FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
La Haute Marche
Javené BP 90203
35302 FOUGERES cedex
FRANCE

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

EIMERYL, 200 MG/ML SOLUTION FOR USE IN DRINKING WATER FOR CHICKENS AND TURKEYS

Date: 26/04/2012

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
La Haute Marche – Javené BP 90203 - 35302 Fougères Cédex - Téléphone : + 33 (0)2 99 94 78 78 - Télécopie : + 33 (0)2 99 94 78 99 - www.anses.fr

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0231/001/DC
Name, strength and pharmaceutical form	EIMERYL , 200 mg/ml solution for use in drinking water for chickens and turkeys
Applicant	GLOBAL VET HEALTH SL C/Capçanes,nº12-bajos. Polígon Agro-Reus. REUS 43206 SPAIN
Active substance(s)	Amprolium hydrochloride
ATC Vetcode	QP51AX09.
Target species	Chickens (broilers, pullets, layers, breeder hens) and turkeys
Indication for use	Treatment of intestinal coccidiosis caused by *Eimeria* spp susceptible to amprolium.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the decentralised procedure	02/02/2012
Concerned Member States for original procedure	BE, DE, DK, EL, IT, UK

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 200 mg/ml amprolium (as hydrochloride) as active substance and excipients propylene glycol, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and purified water.

The product is presented in 100 ml, 1l and 5 litre containers. The particulars of the containers and controls performed are provided and conform to the regulation.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is amprolium hydrochloride, an established substance described in the British Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material.
Batch analytical data demonstrating compliance with this specification have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products *(pharmaceuticals)*

Not applicable.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods have been provided.
Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

G. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.
A shelf-life after dilution as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

This application is submitted in agreement with the Article 13(3), as hybrid application since the test and reference product NEMAPROL 10.6% ORAL SOLUTION differ by a change in strength (quantitative change to the active substance).

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product.

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

As this is an hybrid application according to Article 13 (3), and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant has submitted a Phase II Environmental Risk Assessment which showed that no risk for the terrestrial compartment is expected.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted since the tested product is bioequivalent to the reference product and the product is administered via oral route.

MRLs

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

a. active substances

The active substance, amprolium, is included in table 1 of the MRL regulation 470/2009, as follows:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification
AMPROLIUM	Not applicable	poultry	No MRL required	Not applicable	For oral use only	No entry

b. excipients

The MRL status of excipients of the product EIMERYL is indicated in the following table.

Excipient	MRL status	ADI
Propylene glycol	Table 1, no MRL required	-
Sodium methyl parahydroxybenzoate (E219)	Table 1, no MRL required	-
Sodium propyl parahydroxybenzoate (E217)	Table 1, no MRL required	-

Withdrawal Periods

The tested product will be applied identical withdrawal periods than the reference product that is:

Chickens(broilers, pullets, layers, breeder hens):	Meat and offal:	Zero days
	Eggs:	Zero days
Turkeys:	Meat and offal:	Zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because:

- the tested product and the reference product are bioequivalent and are intended to be used in drinking

water to prepare medicated water of the same concentration,
- the excipients of the tested product are deemed unproblematic as regards tolerance.

The tolerance aspects of this product are identical to the reference product.

Resistance

The applicant has provided sufficient documentation to address parasitic resistance to amprolium.

IV.B Clinical Studies

Since the tested product and the reference product are bioequivalent and are intended to be used in drinking water to prepare medicated water of the same concentration, it can be concluded that the clinical effects of the two products will be the same and no clinical studies are required.

V. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.