

7.3. Administration of Test Material

7.3.1. The test material will be agitated vigorously prior to matter.

7.3.2. Prior to injection of the extract and the control of solution with a concentra

Photographer: William Campbell

Certificate: 93-R-0189

Date and Time: 7/26/2022 1:22 PM

Legal Name: Pacific BioLabs

Inspection No: 2016090000806000

Facility Name: PACIFIC BIOLABS

Description: Administration of test material including dilution instructions for polyethylene glycol

16. ADVERSE EFFECTS

Any specific adverse effects will be dependent upon the nature of the material under test. If adverse effects occur, animals will be evaluated by the veterinary staff, as directed by the attending veterinarian. All animals will be monitored at least once daily. Adverse effects may include moderate erythema and/or edema, eschar formation, biting or continuously scratching at the injection site, inappetance or signs of infection. An evaluation of the animal will be performed and treatment, including anti-inflammatories and/or analgesics, may be initiated at the discretion of the attending veterinarian. The use of anti-inflammatory treatment will be discussed with the Study Director.

For the positive control study, in which a known irritant agent is injected, animals will be administered analgesia according to [REDACTED]. Prior to dosing (Day 1), Buprenorphine will be administered (0.05 mg/kg, SC). If scores greater than 2 for erythema or edema occur, Meloxicam (0.3-0.5 mg/kg, SC, SID) will be administered on Day 2 and Day 3 unless otherwise instructed by veterinarian.

If treatment interferes with the test parameters or the observed adverse effects cannot be ameliorated, the animal will be removed from the study and humanely euthanized.

17. HUMANE ENDPOINTS

In the event that the test article results in pain or distress to the animal, the attending veterinarian will be consulted regarding appropriate treatment and continued use of the animal on the test. At the discretion of the attending veterinarian, in consultation with the Study Director, the affected animal may be provided appropriate veterinary care or may be removed from the study, and humanely euthanized. Moribund animals, including animals that have lost greater than 15% of their body weight, may be euthanized at the discretion of the attending veterinarian.

CFR:2.33(b)(3)

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Description: Description of procedures and communication in the event of adverse effects or humane endpoints.