Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Lincoral-S 222 mg/g + 444.7 mg/g Powder for Use in Drinking Water for Pigs and Chickens

Date Created: September 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Lincoral-S 222 mg/g + 444.7 mg/g Powder for Use in Drinking Water for Pigs and Chickens, Powder for use in drinking water
Applicant	Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium
Active substance	Lincomycin Hydrochloride Spectinomycin Sulphate
ATC Vetcode	QJ01FF52
Target species	Chickens Pigs
Indication for use	Pigs For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis*, and associated enteric pathogens (*Escherichia coli*). The presence of the disease in the group must be established before the veterinary medicinal product is used. Chickens For the treatment and metaphylaxis of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Escherichia coli* and associated with a low mortality rate. The presence of the disease in the group must be established before the veterinary medicinal product is used.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	23/06/2025

I. SCIENTIFIC OVERVIEW

This application is to Great Britain for a generic product, submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC. The reference product is Linco-Spectin 100, 222/444.7 mg/g Powder for Use in Drinking Water for Pigs and Chickens (Vm 42058/4080) marketed by Zoetis UK Limited, which has been authorised in the UK since 22 February 1993.

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, any reactions observed are indicated in the SPC[1]. 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[2] 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.

The distribution category in GB will be POM-V, the same as for the reference product.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains lincomycin hydrochloride and spectinomycin sulphate tetrahydrate and the excipient lactose monohydrate.

The container system consists of thermo-sealed bags The particulars of the containers and controls performed are provided and conform to the regulation.

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The choice of the formulation and the absence of preservative is justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of mixing of raw materials, filling, labelling and packaging.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substances are lincomycin hydrochloride and spectinomycin sulphate tetrahydrate, 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 have been provided.

All excipients comply with the European Pharmacopoeia monographs.

II.C.4. Substances of Biological Origin

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.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable

II.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 production sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for this type of dosage form.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable regulatory 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 regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after a first opening the immediate packaging: 6 months.
Shelf life after dissolution according to directions: 24 hours.
Medicated drinking water should be refreshed or replaced every 24 hours.

Keep the bags tightly closed.
This veterinary medicinal product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Studies have been conducted/bibliographical data has been provided which show that lincomycin hydrochloride acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis. Lincomycin is active against gram-positive bacteria, some anaerobic gram-negative bacteria and mycoplasmas. It has little or no action against gram-negative bacteria such as Escherichia coli. The other active ingredient spectinomycin sulphate tetrahydrate acts by binding to the 30S subunit of the bacterial ribosome and inhibiting protein synthesis. The mechanism by which orally administered spectinomycin acts on pathogens at the systemic level despite poor absorption is not fully elucidated and might rely partly on indirect effects on the gut flora.

Toxicological Studies

Due to the legal basis of the application, no toxicological studies are required.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the potential risks to the user will be the same as for the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- Lincomycin and spectinomycin may cause hypersensitivity (allergy) following inhalation, ingestion or skin contact. Allergic reactions to these substances may occasionally be serious.
- People with known hypersensitivity to lincomycin and/or spectinomycin should avoid contact with the veterinary medicinal product.
- This veterinary medicinal product contains lincomycin and spectinomycin, which may be harmful to the unborn child. Pregnant women should use this veterinary medicinal product with caution.
- Skin and eye contact with the powder and the medicated drinking water should be avoided.
- This product may cause eye and respiratory irritation.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 (FFP2 in general, FFP3 for pregnant women) or a non-disposable respirator to European Standard EN140 with a filter to ENI43.
- Wear gloves and safety glasses during preparation of medicated water and wash any exposed skin immediately after handling the product.
- In the event of eye contact, rinse the affected area with large amounts of clean water.
- If symptoms such as skin rash, persistent cough, or persistent eye irritation appear after exposure, seek medical advice immediately and show the package leaflet or label to the physician.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The $PEC_{soil\ initial}$ values calculated for lincomycin and spectinomycin in combination were above the trigger value of 100 µg/kg for all treatments, and therefore, it was concluded that a Phase II assessment was required for the product.

