**A Bacterial Reverse Mutation Test of PROJECT I**

**11 SUMMARY AND CONCLUSION**

The objective of this study was to assess the potential of PROJECT I for inducibility of gene mutation.

A bacterial reverse mutation test was performed with 5 test strains of bacteria [*Salmonella typhimurium* (TA100, TA1535, TA98, and TA1537) and *Escherichia coli* (WP2*uvrA*)], using the pre-incubation method with and without metabolic activation. Based on the results of the dose-finding test at 5, 15, 50, 150, 500, 1500, and 5000 μg/plate, the main test was performed at 156, 313, 625, 1250, 2500, and 5000 μg/plate.

Test article precipitation was observed at 2500 μg/plate and greater upon addition of the test article formulation, and at 5000 μg/plate on the plates after incubation for 48 hours with and without metabolic activation. Growth inhibition was not observed at up to 5000 μg/plate in any test strain with or without metabolic activation.

In comparison with the negative control, no 2-fold or greater increase in the number of revertant colonies was observed in any test strain with or without metabolic activation.

It was concluded that PROJECT I has no potential to induce gene mutation in bacteria under the conditions of this study.