

Stability of an inactivated Rotavirus-Coronavirus-*E.coli* combination vaccine until at least 28 days after first opening and storage at +2 - +8°C.

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INTRODUCTION

Inactivated vaccines for cattle are typically filled in multi-dose vials and to be used within a few hours after broaching.

Such use is not always possible in practice, especially for small herds, which is inconvenient for the user and lead to medical waste.

OBJECTIVE

To assess the stability of an inactivated Rotavirus-Coronavirus-*E.coli* combination vaccine (Bovilis[®] Rotavec[®] Corona, MSD Animal Health) when stored at 2-8°C for at least 28 days after first opening.

MATERIALS AND METHODS

- ▶ At T0 the required volume of vaccine was withdrawn using a syringe and used for the different T0 tests.
- ▶ Additional volume was removed to keep 50% of the original volume.
- ▶ Broached vials were kept in horizontal position, refrigerated (+2 °C - +8 °C), protected from light for at least 28 days.
- ▶ At T0 and T>28 samples were tested for potency and physical-chemical parameters (stability).
- ▶ At T>28: preservative efficacy was determined.

All testing was performed according to standard procedures for batch testing and in line with the requirements of the European Pharmacopoeia.

The inactivated Rotavirus - Coronavirus - *E. coli* K99 (K99) combination Bovilis[®] Rotavec Corona is stable for at least 28 days after first opening if stored at +2 - +8 °C and protected from light.



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RESULTS

For all three antigens, the potency test results were above the respective specifications both at T0 and T≥28. The actual values were very close to each other without obvious decline in potency (Table 1).

Likewise, the results for the physical-chemical parameters passed the requirements at the T0 and the T≥28 time point (Table 2).

Finally, the preservative efficacy was confirmed at 28 days after broaching and complied with PhEur.5.1.3. (Table 2).

TABLE 1. Potency test results.

Parameter (Specification)	Batch A		Batch B	
	T 0 (first opening) Result	T ≥28 days Result	T 0 (first opening) Result	T ≥28 days Result
In vitro potency BRV (≥437 Units/ml)	1832 U/ml	2301 U/ml	1328 U/ml	1356 U/ml

Parameter (Specification)	Batch C		Batch D	
	T 0 (first opening) Result	T ≥ 28 days Result	T 0 (first opening) Result	T ≥ 28 days Result
In vivo potency BRV (≥ 7.7 log ₂)	8.2	8.0	-	-
In vivo potency BCV (≥ 3.41 log ₁₀)	3.82	3.71	3.87	3.84
In vivo potency E coli K99 (≥0.644 OD units)	0.860	0.967	0.951	0.804

TABLE 2. Physical-chemical tests and preservative efficacy test results.

Parameter (Specification)	Batch A		Batch B	
	T 0 (first opening) Result	T ≥ 28 days Result	T 0 (first opening) Result	T ≥ 28 days Result
Conductivity (<0.5 µS/cm)	0.0 µS/cm	0.0 µS/cm	0.0 µS/cm	0.1 µS/cm
Viscosity (27.5-47.5mPa.s)	35.0 mPa.s	39.5 mPa.s	39.2 mPa.s	40.2 mPa.s
Appearance (Off-white oily emulsion with no indication of phase separation)	Passed	Passed	Passed	Passed
Thiomersal (0.016 - 0.035 mg/ml)	0.028mg/ml	0.030mg/ml	0.029mg/ml	0.034mg/ml
Preservative efficacy (Complies with Ph.Eur.5.1.3)	Not done	Passed	Not done	Passed

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