

INSTITUTO FINLAY

Evaluation of two different potency tests for leptospirosis vaccine vax-SPIRAL®

Dr. Juan Francisco Núñez,¹ Lic. Ester María Fajardo,² Lic. Elizabeth Pérez,³ Lic. Ivis Ontivero,³ Dra. Deolinda Silva³ y Dr. Pedro Muñoz⁴

SUMMARY

Two different potency tests were evaluated, consisting in one-dilution used to determine 50 % lethal dose (LD₅₀) and four-dilution used to calculate 50 % effective dose (ED₅₀), respectively. Our experience has led to propose the four-dilution test for routine lot releasing.

Key words: Vax-SPIRAL, leptospirosis, potency test.

Potency test for the trivalent leptospirosis vaccine vax-SPIRAL®¹ is based on the protection of hamsters against lethal challenge with virulent organisms. Two tests were developed, consisting in one-dilution and four-dilution respectively. The former is used as a routine lot-release test and the latter for stability studies.

In the one-dilution test, 42 hamsters (*Mesocricetus auratus*), 40-60 g, are separated for each serovar contained in the vaccine (*canicola canicola*; *icterohaemorrhagiae copenhageni*; *pomona mozdok*); 6 receive intramuscularly 0.5 mL of the vaccine, diluted 1:5. Other 36 hamsters (controls) are used to determine 50 % Lethal Dose (LD₅₀) and challenge dose (total: 126 hamsters). Challenge is done two weeks later, with 0.5 mL of virulent leptospiras, intraperitoneally. Then, the animals are observed for another two weeks. The

lot passes the test if 80 % of the immunized animals survive, and 80 % of controls receiving the challenge dose die.²

The four-dilution test differs only from the former in the fact that 60 hamsters are required per each serovar; groups of 6 animals are immunized with fivefold dilutions (1:5-1:625) respectively.

Although the requirement for potency is the same, this test permits to calculate 50 % Effective Dose (ED₅₀), allowing the discrimination between the protective capacity of lots in a quantitative form. Our eight-year experience has led to propose the four-dilution test for routine lot releasing, although its expensiveness, as potency can be expressed in much more confident terms, enabling the use of Control Graphs to meet the requirements of our National Control Authority.

¹ Médico Veterinario. Investigador Agregado. Profesor Adjunto.

² Máster en Ciencias Bioquímicas. Licenciada en Biología. Investigadora Auxiliar.

³ Licenciada en Ciencias Farmacéuticas.

⁴ Médico Veterinario.

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Evaluación de 2 pruebas diferentes de potencia para la vacuna vax-SPIRAL® contra la leptospirosis**RESUMEN**

Se evaluaron 2 pruebas diferentes de potencia, consistentes en una dilución usada para determinar 50 % de dosis letal (DL_{50}) y 4 diluciones utilizadas para calcular 50 % de dosis efectiva (DE_{50}), respectivamente. La experiencia de los autores de este trabajo

los conduce a proponer la prueba con dilución 4 para la liberación de rutina del lote.

Palabras clave: Vax-SPIRAL, leptospirosis, prueba de potencia.

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Dr. *Juan Francisco Núñez*. Instituto Finlay. Ave. 27 No. 19805, municipio La Lisa, Ciudad de La Habana. Cuba, CP 11600. Correo electrónico: jnunez@finlay.edu.cu