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

Enrotron Flavour 50 mg

Date: 01. November 2010

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0137/001/DC
Name, strength and pharmaceutical form	Enrotron Flavour **50 mg**, 50 mg, Tablets
Applicant	aniMedica GmbH Im Südfeld 9 D-48308 Senden-Bösensell
Active substance(s)	Enrofloxacin
ATC Vetcode	QJ 01 MA 90
Target species	Dogs
Indication for use	For the treatment of bacterial single or combined infections of the respiratory, alimentary or urinary tract, the skin or wounds, caused by 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).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (2) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	28.07.2010
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	AT, BE, DK, EL, FI, FR, HU, IE, IS, LU, NL, NO, PL, SE, SI, UK

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

II. QUALITY ASPECTS

A. Composition

The product contains 50 mg enrofloxacin / tablet and the following excipients: lactose monohydrate, powdered cellulose, maize starch, povidone 25, silica colloidal anhydrous, magnesium stearate, and beef flavour.

The container/closure system is a blister package consisting of either PVC/aluminium foil or aluminium/aluminium foil. The particulars of the containers and controls performed are provided and conform to the regulation.

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 licensed manufacturing sites.

Process validation data on the product have been presented in accordance with the relevant European guidelines. Process validation for further 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.

Data of the active substance manufacture has been provided in the form of an ASMF documentation.

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.

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E. Control on intermediate products

Not applicable.

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 sites 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 72-hour stability for divided tablets is based on the demonstration of stability for halved tablets of one batch stored three days at 25°C.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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.

Warnings and precautions as listed on the product literature are the same as those of the reference product or updated according to current standards and are adequate to ensure safety of the product to users / the environment / consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, 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.

Toxicological Studies

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

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

User Safety

The applicant has not provided a user safety assessment which has been justified on the basis of the application being for a generic product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

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)

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 included in those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology

The application is made in accordance with Article 13 (2) of Directive 2001/82/EC as amended by Directive 2004/28/EC.

Based on information provided in support of this application it is accepted that the test product is bioequivalent to the reference product Baytril flavour 50 mg Tabletten. One bioequivalence study was conducted in dogs comparing Enrotron flavour 150 mg tablets to Baytril flavour 150mg Tabletten. This study successfully demonstrated the bioequivalence between the two products according to the requirements of the relevant Guideline EMEA/CVMP/016/00-corr-FINAL. The results of this bioequivalence study can be extrapolated to Enrotron flavour 50 mg tablets.

On the basis of being a generic of a reference medicinal product, no further information is required as it has already been presented for the reference product.

Tolerance in the Target Species of Animals

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC.

Based on information provided in support of this application it is accepted that the test product is bioequivalent to the reference product Baytril flavour 50 mg Tabletten. One bioequivalence study was conducted in dogs comparing Enrotron flavour 150 mg tablets to Baytril flavour 150mg Tabletten. This study successfully demonstrated the bioequivalence between the two products according to the requirements of the relevant Guideline EMEA/CVMP/016/00-corr-FINAL. The results of this bioequivalence study can be extrapolated to Enrotron flavour 50 mg tablets.

On the basis of being a generic of a reference medicinal product, no further information is required as it has already been presented for 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

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC.

Based on information provided in support of this application it is accepted that the test product is bioequivalent to the reference product Baytril flavour 50 mg Tabletten. One bioequivalence study was conducted in dogs comparing Enrotron flavour 150 mg tablets to Baytril flavour 150mg Tabletten. This study successfully demonstrated the bioequivalence between the two products according to the requirements of the relevant Guideline EMEA/CVMP/016/00-corr-FINAL. The results of this bioequivalence study can be extrapolated to Enrotron flavour 50 mg tablets.

On the basis of being a generic of a reference medicinal product, no further information is required as it has already been presented for 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.

<None>