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Research Article

Genotoxic and mutagenic potential of 7-methylxanthine: an investigational drug molecule for the treatment of myopia

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Abstract

7-Methylxanthine (7-MX, CAS No. 552-62-5, purity 99.46%) is the first orally administered drug candidate, which showed anti-myopic activity in different pre-clinical studies. In the present study, we investigated the *in-vivo* genotoxic and mutagenic toxicity of 7-MX in Wistar rats using comet/single-cell gel electrophoresis, chromosomal aberration and micronucleus assays after oral administration. For the single-dose study (72 h), two doses of 7-MX 300 and 2000 mg/kg body weight were selected. For a repeated dose 28 d study, three doses (250, 500, and 1000 mg/kg) of 7-MX were selected. The doses were administered via oral gavage in the suspension form. Blood and major vital organs such as bone marrow, lung and liver were used

to perform comet/single cell gel electrophoresis, chromosomal aberration, and micronucleus assays. The *in-vitro* Ames test was performed on TA98 and TA100 strains. In the chromosomal aberration study, a non-significant increase in deformities such as stickiness, ring chromosome, and endoreduplication was observed in bone marrow cells of 7-MX treated groups. These chromosomal alterations were observed upon treatment with doses of 2000 mg/kg single dose for 72 h and 1000 mg/kg repeated dose for 28 d. At a dose of 500 mg/kg, DNA damage in terms of tail length, tail moment, % tail DNA and the olive tail moment was also found to be non-significant in 7-MX treated groups. The Ames test showed the non-mutagenic nature of 7-MX in both strains of TA98 and TA100 of *Salmonella typhimurium* with or without metabolic activation. Thus, the present work is interesting in view of the non- genotoxicity and non-mutagenicity of repeated doses of 7-MX.

Keywords: 7-Methyl xanthine (7-MX CAS No. 552-62-5 purity 99%) Wistar rats comet assay genotoxicity Ames test chromosomal aberration myopia

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Disclosure statement

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