Date of Approval: January 12, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-833

Maropitant Citrate Tablets

(maropitant citrate)

Chewable Tablets

Dogs

Maropitant Citrate Tablets (maropitant citrate) chewable tablets are indicated for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs.

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

Executive Summary

Maropitant Citrate Tablets (maropitant citrate) chewable tablets are approved for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs. The reference listed new animal drug (RLNAD) is Cerenia® (maropitant citrate) tablets, sponsored by Zoetis Inc., under NADA 141-262.

Bioequivalence

For this approval, the Food and Drug Administration (FDA) approved a suitability petition to allow the sponsor to submit an ANADA for a generic animal drug that differs in dosage form from the RLNAD. The RLNAD dosage form is an oral tablet, whereas the generic is a chewable tablet. The Suitability Petition was granted on August 28, 2023 (FDA-2023-P-2155).

The sponsor conducted one *in vivo* blood-level study in dogs to show that the 60 mg Maropitant Citrate Tablets (maropitant citrate) chewable tablet is bioequivalent to the 60 mg Cerenia® tablets. No serious adverse events were reported during the study.

The sponsor conducted a comparative *in vitro* dissolution study for the additional product strengths. Based on the dissolution data, the 16 mg, 24 mg, and 160 mg Maropitant Citrate Tablets (maropitant citrate) chewable tablets qualified for a waiver from the requirement to perform separate *in vivo* bioequivalence studies (a biowaiver). FDA granted a biowaiver for these strengths.

Conclusions

Based on the data submitted by the sponsor for the approval of Maropitant Citrate Tablets (maropitant citrate) chewable tablets, 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 200-833

B. Sponsor

Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:

Sreejith Kurup
Felixvet Inc.
1300 NW Briarcliff Parkway
Suite 100
Kansas City, MO 64150

C. Proprietary Name

Maropitant Citrate Tablets

D. Drug Product Established Name

maropitant citrate

E. Pharmacological Category

Antiemetic

F. Dosage Form

Chewable tablets

G. Amount of Active Ingredient

16 mg, 24 mg, 60 mg, or 160 mg of maropitant as maropitant citrate per tablet

H. How Supplied

Each tablet strength is scored and packaged either in a bottle containing 60 tablets or in blister packs containing 4 tablets per perforated sheet.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

For Prevention of Acute Vomiting in dogs 2 - 7 months of age: Administer Maropitant Citrate Tablets orally at a minimum dose of 2 mg/kg (0.9 mg/lb) body weight once daily for up to 5 consecutive days.

For Prevention of Acute Vomiting in dogs 7 months of age and older: Administer Maropitant Citrate Tablets orally at a minimum dose of 2 mg/kg (0.9 mg/lb) body weight once daily until resolution of acute vomiting.

For Prevention of Vomiting due to motion sickness in dogs 4 months of age and older: Administer Maropitant Citrate Tablets orally at a minimum dose of 8 mg/kg (3.6 mg/lb) body weight once daily for up to 2 consecutive days.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. Indication

Maropitant Citrate Tablets are indicated for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs.

N. Reference Listed New Animal Drug (RLNAD)

Cerenia®; maropitant citrate; NADA 141-262; Zoetis Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an 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.

The sponsor submitted a suitability petition (FDA-2023-P-2155) requesting permission to submit an ANADA for a generic new animal drug that differed in dosage form from the RLNAD. The RLNAD is an oral tablet, whereas the generic sponsor proposed an oral chewable tablet. This petition was approved on August 28, 2023, under 512(n)(3)(C) of the FD&C Act.

For this ANADA, one *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic 60 mg maropitant citrate chewable tablets and RLNAD 60 mg maropitant citrate tablets. The RLNAD is available in 16, 24, 60, and 160 mg tablet sizes. The *in vivo* blood-level study was conducted in 26 healthy, fed 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 60 mg RLNAD Cerenia® tablets and the 60 mg generic maropitant citrate chewable tablets by the average bioequivalence approach as described in the Statistical Methods section below. A waiver from the requirement to demonstrate *in vivo* bioequivalence (biowaiver) for the generic 16 mg, 24 mg, and 160 mg tablet strengths was requested. Dissolution data was used to demonstrate that the generic 16 mg, 24 mg, and 160 mg maropitant citrate tablets are comparable to the generic 60 mg tablet strength used in the *in vivo* blood-level bioequivalence study. Therefore, a biowaiver for the generic 16 mg, 24 mg, and 160 mg maropitant citrate tablets was granted. The study information is summarized below.

