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French agency for veterinary medicinal products

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

VALERAMOL 200 MG/G ORAL POWDER FOR PIGS

Date: 28/09/2023

PRODUCT SUMMARY

EU procedure number	FR/V/0459/001/DC
Name, strength and pharmaceutical form	VALERAMOL 200 MG/G ORAL POWDER FOR PIGS
Applicant	PHARMANOVO VETERINARARZNEIMITTEL GMBH
Active substance(s)	Paracetamol
ATC vetcode	QN02BE01
Target species	Pigs
Indication for use	Symptomatic treatment of fever in the context of respiratory diseases in combination with an appropriate anti-infective therapy, if necessary.

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	Hybrid application of Regulation 2019/6 application in accordance with Article 19 of Regulation (EC) 2019/6 as amended.
Date of completion of the original decentralised procedure	20/09/2023
Concerned Member States for original procedure	AT, DE, EE, HU, LT, LV, PL
Withdrawn CMS during original procedure	/

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) 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 slight reactions observed are indicated in the SPC.

The VMP is safe for the user, the consumer of foodstuffs from treated animals 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.

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

A. Product description

The VMP contains 200 mg of paracetamol (quantitative) and the excipient glucose monohydrate.

The container/closure system corresponds to multilayer bags or plastic containers with tear and lid.

The choice of the formulation is justified.

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

B. Description of the manufacturing method

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

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

C. Production and control of starting materials

The active substance is paracetamol, an established substance described in the European Pharmacopeia. 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.

A certificate of suitability (CEP) issued by the EDQM has been provided and 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.

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. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

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

Stability data on the active substance are covered by the CEP.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

This application is being made according to the provisions of Article 19 (Hybrid application) of Regulation 2019/6. No toxicological data were provided.

User safety

No user risk assessment has been provided. The proposed user warnings by the applicant are identical from those of the reference product. It is accepted that the candidate product has a similar

user risk profile than the reference product and that no further assessment is required for the candidate product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

PEC calculations are above 100 µg/kg and a phase II should be required. However, the applicant is referring to article 18 (7) of regulation 2019/6. Since the reference product was authorized after the 1st October 2005 (Pracetam 200 mg/g, 2009), according to the applicant no phase II is required.
As the use of the hybrid product is not expected to increase the environmental exposure compared to the reference product, no phase II is required.

B. Residues documentation

Residue tests

No data were provided as this application is made in accordance with the Article 19 of the Regulation (EU) 2019/6 and the fact that the candidate product is orally administered at the same dose as the reference product.

Maximum Residue Limits

The **active substance** paracetamol is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010, as follows

Pharmacologically active substance(s)	Marker residue	Animal species	MRL	Target tissues	Other provisions	Regulation
Paracetamol	Not applicable	Porcine	Not MRL required	Not applicable	For oral use only	37/2010 of 22.12.2009

The **excipients** listed in section 2 of the SPC is considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product, as follows.

Excipient	MRL status
Glucose monohydrate	Out of scope

The composition of the product VALERAMOL 200 MG/G ORAL POWDER FOR PIGS is acceptable according to the European Regulation (EC) No 470/2009.

Withdrawal Periods

The meat and offal withdrawal period of zero days should apply for the drinking water use in line with the reference product PRACETAM 200 MG/G POWDER FOR USE IN DRINKING WATER FOR PIGS.

The meat and offal withdrawal period of 1 day should apply for the dry and liquid feed use in line with the reference product PRACETAM 10 % PREMIX FOR MEDICATED FEEDING STUFF FOR PIGS.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

Pharmacology

Given the legal basis of this application and the claim of bioequivalence between candidate and reference products, the omission of pharmacodynamics/pharmacokinetics data is considered acceptable, as this information may be extrapolated from the reference product.

The bioequivalence was demonstrated according to the section 5.3 of the bioequivalence GL EMA/CVMP/016/2000-Rev4*) for the drinking water and feed use.

Tolerance in the target species of animals

It is accepted that the target animal safety profile of the test product will be the same as that of the reference product. The text in sections 3.6 and 3.10 of the proposed SPC is in line with the text of the reference product.
The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

No clinical trials were performed.

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.