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EVALUATION OF POTENCY OF MUMPS VACCINE USED IN IRAN: COMPARISON OF WHO AND NIBSC METHOD IN CELL CULTURE

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Abstract:

Vaccination against mumps is included in world Health Organization (WHO) program of global immunization. Safety and efficacy of vaccines must be confirmed by control units in charge of public health. In Iran, the secondary control on potency of vaccine has not been set up yet. We decided to overcome this problem by developing WHO and NIBSC methods in Food and Drug Control Lab. Nine dilutions of vaccine from 10⁻¹ to 10⁻⁵ in 0.5log₁₀ steps were mixed with Vero cell suspension. In WHO method, the cell suspension was seeded in octaplicate (8 wells of each dilution) in 24-well plate and incubated at 36°C for 10 days, during which the cells were checked for cytopathic changes everyday and positive wells were recorded. We used 5% serum and 1 × 10⁵ cells for the assays. The test was repeated with six different vaccines produced in one batch. The mean potency was 10^{4.475±0.134} CCID₅₀/vial for each ten-dose vial. For NIBSC method the dilutions of vaccine were added to hexaplicate (6 well per dilution) in 24-wells plate. After 3 hours, the medium was removed and overlay was added. Then the plates were incubated at 35°C for 10 days. After incubation period, the plaques were stained with methyl violet and counted. This assay was repeated three times and the mean of results was 5.93 log₁₀ PFU/dose. Results indicate that the potency of the vaccine is in acceptable range in either method. WHO method is simple and less time consuming compared to NIBSC method.

Keywords:

Mumps , potency , cytopathic effect , Vero cell

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