DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Labimycin LA 300 mg/ml solution for injection

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0406/001/DC
Name, strength and pharmaceutical form	Labimycin LA 300 mg/ml solution for injection
Applicant	LABIANA Life Sciences S.A. Calle Venus, 26. Polígono Industrial Can Parellada 08228 Terrasa (Barcelona) - Spain
Active substance(s)	Oxytetracycline
ATC Vetcode	QJ01AA06
Target species	Cattle, sheep and pigs
Indication for use	This veterinary medicinal product is indicated for the control and treatment of a wide range of common systemic, respiratory, urinary and local infections. **Cattle:** Treatment of respiratory infections caused by strains of *Histophilus somni*, *Mannheimia haemolytica, Pasteurella multocida, Mycoplasma bovis*. Treatment of metritis caused by strains of *Arcanobacterium pyogenes*. Treatment of navel/joint infections caused by strains of *Dichelobacter nodosus Fusobacterium necrophorum and Prevotella melaninogenicus*. **Sheep:** Treatment of respiratory infections caused by strains of *Mannheimia haemolytica* and *Pasteurella*. Treatment of genital infections caused by strains of *Arcanobacterium pyogenes*, *Chlamydophila spp* and *Dermatophilus congolensis*. Treatment of navel/joint infections caused by strains of *Dichelobacter nodosus Fusobacterium necrophorum and Prevotella melaninogenicus*. **Pigs:** For the treatment of respiratory infections caused by strains of *Bordetella bronchiseptica* and *Pasteurella*. For the treatment of Erysipelas caused by strains of *Erysipelothrix rhusiopathiae*. For the treatment of Atrophic rhinitis caused by strains of *Bordetella bronchiseptica* and *Pasteurella multocida*. **Other infections:** Treatment of mastitis caused by strains of *Staphylococcus aureus, Streptococcus agalactiae* and *Escherichia coli*. Treatment of enzootic abortus caused by strains of *Chlamydia abortus* and *Chlamydia psittaci*. Treatment of genital infections and Poliartritis caused by strains of *Chlamydia abortus* and *Mycoplasma spp*.

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 - *Generic* of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	Day 210: 02/03/2022
Date product first authorised in the ReferenceMemberState (MRP only)	N/A
Concerned Member States for original procedure	EL, HU, PT, RO

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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 risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains oxitetracycline dihidrate (300 mg) and sodium formaldehyde sulfoxylate, magnesium oxide light, dimethylacetamide, ethanolamine and water for injection.

The container/closure system is an amber glass vial of hydrolytic class I closed with a rubber-bromobutyl septum and an aluminium capsule (multiple dose container).

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 oxitetracycline dihidrate, an established active substance described in the European. 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.

Certificate 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.

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specifications control 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.

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 (18 months) when stored under the approved conditions (Store below 25ºC. Keep the vial in the outer carton in order to protect from light).

G. Other Information

Not applicable.

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 and residue 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 consumers..

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, results of pharmacological tests are not required.

Toxicological Studies

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, results of toxicological tests are not required.

User Safety

A brief user safety assessment has been presented. Since the candidate product has the same composition in active substances and excipients than the reference product, it is assumed that the risks for the user will be similar to those associated with the use of 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

During the original DCP directive 82/2001 was in forced. Cattle and sheep were the target species. The applicant provided an environmental risk assessment. The PECsoil initial values determined for the target species fall below the trigger value of 100 µg/kg and, therefore, assessment ended in Phase I.

During the procedure, ES/V/0406/001/X/001/G, Regulation 2019/6 was in forced, pigs were included as target species. The applicant has proven that in the EU there are generic VMPs authorised with the same active substance, the same pharmaceutical form, indicated for use in the same target species, administered at the same or a higher total dose as the proposed generic VMP, and which have been authorised after 1 October 2005. Therefore, in accordance with article 18.7 of the Regulation 2019/6 and the Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6, an ERA has not been requested to this applicant as it is 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

III.B Residues documentation

Residue Studies

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, results of residue depletion tests are not required.

MRLs

The active substance oxytetracycline is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010.

MRLs are listed below:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues
Oxytetracycline	Sum of parent drug and its 4-epimer	All food-producing species	100µg/kg 300µg/kg 600µg/kg 100µg/kg 200µg/kg	Muscle Liver Kidney Milk Eggs

Withdrawal Periods

The same withdrawal periods than the reference product are proposed:

Cattle:
Meat and offal: 35 days
Milk: 7 days

Sheep:
Meat and offal: 35 days
Milk: 9 days

Pigs:
Meat and offal: 28 days

IV. CLINICAL ASSESSMENT (EFFICACY)

For generics, insert in the relevant sections as appropriate:

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.

Resistance

The bibliography information provided suggests that that oxytetracycline could be used for the indications proposed providing the warnings included in the SPC are applied.

Adequate warnings and precautions appear on the product literature.

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

Administrative/Safety/efficacy changes

Summary of change **(Type; application number)**	**Section updated in Module 3**	**Approval date**
VRA - I.III.1.a.: Other changes specific to veterinary medicinal products to be administered to food-producing animals. Addition of a food-producing target animal species. *Addition of pigs as target species* **VRA - G.I.18.:** One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004**.** *One-off alignment of the product information with version 9.0 of the QRD.* (ES/V/0406/001/X/001/G)	IB IIIA IIIB IV	28/10/202