Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Enro-Sleecol (DE, IE)

Enroshort (BE)

Date: 01 August 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0335/001/DC
Name, strength and pharmaceutical form	Enro-Sleecol, 100 mg/ml oral solution
Applicant	KRKA d.d. NOVO mesto Smarjeska cesta 6 8501 NOVO MESTO SLOVENIA
Active substance(s)	Enrofloxacin
ATC Vetcode	QJ01MA90
Target species	Chickens, turkeys
Indication for use	For the treatment of diseases of the respiratory and alimentary tracts of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, colibacillosis and salmonellosis), where clinical experience supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	26 January 2011
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	BE and IE (former RMS)

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 100 mg/ml enrofloxacin and the excipients potassium hydroxide, hypromellose, benzyl alcohol and purified water.

The container/closure system consists of a 100 ml type III amber glass container with cap and sealing liner with a 25 ml polypropylene dosing cup, a 1 litre high density polyethylene bottle with a 50 ml polypropylene dosing cup, and of a 5 litre high density polyethylene bottle.

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 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 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 when stored under the approved conditions.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

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(e) of the Guideline for Conduct of Bioequivalence Studies (EMEA/CVMP/016)) is accepted because the product is an oral solution containing an active substance in the same concentration as a product approved for use in the same target species, and it contains no inactive substance that can significantly affect the absorption of the active substance.

As the test product is bioequivalent to Baytril 10% Oral Solution, it is accepted that the safety profile (safety to the target species and safety to the user) will be similar to that of the reference product.

A comprehensive environmental risk assessment was presented in support of this application. Based on the data presented, it is accepted that enrofloxacin, when used in accordance with the proposed recommendations for use, does not pose an unacceptable risk to the environment.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted.

MRLs

Enrofloxacin is listed in Annex I of Council Regulation 2377/90.

The excipients in the formulation are listed in Annex II of Council Regulation 2377/90 or are generally regarded as safe.

Withdrawal Periods

As the test product is bioequivalent to Baytril 10% Oral Solution, it is accepted that there will be no difference between products with respect to depletion of residues of enrofloxacin. The proposed withdrawal period for the test product for both chickens and turkeys is the same as that authorised for the reference product in the RMS and can be accepted.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

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(e) of the Guideline for Conduct of Bioequivalence Studies (EMEA/CVMP/016)) is accepted because the product is an oral solution containing an active substance in the same concentration as a product approved for use in the same target species, and it contains no inactive substance that can significantly affect the absorption of the active substance.

Tolerance in the Target Species of Animals

No target animal safety studies were conducted.

Given that:

- The product is an oral dose form,
- Bioequivalence with the reference product Baytril 10% 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.

The information relating to adverse reactions ('None') and overdose ('Do not exceed the recommended dose. In accidental overdose, there is no antidote and treatment should be symptomatic.') included on the SPC for the test product is the same as that included on the SPC of the reference product, Baytril 10% Solution, in Ireland.

Resistance

Statements relating to appropriate use of fluoroquinolones, in accordance with the requirements of EMEA/CVMP/416168/06 (Reflection Paper on the use of fluoroquinolones in food producing animals - Precautions for use in the SPC regarding prudent use guidance), are included on the SPC.

IV.B Clinical Studies

The indications and posology proposed for the test product reflect the approved indications and posology for the reference product, Baytril 10% Solution. As the test product is bioequivalent to Baytril 10% Oral Solution, it is accepted that the efficacy profile will be similar to that 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 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

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 Heads of Veterinary Medicinal 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.

•	01 August 2019	Change of RMS from IE to DE
•	15 March 2019	Change in the pharmacovigilance system
•	04 September 2019	Change in the distributor in Germany
•	29 May 2018	Change in indication for use
•	16 February 2015	Submission of an updated CEP
•	09 April 2014	Change in the pharmacovigilance system
•	25 March 2014	Extension of the withdrawal period from 3 days to 7 days for chickens and 13 days for turkeys
•	10 September 2013	Change in the Marketing Authorisation Holder from Eurovet Animal Health BV to KRKA d.d. NOVO mesto
•	23 January 2013	Introduction of a new active substance manufacturer
•	23 January 2013	Change in the address of the active substance manufacturer
•	10 April 2012	Change in the pharmacovigilance system
•	30 January 2012	Change in the distributor in Germany
•	12 January 2012	Change in the Marketing Authorisation Holder from Dechra Veterinary Products Deutschland GmbH to Eurovet Animal Health BV in Germany