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

APSALIQ COLISTIN 3,000,000 IU/ml solution for use in drinking water/milk for pig, cattle, sheep, chickens and turkeys

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0270/001/ DC
Name, strength and pharmaceutical form	APSALIQ COLISTIN 3,000,000 IU/ml solution for use in drinking water/milk for pig, cattle, sheep, chickens and turkeys
Applicant	ANDRÉS PINTALUBA S.A. POLÍGONO INDUSTRIAL AGRO-REUS C/ PRUDENCI BERTRANA Nº 5 43206 - REUS (TARRAGONA) SPAIN
Active substance(s)	Colistin (as sulphate)
ATC Vet code	QA07AA10
Target species	Cattle (calf), sheep (lamb), pig, chicken and turkey
Indication for use	Treatment and metaphylaxis of enteric infections caused by non-invasive E.coli susceptible to colistin.

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

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 13.3 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	25/01/2017
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	BG, CZ, CY, HU, IT, PL, PT, RO, SK

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 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 3,000,000 UI/ml of colistin (as sulfate), benzyl alcohol, disodium edetate and purified water.

The container/closure system is white fluorinated high density polyethylene bottles closed with a high density polyethylene screw cap with thermosealing Aluminium / Polyethyleneterephtalate / Polyethylene discs. 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 colistin sulfate 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

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control on intermediate products

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)

For generics, insert in the relevant sections as appropriate:

As this is a hybrid application according to Article 13(3), and bioequivalence with a reference product has been demonstrated, results of safety and residue 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 similar to those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

III.A Safety Testing

Pharmacological Studies

No pharmacological data are provided because this is a hybrid application according to Article 13(3) of the Directive 2001/82/EC as amended, and the bioequivalence between the test and the reference product is demonstrated.

Toxicological Studies

No toxicological data are provided because this is a hybrid application according to Article 13(3) of the Directive 2001/82/EC as amended, and the bioequivalence between the test and the reference product is demonstrated.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that implementing the indicated protective measures, the use of the product poses an acceptable risk.

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 further assessment was required.
The assessment concluded that the use of the product poses an acceptable risk for the environment when it is used as recommended.
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

The applicant has provided no data in support of consumer safety because this is a hybrid application.

MRLs

The active substance, colistin, is included in Table 1 of the Annex of Commission Regulation (EU) No. 37/2010 in accordance with the following table:

Active substance	Marker residue	Animal specie	MRL (µg/kg)	Target tissue
Colistin	Colistin	All food producing species	150 150 150 200 50 300	Muscle Fat Liver Kidney Milk Egg

Withdrawal Periods

The applicant claims and demonstrates exemption from conducting *in vivo* bioequivalence studies. The proposed withdrawal periods are the same as those authorised for the reference product: 1 day for meat and offal in Cattle (calf), sheep (lamb), pig, chicken and turkey and zero days for eggs are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

For generics, insert in the relevant sections as appropriate:

As this is a hybrid application according to Article 13.3, 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