College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

Coffea Praeparata

Created: December 2019

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Coffea Praeparata, Solution for oral use
Applicant	SaluVet GmbH Stahlstraße 5 88339 Bad Waldsee Germany
Active substance(s)	Decoctum from Coffea arabica tosta (ratio coffea to decoctum = 1:3) 100,0 ml
Target species	Horses, cattle, sheep, goats, dogs, cats, rabbits, pigs, guinea pigs
Indication for use	According to anthroposophical knowledge of nature: To harmonise the metabolic and neurosensory system, by strengthening the rhythmic system: - for the prevention and treatment of diarrhoea and respiratory disorders in young animals As a supportive therapy in: - disturbances to the general state of health - disorders associated with fever - circulatory disorders - reduced demand for feeding and suckling - impaired gastrointestinal motility - respiratory disorders The use of this anthroposophical veterinary remedy for the above applications is based on a long tradition. In severe forms of these disorders, clinically validated therapy is indicated.

MODULE 2

The Summary of Product Characteristics for this homeopathic product is available on the Diergeneesmiddeleninformatiebank.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended. Based on article 19 of Directive 2001/82/EC Homeopathic veterinary medicinal products other than those referred to in Article 17(1) shall be authorised in accordance with Articles 12, 13a, 13b, 13c, 13d and 14.
Date of authorisation	6 October 2020

I. SCIENTIFIC OVERVIEW

Coffea Praeparata is a generic application according to Article 13(1) of Directive 2001/82/EC as amended. The reference product is COFFEA PRAEPARATA. Authorisation number: Z.Nr.: 8-00280. Authorised since 15 April 1996 in Austria.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

This homoeopathic medicinal product consists of a decoction from Coffea tosta (ratio drug to decoction 1:3) as the active substance, without excipients.

The container/closure system includes a brown glass bottle, glass type III (Ph. Eur.) in sizes 20 and 100 ml with a low density polyethylene syringe insert Luer fitting, a polypropylene screw cap and a polypropylene and high density polyethylene Luer syringe in size 5 or 20 ml (dosing aid).

The formulation is in use and authorised since decades. The absence of preservative is justified.

B. Method of Preparation of the Product

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

The product is manufactured using conventional manufacturing techniques, in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is a decoction from Coffea tosta (ratio drug to decoction 1:3). Coffea tosta is an established substance described in the German Homoeopatic Pharmacopoeia (GHP). 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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products (pharmaceuticals)

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 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

As the active substance is identical to the finished product, for stability data on the active substance is referred to the stability data of the active substance when stored under the approved conditions the finished product.

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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13, and the product is identical to the reference product, results of pharmaco-toxicological tests are not required.

The pharmaco-toxicological aspects of this product are identical to the reference product.

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 and consumers.

User Safety

As this is a generic application according to Article 13, and the product is identical to the reference product, studies on the safety of users 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.

Environmental Risk Assessment

For a generic application a separate Environmental Risk Assessment is required.

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 active substances are highly diluted natural substances, the use of the highly diluted substances will not alter the concentration or distribution of the substance in the environment.

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 the environment.

MRL and withdrawal periods

As this is a generic application according to Article 13, and the product is identical to the reference product residue studies are not required. The withdrawal period for this product is equivalent to those of the reference product. A withdrawal period of zero days can be granted for all target species.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A & IV.B Pre-Clinical and Clinical Studies

As this is a generic application according to Article 13, and the product is identical to the reference product, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

As the composition of the product is identical to the reference product, no data on the tolerance in the target species is required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure the tolerance in the target species.

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 quality and safety of the product for the target species, humans and the environment is acceptable.