1. **Identification**

Catalogue code: Y0001512  
Unit Quantity*: ca 5000 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**

Human Immunoglobulin (Fc function and distribution of molecular size) BRP batch 2 is intended for use as the reference preparation for the Test for Fc function of immunoglobulin (2.7.9.) and the Test for distribution of molecular size of immunoglobulins performed according to the specifications of the monographs Human normal immunoglobulin (0338) and Human normal immunoglobulin for intravenous administration (0918). Each vial contains:

5 g of immunoglobulin G.

**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 100 mL of water R. Carefully mix and stir very gently, avoiding foaming, until complete dissolution. Check by visual inspection that complete dissolution has been achieved prior to use. The solution thus obtained contains 50 mg/mL of immunoglobulin G. Use as soon as possible after reconstitution. Do not freeze. The reconstituted solution may be stored at the user’s risk under defined validated conditions such as +4°C for a maximum of 14 days without freezing.

**Validity requirements:** the preparation to be examined complies with the test if the index of Fc function (IFc) is not less than 60 per cent.

In cases where only the Test for distribution of molecular size of immunoglobulins is performed (without the Fc function test or in a different laboratory), the use of Human Immunoglobulin (molecular size) BRP (Catalogue number Y0000488) is recommended.

**Note:** Human Immunoglobulin (Fc function and distribution of molecular size) BRP batch 2 is **not intended for use as the reference preparation for the Test for anti-complementary activity (2.6.17).** For this test, the Human Immunoglobulin (ACA and distribution of molecular size) BRP (Catalogue number Y0001504) must be used.
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 +5°C ± 3°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
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