt) obtained didn't show antioxidant properties against free radicals. The results of this work confirmed the potentialities of this species for biological purposes. Rev. Biol. Trop. 59 (1): 000-000. Epub 2011 March 01.

Biography

Kethia L. González has completed his MSc at the age of 28 years from Havana University. She is junior researcher from department of Chemistry in CEBIMAR. She has published more than 10 papers in international journals and she has participated in more than 20 scientific-technical reports in international and national scientific congress.

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