Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

OCNIL 400 mg/g Powder for use in drinking water

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0242/001/DC
Name, strength and pharmaceutical form	OCNIL 400 mg/g powder for use in drinking water *(ES, CY, EL, IE, IT, PT, UK)* DOPHALIN 400 mg/g powder for use in drinking water *(AT, EE, FR, LT, LV, RO, PL)*
Applicant	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23 08028 – BARCELONA Spain
Active substance(s)	Lincomycin
ATC Vet code	QJ01FF02
Target species	Chickens (broilers)
Indication for use	Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin. The presence of the disease in the group must be established before the product is used.

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
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F-DMV-25-03

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	Day 210: 24/05/2017
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, CY, EE, EL, FR, IE, IT, LT, LV, PL, PT, RO, UK

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 and the consumer of foodstuffs from treated animals. A risk for the environment was identified (terrestrial plants). Risk Mitigation Measures (RMM) were discussed during the authorisation procedure finding no one feasible. 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 risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 400 mg/g of lincomycin (equivalent to 450 mg/g of lincomycin hydrochloride) as active substance and the excipients silica colloidal anhydrous and lactose monohydrate

The container/closure system is 1 kg bag, complex bags which are made of polypropylene, metalized polyester and polyethylene. 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 lincomycin hydrochloride, an established active 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control on intermediate products

Not applicable

F. 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.

G. 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.

The claim of a 24 hours stability after reconstitution is based on the demonstration of stability according to the proposed administration form and stored as requested in the proposed labelling.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13.1 - Generic application of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

The safety aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and the consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13.1, and bioequivalence with a reference product has been demonstrated, results of pharmacological studies are not required.

Toxicological Studies

As this is a generic application according to Article 13.1, and bioequivalence with a reference product has been demonstrated, results of pharmacological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that that the potential risks to the user will be the same as those posed by the reference product.

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was required. The assessment concluded that the use of the veterinary medicinal product according to the SPC poses a risk for terrestrial plants. No feasible risk mitigation measures were found.

The risks are communicated to the user in the SPC: 5.3 “Lincomycin is known to be toxic to terrestrial plants and cyanobacteria.” and 6.6 “Dangerous for organisms of pure water (as cyanobacteria). Do not contaminate surface waters or ditches with product or

used container." Considering the high toxicity of the active substance to cyanobacteria it was preferred to include also information regarding this taxon.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted since this is a generic application according to Article 13.1 - Generic application of Directive 2001/82/EC, and, the applicant shall not be required to provide the results of residues tests because all these data are in the documentation that supports the marketing authorization of the reference product.

MRLs

Lincomycin is listed in table 1 of the Comission Regulation (EU) No 37/2010 for all food producing species.

MRLs are listed below:

	All food producing species
Muscle	100 µg/kg
Liver	500 µg/kg
Kidney	1500 µg/kg
Fat / skin	50 µg/kg
Milk	150 µg/kg
Eggs	50 µg/kg

Withdrawal Periods

Based on the rational provided above, the following withdrawal period are justified:

CHICKEN

Meat and offal: 5 days

Not authorised for use in laying birds producing eggs for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1), 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.

IV.A Pre-Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, pre-clinical studies are not required.

IV.B Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, clinical studies are not required.

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.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

None