FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

BANACEP vet 20 film-coated tablet for dogs

Date: 10 January 2012

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0180/002/DC
Name, strength and pharmaceutical form	BANACEP vet 20 film-coated tablet for dogs
Applicant	LABORATORIOS CALIER, S.A. BARCELONES, 26 (PLA DEL RAMASSA) LES FRANQUESES DEL VALLES (BARCELONA) ESPAGNE
Active substance(s)	Benazepril (as hydrochloride)
ATC Vetcode	QC09AA07
Target species	Dogs
Indication for use	In dogs weighing more than 20 kg bw: Treatment of congestive heart failure.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Extension according to Regulation 1234/2008
Date of completion of the original decentralised procedure	13/02/2008
Concerned Member States for original procedure	BE, DE, EL, ES, IT, NL, PL, PT, 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 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 18.42 mg/tablet benazepril (hydrochloride) as the active substance and the excipients cellulose microcrystalline, lactose monohydrate, povidone, maize starch, colloidal silica anhydrous, magnesium stearate, hypromellose, macrogol 8000, titanium dioxide (E-171), iron oxide yellow (E-172), iron oxide red (E-172) and iron oxide black (E172).
The container/closure system is a blister made of clear film of PVC/PE/PVDC and aluminium film. 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 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

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substance is benazepril hydrochloride, 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.

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 satisfactorily demonstrated.

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 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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

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Pharmacological Studies

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product BANACEP VET 5 film-coated tablet for dogs and cats of LABORATORIOS CALIER.

As this application is in accordance with a line extension as referred in Annex II of Regulations (EC) nº1234/2008, and that bioequivalence with the reference product has been demonstrated, the applicant shall not be required to provide the results of pharmacological tests.

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

Toxicological Studies

As this application is in accordance with a line extension as referred in Annex II of Regulations (EC) nº1234/2008 and that bioequivalence with the reference product has been demonstrated**,** the applicant shall not be required to provide the results of toxicological tests.

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

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.

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.

III.B Residues documentation

These products are intended for non-food producing species, thus there was no necessity to provide data for this section.

IV. CLINICAL ASSESSMENT (EFFICACY)

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because the tested product and the reference product have similar formulations and are bioequivalent.

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

Based on the

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conclusion made for the reference product, the product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

As this is an extension application as referred in annex II of Regulations (EC) nº 1234/2008, and bioequivalence with the 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.