Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

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

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dophacyl T

Date: 27 April 2022

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0331/001/DC
Name, strength and pharmaceutical form	Dophacyl T, 1000 mg/g, powder for use in drinking water
Applicant	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands
Active substance(s)	Sodium salicylate
ATC Vetcode	QN02BA04
Target species	Turkeys
Indication for use	Symptomatic treatment of inflammatory respiratory diseases, if necessary in combination with an appropriate anti-infective therapy.

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 original decentralised procedure	06 May 2020
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure Repeat Use CMS	France, Italy, Poland Austria, Croatia, Hungary, Ireland, Netherlands, Portugal, Romania and Spain

I. SCIENTIFIC OVERVIEW

This is an application according to Art. 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC. Dophacyl T is a generic to Avicylat 1000 mg/g authorised in Germany since 2011 under the marketing authorisation number 401349.00.00. Dophacyl T is concluded to be bioequivalent to the German reference product. Therefore, the safety and efficacy aspects of this product are considered to be identical to the reference product Avicylat. Information on adverse effects and proper use are adequately indicated in the SPC.
The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
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 overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains sodium salicylate as active substance. The product does not contain any excipients.

The container/closure system consists of a white square container made of polypropylene with a polypropylene lid and white plastic handle (bucket) or a white cylindrical polypropylene container with a white low-density polyethylene lid (securitainer).

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 at 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 sodium salicylate, 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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products

Not applicable.

E. 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.

F. 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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

The hazard and risk posed for Dophacyl T to the user is identical to that identified for the reference product. To minimize the user risk adequate warnings and mitigation measures are included in the product literature.
Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users.

III.A Safety Testing

Toxicological Studies

No new toxicological data were provided by the applicant as this is an application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.

User Safety

A comprehensive user safety assessment largely in compliance with the Guideline on user safety for pharmaceutical veterinary medicinal products (EMA/CVMP/543/03-Rev.1) was provided. Relevant issues including hazard identification, determination of toxicological reference values (TRV), exposure and risk analysis have been addressed.
Warnings and precautions as listed in the product literature are adequate to ensure the safety of users when the product is handled as recommended.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because it could be shown that the use of the natural compound sodium salicylate does not alter the concentration and distribution of the substance in the environment.

III.B Residues documentation

Residue Studies

This is a generic application according to Article 13 (1), and bioequivalence with a reference product has been accepted according to exemption 7.1. c) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2.). Residue depletion studies are not required.

MRLs

Sodium salicylate is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (*according to Article 14(7) of Regulation (EC) No 470/2009*)	Therapeutic Classification
Sodium salicylate	NOT APPLICABLE	Bovine, porcine	No MRL required	NOT APPLICABLE	For oral use. Not for use in animals from which milk is produced for human consumption.	NO ENTRY
		All food producing species except fin fish	No MRL required	NOT APPLICABLE	For topical use only.	
	Salicylic acid	Turkey	400 µg/kg 2 500 µg/kg 200 µg/kg 150 µg/kg	Muscle Skin and fat in natural proportions Liver Kidney	Not for use in animals producing eggs for human consumption.	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents

Withdrawal Periods

The same withdrawal periods as for the reference product were set.

Meat and offal: 2 days.

Not for use in birds producing eggs for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

This is a generic application according to Article 13 (1), and bioequivalence with a reference product has been accepted according to exemption 7.1. c) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2.). Therefore, efficacy studies are not required.

IV.A Pre-Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been accepted, provision of preclinical data was not required. With the exception of minor editorial amendments, the information on pharmacodynamics, pharmacokinetics as well as contraindications and precautions are in line with the product information given for the reference product. The target animal safety aspects are considered to be identical to the reference product.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been accepted, provision of clinical data was not required. The efficacy claims 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 Heads of Veterinary Medicinal 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.