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

Clostridium tetani guinea pig antiserum (for vaccines for human use) BRP batch 1 consists of 0.5 ml of freeze-dried guinea pig serum and is presented in vials. The BRP has been prepared as described in the Ph. Eur. General Chapter 2.7.8. Assay of tetanus vaccine (adsorbed), Method C. The BRP is intended for use in the assay of tetanus vaccines for human use as described in the Ph. Eur. General Chapter 2.7.8.

The titre of the BRP has been assigned using a toxin neutralisation test in mice. The BRP has an assigned activity of

0.20 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 500 µl of water for injections.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

CAUTION
Clostridium tetani guinea pig antiserum (for vaccines for human 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 delivered upon request.

LITERATURE