Phase II Tier A:

A Phase II tier A data set was provided according to the requirements of the VICH GL 38 and the CVMP guideline in support of the VICH guidelines including studies on physico-chemical properties, environmental fate and effects. Studies were carried out using the active substances lincomycin and spectinomycin unless indicated otherwise.

Physico-chemical properties

Lincomycin

Study type	Guideline	Result
Water solubility	OECD 105	505.70 mg/l (pH 5, 20°C) 362.20 mg/l (pH 7, 20°C) 382.60 mg/l(pH 9, 20°C)
Dissociation constants in water pKa	OECD 112	7.93 Ka (20°C)
UV-Visible Absorption Spectrum	OECD 101	199 nm (acidic) 191 nm (neutral) 213 nm (basic)
Melting Point/Melting Range	OECD 102	156°C
Vapour Pressure	OECD 104	1.2 x 10^{-4} Pa (25°C)
n-Octanol/Water Partition Coefficient $logP_{ow}$	OECD 107	-3.724 (pH 5) -3.789 (pH7) -3.825 (pH 9)

Spectinomycin

Study type	Guideline	Result
Water solubility	OECD 105	52.85 g/l (pH 5, 20°C) 51.88 g/l (pH 7, 20°C) 49.10 g/l (pH 9, 20°C)
Dissociation constants in water pKa	OECD 112	n/a (no absorbance detected)
UV-Visible Absorption Spectrum	OECD 101	Mean molar absorbance 0.338 Ɛ (pH 12.21 at 214 nm)
Melting Point/Melting Range	OECD 102	184.2°C
Vapour Pressure	OECD 104	1.2 x 10-4 Pa (25°C)
n-Octanol/Water Partition Coefficient $logP_{ow}$	OECD 107	>-4.307 (pH 5) >-4.316 (pH 7) >-4.227 (pH 9)

Environmental fate

Lincomycin

Study type	Guideline	Result
Soil Adsorption/Desorption	OECD 106	K_{oc} 44.87 ml/g (geometric mean)
Aerobic and Anaerobic Transformation in Soil	OECD 307	DT_{50} 4.26 days (geometric mean)

Spectinomycin

Study type	Guideline	Result
Soil Adsorption/Desorption	OECD 106	K_{oc} 34.8 ml/g (geometric mean)
Aerobic and Anaerobic Transformation in Soil	OECD 307	DT_{50} 72 days (geometric mean)

Environmental effects
Lincomycin

Study type	Guideline	Endpoint	Result
Algae, Growth Inhibition Test/ *Anabaena flos-aquae*	OECD 201	EC50	356 µg/l
Daphnia sp. immobilisation	OECD 202	EC50	>91.7 mg/l
Fish, acute toxicity/ *Danio rerio*	OECD 203	LC50	>91.7 mg/l
Soil Microorganisms: Nitrogen Transformation Test (28 days)	OECD 216	% effect	No significant effects
Terrestrial Plants, Growth Test/ *S. melongena*	OECD 208	EC50	3.93 mg/kg (biomass)
Earthworm/ *Eisenia foetida* subacute/reproduction	OECD 220/222	NOEC	916.5 mg/kg
Dung fly larvae	OECD 228	EC50	n/a
Dung beetle larvae	OECD draft	EC50	n/a

Spectinomycin

Study type	Guideline	Endpoint	Result

Study type	Guideline	Endpoint	Result
Algae, Growth Inhibition Test/ *Anabaena flos-aquae*	OECD 201	EC50	418.1 µg/l
Daphnia sp. immobilisation	OECD 202	EC50	>79.5 mg/l
Fish, acute toxicity/ *Danio rerio*	OECD 203	LC50	>77.2 mg/l
Soil Microorganisms: Nitrogen Transformation Test (28 days)	OECD 216	% effect	No significant effects
Terrestrial Plants, Growth Test/ *P. aureus*	OECD 208	EC50	16.64 mg/kg (biomass)
Earthworm/ *Eisenia foetida* subacute/reproduction	OECD 220/222	NOEC	48.3 mg/kg
Dung fly larvae	OECD 228	EC50	n/a
Dung beetle larvae	OECD draft	EC50	n/a

