Ph. Eur. Reference Standard - LEAFLET

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

*Clostridium tetani* rabbit antiserum (for vaccines for veterinary use) BRP batch 1 consists of freeze-dried rabbit 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 titre has been assigned using an immunochemical test. The BRP has an assigned activity of 15 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* rabbit 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**