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

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs

Marbofloxacin 40 mg/ml solution for injection for pigs (UK)

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/0200/001/DC
Name, strength and pharmaceutical form	Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs Marbofloxacin 40 mg/ml solution for injection for pigs (UK)
Applicant	Support Pharma, S.L. Calle General Alvarez de Castro, 39. 28010. Madrid, Spain
Active substance(s)	Marbofloxacin
ATC Vet code	QJ01MA93
Target species	Pig (pig for fattening)
Indication for use	Treatment of respiratory infections caused by strains of *Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae* susceptible to marbofloxacin.

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 13.3 of Directive 2001/82/EC as amended.
Date of completion of the original <mutual recognition> <decentralised>procedure	26/03/2014
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT; CY; CZ; DE; EE; EL; IE; IT; LI; LT; PL; PT; SK; 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 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.

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II. QUALITY ASPECTS

A. Composition

The product contains marbofloxacin (40 mg/ml) and disodium edetate, gluconolactone, mannitol and water for injections as excipients.

The container/closure system consists at 50 ml, 100 ml, 250 ml amber type II glass vials, closed with chlorobutyl rubber stopper type I and aluminium collar. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is 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 marbofloxacin, 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.

Details of the active substance manufacture are provided in the form of an ASMF in CTD format.

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 (2 years) when stored under the approved conditions.

The claim of a 28 days stability after broaching is based on the demonstration of stability for batches broached and stored 28 days at 25°C and 60% RH.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

For generics, insert in the relevant sections as appropriate:

MARBOFLOXACIN SUPPORT PHARMA 40 MG/ML FOR PIGS is a generic application according to Article 13.3 of Directive 2001/82/EC, as modified by Directive 2004/28/EC.

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

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

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, pharmacological studies are not required.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, toxicological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the product does not pose an unacceptable risk.
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.
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

The applicant has conducted a residue depletion study which show that residues depleted to below the MRL in all tissues 4 days after the administration of the product. Statistical analysis of the results could not be used to set the withdrawal period. Thus, the alternative approach was used, resulting in a withdrawal period of 6 days in pig meat and offal.

The analytical method was a HPLC with mass spectrometer detection. The method was fully validated.

MRLs

Marbofloxacin is listed in Table I (allowed substances) of Commission Regulation (EU) No 37/2010. The marker substance is marbofloxacin.

MRLs are listed below:

	Pigs
Muscle	150 µg/kg
Liver	150 µg/kg
Kidney	150 µg/kg
Fat + skin	50 µg/kg

Withdrawal Periods

Based on the data provided above, a withdrawal period of 6 days for meat and offal in pigs is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13.3 of Directive 2001/82/EC, as modified by Directive 2004/28/EC, 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.A Pre-Clinical Studies

Pharmacology

A bioequivalence study has been submitted in compliance with the relevant guideline which shows that the test and reference products are bioequivalents.

Tolerance in the Target Species of Animals

The local and general tolerance of the product in the target species was specifically evaluated during the in vivo studies on residues and bioequivalence.

The product literature accurately reflects the type of adverse effects which might be expected.

Resistance

The applicant has submitted a bibliographic review of the resistance situation

Adequate warnings and precautions appear on the product literature.

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