College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board Agency

Graadt van Roggenweg 500
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SODIUM SALICYL 80% WSP

Created: April 2014

Updated: August 2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0133/001/DC
Name, strength and pharmaceutical form	Sodium Salicyl, 800 mg/g, powder for use in drinking water/milk replacer.
Applicant	Dopharma Research B.V. Zalmweg 24 4941 VX Raamsdonksveer the Netherlands
Active substance(s)	Sodium Salicylate
ATC Vetcode	QN02BA04
Target species	Calves, pigs
Indication for use	Cattle: For supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (anti-infective) therapy if necessary. Pigs: For the treatment of inflammation,in combination with concurrent antibiotic therapy.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	21 September 2009 (= first round) 27 May 2011 (= repeat use **:** DK, EE, HU, IE, LV)
Concerned Member States for original procedure	BE, BG, DE, EL, ES, FR, IT, LT, PL, PT, RO, 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.

The safety and efficacy aspects of this product are based on bioequivalence with the European reference product Na-Salicylaat 80% WSP (REG NL 10411). The European Reference Product Na-Salicylaat 80% WSP (REG NL 10411) was referred within the framework of Article 35 of Directive 2001/82/EC on 27 November 2007, concerning all oral soluble powders containing sodium salicylate which are indicated for calves and pigs. The European Commission decision was adopted on 26 September 2008 and is published on the website of European Commission (sodium salicylate, EMEA/V/A-35/29, Community Register).

II. QUALITY ASPECTS

A. Composition

The product contains sodium salicylate at 800 milligram per gram and excipient lactose monohydrate.

The container consists of a cardboard base with aluminium inner lining, PET coating and HDPE lid. Alternatively the product is packed in a PP~~E~~ bucket with PP~~E~~ lid. The particulars of the containers and controls performed are provided and conform to the regulation.

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 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 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.

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 product

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 the claimed shelf life of of 36 months when stored under the approved conditions.

Additional stability studies justify the claimed 3 months in-use shelf-life of the product after opening when stored under the approved conditions, the claimed in-use shelf-life of the medicated drinking water of 24 hours and the 4 hours after reconstitution in milk replacer.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological and toxicological studies

As this is a generic application according to Article 13, and bioequivalence with a reference product (Na-Salicylaat 80%, REG NL 10411) has been demonstrated, results of pharmacological and toxicological tests are not required.

The pharmacological and toxicological aspects of this product are identical to the reference product.

User Safety

As this is a generic application according to Article 13, and bioequivalence with a reference product (Na-Salicylaat 80%, REG NL 10411) has been demonstrated, results of user safety tests are not required.

The user safety aspects of this product are identical to the reference product.

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.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment was 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

Residue Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product (Na-Salicylaat 80%, REG NL 10411) has been demonstrated, results of residue studies are not required.

The residue aspects of this product are identical to the reference product.

MRLs

Sodium salicylate for oral use is listed in Annex II of Council Regulation 2377/90. It is listed in annex II for oral use only, in bovine and porcine, not for use in animals from which milk is produced for human consumption.

Withdrawal Periods

Based on the data provided above, a withdrawal period of 0 days for meat in calves and pigs is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, target animal tolerance studies are not required. The tolerance claims for this product are equivalent to those of the reference product..

IV.B Clinical Studies

Laboratory Trials

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 for this product are equivalent to those of the reference product.

Field Trials

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 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 Heads of Veterinary Medicines 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.

Summary of change	**Section updated**	**Approval date**
Renewal (NL/V/0133/001/R/001)	N/A	29 August 2014
Type II: B.I.a.1 -b) Introduction of a manufacturer of the active substance supported by an ASMF -g) Introduction of a new manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant active substance section of the dossier B.II.b.3 a) Minor change in the manufacturing process B.II.b.4 a) Up to 10-fold compared to the originally approved batch size B.II.b.5 c) Deletion of a nonsignificant inprocess test (NL/V/0133/II/002/G)	N/A	14 December 2016