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Safety and potency test for experimental cell culture based anti-rabies vaccine produced in Ethiopia

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Objective: To determine potency and safety of the experimental formalin inactivated cell culture based anti-rabies vaccines.

Methodology:

Mice: 10-16 g weight, 2 weeks age mice with identical sex were used.

Inactivation: The viral suspension was thawed and formalin inactivation was done using a concentration of 1:5000 vol/vol and incubated at 37^0C for 48 h with shaking twice a day.

Safety Test: Safety test determines the presence of residual virulent virus and any bacterial contamination in the vaccine. Presences of residual virus were done on mice and any other contamination tested bacteriologically.

Potency Test: Potency test determines the degree of protection conferred by the vaccine in immunized mice challenged with challenge virus strain. This test was performed using National Institutes of Health (NIH) test.

Immunization: Mice were immunized at day 0 and 7 with five different concentrations for test vaccine and four different concentrations for control vaccine, 16 mice in each dilution. The control vaccine used was Vero Rab vaccine which was produced by Sanofi Pasteur.

Challenge Test: Standard CVS strain from CDC was used for challenging. Mice were challenged on 14^{th} day of immunization with challenge virus strain (CVS-11) of 25 MLD_{50}/0.03 ml. The mice were observed for 14 days.

Result: Potency of our test vaccine calculated using NIH test was 8.32 IU for ERA and 2.5 IU for PV results were obtained.

Conclusion: Based on the result it can be concluded that, both of our vaccines have higher potency than required for single dose of anti rabies vaccine. Therefore these can be diluted to standard vaccine potency and be used for animal immunization.

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