Date of Approval: July 20, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-835

EnroPro™

(enrofloxacin)

Flavored Antibacterial Tablets

Dogs and cats

EnroPro™ (brand of enrofloxacin) Antibacterial Tablets are indicated for the management of diseases associated with bacteria susceptible to enrofloxacin. EnroPro™ Antibacterial Tablets are indicated for use in dogs and cats.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

Executive Summary

EnroPro™(enrofloxacin) flavored antibacterial tablets are approved for the management of diseases associated with bacteria susceptible to enrofloxacin in dogs and cats. The reference listed new animal drug (RLNAD) is Baytril™ (enrofloxacin) Taste Tabs™, sponsored by Elanco US Inc., under NADA 140-441.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in fasted dogs to show that the 136 mg EnroPro™ flavored antibacterial tablets are bioequivalent to the 136 mg Baytril™ Taste Tabs™. No serious adverse events were reported during the study. The sponsor also conducted one *in vivo* blood-level study in cats to show that the 22.7 mg EnroPro™ flavored antibacterial tablets are bioequivalent to the 22.7 mg Baytril™ Taste Tabs™. No serious adverse events were reported during the studies.

The sponsor conducted a comparative *in vitro* dissolution study for the additional product strengths. Based on the dissolution data, the 22.7 mg and 68 mg strength EnroPro™ (enrofloxacin) flavored antibacterial tablets qualified for a waiver from the requirement to perform separate *in vivo* bioequivalence studies (a biowaiver) in dogs, and the 68 mg and 136 mg strength EnroPro™ (enrofloxacin) flavored antibacterial tablets qualified for a biowaiver in cats. FDA granted a biowaiver for the 22.7 mg and 68 mg tablet strengths in dogs and the 68 mg and 136 mg tablet strengths in cats.

Conclusions

Based on the data submitted by the sponsor for the approval of EnroPro™ (enrofloxacin) flavored antibacterial 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 200-835

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

C. Proprietary Name

EnroPro™

D. Drug Product Established Name

enrofloxacin

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Flavored antibacterial tablets

G. Amount of Active Ingredient

22.7 mg, 68 mg, or 136 mg of enrofloxacin per tablet

H. How Supplied

22.7 mg strength in bottles containing 100 and 500 double scored tablets.
68 mg strength in bottles containing 50 and 250 double scored tablets.
136 mg strength in bottles containing 50 and 200 double scored tablets.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Dogs: Administer orally at a rate to provide 5-20 mg/kg (2.27 to 9.07 mg/lb) of body weight. Selection of a dose within the range should be based on clinical experience, the severity of disease, and susceptibility of the pathogen. Animals which receive doses in the upper-end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, and vomition.

Weight of Dog	Once Daily Dosing Chart			
	5.0 mg/kg	10.0 mg/kg	15.0 mg/kg	20.0 mg/kg
9.1 kg (20 lb)	2 x 22.7 mg tablets	1 x 22.7 mg plus 1 x 68 mg tablets	1 x 136 mg tablet	1 x 136 mg plus 2 x 22.7 mg tablets
27.2 kg (60 lb)	1 x 136 mg tablet	2 x 136 mg tablets	3 x 136 mg tablets	4 x 136 mg tablets

Cats: Administer orally at 5 mg/kg (2.27 mg/lb) of body weight. The dose for dogs and cats may be administered either as a single daily dose or divided into two (2) equal daily doses administered at twelve (12) hour intervals. The dose should be continued for at least 2-3 days beyond cessation of clinical signs, to a maximum of 30 days.

Weight of Cat	Once Daily Dosing Chart (5 mg/kg/day)
5 lb (2.27 kg)	½ x 22.7 mg tablet
10 lb (4.5 kg)	1 x 22.7 mg tablet
15 lb (6.8 kg)	1 and ½ x 22.7 mg tablets or ½ x 68 mg tablet

K. Route of Administration

Oral

L. Species

Dogs and cats

M. Indication

EnroPro™(brand of enrofloxacin) Antibacterial Tablets are indicated for the management of diseases associated with bacteria susceptible to enrofloxacin. EnroPro™ Antibacterial Tablets are indicated for use in dogs and cats.

