College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

FIXR Rota Corona Coli

Created: November 2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0361/001/DC
Name, strength and pharmaceutical form	FIXR Rota Corona Coli, emulsion for injection for cattle
Applicant	Kernfarm B.V. De Corridor 14D 3621 ZB Breukelen The Netherlands
Active substance(s)	Inactivated bovine rotavirus, strain TM-91: RP ≥ 1 Inactivated bovine coronavirus, strain C-197: RP ≥ 1 Inactivated *E. coli* expressing F5 (K99) adhesin, strains 3014, 3015 and 3016: RP ≥ 1
ATC Vetcode	QI02AL01
Target species	Cattle (pregnant heifers and cows).
Indication for use	Active immunisation of pregnant heifers and cows for the purpose of passive immunisation of calves against gastro-enteric diseases caused by rotavirus, coronavirus and enteropathogenic *E. coli* strains. Onset of immunity: In calves fed from mothers and in calves fed with colostrum collected from the vaccinated cows the passive protection starts when feeding begins. Duration of immunity: In calves fed with colostrum collected from the vaccinated cows their passive protection against infection lasts until feeding with colostrum is interrupted. The calves fed from mothers are protected against the infection by colostral and lactogenic immunity for the first 2 – 4 weeks of life.

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(4) – similar biological application, of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	Not applicable.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	BE

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.
The safety and efficacy aspects of this product are identical to the reference product. No public assessment report is available for the reference product, therefore no details are available in this section.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains inactivated bovine rotavirus strain TM-91 sufficient to induce a Relative Potency of at least 1 (RP ≥1), inactivated bovine coronavirus strain C-197, RP ≥1 and inactivated *E. coli* expressing F5 (K99) adhesin, strains 3014, 3015 and 3016 RP ≥1 and the adjuvant Montanide ISA VG70 as well as excipients Thiomersal and Formaldehyde.
The container/closure system consists of hydrolytic type I or II glass vials or HDPE bottles closed with chlorobutyl rubber stoppers and sealed with aluminium caps.
The choice of the adjuvant, vaccine strain, formulation, inactivating agent and the presence of preservative are justified.
The inactivation process and the detection limit of the control of inactivation are correctly validated.
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.

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: inactivated bovine rotavirus strain TM-91, inactivated bovine coronavirus strain C-197 and inactivated *E. coli* expressing F5 (K99) adhesin, strains 3014, 3015 and 3016, established active substances described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.
The active substance specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with these specifications have been provided.

Starting materials of non-biological origin used in production comply with European pharmacopoeia monographs or in-house specifications.
Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Guidelines; any deviation was adequately justified.
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 3 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; any deviation from these requirements is justified. The tests include in particular appearance, extractable volume, sterility, inactivation control, potency, identity, bacterial endotoxins, residual formaldehyde, thiomersal content, viscosity and airtightness.
The demonstration of the batch to batch consistency is based on the results of 8 batches produced according to the method described in the dossier.

F. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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 product throughout its shelf life when stored under the approved conditions.
The in-use shelf-life of the broached vaccine is supported by the data provided.

III. SAFETY ASSESSMENT

As this is an application in accordance with Article 13(4) of Directive 2001/82/EC as amended, and the product is identical to the reference product, results of safety tests are not required.

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

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Kernfarm B.V.	DCP
	Publicly available assessment report

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

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. The assessment concluded that the risk to the environment is practically zero. No special precautions to reduce the risk to the environment are therefore 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 application in accordance with Article 13(4) of Directive 2001/82/EC as amended, and the product is identical to the reference product, 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 Veterinary 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.