bio outsource
cGMP compliant biotesting

Vaccine in Europe
European Pharmacopiea

Characterisation of MVSS/MCB

Master Cell Bank

- Morphology – light microscopic observations
- Identity – DNA Fingerprinting
- Sterility (1% of cell bank)
- Mycoplasma test which complies with EP 2.6.7

Working Cell Bank

- Morphology – light microscope observations
- Identity – DNA Fingerprinting
- Sterility (1% of cell bank)
- Mycoplasma test which complies with EP 2.6.7
- *in vitro*/haemagglutinating virus test using Simian and Human cells
- co-cultivation test with simian and human cells
- Test in adult and suckling mice and eggs using 10^7 cells
- Species specific tests inc. Bovine and Porcine viruses
- Tests for Retroviruses including PERT, TEM, Intfectivity assays

End of Production Bank

- Morphology – light microscope observations
- Identity – DNA Fingerpriniting
- Co-cultivation test with simian and human cells
- Test in adult and suckling mice and eggs using 10^7 cells
- Species Specific tests
- Tests for Retroviruses including PERT, TEM and Infectivity assays

MVSS Testing

- Identity using appropriate methods
- Sterility (1% of virus bank)
- Mycoplasma which complies with EP 2.6.7
- Infectious titre
- tests in adult and suckling mice, and Guinea Pigs
- *in vitro*/haemagglutinating virus test using Simian and Human cells

Production Control Cell Testing

- Observation – light microscopy
- Haemagglutination test on 25% of cultures
- 14 Day *in vitro* – MRC-5, Vero

Characterisation of Virus Bulk Harvests

- Sterility (10mL)
- Mycoplasma (10mL)
- 14 Day *in vitro* – MRC-5, Vero (50mL)
- *in vivo* egg assay as appropriate

Final Product Testing

- **pH (2.2.3).** Liquid vaccines, after reconstitution where applicable, comply with the limits for pH approved for the particular preparation.
- **Adjuvant.** If the vaccine contains an adjuvant, the amount is determined and shown to be within acceptable limits with respect to the expected amount (see also the tests for aluminium and calcium below).
- **Aluminium** (2.5.13): maximum 1.25 mg of aluminium (Al) per single human dose where an aluminium adsorbent has been used in the vaccine, unless otherwise stated.
- **Calcium** (2.5.14): maximum 1.3 mg of calcium (Ca) per single human dose where a calcium adsorbent has been used in the vaccine, unless otherwise stated.
- **Free formaldehyde** (2.4.18): maximum 0.2 g/l of free formaldehyde in the final product where formaldehyde has been used in the preparation of the vaccine, unless otherwise stated.
- **Phenol** (2.5.15): maximum 2.5 g/l in the final product where phenol has been used in the preparation of the vaccine, unless otherwise stated.
- **Water** (2.5.12): maximum 3.0 per cent m/m for freeze-dried vaccines, unless otherwise stated.
- **Extractable volume** (2.9.17). Unless otherwise justified and authorised, it complies with the requirement for extractable volume.
- **Bacterial endotoxins.** Unless otherwise justified and authorised, a test for bacterial endotoxins is carried out on the final product. Where no limit is specified in the individual monograph, the content of bacterial endotoxins determined by a suitable method (2.6.14) is less than the limit approved for the particular product.

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