Exposure assessment (Predicted exposure concentration)

PEC values for soil, groundwater and surface water were calculated using the equations provided in the CVMP guidelines. The dose and duration of treatment were taken from the proposed SPC of the product. The following PEC values were calculated.

Lincomycin

Target animal	PEC		
	Soil (µg/kg)	Groundwater (µg/l)	Surface water (µg/l)
Weaner pig	202.5	49.2	16.4
Fattening pig	137.4	35.3	11.2
Broiler	1033.7	251.3	83.8
Replacement layer	229	55.7	18.6
Breeder broiler	65.1	15.8	5.3

Spectinomycin

Target animal	PEC		
	Soil (µg/kg)	Groundwater (µg/l)	Surface water (µg/l)
Weaner pig	418.2	126.5	42.2
Fattening pig	283.7	85.7	28.6
Broiler	2134.6	645.5	215.1
Replacement	472.8	142.9	47.6

Target animal	PEC		
layer			
Breeder broiler	134.4	40.6	13.5

Risk Characterisation (Risk Quotient)

Using the assessment factors (AF) in VICH guidelines predicted no effect concentrations (PNEC) were calculated and compared with the PEC values for each target animal as follows.

Lincomycin

Weaner pig

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.365 mg/l	100	3.65 µg/l	16.4 µg/l	4.61
Daphnia sp. immobilisation	EC_{50}: >91.7 mg/l	1000	91.7 µg/l	16.4 µg/l	3.15
Fish, acute toxicity	LC_{50}: >91.7 mg/l	1000	91.7 µg/l	16.4 µg/l	0.18
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 3.93 mg/l	100	39.3 µg/kg	202.5 µg/kg	5.15
Earthworm reproduction	NOEC: 916.5 mg/l	10	39.3 µg/kg	202.5 µg/kg	0.0022
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Fattening pig

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.365 mg/l	100	3.65 µg/l	11.2 µg/l	3.15
Daphnia sp. immobilisation	EC_{50}: >91.7 mg/l	1000	91.7 µg/l	11.2 µg/l	0.12
Fish, acute toxicity	LC_{50}: >91.7 mg/l	1000	91.7 µg/l	11.2 µg/l	0.12
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 3.93 mg/l	100	39.3 µg/kg	137.4 µg/kg	3.50
Earthworm reproduction	NOEC: 916.5 mg/l	10	39.3 µg/kg	137.4 µg/kg	0.0015
Dung fly larvae	n/a	n/a	n/a	n/a	n/a

Test organism	End point	AF	PNEC	PEC	RQ
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Broiler

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.365 mg/l	100	3.65 µg/l	83.8 µg/l	23.54
Daphnia sp. immobilisation	EC_{50}: >91.7 mg/l	1000	91.7 µg/l	83.8 µg/l	0.91
Fish, acute toxicity	LC_{50}: >91.7 mg/l	1000	91.7 µg/l	83.8 µg/l	0.91
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 3.93 mg/l	100	39.3 µg/kg	1033.7 µg/kg	26.30
Earthworm reproduction	NOEC: 916.5 mg/l	10	39.3 µg/kg	1033.7 µg/kg	0.0113
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Replacement layer

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.365 mg/l	100	3.65 µg/l	18.6 µg/l	5.22
Daphnia sp. immobilisation	EC_{50}: >91.7 mg/l	1000	91.7 µg/l	18.6 µg/l	0.20
Fish, acute toxicity	LC_{50}: >91.7 mg/l	1000	91.7 µg/l	18.6 µg/l	0.20
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 3.93 mg/l	100	39.3 µg/kg	229.0 µg/kg	5.83
Earthworm reproduction	NOEC: 916.5 mg/l	10	39.3 µg/kg	229.0 µg/kg	0.0025
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Broiler breeder

