Safety assessment studies of probiotic Saccharomyces boulardii strain Unique 28 in Sprague-Dawley rats

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Summary:

Background:

Strains of Saccharomyces boulardii, a probiotic yeast, have been found to be effective in the treatment of diarrhoea, inflammatory bowel disease, irritable bowel syndrome and other conditions.

Materials and Methods:

In the present study, Unique 28, a strain of S. boulardii isolated and characterised in our laboratory, was evaluated for its safety assessment. Acute and subacute toxicity tests were performed in rats. The dose of Unique 28 (5×10(9) cfu/g) fed orally was, up to 6,500 mg per kg of b.w. (body weight) for acute toxicity and up to 1,300 mg per kg of b.w. for sub-acute toxicity studies.

Results:

This dose was well tolerated and there was no morbidity or any kind of toxic clinical symptoms displayed either in male or female rats. Moreover, the results of sub-acute toxicity studies using Unique 28 administered for 14 weeks indicated that there were no clear unwanted treatment related effects.

Conclusion:

Overall results of this toxicology assessment indicate that Unique 28 is safe for human consumption.