BRP INFORMATION LEAFLET Ph. Eur. Reference Standard
Hepatitis E virus RNA for NAT testing BRP batch 1

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.

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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**