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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DOXIPULVIS 500 MG/G POWDER FOR USE IN DRINKING WATER / MILK REPLACER

DATE: 12/09/2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0298/001/DC
Name, strength and pharmaceutical form	DOXIPULVIS 500 MG/G POWDER FOR USE IN DRINKING WATER / MILK REPLACER
Applicant	SP VETERINARIA SA Ctra Reus Vinyols km 4.1 Riudoms (43330) Spain
Active substance(s)	Doxycycline (As doxycycline hyclate)
ATC Vetcode	QJ01AA02
Target species	Cattle (pre-ruminant calves), pigs, chickens (broilers, breeders) and turkeys (broilers, breeders)
Indication for use	In calves: - Treatment and metaphylaxis of respiratory and digestive infections caused by micro-organisms susceptible to doxycycline. In pigs: - Treatment and metaphylaxis of respiratory infections caused by micro-organisms susceptible to doxycycline. In chickens and turkeys: - Treatment and metaphylaxis of respiratory infections due to micro-organisms susceptible to doxycycline. The presence of the disease in the herd/flock should be established before metaphylactic treatment.

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	Application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Reference product (RP)	RONAXAN P.S. 5 % POUDRE POUR SOLUTION BUVABLE
Marketing authorisation holder	DOPHARMA FRANCE S.A.S.
Marketing authorisation number EU procedure number	FR/V/8672049 0/1985
Date of authorisation	09/07/1985
Proprietary data have been submitted for the following part of the dossier	No proprietary data : legal basis determined by the pharmaceutical form.
Date of completion of the original decentralised procedure	27/07/2016
Concerned Member States for original procedure	CY, DE, EL, ES, HU, IE, IT, MT, PL, PT, RO, UK
Concerned Member States for subsequent recognition procedure	BG

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

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 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 doxycycline (as doxycycline hyclate) and citric acid anhydrous as excipient.
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 licensed manufacturing sites.
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 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 sites 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.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is an application according to Article 13 (3), and bioequivalence with a reference product has been demonstrated, results of pharmacology and toxicology tests are not required.

Toxicological Studies

Bioequivalence of the product with the reference product can be assumed and toxicology of the active substance has previously been addressed for this product. Cross reference is made to this data and no further data is required

User Safety

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.

Ecotoxicity

The applicant has provided a phase I and phase II environmental risk assessment in compliance with the relevant guideline

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

No residue depletion studies were conducted since the test product is assumed and accepted to be bioequivalent to the reference product and the product is administered via oral route at the same dosage regimen as the one of the reference product.

MRLs

The active substance is included in table 1 of the MRL regulation 470/2009, as follows:

a. active substances

DOXYCYCLINE						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
doxycycline	bovine	100 µg/kg 300 µg/kg 600 µg/kg	Muscle Liver kidney	Not for use in animals from which milk or eggs are produced for human consumption	Anti-infectious agents/ Antibiotics	37/2010 of 22.12.2009
	Porcine, poultry	100 µg/kg 300 µg/kg 300 µg/kg 600 µg/kg	Muscle Fat + skin Liver Kidney			
doxycycline	All food producing species	100 µg/kg 300 µg/kg 300 µg/kg 600 µg/kg	Muscle Fat Liver kidney	For fin fish the muscle MRL relates to “muscle and skin in natural proportions” MRLs for fat, liver and kidney do not reply to fin	Agents-infectious agents/ Antibiotics	2015/151 of 30/01/2015

				fish. For porcine and poultry species the fat MRL relates to “skin and fat in natural proportions” Not for use in animals from which milk or eggs are produced for human consumption.		

b. excipients

The MRL status of excipients of the product is indicated in the following table.

Excipient	MRL status
Anhydrous citric acid	Food additive

Withdrawal Periods

In order to address the concern relative to consumer safety, the following withdrawal periods were retained:

Species	Tissues	Withdrawal periods
Calves	Meat & offal	14 days
Pigs	Meat & offal	6 days
Chicken	Meat & offal	7 days
Turkey	Meat & offal	12 days
	Eggs	Not authorized for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of onset of the laying period.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies (pharmaceuticals only)

Pharmacology

As this is an application according to Article 13 (3), and bioequivalence with a reference product is established due to the nature of the products, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product. No further data were submitted.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13 (3), and bioequivalence with a reference product is established due to the nature of the products, efficacy

studies are not required. The efficacy claims for this product are equivalent to those of the reference product. No further data were submitted.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product is established due to the nature of the products, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product. No further data were submitted.

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.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

Sequence of significant variations

Changes to Part 1 of the dossier

Summary of change (Application number)	**Approval date**
SRP to include Bulgaria as CMS (FR/V/0298/001/E/001)	05/05/2025
G.I.17.b : Changes in relation to MR/SR procedures - Adaptation of the Product Information for the original Concerned Member States after a SRP (G.I.17.b) (FR/V/0298/001/A/006) Update to align the SPC to current guidelines (SPC of antimicrobials, QRD v9.1 regarding section 5.1)	12/12/2025