N. Reference Listed New Animal Drug (RLNAD)

Baytril™ Taste Tabs™; enrofloxacin; NADA 140-441; Elanco US 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, two *in vivo* blood-level studies were conducted to demonstrate product bioequivalence using the generic and RLNAD enrofloxacin 136 mg tablets in dogs and the generic and RLNAD enrofloxacin 22.7 mg tablets in cats. The RLNAD is available in 22.7 mg, 68 mg, and 136 mg chewable tablet sizes. The *in vivo* blood-level study in dogs was conducted in twenty-four healthy, fasted dogs, and the *in vivo* blood-level study in cats was conducted in twenty-four healthy, fasted cats. 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 136 mg Baytril™ (enrofloxacin) Taste Tabs™ antibacterial tablets and the 136 mg generic EnroPro™ (enrofloxacin) flavored antibacterial tablets in dogs, and the 22.7 mg Baytril™ (enrofloxacin) Taste Tabs™ antibacterial tablets and the 22.7 mg generic EnroPro™ flavored antibacterial tablets in cats by the average bioequivalence approach as described in the Statistical Methods sections below. A biowaiver for the generic 22.7 mg and 68 mg flavored antibacterial tablets in dogs, and for the generic 68 mg and 136 mg flavored antibacterial tablets in cats was requested. Dissolution data was used to demonstrate that the generic 22.7 mg and 68 mg tablets are comparable to the generic 136 mg tablet strength used in the *in vivo* blood-level bioequivalence dog study, and the generic 68 mg and 136 mg tablets are comparable to the generic 22.7 mg tablet strength used in the *in vivo* blood-level bioequivalence cat study. Therefore, a biowaiver for the generic 22.7 mg and 68 mg generic tablets in dogs, and the generic 68 mg and 136 mg tablets in cats was granted. The study information is summarized below.

A. Blood-level Bioequivalence Study in dogs

Title: A masked, Randomized, Two Period, Two Sequence, Two Treatment, Single Dose Oral, Cross Over Bioequivalence Study of Enrofloxacin Flavored Tablets (136 mg) and Baytril™ Taste Tablets (136 mg) in Healthy Beagle Dogs under Fasted Conditions. (Study No. VLL/1124/BE003)

Study Dates: March 20, 2025, to April 15, 2025

Study Locations:

In-life phase: Telangana, India

Bioanalytical testing: Andhra Pradesh, India

Study Design:

Objective: The objective of this study was to assess the blood level bioequivalence of the test item (generic EnroPro™(enrofloxacin) Flavored Tablets 136 mg) compared to the reference item (Baytril™ (enrofloxacin) Taste Tabs™ Antibacterial Tablets 136 mg) when administered orally to fasted dogs.

Study Animals: Twenty-four healthy male (neutered) and female (spayed) beagle dogs, 1-3 years of age and weighing 8-11 kg on study day 0.

Experimental Design: A randomized, masked, two-period, two-sequence, single-dose crossover study conducted according to Organization for Economic Cooperation and Development Principles of Good Laboratory Practice.

Drug Administration: Each animal received 136 mg of either the generic or RLNAD enrofloxacin tablet according to their randomized treatment sequence (generic/RLNAD or RLNAD/generic).

Measurements and Observations: The plasma concentrations of enrofloxacin 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 with 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 1). The mean values of T_{MAX} obtained for the generic article and RLNAD were summarized.

Table 1. Bioequivalence Evaluation

Parameter	Generic Mean	RLNAD Mean	Ratio◊	Lower 90% CI	Upper 90% CI
AUC (ng/mL)*hour	9510.51†	9251.76†	1.03	0.98	1.07
C_{MAX} (ng/mL)	2223.11†	2330.54†	0.95	0.91	1.00
T_{MAX} (hours) (SD)‡	1.44 (0.50) ‡	1.33 (0.51)‡	NE	NE	NE

† Geometric mean

‡ Arithmetic mean and standard deviation (SD)
◊ Ratio = Generic/RLNAD
CI = confidence interval
NE = not estimated

Adverse Reactions:

There were no serious adverse events related to the test or reference article reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 136 mg EnroPro™ (enrofloxacin) flavored antibacterial tablets and the RLNAD 136 mg Baytril™ (enrofloxacin)Taste Tabs™ tablets are bioequivalent in dogs.

B. Blood-level Bioequivalence Study in Cats

Title: Pivotal Bioequivalence Study of BAYTRIL™ (Enrofloxacin) Taste Tabs™ Antibacterial Tablets and a Generic Formulation of Enrofloxacin Flavored Tablets when Administered Orally to Cats in a Fasted State. (KFI-108-BF-3122)

Study Dates: February 13, 2025, to March 8, 2025

Study Locations:

In-life phase: Ontario, Canada

Bioanalytical testing: Andhra Pradesh, India

Study Design:

Objective: The objective of this study was to assess the pharmacokinetics and bioequivalence of test item (generic EnroPro™(enrofloxacin) Flavored Tablets 22.7 mg) compared to reference item (Baytril™ (enrofloxacin) Taste Tabs™ Antibacterial Tablets 22.7 mg) when administered orally to fasted cats.

