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Vaccine development

FMDV VACCINE (RONAVAC®) POTENCY, STABILITY, SAFETY AND EFFICACY TEST

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Objectives:

The aim of this study was to determine efficacy, potency, safety and shelf-life of the novel Foot-and-Mouth Disease virus vaccine trade named Ronavac®. This product is an unconcentrated polyvalent vaccine and contains all four strains of FMDV which are circulating in Iran (Asia, A_{05}, O_{2010}, $O_{panasia}$).

Methods:

A vial of vaccine (randomly selected) was incubated at 37 °C for one week in order to test the stability of vaccine with an accelerated protocol (every 1 week at 37 °C equals to 1 year at 2-8 °C storage). Gel stability and pH was checked after incubation period. Before commencing the challenge, vaccine quality control assays (including bacterial, fungal, viral, mycoplasma contamination and total protein concentration, integrity and purity) were done using polymerase chain reaction, routine culture, method of Barteling *et al.,* 1974 and SDS-PAGE.

Healthy FMDV seronegative calves (6-12 month-old) were divided into 8 groups as listed here: Full dose group, 1/3 dose group and 1/9 dose group (5 calves per group), negative control group, double dose group, bovine tongue adaptation group, bovine tongue titration group and stability test group (2 calves per group). Phosphate buffer saline (PBS) was used to dilute the vaccine. All calves were tested for presence of antibodies against FMD virus (10 days before vaccination and test). A standard strain of virus ($O_{panasia}$) was adapted to calves in order to use in final challenge. Blood samples collected on the day of vaccination and 1, 2 and 3 weeks post-vaccination then sera were stored at -20 °C. Efficacy and potency of this product was evaluated due to virus neutralization test results on IB-RS-2 cell line.

Result:

Quality control tests showed no microbial contamination. Injection of double dose vaccine did not cause any post-vaccinal complications. 1 week incubation period for vaccine had no adverse effects on product's quality and its immunizing capability. This product produced 100% protection due to clinical manifestations. Antibody against FMDV was significantly increased after vaccination. Protective dose in 50% of population per 1 dose of vaccine (PD50%/Dose) was calculated 7.07 using the method of Reed & Meunch and it was calculated 6.73 using the Pirbright FMD reference laboratory method.

Conclusion

The results of this study showed that Ronavac® can be considered as a standard solution to cease the large economic loss caused by Foot-and-Mouth Disease every year due to its high potency and efficacy and of course long shelf-life in addition to its acceptable safety.