



**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 Sodium Chloride 9 mg/ml solution for injection/infusion (FR, AT, BE, HU, NL, PL)**

**Aqupharm 1 (9 mg/ml) solution for injection/infusion (UK/IE)**

**Natriumklorid Animalcare 9 mg/ml solution for injection/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	Aqupharm Sodium Chloride 9 mg/ml solution for injection/infusion
Applicant	Animalcare Limited 10 Great North Way York YO26 6RB United of kingdom
Active substance(s)	Sodium Chloride
ATC Vetcode	QB05BB01
Target species	Cattle, horses, sheep, goats, pigs, dogs, cats and rabbits.
Indication for use	Correction of water: sodium imbalances. Treatment of metabolic alkalosis. Rehydration in disease conditions which result in excessive loss of water and sodium chloride, and during and after surgery. A vehicle solution for the administration of other compatible drugs.

## **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 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 9 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.

(i)

##### **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 substance is sodium chloride, 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**

A re-test period for the active substance 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, 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 substance is included in table 1 of the MRL regulation 470/2009, as follows:

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

##### **b. excipients**

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

<b>Excipients</b>	<b>MRL status</b>
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.
- and the generic product is indicated for the same uses, at the same dose rates and via the same route of administration as 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.