MINISTERIO
DE SANIDAD
Y POLÍTICA SOCIAL

agencia española de
medicamentos y
productos sanitarios

SUBDIRECCIÓN GENERAL
DE MEDICAMENTOS
DE USO VETERINARIO

Agencia Española de Medicamentos y Productos Sanitarios

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Edificio 8
C/Campezo 1,
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

DRAFT PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

COLMYC 100 mg/ml Inyectable solution for injection for cattle and pigs

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0150/001/DC
Name, strength and pharmaceutical form	Colmyc 100 mg/ml Inyectable solution for injection for cattle and pigs
Applicant	SP VETERINARIA SA Ctra. Reus Vinyols km 4.1 43330 Riudoms Tarragona (Spain)
Active substance(s)	Enrofloxacin
ATC Vet code	QJ01MA90
Target species	Cattle and pigs
Indication for use	Antibacterial with anti-mycoplasma action for the treatment of infectious diseases in cattle and pigs, caused by the following sensitive bacteria, Grampositive, Gramnegative and mycoplasma, sensitive to enrofloxacin.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article < > of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23/03/2010
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	BE, BG, DE, EL, HU, IT, LU, NL, PL, PT, RO

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, 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 enrofloxacin (100 mg/ml) and excipients (n-butyl alcohol, potassium hydroxide and water for injection.

The container/closure system are amber polypropylene vials of 50, 100 and 250 ml with a rubber-butyl stopper and aluminium capsule with a Flip-Off sealing. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified.

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.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is enrofloxacin, an established active substance. The manufacturing authorisation holder certifies that 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.

A copy of the ASMF of Zhejiang Guobang Pharmaceutical Co. Ltd. (China) has been included.

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

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.

The claim of 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at 25º±2ºC/60±5%RH protected from light.

H. Genetically Modified Organisms

None of the starting materials used in the manufacture of the product contains genetically modified organisms.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

<None>