HEPATITIS A VACCINE (INACTIVATED, NON-ADSORBED) BRP batch 2

Intended use

This leaflet supplements the currently valid European Pharmacopoeia monograph(s) and/or general chapter(s) describing the suitable use of this Reference Standard.

Further information about the Reference Standards is available in the on-line catalogue currently at http://crs.edqm.eu (such as, batch validity statement and safety data sheet).

Instruction

Hepatitis A vaccine (inactivated, non-adsorbed) BRP batch 2 is intended for use as the reference preparation for the in vitro measurement of antigen content by ELISA of hepatitis A vaccines as described in Chapter 2.7.14 Assay of hepatitis A vaccine. It consists of a liquid preparation (1 mL/vial) of aqueous, formalin-inactivated, non-adjuvanted hepatitis A virus antigen with a declared potency of 1350 IU/mL.

Storage

Keep vials unopened below -50°C.

Use

The BRP must be aliquoted and re-frozen before use.

- Allow the vial and contents to thaw on ice.
- Tap gently to collect material at the bottom.
- Prepare suitable single-use aliquots in sterile pre-cooled microtubes (e.g. 200 µL/tube).
- Freeze below -50°C for at least 24 hours before use.
- Use each aliquot only once. Discard the remaining material after the assay. Do not re-freeze or re-use.

Caution

Hepatitis A vaccine (inactivated, non-adsorbed) BRP batch 2 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 is delivered upon request.
Literature


Signature

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