Date of Approval: January 12, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-734

Praziquantel Tablets

Chewable tablets

Dogs

Praziquantel Tablets 34 mg canine cestocide are indicated for the removal of the following canine cestodes: *Dipylidium caninum, Taenia pisiformis*, *Echinococcus granulosus* and for removal and control of *Echinococcus multilocularis.*

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

Executive Summary

Praziquantel Tablets 34 mg canine cestocide are approved for the removal of the following canine cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multiocularis* in dogs. Praziquantel Tablets are a generic version of Droncit™ (praziquantel tablets) 34 canine cestocide.

Bioequivalence

For this approval, FDA approved a suitability petition to allow the sponsor to submit an abbreviated new animal drug application (ANADA) for a generic animal drug that differs in dosage form from the reference listed new animal drug (RLNAD). The change in dosage form from a compressed tablet to a compressed chewable tablet was approved May 15, 2019 (FDA-2019-P-0916).

The sponsor conducted one *in vivo* blood-level study in healthy, fasted dogs to show that the 34 mg Praziquantel Tablets are bioequivalent to the 34 mg Droncit™ tablets. No serious adverse events were reported during the study.

Conclusion

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.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-734

B. Sponsor

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

Drug Labeler Code: 086101

U.S. Agent Name and Address:
James H. Schafer, DVM
Schafer Veterinary Consultants, LLC
800 Helena Court
Fort Collins, CO 80524

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

34 mg per tablet

H. How Supplied

50 and 150 tablets per container

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Administer directly by mouth 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:

Dogs and Puppies*

5 lbs and under	½ tablet
6-10 lbs	1 tablet
11-15 lbs	1 ½ tablets
16-30 lbs	2 tablets
31-45 lbs	3 tablets
46-60 lbs	4 tablets
Over 60 lbs	5 tablets maximum

*Not intended for use in puppies less than 4 weeks of age.

K. Route of Administration

Oral

L. Species/Class

Dogs

M. Indications

Praziquantel Tablets 34 mg canine cestocide are indicated for the removal of the following canine cestodes: *Dipylidium caninum, Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

N. Reference Listed New Animal Drug

Droncit™ 34 canine cestocide; 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 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 the dosage form from the RLNAD. The sponsor requested a change in dosage form from a compressed tablet to 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) 34 mg tablets. The RLNAD is approved in a 34 mg tablet size for dogs. 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 34 mg RLNAD (praziquantel tablets) tablet and the 34 mg generic (praziquantel tablets) by the average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

O. Blood-level Bioequivalence Study in Dogs

Title: Pivotal Bioequivalence Study of Droncit Tablets and a Generic Formulation of Praziquantel Chewable Tablets Administered Orally to Dogs (Study No. 080-BC-2319).

Study Dates: August 18, 2020 to February 11, 2021

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 34 mg Praziquantel Tablets and the RLNAD 34 mg Droncit™ (praziquantel tablets) in fasted dogs.

Study Animals: 24 intact male Beagle dogs, 16 months of age, and weighing between 10.1 to 13.1 kg.

Experimental Design: A randomized, masked, two-period, two-sequence, single-dose crossover study conducted according to Good Laboratory Practice for Nonclinical Laboratory Studies (US CFR Title 21, Part 58).

Drug Administration: Each animal received two 34 mg tablets of either the generic or RLNAD praziquantel tablets according to their randomized treatment sequence (generic/RLNAD or 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 two-period, two-sequence, two-treatment, single-dose crossover design using 24 dogs with a 7-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	1990[†]	2138[†]	0.93	0.85	1.01
C_{MAX} (ng/mL)	652[†]	682[†]	0.96	0.82	1.12
T_{MAX} (hours) (SD)[‡]	1.01 (0.45)[‡]	1.26 (0.61)[‡]	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 reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 34 mg Praziquantel Tablets and the RLNAD 34 mg (praziquantel tablets) 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 Praziquantel Tablets:

WARNING: Keep out of reach of children. Not for human use. For customer service or to obtain product information, including Safety Data Sheet, call 1-833-571-1525.

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 indications listed in Section I.M. above.