Product name: BENADIL 5 mg/20 mg, film-coated tablets	Application number: 6605/2024
Applicant: VetViva Richter GmbH	MRP/DCP: CZ/V/0111/002-003/E/001
Publicly available assessment report	

Institute for State Control of Veterinary Biologicals and Medicines
Hudcova 56a
621 00 Brno
Czech Republic
(Reference Member State)

SUBSEQUENT RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

BENADIL 5 mg, film-coated tablets for dogs and cats
BENADIL 20 mg, film-coated tablets for dogs

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PRODUCT SUMMARY

EU Procedure number	CZ/V/0111/002-003/E/001
Name, strength and pharmaceutical form	BENADIL 5 mg, film-coated tablets for dogs and cats BENADIL 20 mg, film-coated tablets for dogs
Applicant	VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
Active substance(s)	Benazepril hydrochloride
ATC Vetcode	QC09AA07
Target species	Dogs, cats (BENADIL 5 mg) Dogs (BENADIL 20 mg)
Indication for use	Dogs: Treatment of congestive heart failure. Cats: Reduction of proteinuria associated with chronic kidney disease.

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PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

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SUMMARY OF ASSESSMENT

Legal basis of original application	Generic application in accordance with Article 13.1. of Directive 2001/82/EC as amended.
Reference product (RP) Marketing authorisation holder MS where the RP is or has been authorised Marketing authorisation number EU procedure number Date of authorisation	FORTEKOR, 5mg, Film-coated tablet, FORTEKOR, 20mg, Film-coated tablet Novartis Animal Health d.o.o CZ 96/050/01 – C, 96/517/96 - C - 22/08/1996; MA withdrawn on 05/03/2012
Date of completion of the original decentralised procedure	08/06/2016
Concerned Member States for original procedure	BE, DE, FR, HU, LU, NL, PL, PT, SK, UK(NI)
Concerned Member States for subsequent recognition procedure	1th wave: AT, BG, CY, DK, EL, ES, HR, NO, RO, SE

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1. 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.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The product contains Benazepril hydrochloride 5 mg or 20 mg as the active substance and the excipients Lactose monohydrate, Cellulose microcrystalline, Starch pregelatinized, Castor oil hydrogenated, Crospovidone, Silica colloidal anhydrous and coating (Macrogol poly(vinyl alcohol) grafted copolymer, Poly(vinyl alcohol, Silica colloidal anhydrous, Talc, Macrogol 6000, Titanium dioxide, Iron oxide red (E172)

The tablets are packed into blisters consisting of:

- 5mg tablets: aluminium foil and a transparent PCTFE/PVC film or alternatively aluminium blister foil (oPA/PVC)
- 20mg tablets: aluminium foil and a transparent PVDC/PVC film or alternatively aluminium blister foil (oPA/PVC)

The product is developed as a generic to Fortekor tablets by Novartis. Both products contain the same active substance at the same dose of the active substance and in the same pharmaceutical form. The pharmaceutical development is adequately described.

B. Description of the manufacturing method

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

The manufacture consists of preparation of the bulk powder that is further sieved, compressed into tablet cores, the cores are coated and final tablets are packed into blisters.

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

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C. Production and control of starting materials

The active substance Benazepril HCl is described in Ph. Eur. monograph and it is controlled accordingly. The scientific data are replaced by EDQM Certificate of Suitability. Additional controls are included in the Applicant´s own specification that reflect the final use in tablets.

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.

The product contains number of excipients. They are controlled according to their respective Ph. Eur. monographs except for non-pharmacopoeial excipients (coating and ferri oxide) for which in-house monographs are established and regarded acceptable.

Quality control of the container-closure system is described and considered adequate.

The only substance of animal origin is milk that is used for the excipient Lactose monohydrate. No other material of human or animal origin are used. Satisfactory TSE declaration is provided.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. It covers tests on appearance, dimensions, average weight, uniformity of mass, uniformity of dosage units, hardness, water content, disintegration time, dissolution, microbiological quality, identification and assay of Benazepril and its related substances. 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 tests

For one source of the active substance, the stability data have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance for the proposed retest period. For the second source, retest period is declared on the EDQM Certificate of Suitability.

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:

- 5mg: shelf-life 2 years
- 20mg: shelf-life 3 years

The claim of a 2 days stability for divided tablets is supported by suitable stability studies.

G. Other Information

Not applicable

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 13, results of pharmacological and toxicological tests are not required.
Warnings and precautions as listed on the product literature were updated and are adequate to ensure safety of the product to users and the environment.

III.A Safety Tests

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline and the 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 - dogs and cats.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18, 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.

A. Pre-Clinical Studies

Pharmacology

The applicant has provided results of the bioequivalence studies, which were performed for the initial marketing authorisation (1st wave) to show bioequivalence of the reference and candidate product in both target species dogs and cats. Bioequivalence with a reference product has been demonstrated, thus no further data are required.

Tolerance in the Target Species of Animals

Since the date of the original authorisation, no variations relating to tolerance in the target animals have been approved, thus no further data on tolerance in target animals are required.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

B. Clinical trials

Since the date of the original authorisation, no variations relating to efficacy aspects of the product have been approved, thus no data on the clinical aspect are required.

5. 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.

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POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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.

Changes to Part 1 of the dossier (administrative)

Summary of change (Application number)	**Section updated**	**Approval date**
Change to product name CZ/V/0111/002-003/IB/007	Part IB	28/12/2019

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Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	**Approval date**
B.II.e.5.a.1 Change in the pack size of the finished product CZ/V/0111/001-003/IA/001	26/04/2013
B.III.1.a.3 Addition of a new API manufacturer CZ/V/0111/001-003/IA/002	08/09/2015
Both strengths: - B.II.d.1.z Change in the specification parameters and/or limits of the finished product 5mg only: - B.II.f.1.a.1 Reduction of the shelf life of the finished product as packaged for sale - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product CZ/V/0111/002-003/IB/003	10/04/2017
B.III.1.a.2 Updated CEP from already approved manufacturer CZ/V/0111/002-003/IA/004	12/07/2018
B.II.b.2.c.1 Change to batch release arrangement CZ/V/0111/002-003/IA/006	19/12/2019
B.II.b.1.a Addition of a manufacturing site for secondary packaging CZ/V/0111/002-003/IA/008	19/12/2019
5mg only: B.II.d.1.e – Change in the specification of the finished product. CZ/V/0111/002/II/0010	12/11/2020
B.II.d.2.a Minor changes to an approved test procedure of the finished product CZ/V/0111/002-003/IA/011	09/05/2021
F.II.b.3.a Minor change in the manufacturing process of the finished product	12/09/2022

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B.3.k Deletion of a non-significant in-process test during the manufacture of the finished product (Deletion of an obsolete test) B.3.n Deletion of a non-significant parameter in the release specification of the finished product	08/09/2022
F.II.b.1.c Addition of a manufacturing site for the manufacturing process of the finished product CZ/V/0111/002-003/A/013	01/07/2022
B.20 – Addition of a primary packaging site of a non-sterile finished product B.21 – Addition of a secondary packaging site of a finished product B.22 – Change to batch control arrangements and quality testing for a finished product	01/07/2022
B.34 Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product	17/06/2022
5mg only: B.26.a Change in batch size of the finished product – up to 10-fold increase.	17/08/2023
B.3.a Deletion of a manufacturing site for the finished product	11/01/2024