MEB agency / Veterinary Medicinal Products Unit
The Netherlands

College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cepedol Vet 20 mg, 50 mg, 80 mg, 120 mg chewable tablets for dogs

NL/V/0406/001-004/DC

PRODUCT SUMMARY

EU procedure number	NL/V/0406/001-004/DC
Name, strength and pharmaceutical form	Cepedol Vet 20 mg, 50 mg, 80 mg, 120 mg chewable tablets for dogs (AT/BE/DK/EL/FI/IT/LT/LV/NL/NO/SE) Cepedol Vet, 20 mg, 50 mg, 80 mg, 120 mg chewable tablets for dogs (EE) Tramatab 20 mg, 50 mg, 80 mg, 120 mg chewable tablets for dogs (CZ/DE/ES/HU/IE/PL/PT/SK/UK(NI)) Tramatab S, M, L, XL comprimé à croquer pour chiens (FR)
Applicant	CP Pharma Handelsgesellschaft mbH Ostlandring 13, 31303 Burgdorf, Germany
Active substance(s)	Tramadol hydrochloride
ATC vetcode	QN02AX02
Target species	Dogs
Indication for use	Reduction of acute and chronic mild soft tissue and musculoskeletal pain.

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CP Pharma Handelsgesellschaft mbH	DCP
Publicly available assessment report	

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).

SUMMARY OF ASSESSMENT

Legal basis of original application*	50 mg tablets: Generic application according to Art. 18 of Regulation (EU) 2019/6 as amended. 20 mg, 80 mg, 120 mg tablets: Hybrid application according Art 19 of Regulation (EU) 2019/6 as amended.
Reference product (RP)	ALTADOL 50 mg compresse solubili per cani
Marketing authorisation holder	FORMEVET S.r.l. - Via Correggio 19, 20149 Milano - Italia
MS where the RP is or has been authorised	IT
Marketing authorisation number	Confezione da 30 compresse – A.I.C. n. 103703029 Confezione da 100 compresse – A.I.C. n. 103703031
EU procedure number	-
Date of authorisation	9 July 2005
Date of completion of the original decentralised procedure	20 December 2023
Concerned Member States for original procedure	AT, BE, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LV, NO, PL, PT, SE, SK, UK(NI).

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.
It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The veterinary medicinal 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 VMP 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 The veterinary medicinal products are based on bioequivalence with the Reference Product. Warnings, statements and precautions are adopted from the reference product. Additional statements have added, based on increased knowledge and the current state of science.

2. QUALITY DOCUMENTATION

A. Composition

The proposed tablets contains 20 mg, 50 mg, 80 mg or 120 mg tramadol hydrochloride and the excipients microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate, hydrated colloidal silica and chicken flavour.
The tablets are light brown with brown spots, round and convex flavoured tablets with a cross-shaped break line on one side.

The VMP is packed in aluminium-aluminium blisters.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.
A bioequivalence study is waived for the generic Tramadol hydrochloride 50 mg tablets. According to the comparative dissolution profiles, a biowaiver can be granted for the 20, 80 and 120 mg tablets.

B. Method of Preparation of the Product

The VMP is manufactured in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The VMP is manufactured using conventional manufacturing techniques. The tests performed during manufacture are described and regarded to be acceptable. Suitable validation results on two production scaled batches have been provided.
The tests performed during production are described.

C. Control of Starting Materials

The active substance tramadol hydrochloride 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 CEPs are used. Valid versions of the CEP's are provided.

The active substance specification is adequate to control the quality of the material. Batch analytical data on three batches per drug substance supplier demonstrating compliance with the proposed specification have been provided.

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

Lactose monohydrate is manufactured from milk sourced from healthy animals in the same conditions as milk collected for human consumption. Further, no other ruminant materials, with the exception of calf rennet, are used in its preparation.

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.

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.

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. No OOS results or trends are observed in the stability studies at long term and accelerated conditions. The ¼ tablets remain within the requirements during the in-use stability study.

Photostability study data demonstrated that the veterinary product is not sensitive to light. Based on these findings the claimed shelf life of 3 years without special storage conditions is acceptable.

G. Other Information

N.A.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 (for the 50 mg chewable tablets) respectively hybrid applications according to Article 19 of Regulation (EC) 2019/6 (for the 20 mg, 80 mg and 120 mg chewable tablets) and bioequivalence with the

reference VMP 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 VMP 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 VMP to users and the environment.

A. Safety Testing

User safety

Being a generic (50 mg) respectively a hybrid (20 mg, 80 mg and 120 mg) procedure the applicant refers to the reference product for information on this section.

Additionally, 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 VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.
The VMP is not expected to pose an unacceptable risk for the environment when used according to the SPC.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 (for the 50 mg chewable tablets) respectively hybrid applications according to Article 19 of Regulation (EC) 2019/6 (for the 20 mg, 80 mg and 120 mg chewable tablets) and bioequivalence with the reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP and are aligned with the recent knowledge and the current state of science.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

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 VMP.

None