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Information Leaflet Ph. Eur. Reference Standard

Human immunoglobulin for Fc function BRP batch 2

1. Identification

Catalogue code: **Y0001966**

2. Scientific Information

2.1 Intended use

Human immunoglobulin for Fc function BRP is intended for use as the reference preparation for the *Test for Fc function of immunoglobulin* as described in the European Pharmacopoeia general chapter 2.7.9 and performed as required by the monographs *Human normal immunoglobulin for intravenous administration (918)* and *Human normal immunoglobulin for subcutaneous administration (2788)*.
Each vial contains 10 mL of a 10% *(W/V)* sterile liquid formulation of highly purified immunoglobulin G. This concentration is given for information only and is not to be considered accurate from an analytical point of view.

The undiluted BRP may be used as reference preparation for the test for Fc function of immunoglobulins for a maximum of 14 days after first opening, if stored under defined validated conditions at + 5°C ± 3°C and handled aseptically.

2.2 Instructions for use

Operate under a laminar flow in order to avoid microbial contamination. Open the original container with precautions. Wear gloves. If the BRP is to be re-used, take out the necessary volume to perform the test then re-cap the container tightly and place it immediately back to +5°C ± 3°C.

- Dilute the appropriate volume of the preparation to be examined with albumin barbital buffer as described in general chapter 2.7.9
- Perform the test for Fc function as described in general chapter 2.7.9

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.

CAUTION : Human immunoglobulin for Fc function BRP batch 2 is not appropriate for administration to humans or animals.

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 variability of method for which the reference standard is used. Please also refer to Ph. Eur. chapter 5.12.

2.4 Validity

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

3. Storage conditions

Store the original container at + 5°C ± 3°C upon receipt. Do not store at lower temperatures. Do not freeze.

After opening, the BRP may be stored at + 5°C ± 3°C in a tightly closed container and may be used for up to 14 days provided it is handled appropriately to avoid microbial contamination.

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

Karra D, Regourd E, Costanzo A. Collaborative study for the establishment of the human immunoglobulin BRP replacement batches. *Pharmeuropa Bio & Sci Notes* 2018(3):37-61.

Pharmeur Bio & Sci Notes is an open-access publication that is freely available on the EDQM website (www.edqm.eu).

Further information available on 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

– *Safety*

In the event of any safety concerns, please read carefully the safety data sheets or safety data statements available for each product. It is for Purchasers to determine independently the risks associated with the items and to take appropriate safety measures, including the provision of appropriate information, equipment and training of those persons coming into contact with the item.

– *Warranties*

Except for the use of Reference Standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and by professionals with the necessary technical skills and at their own discretion and risk, the EDQM makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for any particular purpose except that as described above.

The EDQM does not guarantee that the items will meet the Purchaser's specific expectations. The EDQM only guarantees that the items (i) were fit for use according to EDQM's intended use of the product ;(ii) were fit for use at the moment that they were handed over to the carrier being responsible for the delivery of the items to the Purchaser with such accessories including packaging, delivery instructions or other instructions for the item's delivery and reception as the Purchaser may expect to receive; and (iii) possess qualities and performance capabilities which are normal in goods of the same type and which the Purchaser may expect given the nature of the goods and the information provided on the EDQM's website and (iv) the carrier and the Purchaser received clear and accurate instructions for the item's delivery and reception. No other guarantees, whether explicitly or implied, are given by the EDQM. The EDQM does not guarantee that the purchase or use of the items will not infringe any intellectual property rights, in particular patents.

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In no event shall the EDQM be liable for any damages due to the use of items, included, but not limited to loss of business, loss of profit, loss of use, loss of opportunity, 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 damages or costs.

Any liability of the EDQM for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted internationally accepted commercial standards; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

9. Arbitration & Applicable Law

The aim of the EDQM is to settle any disputes amicably in the framework of its Terms and Conditions. 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 EDQM and the Purchaser as regards the application of these General Terms 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.

This transaction shall be governed by the Council of Europe's relevant regulatory framework, complemented, where necessary, by French national substantive law.

10. Adoption

The suitability for intended use has been officially adopted by the European Pharmacopoeia Commission.

11. Signature

This document is approved by:

Head of the Quality and Risk Management Section

Name: Caroline OFFERLE

Date: 12/10/2020