Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

HYDRODOXX (Diludox in Spain) 500 mg/g powder for use in drinking water for chickens and pigs

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0132/001/DC
Name, strength and pharmaceutical form	HYDRODOXX 500 mg/g powder for use in drinking water for chickens and pigs
Applicant	HUVEPHARMA NV Uitbreidingstraat 80, 2600 Antwerpen Belgium
Active substance(s)	Doxycycline (hyclate)
ATC Vet code	QJ01AA02
Target species	Chickens (broilers) Pigs (fattening pigs)
Indication for use	In chickens (broilers): prevention and treatment of Chronic Respiratory Disease (CRD) caused by *Mycoplasma gallisepticum.* In pigs (fattening pigs): prevention and treatment of porcine respiratory complex complicated by sensible strains of *Pasteurella multocida.*

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

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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 Article 13 (1) Directive 2001/82/EC – Generic application
Date of completion of the original decentralised procedure	25/02/2009
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, BG, CZ, DE, DK, FR, HU, IE, IT, NL, PL, 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.

II. QUALITY ASPECTS

A. Composition

The product contains 500 mg/g of Doxycycline (as hyclate) as active substance and citric acid anhydrous as diluent.

The container/closure system is a bag of 1 kg composed of the following three layers

polyester, aluminium and lineal low density polyethylene.

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

The choice of the formulation 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.

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 Doxycycline hyclate, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practices.

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.

A copy of the Ph. Eur. Certificate of suitability (Nº R1-CEP 2000-165-Rev 01) has been provided to confirm the suitability of the monograph for controlling doxycycline hyclate raw material produced by Yangzhou Pharmaceutical Factory.
Certificates of analysis have been submitted.

The excipient citric acid anhydrous complies with its corresponding monograph of European Pharmacopoeia. Certificate of analysis for the excipient is submitted.

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

J. Other Information

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was required. The assessment concluded that there is no risk for the environment. No Warnings are therefore required.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, based on the bioequivalence of Doxycycline (hyclate) 50 mg/g oral powder and the reference product Doxicivall powder, 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 current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).