Date of Approval: July 11, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-816

Meloxisol™

(meloxicam oral suspension)

Dogs

Meloxisol™ oral suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

Executive Summary

Meloxisol™ (meloxicam oral suspension) 1.5 mg/mL is approved for the control of pain and inflammation associated with osteoarthritis in dogs. The reference listed new animal drug (RLNAD) is Metacam® (meloxicam oral suspension) 1.5 mg/mL, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-213.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in dogs to show that the 1.5 mg/mL Meloxisol™ oral suspension is bioequivalent to the 1.5 mg/mL Metacam® oral suspension. No serious adverse events were reported during the study.

Conclusions

Based on the data submitted by the sponsor for the approval of Meloxisol™ 1.5 mg/mL oral suspension, FDA determined that the drug is safe and effective when used according to the label.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-816

B. Sponsor

Cronus Pharma Specialities India Private Ltd.
Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd.,
Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy,
Hyderabad, Telangana, 500108, India

Drug Labeler Code: 069043

U.S. Agent Name and Address:

Jodi Beaudry, MSc
J^2 Consulting LLC
45 Bugling Elk Ln
Columbus, MT 59019

C. Proprietary Name

Meloxisol™

D. Drug Product Established Name

meloxicam oral suspension

E. Pharmacological Category

Non-steroidal anti-inflammatory

F. Dosage Form

Oral suspension

G. Amount of Active Ingredient

1.5 mg/mL

H. How Supplied

30 mL, 100 mL, and 200 mL bottles with measuring syringes

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Meloxisol™ oral suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1,

Meloxisol™ oral suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringes are calibrated to deliver the daily maintenance dose in pounds.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. Indication

Meloxisol™ oral suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

N. Reference Listed New Animal Drug

Metacam®; meloxicam oral suspension; NADA 141-213; Boehringer Ingelheim Animal Health USA, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required.

For this ANADA, one *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic and RLNAD 1.5 mg/mL meloxicam oral suspension. The *in vivo* blood-level study was conducted in 24 healthy, fasted dogs. The pivotal parameters to evaluate bioequivalence are the observed maximum plasma drug concentration (C_{MAX}) and area under the concentration-time curve (AUC) from time 0 to the last sampling time before the first unquantifiable concentration after C_{MAX}. Bioequivalence was demonstrated between the 1.5 mg/mL RLNAD meloxicam oral suspension and the 1.5 mg/mL generic meloxicam oral suspension by the average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

Blood-level Bioequivalence Study in Dogs

Title: Plasma Bioavailability Study of Test Article Meloxicam Oral Suspension, 1.5 mg/mL and Reference Article Metacam® (meloxicam oral suspension) 1.5 mg/mL Administered Orally in the Dog. (Study No. 19247)

Study Dates: February 25, 2021 to November 26, 2021

Study Locations:

In-life phase: Telangana, India

Bioanalytical testing: Andhra Pradesh, India

Study Design:

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 1.5 mg/mL Meloxisol™ (meloxicam oral suspension) and the RLNAD 1.5 mg/mL Metacam® (meloxicam oral suspension) in fasted dogs.

Study Animals: Twenty-four intact male beagles, weighing approximately 10 kg to12 kg, and approximately 2 years to 4 years of age.

Experimental Design: A randomized, masked, two-period, two-sequence, single-dose crossover study conducted according to Good Laboratory Practice for Nonclinical Laboratory Studies.

Drug Administration: Each animal received 2.2 mg of either the generic or RLNAD meloxicam oral suspension according to their randomized treatment sequence (generic/RLNAD or RLNAD/generic).

Measurements and Observations: The plasma concentrations of meloxicam were measured using a validated bioanalytical method. Pharmacokinetic parameters were determined for each animal individually in each period. Animal observations were made throughout the study for assessment of general health and adverse events.

Statistical Methods:

The laboratory study was conducted as a randomized, masked, two-period, two-sequence, two-treatment, single-dose crossover design using 24 dogs with a 14-day washout between periods. Appropriate randomization of animal to sequence and pen/treatment order was performed. Primary variables evaluated were C_{MAX} and AUC. Time to maximum concentration (T_{MAX}) was summarized and evaluated clinically.

A mixed-effect model was used to evaluate bioequivalence. The model included fixed effects of treatment, sequence and period, and a random effect of subject nested within sequence. Prior to the analysis, C_{MAX} and AUC were natural logarithm transformed. Bioequivalence is established because the back-transformed estimated upper and lower bounds of the 90% confidence interval for geometric mean ratios (generic:RLNAD) of both C_{MAX} and AUC are contained within the acceptance limits of 0.80 to 1.25.

Results:

As seen in the table below, C_{MAX} and AUC fall within the prescribed bounds (Table II.1). The mean values of T_{MAX} obtained for the generic article and RLNAD were summarized.

Table II.1. Bioequivalence Evaluation

Parameter	Generic Mean	RLNAD Mean	Ratio◊	Lower 90% CI	Upper 90% CI
AUC (ng/mL)*hour	25661.7†	25701.4†	1.00	0.93	1.07
C_{MAX} (ng/mL)	827.5†	863.4†	0.96	0.90	1.02
T_{MAX} (hours) (SD)‡	4.13 (1.80)‡	3.40 (1.43)‡	NE	NE	NE

† Geometric mean
‡ Arithmetic mean and standard deviation (SD)
◊ Ratio = Test/Reference
CI = confidence interval
NE = not estimated

Adverse Reactions:

There were no serious adverse events reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 1.5 mg/mL meloxicam oral suspension and the RLNAD 1.5 mg/mL Metacam® (meloxicam oral suspension) are bioequivalent in dogs.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Meloxisol™ 1.5 mg/mL oral suspension:

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. **For oral use in dogs only**.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Meloxisol™ 1.5 mg/mL oral suspension, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.