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.365 mg/l	100	3.65 µg/l	5.3 µg/l	1.48

Test organism	End point	AF	PNEC	PEC	RQ
Daphnia sp. immobilisation	EC_{50}: >91.7 mg/l	1000	91.7 µg/l	5.3 µg/l	0.06
Fish, acute toxicity	LC_{50}: >91.7 mg/l	1000	91.7 µg/l	5.3 µg/l	0.06
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 3.93 mg/l	100	39.3 µg/kg	65.1 µg/kg	1.66
Earthworm reproduction	NOEC: 916.5 mg/l	10	39.3 µg/kg	65.1 µg/kg	0.0007
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Spectinomycin

Weaner pig

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.418 mg/l	100	4.18 µg/l	42.2 µg/l	10.1
Daphnia sp. immobilisation	EC_{50}: >79.5 mg/l	1000	79.5 µg/l	42.2 µg/l	0.53
Fish, acute toxicity	LC_{50}: >77.2 mg/l	1000	77.2 µg/l	42.2 µg/l	0.55
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 16.64 mg/l	100	166.4 µg/kg	418.2 µg/kg	2.51
Earthworm reproduction	NOEC: 48.3 mg/l	10	4830 µg/kg	418.2 µg/kg	0.09
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Fattening pig

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.418 mg/l	100	4.18 µg/l	28.6 µg/l	6.8
Daphnia sp. immobilisation	EC_{50}: >79.5 mg/l	1000	79.5 µg/l	28.6 µg/l	0.36
Fish, acute toxicity	LC_{50}: >77.2 mg/l	1000	77.2 µg/l	28.6 µg/l	0.37

Test organism	End point	AF	PNEC	PEC	RQ
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 16.64 mg/l	100	166.4 µg/kg	283.7 µg/kg	1.70
Earthworm reproduction	NOEC: 48.3 mg/l	10	4830 µg/kg	283.7 µg/kg	0.06
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Broiler

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.418 mg/l	100	4.18 µg/l	215.1 µg/l	51.4
Daphnia sp. immobilisation	EC_{50}: >79.5 mg/l	1000	79.5 µg/l	215.1 µg/l	2.71
Fish, acute toxicity	LC_{50}: >77.2 mg/l	1000	77.2 µg/l	215.1 µg/l	2.79
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 16.64 mg/l	100	166.4 µg/kg	2134.6 µg/kg	12.83
Earthworm reproduction	NOEC: 48.3 mg/l	10	4830 µg/kg	2134.6 µg/kg	0.44
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Replacement layer

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.418 mg/l	100	4.18 µg/l	47.6 µg/l	11.4
Daphnia sp. immobilisation	EC_{50}: >79.5 mg/l	1000	79.5 µg/l	47.6 µg/l	0.60
Fish, acute toxicity	LC_{50}: >77.2 mg/l	1000	77.2 µg/l	47.6 µg/l	0.62
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 16.64 mg/l	100	166.4 µg/kg	472.8 µg/kg	2.84
Earthworm reproduction	NOEC: 48.3 mg/l	10	4830 µg/kg	472.8 µg/kg	0.10
Dung fly larvae	n/a	n/a	n/a	n/a	n/a

Test organism	End point	AF	PNEC	PEC	RQ
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

Broiler breeder

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC_{50}: 0.418 mg/l	100	4.18 µg/l	13.5 µg/l	3.2
Daphnia sp. immobilisation	EC_{50}: >79.5 mg/l	1000	79.5 µg/l	13.5 µg/l	0.17
Fish, acute toxicity	LC_{50}: >77.2 mg/l	1000	77.2 µg/l	13.5 µg/l	0.17
Soil Microorganisms:	n/a	n/a	n/a	n/a	n/a
Terrestrial Plants, Growth	EC_{50}: 16.64 mg/l	100	166.4 µg/kg	134.4 µg/kg	0.81
Earthworm reproduction	NOEC: 48.3 mg/l	10	4830 µg/kg	134.4 µg/kg	0.03
Dung fly larvae	n/a	n/a	n/a	n/a	n/a
Dung beetle larvae	n/a	n/a	n/a	n/a	n/a

