MEB agency / Veterinary Medicinal Products Unit
The Netherlands

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

TRAMADOG 50 mg tablet for dogs

(NL/V/0359/001/DC)

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0359/001/DC
Name, strength and pharmaceutical form	Name: TRAMADOG Strength: 50 mg Pharmaceutical form: tablet
Applicant	DOMES PHARMA 3 rue André Citroën 63430 PONT-DU-CHATEAU FRANCE
Active substance(s)	Tramadol
ATC Vetcode	QN02AX02
Target species	Dog.
Indication for use	For the reduction of acute and chronic mild soft tissue and musculoskeletal pain.

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(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	22 December 2021.
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NO, PL, PT, RO, SE, SI, SK, UK (NI).

1. SCIENTIFIC OVERVIEW

Tramadog 50 mg tablet for dogs 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.
Tramadog 50 mg tablet for dogs 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.

The safety and efficacy aspects of *Tramadog 50 mg tablet for dogs* are based on bioequivalence with the Italian reference product *Altadol 50 mg compresse solubili per cani*, which has been authorized in Italy since 9 July 2005. The marketing authorisation holder of the reference product is FORMEVET S.r.l. Warnings statements and precautions are adopted from the reference product. Additional statements have been added, based on increased knowledge and the current state of science.

2. QUALITY ASPECTS

A. Composition

The proposed tablet contains 50 mg tramadol hydrochloric acid and the excipients microcrystalline cellulose, pregelatinised corn starch, beef flavour, saccharin sodium, colloidal anhydrous silica, magnesium stearate and masking flavour. The tablet is scored and meant to be broken into two or four equal parts.

The product is packed in PVC/PVDC-aluminium blisters.

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 in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. The tests performed during manufacture are described and regarded to be acceptable. Suitable validation results on one pilot scale batch and two commercial scale batches have been provided.

C. Control of Starting Materials

The active substance tramadol hydrochloric acid is an established active substance described in the European Pharmacopoeia (monograph 1681). The active substance is manufactured in accordance with the principles of good manufacturing practice. For the manufacture of the active substance a CEP is used and a valid version of the CEP is provided.

The active substance specification is adequate to control the quality of the material. Absence of microbiological quality testing for the drug substance has been adequately justified. Batch analytical data demonstrating compliance with the proposed specification have been provided.

All excipients are in conformity with the Ph. Eur. requirements with the exception of the beef flavour and masking flavour for which in-house specifications are used. For the pharmacopoeial excipients, where relevant, additional functionality related characteristics are included. Magnesium stearate is of vegetable origin.

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

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The applicant has justified that residual moisture will be tested for information only. The proposed dissolution limit is acceptable. The limits for individual and total degradation products are acceptable.

Validation data for the analytical methods have been provided, as well as batch analytical data from the proposed production site, demonstrating compliance with the specification.

Reference standards tramadol hydrochloride EPCRS, impurity A EPCRS and impurity E EPCRS are used for the control of the drug substance.

F. Stability

Stability data on the drug substance have been provided in accordance with applicable European guidelines. Based on the submitted data, a retest period of 5 years (i.e. 60 months) can be granted.

Stability data on the finished product have been provided in accordance with applicable European guidelines. Photostability study data demonstrated that the veterinary product is not sensitive to light. The provided stability data for the finished product is sufficient to extrapolate the shelf life to 36 months without special storage conditions. No specific storage conditions are required.

In-use stability data have been provided. In-use stability data at shelf life will be provided in due course.

G. Other Information

Not applicable.

3. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, results of toxicological, pharmacological and clinical tests tests are not required.

Warning statements and precautions as listed in the product literature are based on those of the reference products and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users and the environment.

3.A User Safety

User Safety

Being a generic procedure the applicant refers to the reference product for information on this section. Additionally, the applicant has provided a user safety assessment. Combined with increased knowledge and the current state of science, warning statements and precautions have been added to the product literature, ensuring safety to users of the product.

Ecotoxicity

Phase 1
The environmental risk assessment can stop in Phase 1, because the product will be used only in non-food animals.

Conclusion
Based on the data provided, the ERA can stop at Phase 1. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

4. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are based on increased knowledge and the current state of science.

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 specie 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 Vetrinary 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.

None.