College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SALMOPORC, Lyophilisate for oral suspension for pigs

Created: December 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0247/002/DC
Name, strength and pharmaceutical form	SALMOPORC, lyophilisate for oral suspension
Applicant	IDT Biologika GmbH Am Pharmapark 06861 Dessau-Rosslau Germany
Active substance(s)	*Salmonella* Typhimurium mutant (genetically stable, double attenuated, histidine-adenine auxotrophic)
ATC Vetcode	QI09AE02
Target species	Pigs
Indication for use	Active immunisation of suckling and weaned piglets to reduce invasion, colonization and excretion as well as clinical symptoms (pyrexia, reduced feed intake and diarrhea) due to an infection with *Salmonella* Typhimurium.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website:
http://mri.medagencies.org/veterinary/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(4) – similar biological application, of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	6 February 2019
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, CZ, DK, HU, IE, IT, PT, RO, SK, UK

I. SCIENTIFIC OVERVIEW

Salmoporc is a similar biological application according to Article 13(4). The reference product is Salmoporc, authorised in Germany on 22 July 2002 (PEI.V.02340.01.1) by IDT Biologika GmbH. The product concerned by the present application is identical to the reference biological veterinary product as the raw materials used for the production, the manufacturers and the manufacturing processes are the same.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 5 x 10^8 to 5 x 10^9 Colony forming units of *Salmonella* Typhimurium mutant genetically stable, double attenuated (histidine-adenine auxotrophic) and the excipients Sucrose and Bovine serum protein. The container is a 10 ml hydrolytic class I glass vial closed with Lyo stoppers and aluminium crimp caps.

The choice of the vaccine strain is justified, the product does not contain an adjuvant or a preservative which is common and justified in live vaccines.

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 site.

The active substance is manufactured according to standard methods for the culture of bacteria. After the main fermentation the bulk is concentrated and subsequently mixed with

the lyophilisation medium. After filling the product is lyophilised according to standard methods.

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 *Salmonella* Typhimurium genetically stable, double attenuated (histidine-adenine auxotrophic) mutant, an established active substance. 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.

Scientific data have 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.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Control tests during production

The tests performed during production are described and the results of 6 consecutive runs, conforming to the specifications, are provided.

E. Control Tests on the Finished Product

The tests performed on the final product conform to the relevant requirements. The tests include in particular: appearance, reconstitution, identity (including markers), presence of revertants, potency, purity and residual moisture for the lyophilisate.
The demonstration of the batch to batch consistency is based on the results of 6 batches produced according to the method described in the dossier.

F. Stability

The active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its 21 months shelf life when stored under the approved conditions.

The claim of a 4-hour in-use stability is based on the demonstration of stability for three batches reconstituted in physiological saline and one batch reconstituted in drinking water and stored for 4 hours at room temperature.

G. Other Information

Not applicable

Salmoporc	NL/V/0247/002/DC
IDT Biologika GmbH	DCP
	Publicly available assessment report

III. SAFETY ASSESSMENT

As this is an auto-generic application submitted according to Article 13(4) – similar biological application. The biological veterinary medicinal product is identical to the reference product. Results of safety tests are not required, except an Environmental Risk Assessment.

The quality and safety aspects of this product are identical to the reference product.

Warning statements and precautions as listed in the product literature are based on those of the reference product 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, consumers and the environment.

Environmental Risk Assessment

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.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is an auto-generic application submitted according to Article 13(4) – similar biological application. The biological veterinary medicinal product is identical to the reference product and 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

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Vetrinary Medicines Agencies website (www.HMA.eu).

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 product.

None.