CRS INFORMATION LEAFLET
Ph. Eur. Reference Standard

Immunoglobulin for anti-A, anti-B antibodies Limit test BRP batch 1

Immunoglobulin for anti-A, anti-B antibodies Limit test BRP batch 1 consists of a freeze-dried preparation of immunoglobulin in ampoules with haemagglutination reciprocal titres of anti-A and anti-B antibodies of 64 for a 5% IgG solution in the direct haemagglutination test for anti-A, anti-B antibodies in human immunoglobulin for intravenous administration, according to the Ph. Eur. General text 2.6.20. (Method B).

IMPORTANT NOTE
- The Immunoglobulin for anti-A, anti-B antibodies Limit test BRP is to be used only for the re-test of those batches using the direct method that were found to have a titre higher than the Immunoglobulin (anti-A, anti-B antibodies test) Positive control BRP (Cat. code: Y0001688).

STORAGE
Keep ampoules unopened at -20°C ± 5°C.

USE
- Tap the ampoule gently to collect the material at the bottom end before opening.
- Care should be taken to avoid cuts and projectile glass fragments that might enter one's eyes. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure.
- Reconstitute the contents of each ampoule to be tested on the day of the test with 0.5 mL of purified water. Allow several minutes, with occasional vortexing, for reconstitution. Transfer the reconstituted contents to a capped tube. Store at +5°C ± 3°C if necessary. The product may be reconstituted in 0.5 mL of a solution at 0.2g/L sodium azide in purified water or frozen in small aliquots provided that stability under the conditions used is validated by the user.
CAUTION

Immunoglobulin panel for anti-A, anti-B antibodies Limit test 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


SIGNATURE

This document is electronically signed by:

Dr Pierre Leveau
Head of the Quality, Safety and Environment Division