College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Amoxy Active, 697 mg/g, oral powder for pigs and chickens

Date: 1 May 2014

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MODULE 1

PRODUCT SUMMARY

Dutch Registration number	REG NL 113695
EU Procedure number	NL/V/0179/001/DC
Name, strength and pharmaceutical form	Amoxy Active, 697 mg/g, oral powder for pigs and chickens
Applicant	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands
Active substance(s)	Amoxicillin
ATC Vetcode	QJ01CA04 (Penicillins)
Target species	Pig and chicken
Indication for use	Pigs: Treatment of respiratory tract infections, gastro-intestinal tract infections, urogenital infections, ear necrosis, secondary infections following viral infections and septicemia caused by micro-organisms susceptible to amoxicillin Chickens: Treatment of respiratory tract infections and gastro-intestinal tract infections caused by micro-organisms susceptible to amoxicillin.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website:

http://mri.medagencies.org/veterinary/

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	26th of March 2014
Concerned Member States for original procedure	AT, BE, BG, DE, DK, EE, EL, FR, HU, IE, IT, LT, LV, PL, RO, UK

I. SCIENTIFIC OVERVIEW

Amoxy Active, 697 mg/g, oral powder for pigs and chickens is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
The product can be safely used in the target species; possible adverse reactions are indicated in the SPC.
Amoxy Active, 697 mg/g, oral powder for pigs and chickens 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 overall risk/benefit analysis is in favour of granting a marketing authorisation.

The safety and efficacy aspects of Amoxy Active, 697 mg/g, oral powder for pigs and chickens are based on bioequivalence with the reference product Paracilline soluble powder for oral use for pigs and chickens, REG NL 4256.
Warnings statements and precautions are adopted from the reference product.
Additional statements have been added, based on increased knowledge and the current state of science.

II. QUALITY ASPECTS

A. Composition

The product contains amoxicillin trihydrate 800 mg/g and excipients sodium carbonate anhydrous and sodium citrate.

The product is presented in two different multi-dose presentations: a bucket and a securitainer.
The bucket is a white, polypropylene, square bucket provided with a white plastic handle and a fitting white, tamper-evident, polypropylene lid. The bucket is re-closable by the polypropylene lid. Three different sized buckets are used (3.2, 5.7 and 10.8 litres), which contain 1 kg, 2.5 kg and 5 kg of product, respectively.

The securitainer is a white, polypropylene, cylindrical container provided with a white, polyethylene (low-density) closure with thumb-tab for easy opening. Three different

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packsizes are used (300 ml, 700 ml, and 1875 ml) which contain 100, 250, 500 or 1000 grams of product respectively.
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.
The product is manufactured using conventional manufacturing techniques. Process validation data on three pilot scaled batches have been provided. Process validation for fullscale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is amoxicilline trihydrate,an established substance described in the European/British Veterinary 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 drug substance is derived following the CEP procedure.

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

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

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form.

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.

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G. Stability

Stability data on the active substance have not been provided since this has been assessed by the EDQM.
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 of 36 months when stored below 25°C in the proposed packagings.

The claim of a 1 month stability after first opening when stored below 25°C is based on the demonstration of stability for a batch broached and stored 2 months at 25°C/60% RH.

The claim of a 12 hours stability for medicated drinking water is based on the demonstration of stability for a batch diluted in hard water of high pH and soft water of low pH and stored for 24 hours.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users, consumers and the environment.

User Safety

Being a generic procedure the applicant refers to the reference product for information on this section.

Additionally the applicant has provided a user safety assessment. Combined with increased knowledge and the current state of science, warning statements and precautions have been added to the product literature, ensuring safety to users of Amoxy Active, 697 mg/g, oral powder for pigs and chickens.

Ecotoxicity

The applicant provided a phase I environmental risk assessment in compliance with the relevant guidelines, which showed that further assessment was required.

In the phase II environmental risk assessment no risks were identified towards organisms in soil, surface- and groundwater. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

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III.B Residues documentation

Residue Studies

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

The withdrawal period in chickens is based on bioequivalence with OCTACILLINE, powder for oral solution for pigs and chickens, REG NL 10112, a generic of the reference product.

Withdrawal Periods

Based on the above the following withdrawal periods are justified:

Pigs:	meat and offal:	2 days.
Chickens:	meat and offal:	1 day.

Not authorised for use in birds producing eggs for human consumption.
Do not use within 4 weeks before the onset of the laying period.

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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.

Resistance

Adequate warnings and precautions appear on the product literature.

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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.

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