Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Animedazon Spray

Date: 2 October 2008

Revision:28 October 2008,
12 June 2015

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0120/001/DC/
Name, strength and pharmaceutical form	Animedazon Spray, 2.45% w/w, cutaneous spray suspension
Applicant	aniMedica GmbH Im Südfeld 9 48308 Senden
Active substance(s)	Chlortetracycline hydrochloride
ATC Vetcode	QD06AA02
Target species	Cattle, sheep and pigs.
Indication for use	Treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents. The product can be used as part of a treatment for superficial skin and claw infections, in particular interdigital dermatitis (foot rot and foul in the foot) and digital dermatitis caused by micro-organisms sensitive to chlortetracycline.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the Decentralised procedure	30 July 2008
Date product first authorised in the Reference Member State (MRP only)	14 August 2008
Concerned Member States for original procedure Concerned Member States added during Repeat Use procedure:	Austria, Czech Republic, Denmark, France, Greek, Hungary, Ireland, Italy, The Netherlands United Kingdom, Poland, Portugal, Romania and Spain Belgium, Bulgaria, Croatia, Cyprus, Estonia, Iceland Latvia, Lithuania, Norway, Slovenia and Sweden

I. SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this product are identical to CTC Blauspray. The initial application for CTC Blauspray was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. QUALITY ASPECTS

A. Composition

The product contains 3.21 g chlortetracycline hydrochloride / spray container (equivalent to 2.45% w/w chlortetracycline hydrochloride, equivalent to chlortetracycline 2.983 g) and the following excipients: Patent blue V (0.23 g / spray container), isobutane (92.2 g / spray container), isopropyl alcohol, sorbitan trioleate and silica colloidal anhydrous.

The product is filled into a pressurized container of uncoated tin plate with a plastic valve mechanism and spraying nozzle. 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. Process validation for further full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is chlortetracycline hydrochloride, 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.

The suitability of the European Pharmacopoeia monograph has been assessed by the EDQM (European Directorate for the Quality of Medicines & HealthCare). Certificates of suitability 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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL) (*for pharmaceuticals only)*

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

III.A Safety Testing

Pharmacological Studies

See Part IVA Pre-Clinical studies (Pharmacological studies)

Toxicological Studies

Since the application is made on the basis of essentially similarity to a reference product in accordance with Article 13 (1) of Directive 2001/82/EC as amended, data from toxicological studies are not required.

User Safety

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended, a detailed User safety assessment is not required. However, the applicant presented some exposure scenarios in compliance with the relevant guideline which shows that the product can be handled safely when the proposed precautions are observed.
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.

III.B Residues documentation
(Delete for non food producing species and for immunologicals)

Residue Studies

No residue depletion studies were conducted because this is a generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.

MRLs

Chlortetracycline is listed in Annex I of Council Regulation 2377/90 (O.J. L 37/9). The marker substance is the sum of parent drug and its 4-epimer.

MRLs are listed below:

	All food producing species
Muscle	100 µg/kg
Liver	300 µg/kg
Kidney	600 µg/kg
Milk	100 µg/kg
Eggs	200 µg/kg

Withdrawal Periods

Based on the identical composition and the same topical cutaneous administration between the generic and the reference product the same withdrawal periods were set: 0 days for meat and offal in cattle, sheep and pigs and 0 days for milk in cattle and sheep.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, efficacy studies are not required when bioequivalence with a reference product has been demonstrated. Bioequivalence studies with Animedazon Spray and the reference product CTC-Blauspray/Cyclo-Spray in the sense of the CVMP-Guideline on bioequivalence testing of veterinary medicinal products are not required as both products are locally applied and since plasma levels of the active ingredient are not relevant for local efficacy. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies (pharmaceuticals only)

Pharmacology

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended, and having regard that this is a topical product, it is not required to provide data on pharmacology. However, the applicant provided data in accordance with European guidelines, demonstrating that both products possess a high level of consistency in pharmaceutical parameters and will exert comparable antibacterial efficacy in the claimed indications when sprayed onto the skin and claws of the target animals in line with the dosing recommendations.

Tolerance in the Target Species of Animals

As this application is made in accordance with article 13 (1) of Directive 2001/82/EC, the results of target animal safety studies are not required.

Resistance

As this application is made in accordance with article 13 (1) of Directive 2001/82/EC as amended, data on resistance are not required.

IV.B Clinical Studies (pharmaceuticals and immunologicals)

Since the application is made on the basis of essentially similarity to a reference product in accordance with Article 13 (1) of Directive 2001/82/EC as amended, data from clinical studies are not required.

Laboratory Trials

As this application is made in accordance with article 13 (1) of Directive 2001/82/EC, the results of laboratory trials are not required.

Field Trials

As this application is made in accordance with article 13 (1) of Directive 2001/82/EC, the results of field trials are not required.

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 Heads of Veterinary Medicinal Agencies website (www.hma.eu).

Quality changes

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**
Change in the shelf-life of the finished product (DE/V/0120/001/IB/006)	N/A	15/05/2014

Safety/efficacy changes

Summary of change **(Type; application number)**	**Section updated in Module 3**	**Approval date**