**Ph. Eur. Reference Standard - LEAFLET**

**CLOSTRIDIUM TETANI GUINEA PIG ANTISERUM (FOR VACCINES FOR VETERINARY USE) BRP batch 1**

_Clostridium tetani_ guinea pig antiserum (for vaccines for veterinary use) BRP batch 1 consists of freeze-dried guinea pig serum and is presented in vials. The BRP has been prepared from sera obtained by using the immunisation schedule prescribed in the Ph. Eur. monograph _Tetanus vaccine for veterinary use_ (0697). The BRP is needed for the potency testing of tetanus vaccine for veterinary use according to the Ph. Eur. monograph 0697 by using the Toxin Binding Inhibition (ToBI) test or the equivalent immunochemical methodology.

The titres have been assigned using an immunochemical method. The BRP has an assigned activity of:

34 IU/vial

**STORAGE**

Keep vials unopened at –20 °C. Do not store at lower temperatures to avoid deterioration of the rubber stoppers.

**USE**

- Allow the vial and content to reach room temperature.
- Tap vial gently to collect material at the bottom.
- Using an appropriate syringe reconstitute the reference preparation by injecting 800 μl of _water for injections R_ or milliQ water.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

**CAUTION**

_Clostridium tetani_ guinea pig antiserum (for vaccines for veterinary use) BRP batch 1 is 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 is delivered upon request.

LITERATURE