Agencia Española de Medicamentos y Productos Sanitarios

Parque Empresarial Las Mercedes
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28022 – Madrid
España
(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

VETRIMOXIN 50 mg/g
Premix for medicated feeding stuff for pigs

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0122/001/DC
Name, strength and pharmaceutical form	Vetrimoxin 50 mg/g Premix for medicated feeding stuff for pigs
Applicant	Ceva Santé Animale ZI de la Ballastière – B.P. 126 LIBOURNE Cedex FRANCE
Active substance(s)	Amoxicillin (as trihydrate)
ATC Vet code	QJ01CA04
Target species	Pigs (weaned pigs)
Indication for use	In weaned pigs: in herds where infection has been confirmed treatment of infections caused by *Streptococcus suis*.

MODULE 2

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

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Mutual Recognition application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	Day 90: 29/10/2008
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BG, CZ, EL, HU, IT, PL, PT, RO and SK

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.

II. QUALITY ASPECTS

A. Composition

The product contains 50 mg/g of Amoxicillin (as trihydrate) as active substance and liquid paraffin, in a carrier of wheat starch.

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The container/closure system is a bag of 10 kg or 25 Kg composed of the following four layers (from inside to outside): Low density polyethylene, 2 layers of smooth Kraft paper and white anti-slip Kraft paper.

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 Amoxicillin trihydrate, 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 suitability of the Ph.Eur monograph for controlling this amoxicillin trihydrate raw material is confirmed with a copy of the current CEP (R1-CEP 1996-060-Rev 02).

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 three months stability after opening the container is based on the demonstration of stability for a batch opened and stored 3 months at in-use storage conditions.

The claim of three months stability after incorporation into meal or pelleted feed is based on the demonstration of stability in accordance with applicable European guidelines.

H. Genetically Modified Organisms

J. Other Information

Studies carried out on the medicated feed include homogeneity data and segregation data. They are considered appropriate to demonstrate that adequate mixing of the active substance is likely to be achieved in the final feed, as well as that there would be no physical separation

of the medicated premix from the feedingstuff during transport which could result in loss of homogeneity.

Appropriate data have been provided to support the presentation of the dossier as an abridge application for marketing authorisation.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

This is a generic application according to Article 13(1) based on the essential similarity of VETRIMOXIN PREMIX and the approved precursor STABOX PREMIX.

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

The bioequivalence between VETRIMOXIN PREMIX and the reference product is demonstrated.
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, of the environment and of consumers.

III.A Safety Testing

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

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

Ecotoxicity
The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline.
As a part of the Phase I assessment data on degradation of the active substance in manure may be submitted. The protocol of the study submitted satisfies the criteria included in guideline EMEA/CVMP/ERA/418282/2005-corr. The applicant commits itself to submit the results of the study as soon as they are available.

III.B Residues documentation

Residue Studies

The applicant has conducted residue depletion study in edible tissues of pigs which show that no measurable residues of amoxicillin were present three days after the withdrawal of amoxicillin 15 mg/kg bodyweigh per day for 14 consecutive days.

The analytical method was liquid chromatography coupled to a mass-mass detection and was validated.

MRLs

Amoxicillin is listed in Annex I of Council Regulation 2377/90. The marker substance is parent drug.
MRLs are listed below:

Active substance	Marker residue	Animal species	MRLs	Target tissues
Amoxicillin	Parent drug	All food producing species	50µg/kg 4µg/kg	Muscle, kidney, liver, fat Milk

Withdrawal Periods

Based on the data provided above and using the alternative method, a withdrawal period of 3 days for meat in pigs is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, based on the bioequivalence of VETRIMOXIN 50 mg/g Premix for medicated feeding stuff for pigs and the reference product STABOX Premix 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 current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).

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