Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

GLEPTOVEX 200 mg/ml solution for injection for pigs

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/265/001/DC
Name, strength and pharmaceutical form	GLEPTOVEX 200 mg/ml solution for injection for pigs
Applicant	SP VETERINARIA SA Ctra Reus Vinyols km 4.1 Riudoms (43330) Spain
Active substance(s)	Iron (III) (as Gleptoferron)
ATC Vet code	QB03AC
Target species	Pigs (Piglets)
Indication for use	For the prevention and treatment of iron deficiency anaemia in piglets.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	21/09/2016
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	BG, CY, FR, EL, HU, IE, IT, MT, PL, PT, PT, RO, UK

I. SCIENTIFIC OVERVIEW

For public assessment reports for the first authorisation in a range*:*

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 slight 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.

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

II. QUALITY ASPECTS

A. Composition

The product is a solution for injection containing 200 mg/ml of Iron (III) (as gleptoferron complex), and phenol and water for injections as excipients

The solution is filled into polypropylene vials of 100 ml and 200 ml nominal fill volume, provided with a grey (100 ml) or pink (200 ml) bromobutyl rubber stopper and aluminium seal with a Flip-off sealing. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the preservative is justified.

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.

All the entities involved in the manufacture and control of the veterinary medicinal product are identified. Their complying with the GMP are documented properly.

C. Control of Starting Materials

The substance active is Gleptoferron, a known substance not described in the European pharmacopoeia. Its synthesis cannot be separated from the formation of an intermediate product in the manufacture of the finished product, so the supporting documentation of its quality is submitted jointly.

Both the active substance and the intermediate have been manufactured according to good manufacturing practices.

The specifications of both the active substance and the intermediate are considered suitable for their quality control. The certificates of analysis show that the specifications indicated are complied.

D. Control on intermediate products

The controls performed during manufacture have been properly described. As mentioned before, it is not possible to separate the active substance synthesis of the intermediate product manufacture, so the documentation is submitted in conjunction in Part 2C.

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 sites have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the intermediate product have been provided in accordance with applicable European guidelines, and justified the holding time of the intermediate prior to the sterilization and the subsequent packaging.

Finished product stability data justify the proposed shelf-life.

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13 (1) - Generic application of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of safety tests are not required. The safety aspects of this product are equivalent 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, the environment and the consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13 (1) - Generic application of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, results of pharmacological studies are not required.

Toxicological Studies

As this is a generic application according to Article 13 (1) - Generic application of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, results of toxicity studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the product does not involve any risk from the person who administers the product if it is used in accordance with the conditions established in the summary of characteristics.

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the treatment with the product does not cause environmental damage, whenever the product is used according to the instructions from the SPC.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Residue Studies

As this application is in accordance with Article 13 (1) - Generic application of Directive 2001/82/EC, the applicant shall not be required to provide the results of residues tests because all these data are in the documentation that supports the marketing authorization of the reference product.

MRLs

Iron glucoheptonate as well as iron dextran are listed in table 1 of the Commission Regulation (EU) No 37/2010 for all food producing species with no MRL required. As well for the other iron compounds listed in CR (EU) No 37/2010 no MRLs are required. Therefore, this is also considered applicable for the active ingredient of the candidate formulation GLEPTOVEX 200 mg/ml.

MRL are listed below:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues
Iron glucoheptonate	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE
Iron dextran	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE

Concerning MRL status of the excipients, the following is noted:

	Included in Table 1 of Commission Regulation (EU) No 37/2010
Phenol	Yes – No MRL required
Water for injection	No – Included as 'aqua purificata' in the CVMP list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009.

Withdrawal Periods

Based on the data provided above, a withdrawal period of Zero days for meat and offal in pigs are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. 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 (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