Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

DECENTRALISED PROCEDURE
FINAL

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Baytril flavour 25 mg/ml oral suspension for cat

Date: 17.06.2011

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0144/001/DC
Name, strength and pharmaceutical form	Baytril flavour **25 mg/ml oral suspension for cat**, 25 mg/ml, suspension
Applicant	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany
Active substance(s)	Enrofloxacin
ATC Vetcode	QJ01MA90
Target species	Cat
Indication for use	For the treatment of single or mixed bacterial infections of the respiratory, alimentary and urinary tract, skin or wounds caused by the following enrofloxacin-sensitive Gram-negative and Gram-positive bacteria: E.coli, Pasteurella spp, Haemophilus spp. and staphylococci.

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(3) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	23 March 2011
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT; BE; CY; DK; EL; ES; FI; FR; HU; IE; IS; IT; LU; NL; NO; PT; SE; UK

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.
Based on a bioequivalence study 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 based on a bioequivalence study since the claims for this product are equivalent to those of the reference product Baytril flavour 50mg tablets.

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

II. QUALITY ASPECTS

A. Composition

The product contains 25 mg enrofloxacin / ml suspension and the following excipients: sorbic acid (E200), ascorbic acid (E300), polacrilin, dispersible cellulose (microcrystalline cellulose and carmellose sodium), propylene glycol (E1520), vanilla flavour, and purified water.

The container/closure system includes a high density polyethylene bottle with a polyethylene insert, a child resistant closure and a 3 ml polypropylene oral dosing syringe with 0.1 ml graduations. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified.

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. Process validation for full-scale batches will be performed post-authorisation.

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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been declared.

E. <Control on intermediate products> (pharmaceuticals)

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

F. 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.

G. 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.

The claim of a 3-month stability after broaching is based on the demonstration of stability for a batch broached and stored 90 days in a range between 17.8 – 25.7 °C.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL) (*for pharmaceuticals only)*

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

The safety 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 / consumers.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

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.

IV.A Pre-Clinical Studies

Pharmacology

Baytril flavour 25 mg/ml oral suspension for cats is an oral suspension containing enrofloxacin as the active ingredient in a concentration of 25 mg/ml.

The applicant has conducted a bioequivalence study which demonstrated bioequivalence of Baytril flavour 25 mg/ml oral suspension with the reference product.

Tolerance in the Target Species of Animals

As this is an application according to Article 13, and bioequivalence with a reference product has been demonstrated, data on tolerance in the target species is not required.

Resistance

As this is an application according to Article 13, and bioequivalence with a reference product has been demonstrated, data on resistance are not required.

IV.B Clinical Studies (pharmaceuticals and immunologicals)

Field Trials

As this is an 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.

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.

08 June 2019	MA transfer in DE (Bayer Vital GmbH to Elanco GmbH)