

NP 1/16/2018

**PreClinical Research Services, Inc.**  
**Registration Number: 84-R-0072**

**Column E Explanation**

**1. Number of animals used in this study:**

A total of 64 dogs were used on this study.

**2. Species of animals used in this study: Canine**

**3. Explain the procedure producing pain or distress:**

The dog urate model induces an acute synovitis that manifests as local inflammation and lameness that peaks at 2- 6 hr post IA urate injection and resolves by 24 hours. No long term consequences to the acute inflammation have been reported and several studies have utilized repeat injections in the same joint after a period of rest. Animals were treated with analgesics following the 8 hour evaluation if lameness persisted.

Additionally, the proprietary vehicle was compared with a negative control. Clinical signs as a result of the dog urate model were used to support the hypothesis that the proprietary vehicle alone exhibits analgesic properties.

**4. Scientific or regulatory justification for withholding of pain/distress relief:**

Analgesics were withheld because the study evaluated an analgesic and the administration of an analgesic would confound the results of the test article. The results of a previous study suggested that the proprietary vehicle may have analgesic properties. The dog urate model was chosen due to the temporary nature of the inflammation as there is no need to induce long term pain and lameness to investigate the analgesic effects of the two test silk fibroin vehicles.

**5. What, if any, federal regulations require this procedure?**

N/A