1. **Identification**

   **Catalogue code:** Y0000021

   **Unit Quantity *:** ca 50 µg

   *The total amount of material (active substance and excipients, if any) which has been filled in each vial or ampoule, for customs purposes. Circa ("ca") quantity is not to be considered accurate from an analytical point of view.

2. **Scientific Information**

   **2.1 Intended use**

   **Pertussis toxin BRP batch 1** consists of purified freeze-dried pertussis toxin and is presented in vials. It is intended for use in the test for absence of residual pertussis toxin in acellular pertussis vaccine by the mouse Histamine Sensitisation Test (HIST) according to the Ph. Eur. general chapter 2.6.33 and by the CHO clustering assay referred to in the monographs Pertussis vaccine acellular component adsorbed (1356) and Pertussis vaccine acellular co-purified adsorbed (1595). The BRP has an assigned potency of

   **7500 IU/vial for the histamine sensitisation test in mice**

   **1360 IU/vial for the CHO clustering assay**

   **2.2 Instructions for use**

   **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.

   *NB. For use in the CHO clustering assay, dilute the reconstituted BRP in CHO culture medium as appropriate. Wells containing 5 mIU/mL or higher of BRP must exhibit a positive clustering response.*

   **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.

   **2.3 The Uncertainty of the assigned value**

   For this Pharmacopoeial standard the uncertainty of the assigned value is not stated since it is considered to be negligible in relation to the defined limits of the method-specific assays for which the reference standard is used. Please also refer to Ph. Eur. chapter 5.12.

   **2.4 Validity**

   A statement on the validity of the batch (Batch Validity Statement) can be printed directly from the EDQM website (Reference Standards Database).

3. **Storage conditions**

   Keep vials unopened at -20°C ± 5°C. Do not store at lower temperatures to avoid deterioration of the rubber stoppers.
4. **Safety**  
Biological preparation for laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure.

5. **Shipping conditions**  
Please check shipping conditions on the EDQM website (Reference Standards Database).

6. **Additional information**  


Pharmeuropa Bio & Sci Notes is an open-access publication that is freely available on the EDQM website (www.edqm.eu).

EDQM website (Knowledge Database, Reference Standards Database, HelpDesk).

7. **Citation**  
Users shall ensure that any reference made to an EDQM Reference Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the exact name, and catalogue code of the Reference Standard and the exact name and address of EDQM as given on the first page of this information leaflet.

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9. **Adoption**  
The present reference standard has been officially adopted by the European Pharmacopoeia Commission.

10. **Signature**  
This document is electronically signed by:

    Dr Pierre Leveau  
    Head of the Quality, Safety and Environment Division