NEWCASTLE DISEASE VACCINE INACTIVATED BRPs batch 1

The following BRPs are for use in the in vitro ELISA potency assay for inactivated Newcastle Disease vaccines:

**Ph. Eur. BRP batch 1 of Newcastle Disease Virus Reference Antigen**

A lyophilised preparation of formalin inactivated NDV strain Ulster, produced in embryonated SPF eggs. In addition to the viral antigen the preparation contains 5% sucrose and 0.5% bovine serum albumin.

The assigned titre is 6 Ph. Eur. antigen units per vial

The content of 1 vial should be dissolved in 1.5 ml ELISA buffer for use.

The reference antigen should be used as the standard against which the relative potencies are determined in AU.

**Ph. Eur. BRP batch 1 of Newcastle Disease Virus Control Antigen**

A lyophilised preparation of β-propiolactone inactivated NDV strain LaSota produced in embryonated SPF eggs. In addition to the viral antigen the preparation contains 5% sucrose and 0.5% bovine serum albumin.

The content of 1 vial should be dissolved in 1.5 ml ELISA buffer for use.

Individual laboratories should establish an appropriate value in AU for the control antigen during the validation of the method in their laboratory. This value will then be used to monitor the consistency of the assay. It is recommended that alert limits for the control antigen value also be established and that values falling outside the validated range be used as a signal for investigation of potential problems with the assay. Examples of values found for the control antigen in different laboratories can be found in the report of the collaborative study. Based on these values the alert limits for the control antigen in any lab should not be wider than 70% to 140% of the validated value.
Ph. Eur. BRP batch 1 of Newcastle Disease Virus Coating Antibody
A lyophilised preparation of protein-G purified monoclonal antibody specific for the HN antigen of NDV. In addition to the antibody the preparation contains 5% sucrose.

The content of 1 vial should be dissolved in 1.5 ml aqua dest.

Ph. Eur. BRP batch 1 of Newcastle Disease Virus Conjugated Detection Antibody
A lyophilised preparation of protein-G purified monoclonal antibody specific for the HN antigen of NDV conjugated to horse radish peroxidase. In addition to the conjugated antibody the preparation contains 5% sucrose and 0.5% bovine serum albumin.

The content of 1 vial should be dissolved in 1.5 ml ELISA buffer.

USE

- Allow the vials and contents to come to room temperature.
- Tap vials gently to collect material at the bottom.
- Using an appropriate syringe reconstitute the reference preparations by injecting a suitable volume of the diluent. Carefully mix and stir very gently, avoid spuming. Check for total dissolution by visual inspection prior to use.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

STORAGE

Vials should be stored unopened at –20°C before use. Do not store at lower temperatures to avoid deterioration of the rubber stopper.

CAUTION

The NDV BRPs are not appropriate for administration to humans and/or to animals. This preparation must be handled according to the appropriate QA system for biological testing laboratories. Please refer to the corresponding safety data sheet, which can be downloaded from the internet web site of the EDQM (http://www.edqm.eu) or delivered upon request.

LITERATURE