Chapter 3.1.8.

Foot and mouth disease (infection with Foot and Mouth disease virus)

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C. REQUIREMENTS FOR VACCINES

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2. Method of manufacture

The recommended method of virus propagation for antigen production is the growth of FMDV in large-scale suspension cultures or monolayers using cell lines under sterile conditions.

~~Cattle tongue epithelium in surviving conditions in medium with salts but without products of biological origin, may be acceptable for vaccine production but only if the method of production is entirely compliant with the standard requirements referred to in chapter 1.1.8. In addition, in order to remove the risk of contaminating lipid-enveloped viruses, the harvested virus suspension must undergo a validated organic solvent treatment prior to BEI/EI inactivation. A validated procedure is applied to ensure inactivation of all possible extraneous agents and each batch is independently tested in an official laboratory for absence of extraneous agents. Adequate in-process and final products tests are in place to ensure consistency and safety of the final product. Consideration should also be given to minimising the risk of transmission of transmissible spongiform encephalopathy agents (i.e. BSE TSE) by ensuring safe sourcing of the epithelium.~~

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