**Ph. Eur. Reference Standard – LEAFLET**

**PERTUSSIS TOXIN BRP batch 1**

**Pertussis toxin BRP batch 1** consists of freeze-dried pertussis toxin and is presented in vials. It is intended for use in the test for absence of residual toxicity of acellular pertussis vaccine by the mouse Histamine Sensitizing Test according to the Ph. Eur. monograph *Pertussis vaccine (acellular, component, adsorbed)* (1356). The BRP has an assigned Pertussis Toxin content of 50 µg/vial corresponding to 7500 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 an appropriate volume of *water for injections* or distilled water.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

**CAUTION**

Pertussis toxin BRP batch 1 is not appropriate for administration to humans. Administration to animals for purposes other than those described above is also not appropriate. 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](http://www.edqm.eu)) or delivered upon request.

**LITERATURE**