IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Linspec 50/100 mg/ml Solution for injection for dogs, cats, pigs and pre-ruminant calves

PRODUCT SUMMARY

EU Procedure number	IE/V/0238/001/DC
Name, strength and pharmaceutical form	Linspec 50/100 mg/ml Solution for Injection for dogs, cats, pigs and pre-ruminant calves
Active substance(s)	Lincomycin Hydrochloride Spectinomycin sulphate
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd. Loughrea Co. Galway Ireland
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	28th July 2010
Target species	Cattle (pre-ruminating calves), pigs, dogs and cats.
Indication for use	Treatment of respiratory infections, intestinal infections, urinary tract infections, skin infections (including wounds and abscess) and arthritis caused by organisms sensitive to lincomycin and / or spectinomycin.
ATCvet code	QJ01FF52
Concerned Member States	AT, CZ, ES, FR, HU, IT, PL, PT, SK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the 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 Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. 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 slight reactions observed are indicated in the SPC.

The product is safe for the user 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 the active substances lincomycin (as hydrochloride) 50 mg/ml and spectinomycin (as sulphate) 100 mg/ml and excipients benzyl alcohol, sodium hydroxide, hydrochloric acid and water for injections.
The container/closure system consists of a 100 ml translucent polypropylene vial with bromobutyl stoppers and aluminium caps with flip-off seals.
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 substances are lincomycin hydrochloride and spectinomycin sulphate, established substances described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.
The active substance specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with these specifications have 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 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 substances has 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 when stored under the approved conditions.
A 28 day in-use shelf-life is supported by the data provided.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The application was presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).
The reference product is Linco-Spectin Sterile Solution (VPA 10019/094/001).

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 tests are not required.

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

The product was exempt from the requirement for bioequivalence studies on the basis that the product is to be parenterally administered as a solution and contains the same active substances and excipients in the same concentrations as the reference product currently approved for use in the target species.

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 tests are not required.

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I

A Phase II ERA is required as the Phase I assessment showed that the sum of the predicted environmental concentration for both active substances in soil will exceed the trigger of 100 µg/kg.

Phase II Tier A
A Phase II Tier A assessment was conducted.

Based upon the data provided, the product will not present an unacceptable risk for the environment and a Tier B assessment is not necessary.

Conclusion
Based on the data provided the product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues Documentation

Residue Studies

The application has been submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). In accordance with Article 13.1, *'the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product…'*.
No residue depletion studies were conducted because the product has the same qualitative and quantitative composition in terms of active substances and excipients as the reference product. It is accepted that there will be no difference between products with respect to residue depletion from the primary target tissues.

MRLs

Lincomycin is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

	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

Spectinomycin is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

	ALL FOOD PRODUCING SPECIES (EXCEPT OVINE)
Muscle	300 µg/kg
Liver	1000 µg/kg
Kidney	5000 µg/kg
Fat/ skin	500 µg/kg
Milk	200 µg/kg

Withdrawal Periods

The applicant's proposal to apply the same withdrawal periods as approved for the reference product was considered to be appropriate.

The following withdrawal period information was accepted:

Meat and Offal
Pigs: 14 days
Pre-ruminating calves: 21 days

IV. CLINICAL ASSESSMENT

The application was presented in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product is Linco-Spectin Sterile Solution (VPA 10019/094/001).

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13(1), and the test product is accepted as being identical to the authorised reference product, the omission of target animal safety studies is considered justified. The potential adverse reactions for this product are the same as those of the reference product.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies (pharmaceuticals and immunologicals)

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.

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 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 on the HPRA website.

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:

Safety/Efficacy Changes

Summary of change (Application number)	**Approval date**
Addition of target species – pigs, pre-ruminant calves (IE/V/0238/001/dx/002)	31st July 2013