A. Blood-level Bioequivalence Study in Dogs

Title: Pivotal Bioequivalence Study of Cerenia® Tablets and a Formulation of Generic Maropitant Citrate Chewable Tablets when Administered Orally to Dogs in a Fed State. (Study No. MRPC-KC2-11124)

Study Dates: July 17, 2024 to January 24, 2025

Study Locations:

In-life phase: Ontario, Canada

Bioanalytical testing: Ontario, Canada

Study Design:

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 60 mg maropitant citrate chewable tablets and the RLNAD 60 mg Cerenia® (maropitant citrate) tablets in fed dogs.

Study Animals: Twenty-six, healthy male and female (intact and spayed) dogs between 7 months to 5 years of age and weighing 7.4 to 9.7 kg.

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 60 mg of either the generic or RLNAD maropitant citrate according to their randomized treatment sequence (generic/RLNAD or RLNAD/generic).

Measurements and Observations: The plasma concentrations of maropitant citrate 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 26 dogs with a 14-day

washout between periods. Appropriate randomization of animals 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	9213†	9438†	0.98	0.93	1.02
C_{MAX} (ng/mL)	690.8†	742.1†	0.93	0.89	0.98
T_{MAX} (hours) (SD)‡	2.0 (0.60)‡	1.8 (0.63)‡	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 60 mg maropitant citrate chewable tablets and the RLNAD 60 mg Cerenia® (maropitant citrate) tablets are bioequivalent in dogs.

B. Bioequivalence Waiver

A pivotal *in vivo* blood bioequivalence study was conducted using the 60 mg maropitant citrate tablet strength. A waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) for the generic 16 mg, 24 mg, and 160 mg tablet strengths was requested. To qualify for a biowaiver for each of these product strengths, comparative *in vitro* dissolution studies were conducted to determine the dissolution profiles of the generic and RLNAD 16 mg, 24 mg, 60 mg, and 160 mg maropitant citrate tablet strengths. Comparisons were made between the following tablets:

- Generic 60 mg and generic 16 mg tablets
- Generic 60 mg and generic 24 mg tablets
- Generic 60 mg and generic 160 mg tablets
- Generic 16 mg, 24 mg, 60 mg, and 160 mg tablets to the corresponding RLNAD 16 mg, 24 mg, 60 mg, and 160 mg tablets

The test conditions were as follows:

- Dissolution apparatus: USP Apparatus I (basket)
- Dissolution medium: 0.01 N HCl
- Dissolution medium volume: 900 mL
- Temperature: 37 °C
- Paddle speed: 75 rpm
- Number of vessels: 12
- Data points: 5, 10, 15, 20, 30, and 45 minutes

The generic drug lot number used in the *in vivo* bioequivalence study was the same lot used to support the *in vitro* profile comparisons. Analytical method validation was required to ensure that the quantification of drug concentrations in all samples was accurate and precise.

The use of mean data was not necessary since all profiles were rapidly dissolving and f_2 (similarity factor) calculations were not applicable.

A summary of the results is presented in Table II.2 below:

Table II.2. Similarity Results

Dissolution Comparison	Similarity Results
60 mg generic to the 16 mg generic	> 85% dissolved in 15 minutes
60 mg generic to the 24 mg generic	> 85% dissolved in 15 minutes
60 mg generic to the 160 mg generic	> 85% dissolved in 15 minutes
16 mg generic to the 16 mg RLNAD	> 85% dissolved in 15 minutes
24 mg generic to the 24 mg RLNAD	> 85% dissolved in 15 minutes
60 mg generic to the 60 mg RLNAD	> 85% dissolved in 15 minutes
160 mg generic to the 160 mg RLNAD	> 85% dissolved in 15 minutes

Study results demonstrate similar dissolution profiles for all comparisons. However, because of rapid dissolving characteristics (> 85% in 15 minutes) in all strengths, a dissolution profile comparison using the f_2 test is unnecessary. When comparative profiles between tablets do not require an f_2 test because of rapid dissolution or when the f_2 value is ≥ 50, the product strengths used in the comparison qualify for a biowaiver. Therefore, a biowaiver for the generic 16 mg, 24 mg, and 160 mg tablet strength (maropitant citrate) tablets is granted.

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, FDA 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 Maropitant Citrate Tablets:

WARNINGS: Not for use in humans. Keep out of the reach of children. In case of accidental ingestion, seek medical advice. Topical exposure may elicit localized allergic skin reactions in some individuals. Repeated or prolonged exposure may lead to skin sensitization. Wash hands with soap and water after administering drug. Maropitant Citrate Tablets are also an ocular irritant. In case of accidental eye exposure, flush with water for 15 minutes and seek medical attention.

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 Maropitant Citrate Tablets, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.