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Effect of trace elements in management of Type 2 diabetes

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Diabetes Mellitus is the commonest major metabolic disease and most prevalent diseases worldwide. A relationship was hypothesized between diabetes mellitus and trace elements in contemporary research. There was convincing evidence of role of trace elements in various metabolic processes. Furthermore, insulin action was found to be potentiated by some trace elements like chromium, magnesium, vanadium, zinc, manganese, molybdenum and selenium. In order to compare the three combinations of trace elements for correction of hyperglycaemia, hyperlipidaemia, glycogen content in liver and activities of some important carbohydrate metabolic enzymes in diabetes mellitus, the anti-diabetic effect and acute oral toxicity of a combination of trace elements were assessed. The anti-diabetic activity of the combination of the trace elements was compared with different non-diabetic and streptozotocin-induced diabetic groups for period of 30 days. The significant outcome was observed in management of type 2 diabetes with respect to cholesterol, triglycerides, lipid peroxidation, glutathione, catalase, glycogen, glucose-6-phosphates in liver on treatment with combination of trace elements. Furthermore, protective effect on pancreas injury was observed in animals treated with combination of trace elements. The strong anti-hyperglycemic and anti-hyperlipidemic effect were observed in streptozotocin-induced diabetic rats justifies the use of combination of trace elements for the managements of diabetes-related complications.

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cGMP considerations for parenteral formulations

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Pharmaceutical formulations have evolved from simple products to sophisticated devices and delivery systems over the last decade. Continuous efforts to make cost effective and safe medicines has always been the forefront of the Indian pharmaceutical industry. Technological advances in the areas of design, manufacturing technology, quality testing, and regulatory compliance of Pharmaceuticals has become challenging. Current Good Manufacturing Practices (cGMP) assist the industry in developing sustainable strategies for quality processes. It has been interestingly observed that the number of batches failing in quality as per regulatory standards has not decreased over the years. Looking at the USFDA recalls it is clear that cGMP violations accounts for the majority of failures. This has led to a lot of introspection. Parenteral products are more vulnerable since they require stringent manufacturing controls to prevent product failure. Problems of particulate matter and sterility account for major reasons. An in-depth study of product recalls was carried out and the causes of failure were classified. Data obtained was analyzed and grouped to assess the findings. Correlation was established as to which cGMP violations were responsible for product failure. Class I, II and III recalls were also correlated with the reasons of product failure. The findings have been tabulated and presented.

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