1. **Identification**

   Catalogue code: Y0001873  
   Unit Quantity *: ca 45 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**

   **2.1 Intended use**

   Hepatitis E virus RNA for NAT testing BRP batch 1 is intended for use in the test of human plasma pools for the detection of contamination by hepatitis E virus RNA as described in the Ph. Eur. monograph 1646 for Human plasma pooled and treated for virus inactivation.

   The BRP consists of freeze-dried human plasma spiked with hepatitis E virus-positive human plasma, presented in vials. Each vial contains the equivalent of 0.5 mL of material and has an assigned content of

   \[ 2.1 \times 10^4 \text{ IU/vial} \ (4.32 \log_{10} \text{ IU/vial}) \]

   After reconstitution in 0.5 mL of nuclease-free molecular biology grade water (see below for instructions for use) the preparation has a concentration of \( 4.2 \times 10^4 \text{ IU/mL} \) (4.62 \( \log_{10} \text{ IU/mL} \)).

   **2.2 Instructions for use**

   - Allow the vial and content to reach room temperature.
   - Tap vial gently to collect material at the bottom.
   - Using appropriate syringe reconstitute the preparation by injecting 0.5 mL of deionised nuclease-free, molecular biology grade water and left for a minimum of 20 minutes with occasional gentle stirring, avoiding spuming.
   - The product should be reconstituted just prior to use. If not used immediately, laboratories may aliquot the remaining material into suitable volumes which should be stored below -70°C. The stability of these aliquots should be determined by the user according to their own local preparation/storage conditions and use, under their own QA procedures.

   **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 is for immediate use and the stability of the contents of opened vials cannot be guaranteed.

4. **Safety**
   Biological preparation for laboratory use only. This preparation contains hepatitis E virus RNA and must be considered hazardous to health. 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, 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 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 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