



**FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
AGENCE NATIONALE DU MEDICAMENT VETERINAIRE**

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Aqupharm Ringer Lactate Solution for Infusion (FR, AT, BE, HU, NL, PL)

Aqupharm 11 (Hartmann's) Solution for Infusion (UK/IE)

Ringer- Lactat Animalcare solution for infusion (IS, DK, FI, SE)

DATE: 12/09/2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0303/001/DC								
Name, strength and pharmaceutical form	<p>Aqupharm 11 (Hartmann's) Solution for Infusion (UK/IE)</p> <p>Ringer- Lactat Animalcare solution for infusion (IS, DK, FI, SE)</p> <p>Aqupharm Ringer Lactate Solution for Infusion (FR, AT, BE, HU, NL, PL)</p> <p>Each ml contains:</p> <p>Active substance:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 80%;">Sodium chloride</td> <td style="text-align: right;">6.00 mg</td> </tr> <tr> <td>Potassium chloride</td> <td style="text-align: right;">0.40 mg</td> </tr> <tr> <td>Calcium chloride</td> <td style="text-align: right;">0.204 mg</td> </tr> <tr> <td>Sodium S-lactate</td> <td style="text-align: right;">3.20 mg</td> </tr> </table> <p>(as sodium lactate (50% w/v))</p>	Sodium chloride	6.00 mg	Potassium chloride	0.40 mg	Calcium chloride	0.204 mg	Sodium S-lactate	3.20 mg
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Potassium chloride	0.40 mg								
Calcium chloride	0.204 mg								
Sodium S-lactate	3.20 mg								
Applicant	<p>Animalcare Limited</p> <p>10 Great North Way</p> <p>York</p> <p>YO26 6RB</p> <p>United Kingdom</p>								
Active substance(s)	Sodium chloride, Potassium chloride, Calcium chloride, Sodium S-lactate (as sodium lactate (50% w/v))								
ATC Vetcode	QB05BB01								
Target species	Cattle, Horses, Sheep, Goats, Pigs, Dogs, Cats and Rabbits								
Indication for use	<p>Treatment of dehydration of extracellular predominance.</p> <p>Treatment and prevention of perioperative hypovolaemia and haemorrhagic shock.</p> <p>Treatment of mild metabolic acidosis.</p>								

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website <http://www.anmv.anses.fr/>

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
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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.

II. QUALITY ASPECTS

A. Composition

The product contains sodium chloride at a concentration of 6.00 mg/ml, potassium chloride at a concentration of 0.40 mg/ml, calcium chloride (as dihydrate) at a concentration of 0.204 mg/ml, and sodium S-lactate (as sodium lactate solution) at a concentration of 3.20 mg/ml and sodium hydroxide, hydrochloric acid and water for injection as excipients.

The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.

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 substances are sodium chloride, potassium chloride, calcium chloride (as dihydrate) and sodium S-lactate (as sodium lactate solution), 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

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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

The active substance sodium S-lactate (as sodium lactate solution) is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

For the other active substances, a re-test period is set in the certificate of suitability issued by EDQM.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL) (*for pharmaceuticals only*)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

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

Toxicological Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

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

User Safety

No user risk assessment has been submitted. The product is a simple aqueous physiological solution of sodium chloride, sodium lactate, potassium chloride and calcium chloride dihydrate, and, because of the nature of the active substances, it is accepted that no user risk assessment is provided.

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

Ecotoxicity

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

No residue studies are provided because the application has been submitted in accordance with article 13(1) of Directive 2001/82/EC and the bioequivalence with the reference product has been demonstrated.

MRLs

a. active substances

The active substances are included in table 1 of the MRL regulation 470/2009, as follows:

Marker residue	Animal Species	MRL	Target Tissues	Therapeutic Classification	Regulation
Not applicable	All food producing species	No MRL required	Not applicable	No entry	37/2010 of 22.12.2009

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Not applicable	All food producing species	No MRL required	Not applicable	No entry	37/2010 of 22.12.2009

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

b. excipients

The MRL status of excipients of the product is indicated in the following table.

Excipients	MRL status
Water for injection	Out of scope

Withdrawal Periods

Based on the data provided above a withdrawal period of 0 day for meat and offal in all target species and zero hours for milk are justified

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13 (1), 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.

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because:

- the tested product and the reference product are bioequivalent,
- the excipients of the tested product are identical to the reference product.

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

IV.B Clinical Studies

As this is a generic application according to Article 13 (1), 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.