ABSTRACT

Saffron, a spice is the dried and dark red stigma of *Crocus sativus* flowers, a member of the large *Iridaceae* family. Saffron is characterized by the presence of three main pharmacologically active components: Crocin and its derivatives which are responsible for colour; Picrocrocin responsible for the bitter taste and Safranal, a trepene essential oil obtained through hydrolysis of picrocrocin is responsible for the odour/aroma. Saffron also contains more than 150 volatile and aroma yielding compounds. Saffron is predominantly used to give colour, flavour and aroma to food and has being demonstrated to have many medicinal/therapeutic values. Apart from therapeutic values, toxicity related information has been demonstrated like intrauterine growth retardation and congenital malformations in mouse embryos (Seyed Adel Moallem et al. 2013), abortion at overdosing with high risk of maternal death (Zargari 1993 and Baker and Negbi 1983), increased miscarriage rate in female farmers working in saffron fields (Ajam et al. 2014) etc. Although generally saffron is considered to be safe, the toxicity information is not consistent.

Hence, the present study attempts to evaluate the embryo fetal developmental toxicity (teratogenicity) potential of saffron to induce structural and/or other abnormalities in the fetuses when administered orally to pregnant albino rats (Wistar rats) during gestation days 5 (day of implantation) to gestation day 19. In addition, efforts are made to detect adverse effects of orally administered saffron on the lactating rats and on development of the offspring through weaning. Since manifestation of effect induced during this period may be delayed, observation was continued through sexual maturity of the offspring. The study was designed based on the OECD Guideline for the Testing of Chemicals, TG No. 414 and International Council for Harmonization (ICH), S5 (R2) guideline.
The results demonstrated that oral consumption of saffron in Wistar rats up to the dose of 1000 mg/kg body weight was quite safe during pregnancy period and lactation period. There were no signs of teratogenicity or developmental toxicity and pup’s survivability was unaffected. Physical development and maturation of pups measured in terms of ages of pinna unfolding, incisor eruption, ear/eye opening were unaffected by saffron exposure including the landmark signs of attainment of sexual maturity. Further, it was noted that the prenatal study carried out in Sprague Dawley strain rats to elucidate any strain differences, showed that there were no strain differences between pregnant Wistar and Sprague Dawley rats in the response to the exposure of saffron administered orally.

**KEYWORDS**

Saffron, OECD TG No. 414, teratogenicity, Wistar rats, fetuses