Institute for State Control of Veterinary Biologicals and Medicines
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(Reference Member State – The Czech Republic)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

NaCl Bernburg 9 mg/ml solution for injection/infusion and irrigation solution

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/0175/001/DC
Name, strength and pharmaceutical form	NaCl Bernburg 9 mg/ml solution for injection/infusion and irrigation solution
Applicant	Serumwerk Bernburg AG Hallesche Landstrasse 105b 06406 Bernburg Germany
Active substance(s)	Sodium chloride 9 mg
ATCvet code	QB05BB01
Target species	Cattle, horses, sheep, goats, pigs, dogs, cats, rabbits and guinea pigs.
Indication for use	Correction of sodium imbalances. Treatment of metabolic alkalosis, during as well as after surgery. Rehydration in disease conditions which result in excessive loss of water and sodium and sodium chloride, as well as during and after surgery. Vehicle for the administration of other compatible drugs. Externally for irrigation of wounds and moisturizing of dressings.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	27/04/2022
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	DE

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. Qualitative and quantitative particulars

The product is solution for injection/infusion and irrigation solution that contains the active substance Sodium chloride 9.0 mg/mL and the excipients Hydrochloric acid, Sodium hydroxide and Water for injection. The container-closure systems are:

- 500 ml: Polypropylene (PP) bag with polycarbonate cone, butyl rubber stopper and bordered aluminium/polypropylene cap, overwrapped in polypropylene foil.

- 5000 ml: Polyvinylchloride (PVC) bag with polycarbonate cone, butyl rubber stopper and bordered aluminium/polypropylene cap, overwrapped in polyamide/polypropylene foil.

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 at a licensed manufacturing sites.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines. The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is Sodium Chloride, an established active 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.

Certificates of suitability issued by the EDQM have been provided. No TSE risk is identified considering the nature of the substance (inorganic salt).

The excipients are described in the Ph. Eur. monographs and they are controlled accordingly.

The quality control packaging materials and its components is adequately described.

D. Control on intermediate products

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 product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

F. Stability

Retest periods are established on with reference to the information provided on the Certificates of Suitability. In case retest period is not established for the given manufacturer, the company applies retesting immediately prior to use of the substance in the manufacture the finished product.

Stability data on the finished product have been provided in accordance with applicable European guidelines. The studies demonstrate satisfactory stability of the product to grant the shelf life 2 years without storage restrictions.

Considering the nature of the dosage form (sterile solution without preservatives), no in-use shelf-life can be granted and the product has to be used immediately after opening the immediate packaging.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

This application has been submitted in accordance with article 13.3 - hybrid application of Directive 2001/82/EC, as amended by Directive 2004/28/EC. Consequently, as details on toxicology have been sufficiently described in the file of the reference product, no further documentation is needed.

User Safety

The applicant has submitted the user safety risk assessment without the results of the toxicity studies referring to the generic type of application and because of the reference and candidate products to be fully identical in terms of qualitative and quantitative composition, and because of the candidate product being proposed for identical indications and according to the posology established for the reference product(s). The user risk assessment (URA) also refers to the generic type of application. These show that risks for the user listed in the SmPC are acceptable. Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users.

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 natural substance, the use of which will not alter the concentration or distribution.

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

III.B Residues documentation

Residue Studies

This application has been submitted in accordance with article 13(3) of Directive No 2001/82/EC as amended, so called hybrid application.

No own residue depletion studies were conducted.

MRLs

The active substance has been included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 in accordance with the following conditions:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Sodium Chloride	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY

Regarding excipients: the substances hydrochloride acid and sodium hydroxide have been included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Water is mentioned in the list of substance considered as not falling within the scope of Regulation (EC) No 470/2009.

Withdrawal Periods

The following text of the withdrawal periods is included in section 4.11 of the SPC (similarly in the other texts):
Cattle, horses, sheep, goats, pigs, rabbits:
Meat and offal: zero days.
Milk: zero hours.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and equivalence 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.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

None.