Study on the potential toxicity of a thymoquinone-rich fraction nanoemulsion in Sprague Dawley rats

Abstract

Toxicological studies constitute an essential part of the effort in developing an herbal medicine into a drug product. A newly developed thymoquinone-rich fraction nanoemulsion (TQRFNE) has been prepared using a high pressure homogenizer. The purpose of this study was to investigate the potential acute toxicity of this nanoemulsion in Sprague Dawley rats. The acute toxicity studies were conducted as per the OECD guidelines 425, allowing for the use of test dose limit of 20 mL TQRFNE (containing 44.5 mg TQ)/kg. TQRFNE and distilled water (DW) as a control were administered orally to both sexes of rats on Day 0 and observed for 14 days. All the animals appeared normal, and healthy throughout the study. There was no observed mortality or any signs of toxicity during the experimental period. The effects of the TQRFNE and DW groups on general behavior, body weight, food and water consumption, relative organ weight, hematology, histopathology, and clinical biochemistry were measured. All the parameters measured were unaffected as compared to the control (DW) group. The administration of 20 mL TQRFNE /kg was not toxic after an acute exposure.

Keyword: Sprague-Dawley rats; Nanoemulsion; Thymoquinone rich fraction; Acute oral toxicity; Histopathology; Hematology