IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

CHLOROMED 150 mg/g Premix for Medicated Feedingstuff for Calves

PRODUCT SUMMARY

EU Procedure number	IE/V/0211/001/DC
Name, strength and pharmaceutical form	CHLOROMED 150 mg/g Premix for Medicated Feedingstuff for Calves
Active substance(s)	Chlortetracycline hydrochloride
Applicant	Univet Ltd. Tullyvin Cootehill Co. Cavan Ireland
Legal basis of application	Article 13(1) of Directive 2001/82/EC, as amended (generic application)
Date of completion of procedure	02/08/2009
Target species	Calves
Indication for use	The product is indicated in the treatment of respiratory disease in calves caused by *Pasteurella spp*., sensitive to chlortetracycline.
ATCvet code	QJ01AA03
Concerned Member States	AT, DE, HU, BG, UK

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; potential adverse effects are detailed 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

Active substance

Chlortetracycline Hydrochloride 150 mg/g

Excipients

Colloidal anhydrous silica

Medium Chain Triglycerides

Soya Bean Meal

The immediate packaging is a white low density polyethylene liner. This bag is sealed with a plastic tie and placed inside a triple-layered paper bag which is then stitched.

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 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 site have been provided demonstrating compliance with the specification.

The tests performed on the final product conform to the relevant requirements;
The demonstration of the batch to batch consistency is based on the results of batches produced according to the method described in the dossier.

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 current application is presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is CTC 15% w/w Premix authorised in Ireland (VPA 10990/39/2).

Given that the formulations of CHLOROMED and CTC 15% are identical in all respects (identical active and inactive substances, physiochemical properties and manufacturing process), the Applicant claims exemption from the need to conduct bioequivalence studies 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, CTC 15% w/w Premix.

A user safety assessment was not presented with the application. Given the nature of this application, it is accepted that the risk to the user posed by this product will be the same as that of the reference product. The agreed user safety statements are in line with user safety warnings agreed for similar chlortetracycline-containing veterinary medicinal products recently approved through European procedures.

An ERA was provided. Based on the data provided, it is accepted that the product does not pose an unacceptable risk to the environment.

III.B Residues Documentation

Residue Studies

Given that bioequivalence with an authorised reference product is claimed, the withdrawal period authorised for the reference product (that is, 35 days for calves) can be applied to Chloromed 150 mg/g Premix. The authorised withdrawal period for the reference product is based on satisfactory confirmatory residue studies.

IV CLINICAL ASSESSMENT (EFFICACY)

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 CTC 15% w/w Premix authorised in Ireland (VPA 10990/39/2).

Given that the formulations of CHLOROMED and CTC 15% w/w Premix are identical in all respects (identical active and inactive substances, physiochemical properties and manufacturing process), the Applicant claims exemption from the need to conduct bioequivalence studies 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, no efficacy data are presented. The Applicant makes reference to the authorised indications/posology of the reference product in the RMS.

In terms of efficacy and target animal safety, it is accepted that the test product will be identical to the reference product; therefore, the proposed indications and recommended treatment regimen can be accepted.

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.