



MINISTERIO
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agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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

MUTUAL RECOGNITION PROCEDURE

DRAFT PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DEXAVEX 2 mg/ml solution for injection

CORREO ELECTRÓNICO

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temporalIP000794.doc

F-DMV-25-02

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0271/001/MR
Name, strength and pharmaceutical form	ES: DEXAVEX 2 mg/ml solution for injection PT: DEXINJET 2 mg/ml solution for injection
Applicant	SP VETERINARIA S.A. Ctra Reus Vinyols km 4.1 Riudoms (43330) SPAIN
Active substance	Dexamethasone
ATC Vet code	QH02AB02
Target species	Cattle, horses, pigs, dogs and cats
Indication for use	Cattle, horses, pigs,dogs and cats: - Treatment of inflammatory or allergic processes. Cattle : - Induction of parturition. - Treatment of primary ketosis Horses: - Treatment of arthritis, bursitis or synovitis

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	Mutual Recognition application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	Day 90: 22/02/2017 (Early end of procedure: 07/02/2017)
Date product first authorised in the Reference Member State (MRP only)	15/01/2013
Concerned Member States for original procedure	PT

1. 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 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.

2. QUALITY ASPECTS

A. *Composition*

The product contains 2.0 mg/ml of dexamethasone (as dexamethasone sodium phosphate) and the excipients benzyl alcohol, sodium citrate, sodium chloride, citric acid/sodium hydroxide (for pH adjustment) and water for injections.

The container/closure system consists of colourless polypropylene vials of 50 ml closed with bromobutyl rubber closures and aluminium capsules with flip-off sealing.

The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are 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.

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 dexamethasone sodium phosphate, an established 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.

Data relating to the active substance is presented in the form of a Ph. Eur. Certificate of Suitability (CEP).

D. *Control on intermediate products*

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

The Certificate of Suitability (CEP) of the active substance from the proposed source specifies the re-test period and storage 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.

The in-use shelf-life of 28 days after broaching is supported by the data provided.

G. Other Information

Not applicable.

3. SAFETY AND RESIDUES ASSESSMENT

For generics, insert in the relevant sections as appropriate:

As this is a generic application according to Article 13 (1) of the Directive 2001/82/EC, amended by Directive 2004/28/EC, and bioequivalence with a reference product has been demonstrated, results of safety 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 the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and the consumers.

A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13 (1) of the Directive 2001/82/EC, amended by Directive 2004/28/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) of the Directive 2001/82/EC, amended by Directive 2004/28/EC, and bioequivalence with a reference product has been demonstrated, results of toxicological 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.

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

B Residues documentation

Residue Studies

As this application is in accordance with the Article 13 (1) of the Directive 2001/82/EC, amended by Directive 2004/28/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

Dexamethasone is listed in table 1 of the Commission Regulation (EU) No 37/2010 for bovine, porcine and equidae. The marker substance is Dexamethasone.

MRLs are listed below:

	Bovine	Porcine	Equidae
Muscle	0.75 µg/kg	0.75 µg/kg	0.75 µg/kg
Liver	2.0 µg/kg	2.0 µg/kg	2.0 µg/kg
Kidney	0.75 µg/kg	0.75 µg/kg	0.75 µg/kg
Milk	0.3 µg/kg		

Concerning MRL status of the excipients, all of them are widely used in this type of veterinary medicinal products, and it is not necessary the establishment of maximum residue limits in order to protect public health.

Withdrawal Periods

The applicant proposes the same withdrawal time as approved for the reference product. As this is a generic application according to Article 13 (1) of the Directive 2001/82/EC, amended by Directive 2004/28/EC, and bioequivalence with a reference product has been demonstrated, the following withdrawal periods are justified:

Cattle meat and offal: 8 days

milk: 72 days

Porcine meat and offal: 2 days

Horse meat and offal: 8 days

Not authorised for use in horses producing milk for human consumption.

4. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1), 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.

A Pre-Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, pre-clinical studies are not required.

B Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, clinical studies are not required.

5 . 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