

STUDY SUMMARY

The potential biological reactivity of a mammalian cell culture (mouse fibroblast L929) in response to exposure to the extract of the test article, Gel-Pak standard gel material, X0 retention level, was determined. The test article was extracted in Minimum Essential Medium (MEM) with 10% Fetal Bovine Serum (referred to as complete MEM) for 24 ± 2 hours at 37 ± 1 °C. Negative and positive controls were prepared similarly. The maintenance medium of L929 cells grown in 6-well plates was replaced with the neat (100%) extracts in 3 replicates, and the cells were incubated for 48 ± 2 hours at 37 ± 1 °C. The biological reactivity of the cells following the exposure to the extracts was visually observed with a microscope, and graded on a scale of 0 to 4.

There was no biological reactivity (Grade 0) of the cells exposed to the test article extract. The response obtained from the positive and negative control article extracts confirmed the suitability of the test system.

Based on the criteria of the protocol and the ISO 10993-5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.

Test performed by Toxikon (Independent Laboratory), Final GLP Report. No. 13-04511-G1 dated February 6, 2014. Complete test report can be provided upon request.