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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

GASTROBIM 370 mg/g oral paste for horses

DATE : 06/10/2020

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0405/001/DC
Name, strength and pharmaceutical form	GASTROBIM 370 mg/g oral paste for horses
Applicant	BIMEDA ANIMAL HEALTH UNIT 2/3/4 AIRTON CLOSE, TALLAGHT DUBLIN 24 IRELAND
Active substance(s)	Omeprazole
ATC Vetcode	QA02BC01
Target species	Horses
Indication for use	For treatment and prevention of gastric ulcers.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

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 decentralised procedure	29/07/2020
Concerned Member States for original procedure	AT, BE, DE, DK, EE, ES, IE, IT, LV, LT, NL, PL, PT, SE

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 reactions observed 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 370 mg/g of omeprazole and excipients butylhydroxytoluene, calcium stearate, castor oil hydrogenated, triglycerides medium-chain, monoethanolamine, potassium sorbate, refined sesame oil, sodium stearate, ferric oxide yellow and apple flavour.
The packaging of the finished product is as described on the SPC. The particulars of the containers and performed controls 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.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is omeprazole, an established active substance. 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

Scientific data and/or certificates of suitability issued by the EDQM have 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.

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

A re-test period for the active substance is set in the certificate of suitability issued by EDQM.

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.
An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

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

Warnings and precautions as listed on the product literature are mostly the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and the consumers.

III.A Safety Testing

Pharmacological Studies

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

A bioequivalence study was provided, based on a crossover pharmacokinetic study involving GASTROBIM 370 mg/g ORAL PASTE FOR HORSES and the reference product GASTROGARD 370 mg/g pate orale pour chevaux (Merial Animal Health Ltd, Marketing authorisation number FR/V/10267358/2004).

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

Toxicological Studies

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

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

User Safety

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of a user safety assessment is not required.

However, the applicant has provided a user safety assessment in compliance with the relevant guideline.

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

As this product may cause irritation and hypersensitivity reactions, avoid direct contact with skin and eyes. Use impervious gloves and do not eat or drink when handling and administering the product. Wash hands or any exposed skin after use. Oral syringe should be returned to the original carton and suitably stored to prevent access by children.

In case of contact with eyes, wash immediately with clean running water and seek medical advice and show the package leaflet or the label to the physician if symptoms persist. Persons developing a reaction after contact with the product should avoid handling the product in future.

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 depletion study was provided following administration of the candidate product.

MRLs

The active substance, omeprazole, is included in table 1 of European Regulation (EU) No.37/2010, as follows :

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
Not applicable	Equidae	No MRL required	Not applicable	For oral use only	No entry	37/2010 in 22.12.2009

An acceptable daily intake (ADI) was defined for omeprazole. It is 7 µg/kg bw (*i.e.* 420 µg/person).

The composition of the product GASTROBIM 370 MG/G ORAL PASTE FOR HORSES is acceptable according to the Regulation (EC) No.470/2009.

Withdrawal Periods

Given the legal basis of the application, Article 13(1) generic, and the facts that the product is orally administered at the same dose as the reference product, and the bioequivalence is demonstrated, it is accepted that a residue depletion study is not required and that the withdrawal periods agreed for the reference product can be applied to the candidate product.

The satisfactory withdrawal periods for the candidate product are summarized in the following table :

Species	Tissues	Withdrawal periods
Horses	Meat & offal	1 day
	Milk	Not permitted for use in mares producing milk for human consumption

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

GASTROBIM 370 MG/G ORAL PASTE FOR HORSES contains omeprazole. It is intended via the oral route for the treatment and prevention of gastric ulcers in horses.

It is a generic application for a marketing authorisation in accordance with Article 13.1 of Directive 2001/82/EC, as amended. The cited reference product is GASTROGARD, from MERIAL authorized in 02/02/2004.

As it is an abridged application, no data was provided to document the pharmacodynamic, pharmacokinetic parts. This is accepted.

Pharmaceutical form

The test and the reference products have the same pharmaceutical form: oral paste.

Active substance qualitative and quantitative composition

The test and reference products have the same qualitative and quantitative composition in active substance: 370 mg of omeprazole per gram of product.

Bioequivalence studies

An *in vivo* bioequivalence study was performed between the reference product GASTROGARD and the candidate product in horse. The bioequivalence was demonstrated between the two products.

The pharmacokinetic particulars of GASTROBIM 370 MG/G ORAL PASTE FOR HORSES are summarized in the corresponding section of the SPC.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, it is considered acceptable that studies on tolerance in the target species are not required.

The product is indicated for the same claims, at the same dosages and via the same route of administration as the reference product.

The text of sections 4.6 and 4.10 of the SPC are in line with the text in the authorised SPC of the reference product.

Resistance

Not relevant

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with the reference product GASTROGARD has been demonstrated, efficacy studies are not required. The efficacy claim for this product is based on the indications for use of the reference product, *i.e.* “For treatment and prevention of gastric ulcers”.

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 (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