RQ values for lincomycin were >1 in algae and plants (all target species) and >1 for spectinomycin in algae (all target species), *daphnia* (broilers), fish (broilers), and plants (weaner pig, fattening pig, broiler, replacement layer). Following the refinement of PEC values based on FOCUS modelling and degradation in manure, unacceptable risks were still identified for algae and plants (both active substances), as well as *daphnia* and fish (spectinomycin); accordingly, further assessment of environmental risk was required.

Tier B assessment could not be performed for *daphnia* or fish due to a lack of chronic ecotoxicological data. Unacceptable risks were still identified for algae and plants (both active substances) when using chronic ecotoxicological data and refined PECs at Tier B. Following higher tier testing using species sensitivity distribution (SSD), unacceptable risks were still identified for plants with respect to spectinomycin. As RQ values >1 were recorded for *daphnia* in Tier A in relation to spectinomycin, risks towards sediment-dwelling species were considered in Tier B. No unacceptable risks were identified for sediment-dwelling species following a PEC refinement.

Using further refinement of PECs and consideration of risk mitigation measures (diluting manure 1:3 prior to land application and ploughing to a depth of 20 cm), no unacceptable risks were identified for algae, *daphnia,* or fish, however, unacceptable risks were still identified for groundwater ecosystems.

Identified environmental properties of concern (toxic to cyanobacteria and groundwater ecosystems for lincomycin, very persistent in the environment, toxic to terrestrial plants, cyanobacteria, and groundwater ecosystems for spectinomycin) are communicated in the SPC and QRD.

III.B.2 Residues documentation
Residue Studies

No residue depletion studies were conducted as these were not required due to the legal base of the application.

Maximum Residue Limits (MRLs)

Lincomycin hydrochloride is listed in Table 1 of Regulation 37/2010 and MRLs have been established for edible tissues.

MRLs are listed below:

	Porcine	Poultry
Muscle	100 µg/kg	100 µg/kg
Liver	500 µg/kg	500 µg/kg
Kidney	1500 µg/kg	1500 µg/kg
Fat / skin	50 µg/kg	50 µg/kg
Eggs	N/A	50 µg/kg

Spectinomycin sulphate tetrahydrate is listed in Table 1 of Regulation 37/2010 and MRLs have been established for edible tissues.

MRLs are listed below:

	Porcine	Poultry
Muscle	300 µg/kg	300 µg/kg
Liver	1000 µg/kg	1000 µg/kg
Kidney	5000 µg/kg	5000 µg/kg
Fat / skin	500 µg/kg	500 µg/kg

Withdrawal Periods

Based on the data provided, a withdrawal period of zero days for meat and offal in pigs and 5 days for meat and offal in chickens are justified.

The product is not for use in birds producing or intended to produce eggs for human consumption.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Pharmacology studies were not required because this is a generic application submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC and bioequivalence with the reference product has been established.

Tolerance in the Target Species

Tolerance studies were not required because this is a generic application submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC and bioequivalence with the reference product has been established.

Resistance

The bibliography/information provided suggests that some resistance to the active substances is reported and that *in vitro* results showed that each *L. intracellularis* isolate has a different antimicrobial sensitivity pattern.
The other resistance statements and warnings in the SPC reflect those of the reference product and are satisfactory. Adequate warnings and precautions appear on the product literature.

IV.II. Clinical Documentation

Laboratory Trials

No clinical data have been submitted as this is a generic application submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC and bioequivalence with the reference product has been established.

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 benefit/risk profile of the product is favourable.

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)