IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

COLMYC 25 mg/ml ORAL SOLUTION for calves.

PRODUCT SUMMARY

EU Procedure number	IE/V/0254/001/DC
Name, strength and pharmaceutical form	COLMYC 25 mg/ml ORAL SOLUTION for calves
Active substance(s)	Enrofloxacin
Applicant	SP VETERINARIA SA Crta Reus Vinyols km 4.1 Riudoms 43330 Spain
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	29th October 2010
Target species	Calves
Indication for use	Treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica* Treatment of gastro-intestinal infection due to *Escherichia coli*. To be used where clinical experience and/or sensitivity testing indicates enrofloxacin as the drug of choice.
ATCvet code	QJ01MA90
Concerned Member States	DE, IT, RO, PL, EL, ES

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

II. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

The product contains the active substance enrofloxacin (25 mg/ml) and excipients benzyl alcohol, potassium hydroxide, hypromellose and purified water.
The container/closure system consists of high density polyethylene containers of 100 ml, 500 ml, 1L and 5L with green high density polyethylene screw caps.
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 enrofloxacin, 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.

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 substance enrofloxacin has 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.

G.Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.ASafety Testing

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

Exemption from bioequivalence studies (in accordance with paragraph 4(b) of the Guideline for Conduct of Bioequivalence Studies (EMEA/CVMP/016/00-corr-FINAL)) is accepted because the product is to be orally administered as a solution and contains the same active substance and excipients in the same/similar concentrations as a veterinary medicinal product currently approved for use in the target species (Baytril 2.5% Oral Solution).

As bioequivalence is accepted for the test product and Baytril 2.5% Oral Solution, it follows that the safety profile will be similar with regards to target animal safety and user safety.

A comprehensive environmental risk assessment was presented in support of this application. Based on the information provided, it can be concluded that the use of the product as recommended does not constitute a risk for the environment.

III.BResidues Documentation

Residue Studies

No residue depletion studies were provided.

MRLs

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

	BOVINE
Muscle	100 µg/kg
Liver	300 µg/kg
Kidney	200 µg/kg
Fat/ skin	-
Milk	-

Withdrawal Periods

Given that bioequivalence is accepted, it follows that there will be no difference between products with respect to depletion of residues of enrofloxacin. The withdrawal period for the reference product in Ireland is 8 days. While an 8 day withdrawal period is acceptable to Ireland, the applicant agreed to apply an 11 day withdrawal period at the request of one Concerned Member State. The proposed calf withdrawal period can be accepted.

IV. CLINICAL ASSESSMENT

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

Exemption from bioequivalence studies (in accordance with paragraph 4(b) of the Guideline for Conduct of Bioequivalence Studies (EMEA/CVMP/016/00-corr-FINAL)) is accepted because the product is to be orally administered as a solution and contains the same active substance and excipients in the same/similar concentrations as a veterinary medicinal product currently approved for use in the target species (Baytril 2.5% Oral Solution).

As the test product is considered to be bioequivalent to Baytril 2.5% Oral Solution, it is accepted that the efficacy profile will be similar to that of the reference product.

A target animal safety study specific to the test product has not been presented with the application. Given that:

- The product is an oral dose form,

·Bioequivalence with the reference product Baytril 2.5% oral solution is accepted

·The toxicological profile of the active substance is well known
·The impurity profile in the formulation is satisfactory
·The excipients are recognised as being safe
the absence of tolerance studies specific to the test product can be accepted. It is accepted that the target animal safety profile of the test product will be the same as that of the reference product. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

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:

Quality Changes

Summary of change	Approval date

CRN 7025086 Change in pack size of the finished product: Change in the number of units (e.g. tablets, ampoules, etc.) in a pack: Change outside the range of the currently approved pack sizes (IE/V/0254/001/IB/002)	