



Safety of Bacillus coagulans Unique IS-2 in Rats : Morphological , Biochemical and Clinical Evaluations

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Summary :

Acute and sub-acute oral toxicity of the probiotic strain, Bacillus coagulans Unique IS-2 (MTCC- 5260) was conducted in Sprague Dawley rats. The rats were orally fed with Bacillus coagulans Unique IS-2 at the dose levels of 3250, 6500 mg/kg b.w (5X10⁹ spores /g) for a single day for acute studies. For sub-acute studies, experimental rats received doses of 130, 650, 1300 mg/kg b.w/day (5X10⁹ spores/g) for 14 consecutive days whereas control animals received only water. Half of the rats were sacrificed after 14 days and the remaining after 28 days. The results of this toxicity assessment indicate that there were no treatment related changes in any of the parameters studied - clinical signs, bodyweight, food intake, urinalysis, hematological examinations, clinical chemistry, gross pathology and histopathology at both time intervals i.e after 14 days and 28 days. Bacillus coagulans Unique IS-2 did not exhibit any signs of toxicity up to 1300 mg/kg b.w dose (5X10⁹ cfu/g), when administered for 14 days which was considered as 'No Observed Adverse Effect Level' (NOAEL). These results suggest that the strain Bacillus coagulans Unique IS-2 may be considered as non-pathogenic and safe for human consumption.
