IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Aurofac Granular 250 mg/g Premix for Medicated Feeding Stuff

PRODUCT SUMMARY

EU Procedure number	IE/V/0207/002/DC
Name, strength and pharmaceutical form	Aurofac Granular 250 mg/g Premix for Medicated Feeding Stuff
Active substance(s)	Chlortetracycline hydrochloride
Applicant	Zoetis Belgium S.A, 2nd Floor Building 10 Cherrywood Business Park 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	28th July 2010
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, 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 250 mg/g and excipients Carmellose sodium, Calcium sulphate dihydrate.

The product is packaged into low density polyethylene bags containing 2 kg, 3 kg, 4.8 kg, 6.4 kg, 8 kg, 9 kg, 12 kg, 16 kg, 20 kg, and 25 kg.

The particulars of the containers and controls performed are provided and conform to the regulation.

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 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

The current application is presented as an extension to an existing marketing authorisation. The original authorisation, submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended, was for a 100 mg/g granular premix 'Aurofac (CTC Alpharma) 100 mg/g Granular Premix for medicated feedingstuff'. The nature of the present extension is the addition of a new strength.

The applicant argues that, for the purposes of safety and efficacy, Aurofac 100 mg/g and Aurofac 250 mg/g can be considered comparable based on the fact that:

- The formulations are similar in terms of qualitative composition
- The target mg/kg dose rate for each of the target species is the same for both products,
- While there are differences in quantitative composition, these differences will be very minor following incorporation into feed. It is noted that for treatment of 50 kg pigs (each consuming 2.5 kg feed/day), the incorporation rate of Aurofac 100 mg/g will be 4 kg product per tonne of feed compared to an incorporation rate of 1.6 kg Aurofac 250 mg/g per tonne of feed. Consequently, at the point of intake, there will be no differences between feeding-stuffs medicated with Aurofac 100 mg/g compared to feeding-stuffs medicated with Aurofac 250 mg/g that will impact on bioavailability of the active substance.

In order to confirm the comparability of the 100 mg/g and the 250 mg/g formulations, an *in vitro* dissolution study was performed. The results indicate that the dissolution profiles for both formulations were comparable.

Based on the above, it is accepted that Aurofac 100 mg/g and Aurofac 250 mg/g can be considered equivalent and, therefore, that the safety profile for both products will be the same.

Consequently, as agreed for Aurofac 100 mg/g, it is accepted that the Aurofac 250 mg/g does not pose an unacceptable risk to either the user or the environment.

III.B Residues Documentation

In line with the withdrawal periods agreed for Aurofac 100 mg/g, withdrawal periods of 10 days and 2 days for pig meat and broilers, respectively, and a withdrawal period of 4 days for eggs can be accepted for Aurofac 250 mg/g.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

The current application is presented as an extension to an existing marketing authorisation. The original authorisation, submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended, was for a 100 mg/g granular premix 'Aurofac (CTC Alpharma) 100 mg/g Granular Premix for medicated feedingstuff'. The nature of the present extension is the addition of a new strength.

The applicant argues that, for the purposes of safety and efficacy, Aurofac 100 mg/g and Aurofac 250 mg/g can be considered comparable based on the fact that:

- The formulations are similar in terms of qualitative composition
- The target mg/kg dose rate for each of the target species is the same for both products,
- While there are differences in quantitative composition, these differences will be very minor following incorporation into feed. It is noted that for treatment of 50 kg pigs (each consuming 2.5 kg feed/day), the incorporation rate of Aurofac 100 mg/g will be 4 kg product per tonne of feed compared to an incorporation rate of 1.6 kg Aurofac 250 mg/g per tonne of feed. Consequently, at the point of intake, there will be no differences between feeding-stuffs medicated with Aurofac 100 mg/g compared to feeding-stuffs medicated with Aurofac 250 mg/g that will impact on bioavailability of the active substance.

In order to confirm the comparability of the 100 mg/g and the 250 mg/g formulations, an *in vitro* dissolution study was

performed. The results indicate that the dissolution profiles for both formulations were comparable.

Based on the above, it is accepted that Aurofac 100 mg/g and Aurofac 250 mg/g can be considered equivalent and, therefore, that the efficacy profile for both products will be the same. The indications and posology agreed for Aurofac 100 mg/g can be applied to Aurofac 250 mg/g.

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.

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.