AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

ISOFLU-VET 1000MG/G INHALATION VAPOUR, LIQUID

DATE : 04/03/2022

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0441/001/MR
Name, strength and pharmaceutical form	Isoflu-vet 1000mg/g Inhalation Vapour, liquid
Applicant	Piramal Critical Care B.V. Rouboslaan 32 (Ground Floor) 2252TR Voorschoten NETHERLANDS
Active substance(s)	Isoflurane 1000 mg/g
ATC Vetcode	QN01AB06
Target species	Horses, dogs, cats, ornamental birds, reptiles, rats, mice, hamsters, chinchillas, gerbils, guinea pigs and ferrets
Indication for use	Induction and maintenance of general anaesthesia.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website https://www.anses.fr/en/thematique/veterinary-medicine-anmv

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.
Date of completion of the original mutual recognition	09/02/2022
Date product first authorised in the Reference Member State (MRP only)	13/10/2016
Concerned Member States for original procedure	CZ - HU - SK

I. SCIENTIFIC OVERVIEW

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 potential reactions are indicated in the SPC.
The product 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 product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 100% isoflurane.
The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
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 fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is isoflurane, an established active substance described in the European Pharmacopoeia. 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable.

F. 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.

G. Stability

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

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

This application is submitted in agreement with the Article 13(1).

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product.

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

The application is made in accordance with Article 13 (1) of Council Directive 2004/28/EC as a generic application. No pharmacological or toxicological data were provided.

User Safety

The applicant provided a limited user safety assessment. Risk mitigation measures proposed by the applicant are identical to those of the reference product. As, the formulation is qualitatively and quantitatively the same as the reference product, it can be accepted that the generic product will not present any greater risk to the user (compared to the reference product).

Environmental Risk Assessment

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 veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted since the tested product is bioequivalent to the reference product.

MRLs

The active substance is included in table 1 of the MRL regulation 37/2010, as follows:

ISOFLURANE ADI = 48 µg/kg						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
Not applicable	Equidae	No MRL required	Not applicable	For use by inhalation	General anaesthetic	2018/1076 of 30/07/2018
Not applicable	Porcine	No MRL required	Not applicable	For use by inhalation in piglets up to 7 days of age		

Withdrawal Periods

The same withdrawal periods as for the reference product are applicable.

Species	**Tissues**	**Withdrawal periods**
Equine	Meat & offal	2 days
	Milk	Do not use in mares whose milk production is intended for human consumption

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

See Part III.A Pharmacological Studies

Tolerance in the Target Species of Animals

No data have been provided. This application has been submitted in accordance with Article 13 (1) of Directive 2001/82/EC, as amended (generic product). Since bioequivalence between the products can be assumed, it is accepted that the tolerance of the candidate product is similar to those of the reference product.

IV.B Clinical Studies

This application is being made according to the provisions of Article 13(1) Generic application of Directive 2001/81/EC, as amended by Directive 2004/28/EC. Since the bioequivalence with the reference product can be assumed, the applicant is not required to submit clinical data. Therefore, 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 veterinary Heads of Agencies website (https://www.hma.eu/veterinarymedicines.html).

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