1. **Identification**

Catalogue code: Y0000285

Unit Quantity *: ca 150 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**

B19 virus DNA for NAT testing BRP batch 1 is intended for use in the test of human plasma pools for the detection of contamination by parvovirus B19 virus DNA by Nucleic acid Amplification Techniques (NAT) as described in the Ph. Eur. general chapter 2.6.21 Nucleic acid amplification techniques and other relevant monographs such as Human plasma (pooled and treated for virus inactivation) (1646), Human Anti-D immunoglobulin (0557) and Human anti-D immunoglobulin for intravenous administration (1527).

The BRP consists of freeze-dried human plasma spiked with parvovirus B19-positive plasma, presented in vials with an assigned titre of

\[ 10^{5.80} \text{ IU/mL (5.8 log}_{10} \text{ or 630.957 IU/mL) when reconstituted in 0.5 mL as prescribed below} \]

For use as 10^4 IU/mL threshold control in conjunction with relevant Ph. Eur. monographs, a 1/101.80 (1/63) dilution of the BRP is required.

2.2 **Instructions for use**

Before any handling, see section 4.

- Allow the vial and content to reach room temperature.
- Tap vial gently to collect material at the bottom.
- Using an appropriate syringe reconstitute by injecting 0.5 mL of water for injections. Stir very gently, avoid foaming. Check by visual inspection that complete dissolution has been achieved prior to use.
- After reconstitution, single-use aliquots can be kept at -70°C or below for future use.
- For further dilution of the reconstituted BRP, parvovirus B19 DNA negative plasma should be used.
- Prepare dilutions just before use. Keep diluted BRP at 2-8°C protected from light and use as soon as possible.

2.3 **The Uncertainty of the assigned value**

According to ISO Guide 34 and ISO Guide 35, for this Pharmacopeial 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
Keep vials unopened at -20°C ± 5°C protected from light. Do not store at lower temperatures to
avoid deterioration of the rubber stoppers.

4. Safety
Level 2 biohazard. Handle only in working areas corresponding to at least:
containment level 2 of the Directive 2000/54/EC or equivalent.

5. Shipping conditions
Please check shipping conditions on the EDQM website (Reference Standards Database).

6. Additional information
Pharmacopoeia Biological Reference Preparation (BRP) for B19 virus DNA testing of plasma pools by
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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The Council of Europe does not offer any warranty concerning the quality or safety of any item supplied, the absence of any
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in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia (Ph. Eur.) by
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will meet the customer’s specific expectations. The Council of Europe also does not guarantee that the purchase or use of the
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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**