Diphtheria vaccine (adsorbed) BRP batch 4 consists of freeze-dried diphtheria toxoid, adsorbed to aluminium hydroxide and containing Haemaccel®, presented in ampoules. It is intended for use in the assay of adsorbed diphtheria vaccine as described in the Ph. Eur. General Chapter 2.7.6. The declared content is

97 IU/ampoule

**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.
- Using an appropriate syringe reconstitute the reference preparation by injecting a suitable volume of water for injections Ph. Eur. 0169 (for example 1.0 ml). Carefully mix and stir very gently, avoiding spuming. Total dissolution of the freeze-dried materials is immediate but has to be checked by visual inspection prior to use. Dilute where appropriate so as to obtain the required concentration.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

**CAUTION**
Diphtheria vaccine (adsorbed) BRP batch 4 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 available from the EDQM upon request.
LITERATURE


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