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MUTUAL RECOGNITION DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

HYPERSOL 500 mg/g Powder for use in Drinking water

Date: 18/02/2013

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0251/001/MR
Name, strength and pharmaceutical form	HYPERSOL 500 mg/g Powder for use in Drinking water
Applicant	QALIAN 34 RUE JEAN MONNET ZONE INDUSTRIELLE D'ETRICHE 49500 SEGRE FRANCE
Active substance(s)	Oxytetracycline (as hydrochloride)
ATC Vetcode	QJ01AA06
Target species	Chickens (broilers, breeding hens) and pigs
Indication for use	Treatment and prevention at the group level of septicaemia, respiratory and gastrointestinal infections caused by bacteria sensitive to oxytetracycline, where the presence of disease in the group has been confirmed.

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 (article 13(1) of Directive 2001/82/CE as amended)
Date of completion of the original mutual recognition procedure	21/12/2012
Date product first authorised in the Reference Member State (MRP only)	30/06/2010
Concerned Member States for original procedure	CZ, EL, HU, IE, IT, PL, PT, RO, ES, UK

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 0.5g/g oxytetracycline (as hydrochloride) and citric acid.

The powder is packed in jar, bucket or bag. 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 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 oxytetracycline hydrochloride, 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.

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.

A shelf-life after opening and a shelf-life after dissolution in water as detailed on the SPC have been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The test product is bioequivalent to the reference product COMPOMIX V TERRASOL, marketed by QALIAN. An exemption from the requirement to provide bioequivalence studies is accepted.

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.

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

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 submitted a Phase I and a Phase II Environmental Risk Assessment which showed that no risk for the aquatic and terrestrial compartments is expected.

III.B Residues documentation

Residue Studies

No residue studies were submitted which is acceptable since the tested and the reference products are bioequivalent and they are intended to be used via oral route.

MRLs

a. active substances

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

OXYTETRACYCLINE						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
Sum of parent drug and its 4-epimer	All food producing species	100 µg/kg 300 µg/kg 600 µg/kg 100 µg/kg 200 µg/kg	Muscle Liver Kidney Milk Eggs	For fin fish the muscle MRL relates to « muscle and skin in natural proportions ». MRLs for fat, liver and kidney do not apply for fish.	Anti-infectious agents/ Antibiotics	37/2010 of 22.12.2009

b. excipients

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

Excipient	MRL status	ADI
Anhydrous citric acid	Table 1, no MRL required	

Withdrawal Periods

The tested product withdrawal periods are based on the reference product documentation:
Meat and offal: 7 days
Eggs: Do not use for birds laying eggs for human consumption

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because the tested product and the reference product are bioequivalent and no excipient of the tested product is expected to have additional adverse effects.

Based on the conclusion made for the reference product, the product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

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 of the tested product are based on the reference product documentation.

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.