Human Immunoglobulin (ACA and molecular size) BRP batch 1

Human Immunoglobulin (ACA and molecular size) BRP batch 1 is intended for use as the reference preparation for the Test for anti-complementary activity of immunoglobulin (2.6.17) 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:

6 g of immunoglobulin G.

STORAGE

Keep vials unopened at +4°C. Do not store at lower temperatures to avoid deterioration of the rubber stoppers.

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 105.4 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.
Anti-complementary activity (ACA). Human Immunoglobulin BRP serves both as ACA negative control and ACA positive control. Prepare the incubation mixtures as follows for the Human Immunoglobulin BRP containing 50 mg/mL of immunoglobulin G:

<table>
<thead>
<tr>
<th></th>
<th>Negative control</th>
<th>Positive Control</th>
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</thead>
<tbody>
<tr>
<td>Immunoglobulin BRP</td>
<td>0.2 mL</td>
<td>0.6 mL</td>
</tr>
<tr>
<td>Gelatin barbital buffer solution</td>
<td>0.6 mL</td>
<td>0.2 mL</td>
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<tr>
<td>Complement</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
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</tbody>
</table>

Carry out the test on the immunoglobulin to be examined and on Human Immunoglobulin BRP in parallel.

Close the tubes and incubate at 37°C for 60 min.

- Add for the **negative control** 0.2 mL of each incubation mixture to 9.8 mL of gelatin barbital buffer solution to dilute the complement.
- Add for the **positive control** 1.0 mL of each incubation mixture to 9.0 mL of gelatin barbital buffer solution to dilute the complement.

Perform complement titration as described in 2.6.17 on each tube to determine the remaining complement activity.

Validity requirements: 10-40 per cent consumption of complement for the negative control, 60-100 per cent consumption of complement for the positive control.

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

Note: Human Immunoglobulin (ACA and molecular size) BRP batch 1 is not intended for use as the reference preparation for the Test for Fc function of immunoglobulin (2.7.9). For this test, the Human Immunoglobulin (Fc function and molecular size) BRP (Catalogue number Y0001512) must be used.

CAUTION

Human Immunoglobulin (ACA and molecular size) BRP batch 1 is not appropriate for administration to humans. This preparation must be handled according to the appropriate QA system for biological testing laboratories. Please refer to the corresponding safety data sheet, which can be downloaded from the internet web site of the EDQM (http://www.edqm.eu) or delivered upon request.

LITERATURE

Calibration of the human immunoglobulin BRPs for ACA and molecular size (batch 1) and for Fc function and molecular size (batches 1 & 2). Pharmeuropa Bio & SN 2012(1).