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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

RINGER LACTATE OSALIA solution for infusion for cattle, horses, dogs and cats

PRODUCT SUMMARY

EU procedure number	FR/V/0442/001/MR
Name, strength and pharmaceutical form	RINGER LACTATE OSALIA solution for infusion for cattle, horses, dogs and cats
Applicant	OSALIA 7 boulevard Saint Denis 75003 Paris France
Active substance(s)	Sodium lactate (as an aqueous solution of (S)-sodium lactate at 60% (m/v)) Sodium chloride Potassium chloride Calcium chloride (as dihydrate)
ATC vetcode	QB05BB01
Target species	Cattle, horses, dogs and cats
Indication for use	Treatment of predominantly extracellular dehydration. Treatment and prevention of perioperative hypovolaemia and haemorrhagic shock. Treatment of mild metabolic acidosis.

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	Application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	RINGER LATTATO S.A.L.F. soluzione per infusione endovenosa per bovini, equini, cani e gatti
Marketing authorisation holder	S.AL.F. S.p.A. Laboratorio Farmacologico
MS where the RP is or has been authorised	Italy
Marketing authorisation number EU procedure number	N°103746
Date of authorisation	15-11-2005

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 3.276 mg sodium (S)-lactate as aqueous solution 60% (w/v), 6.00 mg sodium chloride, 0.40 mg potassium chloride and 0.204 mg calcium chloride (as dihydrate) per ml solution in water for injection.

The container are polypropylene bottles with a chlorobutyl stopper and an aluminium cap or polyolefin bags overwrapped with multilayer polymer. Bags have a double port tube ; the outflow tube is fastened with a polycarbonate funnel closed with a chlorobutyl rubber stopper sealed with an aluminium cap.

The choice of the formulation and 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 substances are sodium (S)-lactate as aqueous solution 60% (w/v), sodium chloride, potassium chloride and calcium chloride (as dihydrate), established active substances described in the European Pharmacopeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with these specifications have been provided.

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

In-process control tests have been carried out on intermediate stages of manufacture in order to verify the consistency of the manufacturing process and the final VMP.

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 when stored under the approved conditions.

G. Other information

None.

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 the reference VMP has been demonstrated, results of safety tests are not required.

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

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users / the environment.

A. Safety tests

Pharmacological studies

As this is an application for a generic veterinary medicinal product submitted under Article 18 of Regulation (EU) 2019/6 and bioequivalence with the reference product has been demonstrated, the results of pharmacological tests are not required.

The pharmacological aspects of this medicinal product are identical to those of the reference product.

Toxicological studies

As this is a generic application submitted in accordance with Article 18 of Regulation (EU) 2019/6, and bioequivalence with a reference VMP has been demonstrated, results of toxicological studies are not required.

The toxicological aspects of this VMP are identical to those of the reference VMP.

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

User safety

The applicant has not provided a user safety assessment.

The application is submitted as a generic procedure according to Article 18 of Regulation (EU) 2019/6. The candidate product has the same quantitative and qualitative composition of 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

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.

B. Residues documentation

Residue tests

No residue depletion studies were conducted because this is an application for a generic veterinary medicinal product submitted under Article 18 of Article 18 of Regulation (EU) 2019/6, for which bioequivalence with a reference product has been demonstrated, and given the intravenous route of administration, the results of residue depletion studies are not required.

Maximum Residue Limits

Active substances are 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
-Sodium chloride	Not applicable	All food producing species	No MRL required	All food producing species	NO ENTRY	NO ENTRY
Calcium chloride (dihydrate)	Not applicable	All food producing species	No MRL required	All food producing species	NO ENTRY	NO ENTRY

Pharmacologically active substance	MRL status
Potassium chloride	Food additive
Sodium lactate	Food additive
Water for injection	Out of scope

Withdrawal Periods

Based on the data provided above, a withdrawal period of

Cattle, horses:

Meat and offal: zero days.

Milk: zero hours are justified.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EU) 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

Tolerance in the target species of animals

No tolerance study has been conducted.
The VMP and the reference VMP have the same qualitative and quantitative composition.
The tolerance profile of this VMP is identical to the reference VMP.
The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

No clinical trials were performed
As this is a generic application according to Article 18 of Regulation (EU) 2019/6, and bioequivalence with a reference VMP has been demonstrated, clinical trials 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.