Achievements and issues for Ph. Eur. Group of Experts on Veterinary Vaccines and Sera (15V)

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Monographs Concerned

- Clostridium novyi (type B) vaccine for veterinary use (0362)
- Clostridium perfringens vaccine for veterinary use (0363)
- Clostridium septicum vaccine for veterinary use (0364)
- Cytotoxic Clostridia
Key Element of the Revision

Tests Concerned

- Residual toxicity (in process)
- Antigen content (in process)
- Residual toxicity of the final product
- Batch potency test
- Identification
Residual toxicity (in process)

Residual toxicity is assessed immediately after detoxification by a test in suitable cell cultures. The result complies with the value specified for the product.

- BSP 130 demonstrated that the move from the mouse test to the test in Vero cells is feasible for C. septicum toxoid
- It is assumed that residual toxicity of C. perfringens and C. novyi toxoids may be assessed in tissue cultures, as well
- According to EU guideline 2010/63 alternative methods must be applied, when available

Antigen content (in process)

The antigen content is determined by a suitable in vitro method such as total combining power (TCP) using appropriate cell cultures as indicators of toxicity, an enzyme-linked immunosorbent assay (ELISA) or any other validated method.

- New test, to monitor consistency of production
- TCP test considered as preferred test, because it is a functional test
- BSP 130 demonstrated that the TCP test using Vero cells is feasible for C. septicum toxoid
- It is assumed that the activity of C. perfringens and C. novyi toxoids can be assessed in a TCP test in tissue cultures, as well
Residual toxicity of the final product

Test deleted
- Justification for this test is no longer given
  - Reversion to toxin probably due to false positive test results
  - Sensitivity of the test questioned

Batch potency test
Identification

Minor editorial issues
- door openers to promote alternative in vitro test methods
Thank you for your attention