MINISTERIO
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agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

UNOFLOX 100 mg/ml Solution for injection

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0299/001/DC
Name, strength and pharmaceutical form	UNOFLOX 100 mg/ml solution for injection
Applicant	SP VETERINARIA SA Ctra Reus Vinyols km 4.1 43330 - Riudoms (SPAIN)
Active substance(s)	Enrofloxacin
ATC Vet code	QJ01MA90
Target species	Cattle and pigs.
Indication for use	Cattle: For the treatment of respiratory tract infections caused by enrofloxacin-sensitive *Histophilus somni*, *Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* spp. For the treatment of Mastitis caused by enrofloxacin-sensitive *E.coli*. Pigs: For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and *Haemophilus parasuis*.

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 Art/icle 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	Day 210: 11/03/2019
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	PT & MT

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 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.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 100 mg of enrofloxacin per ml as active substance and Arginine, n-Butanol, Benzyl alcohol (E 1519) and water for injection as excipients

The container/closure system is amber polypropylene vials or amber glass type II, with bromobutyl stopper and aluminium cap with FLIP-OFF seal.

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.

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

E. 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.

F. 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:

Shelf life of the veterinary medicinal product as packaged for sale in glass vials: 3 years; shelf life of the veterinary medicinal product as packaged for sale in polypropylene vials: 2 years; shelf life after first opening the immediate packaging: 28 days.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

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.

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

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 and consumers.

III.A Safety Testing

Pharmacological, toxicological and other studies

Since this is an application under Article 13(1) of Directive 2001/82/EC, as amended, the applicant is not required to provide data regarding the pharmacology, toxicology or other safety studies.

User Safety

Despite not having provided a user risk assessment, it can be accepted that the proposed formulation will not present any greater risk to the user than that posed by the reference product and therefore, the warnings and precautions can be extrapolated.

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

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentrations in soil in every scenario for both target species are below 100 µg/kg.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because this application is in accordance with Article 13(1) and the applicant shall not be required to provide the results of residues tests because all these data are in the documentation that supports the marketing authorization of the reference product.

MRLs

Enroflaxicin is listed in table 1 of the Commission Regulation (EU) No 37/2010)O.J. enrofloxacin). The marker substance is enrofloxcin.

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	----

The excipients are included in table 1 of Commission Regulation (EU) 37/2010 (No MRL required) or in the list of substances considered as not falling within the scope of Council Regulation (EC) No. 470/2009.

Withdrawal Periods

Since this application for UNOFLOX 100 mg/ml SOLUTION FOR INJECTION is submitted according a generic application, the same withdrawal period as approved for the reference product is applied to the generic product. The following withdrawal periods are justified:

Cattle	Meat and offal	s.c. 14 days
		i.v. 7 days
	Milk	s.c. 120 hours (5 days)
		i.v. 72 hours (3 days)
Pig	Meat and offal	i.m. 12 days.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

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.

IV.B Clinical Studies

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