

[P-26]

13-weeks toxicity study of fructus of *Aristolochiae contorta* in SD rat

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The potential toxicological effects of aristolochic acid (AA), a natural component in Aristolochiaceae family, were investigated. The 13-week toxicity study consisted of groups of 10 SD rat/sex administrated water containing 0, 0.05, 0.5, or 5 mg/kg per day AA (Study 1). The tested groups were terminated on Test Day 90 due to mortality and overt clinical signs of toxicity. The 13-weeks toxicity study consisted of groups of 10 SD rat/sex administrated water containing 0, 21.35, 213.5 or 2135 mg/kg per day aqueous extract of fructus of *Aristolochiae contorta* and 427 mg/kg per day aqueous extract of Korea traditional medicine containing *A. contorta* (Study 2). Groups given 5 mg/kg per day and 2135 mg/kg per day were observed markedly lower body weight gain and feed consumption on Day 50. Standard toxicological parameters were evaluated consistent with existing regulatory guidelines. The primary effect in the 13-weeks study was nephrotoxicity and hyperplasia of epithelial cells in forestomach at doses of ≥ 0.5 mg/kg per day and at dose of 2135 mg/kg per day. The incidence of tumors in SD rat given AA and aqueous extract of fructus of *A. contorta* was increased relative to controls at dose dependent manner. No toxic effect level based on histopathological changes of the 13-weeks study was 0.05 mg/kg per day AA for male and female SD rat.

Keyword : 13-weeks toxicity study, aristolochic acid, *Aristolochiae contorta*, nephrotoxicity