College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Thyrasol 5 mg/ml oral solution for cats

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0369/001/DC
Name, strength and pharmaceutical form	Thyrasol 5 mg/ml oral solution for cats
Applicant	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
Active substance(s)	Thiamazol
ATC Vetcode	QH03BB02
Target species	Cats
Indication for use	The veterinary medicinal product is used in the following indication: For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy. For the long term treatment of feline hyperthyroidism.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://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 (Hybrid)
Date of completion of the decentralised procedure	21 September 2022
Concerned Member States for original procedure	AT, BE, DE, DK, ES, FI, FR, HU, IE, IT, PL, PT, SE, UK(NI)

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.
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.

For applications based on informed consent to another authorisation:

The EU reference product is Felimazole 5 mg omhulde tabletten voor katten, authorised in the Netherlands under MA number REG NL 10211. The marketing authorisation holder of the reference product is Dechra Regulatory B.V.

The claimed reference product 'Felimazole 5 mg omhulde tabletten voor katten' was first authorized in the Netherlands on 12.07.2004 based on a national application referring to Article 12.1. of Directive 2001/82/EC (as amended by Directive 2004/28/EC) and was renewed on 15.5.2009. Date of first authorisation of Felimazole 5 mg Coated Tablets for Cats in the UK was 22 January 2002.

The quality / safety / efficacy aspects of this product is/are identical to 'Felimazole 5 mg omhulde tabletten voor katten'. The initial application for 'Felimazole 5 mg omhulde tabletten voor katten' was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The oral solution contains 5 mg/ ml Thiamazole and the following excipients:

Glycerol, Povidone K30, Sodium benzoate, Hypromellose, Disodium phosphate dihydrate, Sodium dihydrogen phosphate dihydrate, Citric acid, Sodium cyclamate, Sucralose, Anise flavour, Citric acid solution, Sodium hydroxide solution and Water.

The solution is a colourless to slightly coloured, turbid, viscous solution.

The solution is packed in a glass or HDPE bottle and closed with a Child Resistant closure with syringe in-lay, containing 30 , 50, 60 or 100 ml solution.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

A bioequivalence study has been done.

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.

The product is manufactured using conventional manufacturing techniques. However, suitable validation results on two production scale batches per manufacturing site have been provided. The tests performed during production are described.

A bulk holding time of 28 days has been justified.

C. Control of Starting Materials

The active substance thiamazole is an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The proposed ASM has acquired a Certificate of Suitability from EDQM for thiamazole active substance.

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.

Apart from the flavouring, the excipients are in conformity with the Ph.Eur. requirements.

A statement has been provided that the flavouring agent complies to the EC regulation 1334-2008 on flavouring.

The packaging is conformity with the Ph Eur and EU Food Directive.

There are no substances of biological origin within used in the manufacture of this product.

D. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. Most 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.

F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, confirming the retest period 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. The claimed shelf life can be granted for 24 months.

G. Other Information

None

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 toxicological, pharmacological and clinical tests are not required.

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.

Additional statements have been added, based on increased knowledge and the current state of science. Adverse events, warnings and contraindications are indicated in the SPC.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. Combined with increased knowledge and the current state of science, 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.

The environmental risk assessment can stop in Phase I because this product is intended for use in cats and a Phase II assessment is not deemed necessary.

The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

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

An in-vivo bioequivalence study has been provided to demonstrate bioequivalence between the candidate and reference product in cats.

Study aim was to demonstrate bioequivalence of thiamazole in cat plasma after oral administration of reference and generic product. Based upon the findings from this bioequivalence study, it was accepted that the candidate and reference products may be considered bioequivalent in the intended target species.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, tolerance studies are not required. The tolerance claims for this product are equivalent to those of the reference product.

IV.B Clinical Studies

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.

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 Medicines 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.

Quality changes

Summary of change (Application number)	Section updated in Module 3	Approval date

Safety/efficacy changes

Summary of change (Type; application number)	Section updated in Module 3	Approval date