Agencia Española de Medicamentos y Productos Sanitarios

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

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

ES/V/0247/001/DC

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0247/001/DC
Name, strength and pharmaceutical form	ENROSYVA 100 mg/ml solution for injection for cattle and pigs
Applicant	Laboratorios SYVA S.A.U. Avda. Párroco Pablo Díez, 49-57 (24010) León Spain
Active substance(s)	Enrofloxacin
ATC Vet code	QJ01MA90
Target species	Cattle and pigs
Indication for use	Cattle: Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma spp*. Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*. Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*. Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*. Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old. Pigs: Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.* Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.* Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp. Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*. Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

MODULE 2

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

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	29/08/2016
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	PT

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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 slight reactions observed are indicated in the SPC.
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.

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

II. QUALITY ASPECTS

A. Composition

The product contains 100 mg/ml of enrofloxacin and benzyl alcohol, potassium hydroxide and water for injections as excipients.

The container/closure system is a type II coloured glass vial sealed with bromobutyl stoppers and aluminium cap for the 100 ml vial and polypropylene vial sealed with bromobutyl stoppers and aluminium cap for the 250 ml format. 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.

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 described in the European 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. The marketing authorisation holder (MAH) uses the Certificate of Conformity of Ph. Eur. (CEP) procedure

E. Control on intermediate products

The tests performed during production are described.

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 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.

H. Genetically Modified Organisms

J. Other Information

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL) (*for pharmaceuticals only)*

III.A Safety Testing

Pharmacological Studies

Since this is a generic application submitted according to Article 13(1) of Directive 2001/82/EC and bioequivalence with the reference product has been demonstrated results of pharmacological tests are not required.

Toxicological Studies

Since this is a generic application submitted according to Article 13(1) of Directive 2001/82/EC and bioequivalence with the reference product has been demonstrated results of toxicological tests are not required

User Safety

Given that this application was submitted in accordance with Article 13(1) of the Directive and that the test and reference products are identical in terms of both formulation and use, no difference between test and reference product in terms of user safety is expected.

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the use of the product does not entail any risk for the environment when used as recommended in the SPC.
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
(Delete for non food producing species and for immunologicals)

Residue Studies

No residue depletion studies were conducted because this application fulfils the requirements of Directive 2001/82/EC for generics. Therefore, the applicant is exempt to provide the results of proprietary residues studies and analytical methods for the detection of residues .

MRLs

Enrofloxacin is listed in Table I of annex to Commission Regulation 37/2010.

MRLs are listed below:

	Bovine	Porcine
Muscle	100 µg/kg	100 µg/kg
Liver	300 µg/kg	200 µg/kg
Kidney	200 µg/kg	300 µg/kg
Fat / skin	100 µg/kg	100 µg/kg
Milk	100 µg/kg	

Withdrawal Periods

Since both products are identical in terms of active substance and excipients it can be stated that their residue profile will be similar and, therefore, the **withdrawal periods** of the reference product can be applied to ENROSYVA 100 mg/ml solution for injection for cattle and pigs:

Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days

IV. CLINICAL ASSESSMENT (EFFICACY)

For generics, insert in the relevant sections as appropriate:

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.

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

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).

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios