BRP INFORMATION LEAFLET Ph. Eur. Reference Standard

RABIES VACCINE (INACTIVATED) FOR VETERINARY USE BRP batch 5

1. **Identification**
   Catalogue code: R0100000  
   Unit Quantity: 86 mg

2. **Scientific Information**

   2.1 **Intended use**
   This leaflet supplements the currently valid European Pharmacopoeia monograph(s) and/or general chapter(s) describing the suitable use of this Reference Standard. Further Information about the Reference Standard is available in the on-line catalogue currently at http://crs.edqm.eu (such as, batch validity statement and safety data sheet).

   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 1 mL of phosphate buffered saline pH 7.
   - Use a soon as possible after reconstitution. Do not freeze or store for subsequent use.
   - The BRP was established for use in the potency assay according to the Ph. Eur. monograph rabies vaccine (inactivated) for veterinary use (0451).

   **Content**
   The BRP consists of freeze-dried rabies vaccine (inactivated) presented in vials. The BRP has an assigned activity of:

   **10 IU/VIAL**

   2.3 **The Uncertainty of the assigned value**
   According to ISO Guide 34 and ISO Guide 35, 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**
   Store the original container at -20°C ± 5°C. Once opened, the vial/ampoule is for immediate use and the stability of the contents of opened vials or ampoules 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**

Publication in preparation for Pharmeuropa Bio & Scientific Notes.

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.

8. **Warranties, Liability and disputes**

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   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.

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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