TETANUS VACCINE ( ADSORBED ) BRP batch 3

Tetanus vaccine (adsorbed) BRP batch 3 is intended for use in the assay of adsorbed tetanus vaccine as described in the Ph. Eur. General Chapter 2.7.8. The preparation consists of freeze-dried tetanus toxoid adsorbed on AlPO₄₆, stabilised with Haemaccel®, presented in ampoules. It does not contain preservative. The Al³⁺ content is equal to 2 mg/ampoule. The assigned potency is

490 IU/ampoule for challenge assays in guinea-pigs
260 IU/ampoule for challenge assays in mice

STORAGE

Keep ampoules unopened at –20 °C.

USE

- Allow the ampoule and content to reach room temperature.
- Tap ampoule gently to collect material at the bottom.
- Open ampoule in an appropriate way and reconstitute the freeze-dried material by adding an accurately measured suitable volume of water for injections Ph. Eur. 0169 (for example 0.5 mL). Carefully mix and stir very gently, avoiding spuming.
- Use the suspension as soon as possible after reconstitution. Do not freeze or store for subsequent use.

RESULTS OBTAINED WITH TETANUS VACCINE ( ADSORBED ) BRP batch 3

Please be aware that any switch from your in-house standards to the tetanus vaccine (adsorbed) BRP batch 3 might lead to differences in potency estimates of the assayed tetanus vaccine. Re-calibration of your in-house standard against the tetanus vaccine BRP batch 3 is thus strongly recommended, as well as a thorough validation of your SOP.
CAUTION

Tetanus Vaccine (adsorbed) BRP batch 3 is not appropriate for administration to humans. This preparation must be handled according to the QA system for biological testing laboratories. Please refer to the corresponding safety data sheet, which can be downloaded from the Internet site of the EDQM (http://www.edqm.eu) or is delivered upon request.

LITERATURE