IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Chloromed 500 mg/g powder for oral solution for chickens and pigs

PRODUCT SUMMARY

EU Procedure number	IE/V/0884/001/DC
Name, strength and pharmaceutical form	Chloromed 500 mg/g powder for oral solution for chickens and pigs
Active substances(s)	Chlortetracycline hydrochloride
Applicant	Univet Limited Tullyvin Cootehill Co. Cavan. Ireland
Legal basis of application	Generic application (Article 18 of Regulation (EU) 2019/6)
Date of completion of procedure	2/10/2024
Target species	Chickens, pigs
Indication for use	For use in the treatment of infections due to susceptible bacteria in broiler chickens and pigs. Chickens: The veterinary medicinal product is used in the treatment and metaphylaxis of colibacillosis secondary to infectious bursal disease, chronic respiratory disease caused by *Escherichia coli*, and *Pasteurella multocida* infections. Pigs: The veterinary medicinal product is used in the treatment and metaphylaxis of respiratory diseases associated with *Mycoplasma hyopneumoniae*, *Steptococcus suis* and toxigenic strains of *Pasteurella multocida*. It is also used in the treatment and metaphylaxis of rhinitis due to *Bordetella bronchiseptica* and streptococcal meningitis due to *Streptococcus suis* type II. The presence of the disease in the group or flock must be established before the product is used.
ATCvet code	QJ01AA03
Concerned Member States	DK, NL, PL, UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (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 relevant articles of Regulation (EU) 2019/6. 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 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 500 mg/g of chlortetracycline hydrochloride as the active substance and the excipient citric acid.
The container/closure system consists of laminated foil bags of 1 kg in polypropylene buckets with polypropylene or polyethylene snap fit lids or laminated foil bags of 200 g in cardboard boxes or polypropylene buckets containing 5 bags.
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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is chlortetracycline hydrochloride, 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 has 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 has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has 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 has 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

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of pharmacodynamic or pharmacokinetic tests are not required.

Toxicological Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.
The product contains the same concentrations of the active substance and excipient as the reference veterinary medicinal product. In addition, the product is intended to be administered by the same route of administration at the same dose and for the same indications for use in the same species as the reference product. Given no qualitative or quantitative difference in terms of active substance and excipient, no greater risk to the user is anticipated following use of the product than that which already exists for the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant has not provided an environmental risk assessment, instead, reference to the 'Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6' (EMA/CVMP/ERA/622045/2020) has been made. As noted in the reflection paper, an ERA is no longer routinely required in support of a generic application, subject to a number of criteria being satisfied.
While the reference product was authorised before 1 October 2005, a 'similar' VMP has been authorised since that date. That is, one with the same active substance and the same pharmaceutical form indicated for use in the same target species when administered at the same or a higher total dose as the proposed generic VMP. According to the Reflection Paper, where a similar VMP has been authorised after 1 October 2005 "it will be considered that an ERA according to VICH GL38 and/or any other relevant guidelines in effect at that time has been performed by a CA, that the ERA data package provided has been

found to be satisfactory and that appropriate risk mitigation measures are in place (if applicable)." From the information provided it was accepted that a similar VMP has been cited which is supported by a satisfactory ERA data package and appropriate risk mitigation measures. On this basis, and in accordance with the reflection paper, an ERA under Article 18(7) of Regulation (EU) 2019/6 was not required.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted as the product and reference product have the same qualitative and quantitative composition in terms of active substance and excipient (citric acid). The CVMP Guideline on determination of withdrawal periods for edible tissues (EMA/CVMP/SWP/735325/2012 Rev.2) provides the following guidance for generic products: "When the formulation (active and inactive ingredients), the dose schedule, the route(s) of administration and the target species of a specific generic product, are identical to a currently approved product (i.e. the reference product), or it has been adequately justified that any differences in formulation are so minor such that they will not impact on residue depletion, then the withdrawal period of the latter can be used for the former."

The product is intended to be administered by the same route of administration (in drinking water), at the same dose, and for the same indications for use in the same species as the reference product. It was accepted that the formulations are qualitatively and quantitatively similar and that residue depletion studies were not required.

MRLs

Chlortetracycline is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRL (µg/kg)	Target tissue	Other provisions
Chlortetracycline	Sum of parent drug and its 4 epimer	All food-producing species	100 µg/kg 300 µg/kg 600 µg/kg 100 µg/kg 200 µg/kg	Muscle Liver Kidney Milk Eggs	

Withdrawal Periods

Based on the data provided, the following withdrawal periods are justified:

Pigs:

Meat and offal: 6 days.

Chickens:

Meat and offal: 3 days.

Not for use in laying birds producing or intended to produce eggs for human consumption.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been demonstrated, pre-clinical studies are not required.

The efficacy claims for this product are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

No target animal tolerance data specific to the candidate product have been presented, however, given the legal basis of the application and the similarity of formulations, it was accepted that the candidate product will not present any greater risk to the target animal than that posed by the reference product. The omission of product-specific target animal tolerance study data was therefore accepted.

Resistance

The bibliography / information provided did not highlight any new concerns in relation to development of resistance to chlortetracycline in the EU region. As this is a generic application, and the product is administered to the same target species for the same indications at the same posology using the same route of administration, the potential for resistance development is expected to be equivalent to that of the reference product.

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been demonstrated, clinical trials 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.

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 in the Union Product Database (UPD).
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.