Date of Approval: December 22, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-834

Praziquantel Tablets

Chewable Tablets

Cats

Praziquantel Tablets 23 Feline Cestocide are indicated for the removal of the following feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*.

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

Executive Summary

Praziquantel Tablets 23 Feline Cestocide are approved for the removal of the following feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*. The reference listed new animal drug (RLNAD) is Droncit™ (praziquantel tablets) 23 Feline Cestocide sponsored by Elanco US Inc., under NADA 111-798.

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 is a compressed tablet, and the generic animal drug is a compressed, chewable tablet. The associated suitability petition (FDA-2019-P-0916) was approved on May 15, 2019.

The sponsor conducted one *in vivo* blood-level study in cats to show that the 23 mg Praziquantel Tablets are bioequivalent to the 23 mg Droncit™ tablets. No serious adverse events attributed to the generic study drug were reported during the study.

Conclusions

Based on the data submitted by the sponsor for the approval of Praziquantel Tablets, FDA determined that the drug is safe and effective when used according to the label.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-834

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

Praziquantel Tablets

D. Drug Product Established Name

praziquantel tablets

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Chewable tablets

G. Amount of Active Ingredient

23 mg

H. How Supplied

3-count, 50-count, and 150-count bottles

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Praziquantel Tablets 23 Feline Cestocide may be administered directly per os or crumbled and mixed with the feed. The recommended dosage of praziquantel varies

according to body weight. Smaller animals require a relatively larger dosage because of their higher metabolic rate. The optimum dose for each individual animal will be achieved by utilizing the following dosage schedule:

Cats and Kittens*

4 pounds and under	½ tablet
5-11 pounds	1 tablet
Over 11 pounds	1 ½ tablets

*Not intended for use in kittens less than 6 weeks of age.

K. Route of Administration

Oral

L. Species/Class

Cats

M. Indication

Praziquantel Tablets 23 Feline Cestocide are indicated for the removal of the following feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*.

N. Reference Listed New Animal Drug

Droncit™; praziquantel tablets; NADA 111-798; 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.

The sponsor submitted a suitability petition (FDA-2019-P-0916) requesting permission to submit an ANADA for a generic new animal drug that differed in dosage form from the RLNAD. The RLNAD is a compressed tablet, and the generic is a compressed, chewable tablet. This petition was approved on May 15, 2019, 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 and RLNAD (praziquantel tablets) 23 mg tablets. The RLNAD is available in a 23 mg tablet size for cats. The *in vivo* blood-level study was conducted in 32 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 23 mg RLNAD (praziquantel tablets) and the 23 mg generic (praziquantel tablets) by the mixed reference-scaled average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

A. Blood-level Bioequivalence Study in Cats

Title: Pivotal Bioequivalence Study of DRONCIT™ (praziquantel tablets) 23 Feline Cestocide and a Generic Formulation of Praziquantel Chewable Tablets when Administered Orally to Cats in a Fasted State. (Study No. 080-BF-0824)

Study Dates: September 6, 2024 to July 2, 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 23 mg Praziquantel Tablets (praziquantel tablets) and the RLNAD 23 mg DRONCIT™ (praziquantel tablets) in fasted cats.

Study Animals: Thirty-two neutered male cats, 222 days to 342 days of age, and 3.4 to 4.3 kg body weight.

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

Drug Administration: Each animal received 23 mg of either the generic or RLNAD praziquantel tablets according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).

Measurements and Observations: The plasma concentrations of praziquantel 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 four-period, two-sequence, two-treatment, single-dose crossover design using 32 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. Time to maximum concentration (T_{MAX}) was summarized and evaluated clinically.

The reference-scaled average bioequivalence (RSABE) method was used as appropriate to evaluate bioequivalence through the mixed scaling approach. Prior to the analysis, C_{MAX} and AUC values were natural logarithm transformed. The estimated within-subject standard deviation (s_{WR}) of the RLNAD was calculated separately for transformed C_{MAX} and AUC to select the appropriate analysis approach based on FDA Guidances.

- The s_{WR} was less than 0.294 for AUC, so the average bioequivalence method was used to evaluate bioequivalence. The statistical model included fixed effects of treatment, sequence and period, and a random effect of subject nested within sequence. Period was modeled as a repeated factor. Bioequivalence was established because the back-transformed estimated upper and lower bounds of the pertinent 90% confidence interval for geometric mean ratios (generic:RLNAD) were contained within the acceptance limits of 0.80 to 1.25.

- The s_{WR} was equal to or greater than 0.294 for C_{MAX}, so the RSABE method was used, and bioequivalence was established based on the following two criteria:

  - The estimated 95% upper confidence bound for $(\mu_T - \mu_R)^2 - \theta^*\sigma^2_{WR}$ is less than zero (0), where μ_T and μ_R are the population means of the natural log transformed primary variable for the generic article and RLNAD, respectively, $\theta = (\log(1.25) / \sigma_{W0})^2$ and $\sigma_{W0} = 0.25$.

  - The point estimate of the generic to RLNAD geometric mean ratio is contained within the acceptance limits of 0.80 and 1.25.

Results:

As seen in the table below, C_{MAX} and AUC met the pre-specified criteria for bioequivalence (Table II.1). The mean values of T_{MAX} obtained for the generic article and RLNAD were summarized.

Table II.1. Bioequivalence Evaluation

Parameter	s_{WR}	Generic Mean	RLNAD Mean	Ratio[◊]	95% Upper Bound[$]	90% CI for the Ratio
AUC (µg/mL)*hour	0.1075	1871[†]	1888[†]	0.99	NE	(0.96, 1.02)
C_{MAX} (µg/mL)	0.2958	789.9[†]	778.6[†]	1.01	-0.0459	NE
T_{MAX} (hours) (SD)[‡]	NE	1.26 (0.67)[‡]	1.30 (0.77)[‡]	NE	NE	NE

[†] Geometric mean
[‡] Arithmetic mean and standard deviation (SD)
[◊] Ratio = Generic/RLNAD
[$] 95% upper confidence bound for $(\mu_T - \mu_R)^2 - \theta^*\sigma^2_{WR}$
CI = confidence interval
NE = not estimated

Adverse Reactions:

There were no serious adverse events attributed to the generic study drug reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 23 mg Praziquantel Tablets and the RLNAD 23 mg Droncit™ (praziquantel tablets) are bioequivalent in cats.

III. HUMAN FOOD SAFETY

This drug is intended for use in cats. 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 Praziquantel Tablets:

Keep out of the reach of children. Not for human use.

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