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Role of regulatory agencies in approval of nanotechnology products

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Regulatory bodies across world have long encountered the combination of promise, risk, and uncertainty that accompanies emerging technologies. Nanotechnology is not unique in this regard. Materials can exhibit new or altered physicochemical properties at nanoscale dimensions, which can enable the development of novel products. The very changes in biological, chemical and other properties that can make nanotechnology applications so exciting, however, also may merit examination to determine any effects on product safety, effectiveness, or other attributes. The application of nanotechnology may result in product attributes that differ from those of conventionally-manufactured products, and thus evaluations of safety or effectiveness of FDA-regulated products that include nanomaterials or otherwise involve the application of nanotechnology should consider the unique properties and behaviors that nanomaterials may exhibit. Consistent with Executive Order 13563 on improving regulation, as well as with the White House policy statements on regulating emerging technologies and applications of nanotechnology, FDA supports innovation and the safe use of nanotechnology in FDA-regulated products under appropriate and balanced regulatory oversight. By enhancing its scientific expertise and tools necessary to assess the safety and, as applicable, effectiveness of products, FDA is maintaining its product-focused, science-based regulatory policy. Where premarket review authority exists, attention to nanomaterials is being incorporated into standing procedures. Where statutory authority does not provide for premarket review, consultation is encouraged to reduce the risk of unintended harm to human or animal health. Industry remains responsible for ensuring that its products meet all applicable legal requirements, including safety standards. Regulatory bodies collaborate, as appropriate, with domestic and international counterparts on regulatory policy issues.

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The antidiabetic and antilipidemic effects of *caralluma fimbriata*

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Diabetes mellitus (DM) is a serious health problem with high rates of incidence and mortality. DM is characterized by elevated plasma glucose concentrations resulting from insufficient insulin, insulin resistance, or both, leading to metabolic abnormalities in carbohydrates, lipids and proteins The antidiabetic and antilipidemic effects of *Caralluma fimbriata* was investigated in this study using five male wistar rats. The rats were divided into 5 groups comprising of five animals each. These groups include a normal control (administered saline), an extract control (administered 100 mg/kg of extract) and a diabetic control (untreated group). The remaining two groups were administered 100mg/kg and 400 mg/kg of the extract respectively. The study lasted for three weeks although blood samples were obtained from the rat tails after every week. The results show that the extract significantly reduced the hyperglycemia from (Diabetic Control). Likewise, the extract significantly reduced the Total Cholesterol (TC), Triglyceride (TG) and Low-Density Lipoprotein Cholesterol (LDLCholesterol), while increasing the High-Density Lipoprotein Cholesterol (HDL-C). In conclusion, the observations from this study show that *Caralluma fimbriata* has antidiabetic effect and beneficial effects on blood lipid profile, thus justifying the use of the plant by traditional medicine practitioners for the treatment of diabetes mellitus.

Biography

Ms. Snehal s. Naingade , doing M.Pharm in Pharmacology at Tatyasaheb Kore College of Pharmacy Warananagar. Presented posters in various conferences.

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