IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

CTC Alpharma100 mg/g Granular Premix for medicated feedingstuff

PRODUCT SUMMARY

EU Procedure number	IE/V/0207/001/DC
Name, strength and pharmaceutical form	CTC Alpharma100 mg/g Granular Premix for medicated feedingstuff
Active substance(s)	Chlortetracycline hydrochloride
Applicant	Zoetis Belgium S.A 2nd Floor Building 10 Cherrywood Business Park Loughlinstown Co. Dublin
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	27th February 2008
Target species	Pigs and chickens
Indication for use	Pigs As an aid in the treatment and control of swine respiratory disease complex associated with chlortetracycline-sensitive organisms Chickens As an aid in the treatment and control of respiratory and systemic infections associated with chlortetracycline-sensitive organisms
ATCvet code	QJ01AA03
Concerned Member States	AT, BE, CZ, DK, EE, ES, IT, LU, NO, PT, SI, SK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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 benefit/risk analysis is in favour of granting a marketing authorisation.

II QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains chlortetracycline hydrochloride 100 mg/g and excipients carmellose sodium, calcium sulphate dihydrate.

The product is packaged into low density polyethylene bags in pack sizes of 3 kg, 9 kg, 12 kg, 20 kg and 25 kg.

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 at 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 chlorotetracycline, an established active substance which is 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.

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.

D. Control on Intermediate Products

Not applicable.

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 sites 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.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The application was presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is Aurofac 100 Granular authorised in Ireland (VPA 10802/1/1). The reference product has been authorised in the Community for in excess of 10 years.

Given that the formulations of CTC Alpharma (Aureomycin) and Aurofac are identical in all respects (identical active and inactive substances, physiochemical properties and manufacturing process), exemption from the need to conduct bioequivalence studies is claimed in line with section 4, bullet point (c) of the relevant guidance document (EMEA/CVMP/016/00-corr-FINAL). Given that bioequivalence with an authorised reference product is claimed, pharmacological or basic toxicological data have not been presented. For this information, the Applicant refers to the authorised reference product, Aurofac 100 Granular.

Toxicological Studies

The application was presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is Aurofac 100 Granular authorised in Ireland (VPA 10802/1/1). The reference product has been authorised in the Community for in excess of 10 years.

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User Safety

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

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

Environmental Risk Assessment

The applicant provided a complete environmental risk assessment in compliance with the relevant guideline. Based on the data presented, it is accepted that the product when used as recommended does not pose an unacceptable risk to the environment.

III.B Residues Documentation

The current application is presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is Aurofac 100 Granular authorised in Ireland (VPA 10802/1/1). The reference product has been authorised in the Community for in excess of 10 years.

Given that bioequivalence with an authorised reference product is claimed, the withdrawal periods authorised for the reference product can be applied to CTC Alpharma (Aureomycin) 100 Granular.

Based on the information available in relation to the reference product, withdrawal periods of 10 days and 2 days can be accepted for pig meat and broilers, respectively. A withdrawal period of 4 days can be accepted for eggs.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

The current application is presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is Aurofac 100 Granular authorised in Ireland (VPA 10802/1/1). The reference product has been authorised in the Community for in excess of 10 years.

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Tolerance in the Target Species of Animals

The safety of the product for use in the target species is supported by a recent PSUR relating to the reference product which was submitted to the RMS in support of a recent renewal application.

IV.B Clinical Studies

The current application is presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is Aurofac 100 Granular authorised in Ireland (VPA 10802/1/1). The reference product has been authorised in the Community for in excess of 10 years.

Given that the formulations of CTC Alpharma (Aureomycin) and Aurofac are identical in all respects (identical active and inactive substances, physiochemical properties and manufacturing process), exemption from the need to conduct bioequivalence studies is claimed in line with section 4, bullet point (c) of the relevant guidance document (EMEA/CVMP/016/00-corr-FINAL). Given that bioequivalence with an authorised reference product is claimed, the Applicant makes reference to the authorised indications/posology of the reference product in the RMS.

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 benefit/risk profile for the target species is favourable and the quality and safety of the

product for humans and the environment is acceptable.

VI 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 HPRA website.

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.

Changes:
None.