

Column E Explanation  
WuXi AppTec, USDA Annual Report 2010-2011

**Registration Number: 41-R-0061**

1. Number of animals reported in Column E: 1
2. Species (common name) of animals used: New Zealand White Rabbit
3. Explanation of the procedure producing pain and/or distress.

The animal was used under IACUC protocol 07-130B, Rabbit Pyrogen Test. The testing involves restraining the animal in a rabbit stock and placing a rectal probe to monitor body temperature after an intravenous injection of a test article. The animal is monitored at a minimum of every 30 minutes for the duration of the study (no longer than 4 hours). Upon injection of the test article the animal had a severe reaction.

4. Scientific justification of why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with the test results. (For federally mandated testing proceed to question 5)

A veterinarian was immediately notified. The animal was treated for anaphylactic shock with oxygen therapy and a subcutaneous injection of epinephrine. The animal appeared to recover and was observed throughout the day as having mildly labored breathing. The animal was found dead the following morning. It was later noted that the animal experienced a significant electrolyte imbalance due to a sample preparation error.

5. What, if any, federal regulations require the procedure? Cite the agency, the code of federal regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 1113.102).

United States Pharmacopeia (USP) Biological Test and Assays; Section 151, Pyrogen Test

European Pharmacopeia 6.0, 2.6.8 Pyrogens (01/2008:20608)

Method for Ministry of Health, Labor and Welfare (MHLW) Japan; Section 7, Pyrogenicity Tests