
Poster: strategies to reduce animal numbers for testing biologicals

Potency testing of inactivated rabies vaccines for veterinary use: correlation of results between mouse challenge test and serological assay

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The potency of inactivated rabies vaccines for veterinary use is conventionally determined by a mouse challenge test. In this test, vaccinated mice are infected with rabies virus, and the potency is calculated from the resulting survival rate. This method causes severe distress to the test animals and is known to be imprecise and time-consuming. According to the European Pharmacopoeia, also a serological assay may be used for batch potency testing after a suitable correlation with the challenge test has been established. In the serological assay, neutralizing antibody titers induced by vaccination of mice are determined using a rapid fluorescent focus inhibition test (RFFIT). As this alternative method is less painful and requires fewer animals, it meets the 3R criteria of refinement and reduction. However, this assay is not widely used yet, and only few data exist concerning the comparability of both methods. Our results demonstrate a good correlation between the antibody titers obtained in the serological assay and the survival rates of the mouse challenge test. We further show that vaccine batches failing the challenge test were also reliably identified as insufficient in the serological assay. We conclude that the serological assay is a suitable method for the potency testing of inactivated rabies vaccines, and that it is able to replace the mouse challenge test in the long term.

Keywords: rabies vaccine, mouse challenge test, serological assay, RFFIT