DEPARTAMENTO DE
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VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

NEMICINA 500.000 IU/g powder for use in drinking water/milk

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PRODUCT SUMMARY

EU procedure number	ES/V/0436/001/DC
Name, strength and pharmaceutical form	NEMICINA 500.000 IU/g powder for use in drinking water/milk
Applicant	S.P. Veterinaria, S.A. Calle Vinyols Km 4.1 43330 Riudoms (Tarragona) Spain
Active substance(s)	Neomycin sulfate
ATC vetcode	QA07AA01
Target species	Cattle (calves), sheep (lambs), pigs, chickens (broilers, layer hens) and turkeys
Indication for use	Calves, lambs, pigs, broilers, layer hens and turkeys: Treatment of intestinal infections caused by *E. Coli.*

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*	Hybrid application in accordance with Article 19(1) of Regulation (EU) 2019/6.
Reference product (RP)	NEOMYCINSULFAT Powder for oral solution
Marketing authorisation holder	Bela-Pharm GmbH & Co. KG
MS where the RP is or has been authorised	Germany
Marketing authorisation number	MAN: 9187.00.01
EU procedure number	-
Date of authorisation	29/12/1987
Date of completion of the original decentralised procedure	Day 210: 04/06/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	BG, CY, HU, MT, PL, PT, RO.
Withdrawn CMS during original decentralised procedure	-

*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)

2.A. Product description

The VMP contains neomycin sulfate 500.000 IU/mg as active substance. Other ingredients are silica colloidal anhydrous and lactose monohydrate.

The container/closure system consists of thermo-sealed polyethylene/aluminium/polypropylene bags.

The choice of the formulation is justified.

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

2.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.

2.C. Production and control of starting materials

The active substance is neomycin sulfate, an established 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.

Certificate of suitability issued by the EDQM has 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.

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

Not applicable.

2.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<s> have been provided demonstrating compliance with the specification.

2.F. Stability tests

A retest period and their storage conditions are declared at the Certificate of suitability issued by the EDQM.

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 when stored under the approved conditions.

2.G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. Safety tests

Pharmacological studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of pharmacological tests are not required.

Toxicological studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that the candidate formulation will not present an unacceptable risk for the user than the reference product.

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

Environmental Risk Assessment

The application for marketing authorisation of NEMICINA 500.000 IU/g powder for use in drinking water/milk is exempt from submitting an Environmental Risk Assessment (ERA) according to Article 18(7) of Regulation (EU) 2019/6 as an ERA has already been performed for the same active substance and exposure level in the EU in accordance with VICH GL38 ("Guideline on environmental impact assessment for veterinary medicinal products - Phase II" [CVMP/VICH/790/03-FINAL]). Therefore, as there are similar products already authorized in the EU after October 2005 (EMA/CVMP/ERA/622045/2020), a complete data package for environmental risk assessment is not required. No unacceptable environmental risk is expected when the product is used, handled and disposed according to the information included in the SPC.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted because this is a hybrid application according to Article 19, and bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

Neomycin 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**	**Therapeutic Classification**
Neomycin (including framycetin)	Neomycin B	All food producing species	500 µg/kg 500 µg/kg 500 µg/kg 5 000 µg/kg 1 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney Milk Eggs	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'.	Anti-infectious agents/Antibiotics

Withdrawal Periods

The same withdrawal periods than the reference product are proposed:

Calves, lambs, pigs:
Meat and offal: 14 days

Broilers, layer hens, turkeys:
Meat and offal: 7 days
Eggs: Zero days

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 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.

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

None.