Study Animals: Twenty-four healthy male (neutered) and female (spayed) domestic short hair cats between 6 months and 5 years of age and weighing 3.5 to 4.4 kg on study day 0.

Experimental Design: A randomized, masked, two-period, two-sequence, single-dose crossover study conducted according to Organization for Economic Cooperation and Development Principles of Good Laboratory Practice.

Drug Administration: Each animal received 22.7 mg of either the generic or RLNAD enrofloxacin tablet according to their randomized treatment sequence (generic/RLNAD or RLNAD/generic).

Measurements and Observations: The plasma concentrations of enrofloxacin 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 cats 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. 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 2). The mean values of T_{MAX} obtained for the generic article and RLNAD were summarized.

Table 2. Bioequivalence Evaluation

Parameter	Generic Mean	RLNAD Mean	Ratio◊	Lower 90% CI	Upper 90% CI
AUC (ng/mL)*hour	16248.68†	16114.42†	1.01	0.99	1.03
C_{MAX} (ng/mL)	1660.21†	1665.40†	1.00	0.94	1.06
T_{MAX} (hours) (SD)‡	1.17 (0.71) ‡	1.12 (0.47)‡	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 related to the test or reference article that impacted the study outcome.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 22.7 mg EnroPro™ (enrofloxacin) flavored antibacterial tablets and the RLNAD 22.7 mg Baytril™ (enrofloxacin) Taste Tabs™ tablets are bioequivalent in cats.

C. Bioequivalence Waiver

A pivotal *in vivo* blood bioequivalence study was conducted using the 22.7 mg enrofloxacin tablet strength in cats, and the 136.0 mg enrofloxacin tablet strength in dogs. Waivers from the requirement to perform *in-vivo* bioequivalence studies (biowaiver) for the generic 68.0 mg tablets and 136.0 mg tablet strengths for

use in cats; and the generic 22.7 mg tablets and 68.0 mg tablet strengths for use in dogs were requested. To qualify for biowaivers for the additional tablet strengths for use in dogs and cats, *in vitro* dissolution studies were conducted to determine the dissolution profiles of the generic and RLNAD 22.7 mg tablet strength (enrofloxacin), as well as the generic and RLNAD 136.0 mg tablet strength (enrofloxacin). Further, *in vitro* dissolution studies were conducted to determine the dissolution profiles of the generic 22.7 mg, 68.0 mg and the 136.0 mg (enrofloxacin) tablet strengths.

Comparisons were made between the following tablets:

- Generic 22.7 mg and RLNAD 22.7 mg tablets
- Generic 136.0 mg and RLNAD 136.0 mg tablets
- Generic 22.7 mg and Generic 68.0 mg tablets
- Generic 22.7 mg and Generic 136.0 mg tablets
- Generic 68.0 mg and Generic 136.0 mg tablets

Test conditions were as follows:

- Dissolution apparatus: USP Apparatus I (basket)
- Dissolution medium: Citrate buffer at pH 4.00 ± 0.05
- Dissolution medium volume: 900 mL.
- Temperature: 37 °C ± 0.5°C.
- Paddle speed: 100 rpm.
- Number of vessels: 12.
- Data points: 10, 15, 20, 30, and 45 minutes

The generic drug lot numbers used in the *in vivo* bioequivalence study were the same lots 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 if dissolution profiles were rapidly dissolving and f2 (similarity factor) calculations were not applicable.

A summary of the results is presented in Table 3. below:

Table 3. Similarity Results

Dissolution Comparisons	Similarity Results
Cats: RLNAD 22.7 mg to Generic 22.7 mg	> 85% dissolved in 15 minutes
Dogs: RLNAD 136.0 mg to Generic 136.0 mg	> 85% dissolved in 15 minutes
Generic 22.7 mg to Generic 136.0 mg	> 85% dissolved in 15 minutes
Generic 68.0 mg to Generic 136.0 mg	> 85% dissolved in 15 minutes
Generic 22.7 mg to Generic 68.0 mg	> 85% dissolved in 15 minutes

Study results demonstrate similar dissolution profiles for all comparisons. However, because of rapid dissolving characteristics (> 85% in 15 minutes), 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, biowaivers for the generic 68.0 mg tablets and 136.0 mg tablet strengths for use in cats; and the generic 22.7 mg tablets and 68.0 mg tablet strengths for use in dogs were granted.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. 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 EnroPro™:

For use in animals only. Keep out of reach of children.

Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposure. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight.

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