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

LISMAY POWDER FOR USE IN DRINKING WATER

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0283/001/DC
Name, strength and pharmaceutical form	Lismay powder for use in drinking water
Applicant	Laboratorios Maymó, S.A Vía Augusta, 302 08017 Barcelona Spain
Active substance(s)	Spectinomycin (as spectinomycin sulfate tetrahydrate) Lincomycin (as lincomycin hydrochloride)
ATC Vet code	QJ01FF52
Target species	Pigs
Indication for use	For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis* and associated enteric pathogens (*Escherichia coli*) susceptible to lincomycin and spectinomycin. The presence of the disease in the group must be established before the product is used.

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: 22/11/2017
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	PT

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, when used as recommended. A risk for the environment was identified (plants and cyanobacteria). Suitable warnings, precautions and environmental information 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 lincomycin (hydrochloride) (222.0 mg) and spectinomycin (sulfate tetrahydrate) (444.7 mg) as active substances and sodium benzoate as preservative. Other ingredients are lactose monohydrate.

The container/closure system consists in bags composed of a complex of metalized polyester film and low density polyethylene film, bound together by means of polyurethane adhesive containing 150 g or 1.5 kg. The sealling is performed by thermal system. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is justified.

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 substances are lincomycin (hydrochloride) and spectinomycin (sulfate tetrahydrate). Both active substances are described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with these specifications have been provided.

The information on the active substances is provided by presenting a copy of the Certificate of Suitability of the Ph. Eur. procedure (CEP) for that substance, granted by EDQM to the manufacturer.

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

Satisfactory TSE information has been provided in compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

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 substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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 (12 months), when stored under the approved conditions.

The claim of a 6 months stability after broaching is based on the demonstration of stability for a batch broached and stored at a temperature of 25 ± 2 ºC and 60 ± 5 % humidity for 6 months.

The claim of a 24 hours stability after reconstitution is based on the demonstration of stability for a batch diluted according to directions.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13 (1), 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, environment and 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 toxicological studies are not required.

User Safety

Despite not having provided a user risk assessment, it can be accepted that the proposed formulation will not present any greater risk to the user than that 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 product poses a risk for terrestrial plants and cyanobacteria. This risk could not be mitigated by suitable Risk Mitigation Measures.
Suitable environmental information are indicated in the SPC

III.B Residues documentation

Residue Studies

As this application is in accordance with Article 13 (1) - Generic application of Directive 2001/82/EC, 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 as well as Spectinomycin are listed in table 1 of de Annex of the Commission Regulation (EU) No 37/2010 and MRLs have been established for edible tissues. The marker substances are lincomycin and spectinomycin.

MRLs are listed below:

Lincomycin:

	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

Spectinomycin:

	All food-producing species except ovine	Ovine
Muscle	300 µg/kg	300 µg/kg
Liver	1000 µg/kg	2000 µg/kg
Kidney	5000 µg/kg	5000 µg/kg
Fat / skin	500 µg/kg	500 µg/kg
Milk	200 µg/kg	200 µg/kg

Withdrawal Periods

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, a withdrawal period of Zero days for meat in pigs is justified and this is adequate to ensure consumer safety.

Pig (meat and offal): Zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

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

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 is positive.

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

MODULE 4

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 veterinary Heads of Agencies website (www.hma.eu).

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.

None