AGENCE NATIONALE DU

MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

NeoSol 500 000 IU/g
powder for use in drinking water/milk for cattle, chickens, pigs, ducks, turkeys, geese, quails and partridges

PRODUCT SUMMARY

EU procedure number	FR/V/0501/001/DC
Name, strength and pharmaceutical form	NeoSol 500 000 IU/g powder for use in drinking water/milk for cattle, chickens, pigs, ducks, turkeys, geese, quails and partridges
Applicant	HUVEPHARMA Uitbreidingstraat 80 2600 Antwerp Belgium
Active substance(s)	Neomycin
ATC vetcode	QA07AA01
Target species	Cattle (calves), pigs (weaned and fattening pigs), chickens (including laying hens), ducks, turkeys (including turkey hens), geese, quails and partridges.
Indication for use	For treatment of gastrointestinal infections caused by *E. coli* susceptible to neomycin.

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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)	NEOMYCINE 50% VIRBAC, 500 MG/G, Powder for oral solution
Marketing authorisation holder	VIRBAC
MS where the RP is or has been authorised	France
Marketing authorisation number EU procedure number	FR/V/2666590 4/1992 (National procedure)
Date of authorisation	30/06/1992 - abandoned 02/12/2019
Reference to proprietary data of an additional VMP linked to the reference product	NEOMAY
Marketing authorisation holder	LABORATORIOS MAYMO S.A.U.
MS where the RP is or has been authorised	France, from 02/11/2015 on.
Marketing authorisation number EU procedure number	FR/V/7955479 2/2015 (FR/V/0282/001/DC - FR/V/0282/001/E/001)
Part of the dossier referred to	Target species, indications and withdrawal periods
Date of completion of the original decentralised procedure	02/07/2025
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK and UK(NI)

*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 observed reactions 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 500000 IU/mg of neomycin sulfate as active substance and the excipient lactose monohydrate.

The container/closure system is a 100 g sachet made of LDPE/acrylic polymer/ aluminium/ LDPE/ paper closed by thermal system or a zipped 1 kg bag made of LDPE/ aluminium/ polyester closed by thermal system.

The absence of preservative is justified.

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.

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.

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

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 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

A re-test period is set in the Certificate of Suitability of the active substance.

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.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to both reference VMPs has been demonstrated, results of tests are not required.

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

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

A. Safety tests

Pharmacological studies

Toxicological studies

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (generic veterinary medicinal product). According to Article 18, an application for a marketing authorisation for a generic veterinary medicinal product does not need to contain the documentation on safety, providing that the essential similarity is satisfactorily demonstrated in all conditions for use.

Development of resistance and related risk in humans

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (generic veterinary medicinal product). An application for a marketing authorisation for a generic veterinary medicinal product does not need to contain the documentation on safety related to the development of resistance and related risk in humans, providing that the essential similarity is satisfactorily demonstrated in all conditions for use.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

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

Environmental Risk Assessment

This submission is a generic application with a reference product authorised before the 1st of October 2002, but a similar veterinary medicinal product was authorised after the 1st of October 2005. Thus, in line with the “Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6”, no ERA is request for the proposed generic product.

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B. Residues documentation

Residue tests

No residue depletion studies were conducted on the basis that essential similarity with the reference products has been demonstrated.

Maximum Residue Limits

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

NEOMYCIN (including FRAMYCETIN)						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
Neomycin B	All food producing species	500 µg/kg 500 µg/kg 500 µg/kg 5000 µg/kg 1500 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, the fat MRL relates to "skin and fat in natural proportions".	Anti-infectious agents/ Antibiotics	37/2010 of 22.12.2009
Neomycin B	All food producing species	500 µg/kg 500 µg/kg **5500 µg/kg** **9000 µg/kg** 1500 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, the fat MRL relates to "skin and fat in natural proportions".	Anti-infectious agents/ Antibiotics	1056/2013 of 29/10/13

Withdrawal Periods

Based on the data provided above, the withdrawal periods are justified:
Cattle (calves):
Meat and offal: 14 days.

Pigs (weaned piglets and pigs for fattening):
Meat and offal: 3 days.

Chickens, ducks, turkeys, geese, quails and partridges:
Meat and offal: 14 days.
Eggs: zero days.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

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

A. Pre-Clinical Studies

No pre-clinical studies were performed.

Pharmacology

Development of resistance and related risk in animals

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (generic veterinary medicinal product). An application for a marketing authorisation for a generic veterinary medicinal product containing an antimicrobial substance needs to provide bibliographic data about the level of resistance. Adequate information has been provided in support of the application.

Adequate prudent use warnings and precautions appear on the product literature.

Dose determination and confirmation

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and essential similarity to two reference VMPs is considered demonstrated, no dose determination or dose confirmation studies were provided.

Tolerance in the target species of animals

No target animal tolerance data specific to the candidate product have been presented.
However, as this is a generic application, the omission of product-specific target animal tolerance study data can therefore be accepted if the conditions for a generic veterinary medicinal product are met.

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B. Clinical trials

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and essential similarity to both reference VMPs is considered demonstrated, clinical trials are not required.

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.

None