SAFETY ASSESSMENT OF Mo-CBP₄, A PROTEIN FROM MORINGA OLEIFERA SEEDS WITH THERAPEUTICAL PROPERTIES, BY REPEATED DOSE 28-DAY ORAL TOXICITY TEST


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*Moringa oleifera* Lam. has been successfully used in folk medicine due to its analgesic and anti-inflammatory properties. In our research group, a chitin-binding protein from *M. oleifera* seeds, named Mo-CBP₄, which exhibits antinociceptive and anti-inflammatory properties, was purified. This work aimed to assess whether repeated dose treatment with Mo-CBP₄ causes any kind of toxicity in preclinical setting as part of the evaluation of its use as a potential biopharmaceutical drug. This study followed OECD’s Guidelines for repeated dose 28-day oral toxicity test in mice (Guideline 407). Mo-CBP₄ was administered once a day by gavage for 28 days at doses of 10, 40 and 100 mg/kg body weight, corresponding to 1-, 4- and 10-fold the therapeutic dose, respectively. BSA (100 mg/kg) and saline 0.9% were used as controls. During the experimental period, general behavior, mortality, body weight and food intake were recorded. Hematological, biochemical and urinary parameters, as well as relative organ weights were determined at the end of the experiment. Mo-CBP₄ treated mice did not show any change in their behavioral pattern. The body weight gain in Mo-CBP₄ treated female mice, but not in male group, was lower than that in saline treated mice. Reduction in food intake was observed in all groups (experimental and control), that would probably be related to stress induced by oral gavage. Concerning the hematological analysis, male mice treated with BSA and Mo-CBP₄ (40 and 100 mg/kg) showed increased platelet numbers. Regarding the other analyzed parameters, no significant variation was observed. Based on these results, Mo-CBP₄ exhibited low oral toxicity in mice when repeatedly administered, even at a dose 10-fold higher than the therapeutic dose. These results show that no expected relevant risks are associated with the consumption of Mo-CBP₄, providing valuable information for its future use as a biopharmaceutical drug.

Keywords: Moringa; toxicity; chitin-binding protein.

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