This study was conducted to evaluate the pharmacokinetic properties of meloxicam in a sustained release drug delivery matrix. The primary study objective was to determine the pK release profile and assess any injection site reactions to this new subcutaneously administered, formulation of meloxicam in dogs.

Experimental design developed such that all animals (n=6) were administered the same dose rate of the meloxicam sustained release formulation in a single, subcutaneous injection between the shoulders. The actual dose administered was 0.6 mg/kg, 3 times the standard daily dose for dogs (0.2 mg/kg).

The test site was shaved and wiped with alcohol prior to injection. Approximately 3 ml of whole blood was collected from each dog at each of the time points; prior to dosing and post treatment 1, 4, 8, 12, 24, 36, 48, 72 and 96 hours.

Samples were collected in K2 EDTA tubes and processed for plasma. The plasma samples were stored at approximately -20°C until shipped for analysis. Injection sites were observed for any adverse reactions at all of the blood collection time points. Observations for any obvious changes in behavior, appetite or any other adverse event(s) was done prior to dosing, at the 1, 4, 8, 12, 24, 36, 48, 72 and 96-hour time points.

**Housing:**
USDA approved dog runs consisting of galvanized chain link fence, a seamless floor, covered with Poultry Bedding (a wood product)

**Feed / Water**
Commercial diet. Tap water *ad libitum*

**Environmental Conditions:**
Light Cycle: 12 hrs. / 12 hrs. on/off cycle
Temperature Range: 70-75° F
Humidity Range: 23-68%
Maintenance: The room and environmental conditions were maintained as specified in the HQR Standard Operating Procedures.

**Study Design:**

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th># of Animals</th>
<th>Test Article (Concentration)</th>
<th>Dose</th>
<th>Route of Administration</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beagle Dogs</td>
<td>(n=6) Females 3 Males</td>
<td>Meloxicam SR (10 mg/ml)</td>
<td>0.6 mg/kg</td>
<td>Subcutaneous (dorsal, mid-scapula)</td>
<td>Single injection</td>
</tr>
</tbody>
</table>
Inclusion / Exclusion Criteria: Only animals free of obvious abnormalities indicative of health problems and considered to be in good health and body condition were used for the study. Dogs were bled and a complete blood count and serum chemistry were performed on Day -5 to assure the dogs were not exhibiting any clinical disease, especially renal or hepatic disease.

Data Collection:

- Blood sample collections were done at 0, 1, 4, 8, 12, 24, 36, 48, 72, and 96 hours.
- Samples were processed as described above and shipped to a laboratory for analysis of meloxicam levels.
- Injection sites were observed for tissue reactions.
- Any observed changes in behavior, appetite, water consumption were also recorded

Significant Findings:

- Meloxicam SR maintained therapeutic blood levels* up to 72 hours
- No visible injection site irritations reported
- No clinical side effects or changes in normal behavior and appetite

Meloxicam is a proven NSAID with an excellent safety profile for use in dogs. The effective administration of subcutaneous meloxicam for alleviating inflammation and pain in both acute and chronic musculoskeletal disorders has been established in a number of studies.1,2

Previous pain models in dogs have demonstrated antinociceptive efficacy at a dose rate of 0.2 mg/kg SC q24-hr. Pharmacokinetic studies have reported mean plasma concentration / time profiles of meloxicam in dogs at this therapeutic dosage, to be between 300 ng/ml and 400 ng/ml (for 24 hours)*.1

Results recorded in this study (shown in fig 1), indicate that sustained release Buprenorphine SR maintained previously reported therapeutic levels of meloxicam in plasma for up to 72 hours.

**FIG. 1. Mean ± SD plasma concentration profiles for 96 hr. after single sc administration of Meloxicam SR (0.2 mg/kg) to dogs (n = 6).**

During the course of the study, there were no adverse reactions at the injection sites and there were no obvious changes in behavior, appetite or any other adverse events for all of the animals on study.