College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Salicifarm 1000 mg/g powder for use in drinking water/milk for cattle and pigs

NL/V/0432/001/DC

Created: August 2025

PRODUCT SUMMARY

EU procedure number	NL/V/0432/001/DC
Name, strength and pharmaceutical form	Salicifarm 1000 mg/g powder for use in drinking water/milk for cattle and pigs
Applicant	Chemifarma S.p.A. Via Don Eugenio Servadei 16 47122 Forli Italy
Active substance(s)	Salicylic acid 863 mg (corresponding to sodium salicylate 1000 mg).
ATC vetcode	QN02BA04
Target species	Cattle (calves) and pigs
Indication for use	Calves: for supportive treatment of pyrexia in acute respiratory disease in combination with appropriate (e.g. anti-infective) therapy if necessary. Pigs: - for the treatment of inflammation, in combination with appropriate (e.g. anti-infective) therapy if necessary; - to promote recovery of respiration and to reduce coughing in respiratory infections, in combination with concurrent antibiotic therapy.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	NA-SALICYLAAT 100%
Marketing authorisation holder	Dopharma Research B.V.
MS where the RP is or has been authorised	The Netherlands
Marketing authorisation number EU procedure number	REG NL 8913
Date of authorisation	30 November 1998
Date of completion of the original decentralised procedure	06 August 2025
Concerned Member States for original procedure	Bulgaria, Cyprus, Czech Republic, Greece, France, Croatia, Hungary, Italy, Lituania, Poland, Portugal and Romania.
Concerned Member States for subsequent recognition procedure	Not applicable.
Withdrawn CMS during original decentralised procedure	Not applicable.

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter post-authorisation procedures

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains sodium salycilate as active substance. No excipients are included in the VMP.

The VMP is packaged in 500 g or 1 kg containers of high density polyethylene covered with a polypropylen cap and multilayer induction closures or in 1 kg and 5 kg multilayer bags (PET-aluminium-Polythene), closed through heat-sealing.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

The VMP is manufactured using conventional manufacturing techniques.

C. Production and control of starting materials

The active substance sodium salicylate is an established active substance described in the European Pharmacopeia. 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.

No excipients are part of the composition of the finished product. There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

D. Control tests carried out on isolated intermediates during the manufacturing process

No isolated intermediates are formed.

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 VMP.

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 tests

Stability data on the active substances 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 VMP throughout its shelf life of 2 years packaged in white opaque HDPE cans (500 g and 1 kg) closed by a plastic cap including an induction seal liner, or in PET-Al-PE multilayer bags (1 kg and 5 kg).
The drug product should be stored in the original container in order to protect from light.

A shelf life after opening of 6 months, an in-use shelf life of the VMP dissolved in drinking water of 12 hours and dissolved in milk replacer of 6 hours has been demonstrated. The compatibility of the finished product with biocides in drinking water was demonstrated for 12 hours.

G. Other information

The VMP is considered bioequivalent to the reference product since it meets the following condition: *"the test product is an aqueous oral solution at time of administration and contains an active substance in the same concentration as an approved reference veterinary medicinal product presented as an aqueous oral solution at time of administration".*
A dissolution profile study was performed. The results of the test demonstrated that both the VMP and the reference product are very rapidly dissolved in water, irrespective to the pH. The dissolution profile of the products is equivalent, as more than 85% of the products is dissolved within 10 minutes in all three pHs.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

The safety aspects of this VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to users / the environment / consumers.

A. Safety tests

Safety aspects have been sufficiently described in the file of the reference product, no further documentation is needed.

Pharmacological studies

Not required.

Toxicological studies

Not required.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that sodium salicylate may cause hypersensitivity reactions following ingestion, inhalation, or skin contact and it can cause irritation of the skin, eyes and respiratory tract following ingestion and dermal contact.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment.

Although not required, the applicant has provided a Phase II ERA as well.

B. Residues documentation

Residue tests

No residue depletion studies were conducted because bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

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 provision**
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
	Not applicable	All food producing species except fin fish	No MRL required	Not applicable	For topical use only
	Salicylic acid	Turkey	400 µg/kg 2500 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

Withdrawal Periods

Based on bioequivalence to the reference product and the data provided above, a withdrawal period of zero days for meat in pigs and calves is justified. The provision that sodium salicylate is not for use in animals producing milk for human consumption is included in the product literature.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

No pre-clinical studies were performed.

Pharmacology

Not required.

Development of resistance and related risk in animals

Not applicable.

Tolerance in the target species of animals

Not required.

B. Clinical trials

No clinical trials were performed.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

Sequence of significant variations

None.

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	Approval date

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	Approval date