MINISTERIO
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agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Enrocat flavour 25 mg/ml oral suspension for cats

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0294/001/DC
Name, strength and pharmaceutical form	Enrocat flavour 25 mg/ml oral suspension for cats
Applicant	LIVISTO Int'l, S.L. Av. Universitat Autònoma, 29 Cerdanyola del Vallès Barcelona
Active substance(s)	Enrofloxacin
ATC Vet code	QJ01MA90
Target species	Cats
Indication for use	For the treatment of single or mixed bacterial infections of the respiratory, digestive and urinary tract, otitis externa, skin and wounds infections caused by the following enrofloxacin-sensitive Gram-positive and Gram-negative bacteria: Staphylococcus spp., Escherichia coli, Haemophilus spp., and Pasteurella spp

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.3 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	18/12/2019
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BG, CZ, DE, DK, EE, EL, FI, HU, IE, IS, IT, LT, LV, PL, PT, RO, 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. Qualitative and quantitative particulars

The finished product is presented as oral suspension containing 25 mg/ml of enrofloxacin as active substance and sorbic acid. Other ingredients are carmellose sodium, xanthan gum, polysorbate 80, beef flavour and purified water.

The container/closure system is high density polyethylene (HDPE) bottles of 10 ml containing 8.5 ml of the veterinary medicinal product sealed with a child resistant stopper made of polypropylene (PP) with thread and low density polyethylene (LDPE) plug. A 3 ml polypropylene oral dosing syringe is supplied with the medicinal product.

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 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.

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on intermediate products

NA.

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.

G. Other Information

NA

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is an hybrid application according to Article 13.3 on the basis of a different pharmaceutical form, and bioequivalence of the candidate formulation with the reference product is demonstrated, the applicant does not provided any data on pharmacological studies, toxicology or other requirements of this veterinary medicinal product.

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

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users and for the environment.

III.A Safety Testing

Pharmacological Studies

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product. See part IV

Toxicological Studies

As this is an hybrid application according to Article 13 (3), and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of the active substance are identical to the reference product.

Excipients are commonly used in veterinary pharmaceuticals.

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

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

The product will not pose an unacceptable risk for the environment when used in accordance with the proposed SPC.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is an hybrid application according to Article 13.3 on the basis of a different pharmaceutical form, 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

None