1. **Identification**

   Catalogue code: B1142000
   Unit Quantity *: ca 100 mg

   *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**

   The BRP consists of freeze-dried mouse serum.

   **2.1 Intended use**

   Bordetella pertussis mouse antiserum BRP batch 2 is intended for use in the serological potency assay of acellular pertussis vaccine components according to the Ph. Eur. General Chapter 2.7.16 Assay of pertussis vaccine (acellular). The BRP consists of freeze-dried mouse serum. The BRP is presented in vials with an assigned activity of:

   - Anti-pertussis toxin: 37 ELISA Units (ELU) per vial
   - Anti-filamentous haemagglutinin: 114 ELU per vial
   - Anti-pertactin: 44 ELU per vial
   - Anti-fimbrial 2 and 3 antigens: 25 ELU per vial

   **2.2 Instructions for 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 1000 μL of water for injections R or milliQ water
   - Use as soon as possible after reconstitution or aliquot in 20 μL fractions and store at -20°C for up to one year. Storage of the aliquots beyond one year should be carefully checked by implementing appropriate control criteria.

   **2.3 The Uncertainty of the assigned value**

   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**

   Store the original container at -20°C ± 5°C. Do not store at lower temperatures to avoid deterioration of the rubber stoppers. Once opened, the vial/ampoule is for immediate use or must be aliquoted and frozen immediately. Thawed aliquots must be used immediately (the stability of the thawed solution cannot be guaranteed).

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**  

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.

8. **Warranties, Liability and disputes**  
   a) **Warranties**  
The Council of Europe does not offer any warranty concerning the quality or safety of any item supplied, the absence of any defects, or its fitness for any particular purpose except that of use as a Ph. Eur. CRS, BRP or RS for use as reference standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia (Ph. Eur.) by professionals with the necessary technical skills. In particular, the Council of Europe (EDQM) does not guarantee that the items will meet the customer's specific expectations. The Council of Europe also does not guarantee that the purchase or use of the items will not infringe any intellectual property rights, in particular patents.

   The Council of Europe (EDQM) only guarantees that the items meet the above conditions in the moment they are handed over to the carrier being responsible for the delivery of the items to the purchaser and that the carrier and the purchaser have received clear and accurate instructions for the item’s delivery and reception.

   No other warranty, either express or implied, is given by the Council of Europe (EDQM).

   b) **Liability**  
The Council of Europe (EDQM) shall not be liable for the failure to meet the requirements of the legislation of the country where the items are delivered. It is the purchaser’s responsibility to check with the local, regional or national authorities and to make sure that the goods or services that they intend to order may be imported or used in that country. The purchaser is solely responsible for the choice of items, their storage from the time of delivery and their use.

   In no event shall the Council of Europe (EDQM) be liable for any damages due to the use of items, including, but not limited to, lost profits, loss of use, costs of procurement of substitute goods, services or systems, or for any indirect, special, incidental, punitive, or consequential damages, however caused and, whether in contract, tort or under any other theory of liability, whether or not the purchaser has been advised of the possibility of such damage.

   c) **Disputes**  
   In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the Council of Europe (EDQM) and the customer as regards the application of this contract shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.

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