INFORMATION LEAFLET Ph. Eur. Reference Standard

POLIOMYELITIS VACCINE (INACTIVATED) BRP batch 3

1. Identification

Catalogue code: P2160000
Unit Quantity *: ca 0.6 mL

*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

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 statement).

2.2 Instructions for use

- The BRP is for use in the in vitro D-antigen content assay according to the Ph. Eur. monograph 0214
- The material should be thawed before use.

Content

The BRP consists of 0.6 mL per ampoule of a liquid preparation of a concentrated trivalent bulk (Type 1 (Mahoney), Type 2 (MEF1), Type 3 (Saukett)):

320–78–288 DU/mL (IU) for type 1, 2 and 3 poliovirus, respectively

2.3 Uncertainty of the assigned value, when applicable

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

Ph. Eur. RS are periodically tested to ensure their continuous fitness for purpose. For each valid Ph. Eur. RS, a Batch Validity Statement at the time of use can be downloaded and printed from the EDQM website (Reference Standards Database).

3. Storage conditions

In the original container at -80°C ± 10°C, protected from light. Re-instate promptly upon receipt.

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.

8. Warranties, Liabilities and responsibility

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 item 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 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