Diphtheria Toxin BRP batch 1

Diphtheria toxin BRP batch 1 consists of a solution of diphtheria toxin from Corynebacterium diphtheriae Massachusetts 8, Park Williams in 0.75% peptone buffer, filled in glass ampoules. Ampoules contain 1 ml of solution. It is intended for use in the test “Absence of toxin and irreversibility of toxoid” in Vero cells, as described in the Ph. Eur. monograph Diphtheria vaccine (adsorbed) (0443).

Nominal concentration of Diphtheria toxin: 1 Lf/ml (0.4 µg/ml)
Systemic toxicity: 77.6 LD$_{50}$/ml (determined in the subcutaneous challenge test in guinea pigs)
Maximum intradermal toxicity: 75,000 Lr/Lf (determined in guinea pig intradermal skin test)
(Lr = minimal reactive dose; administration of 0.2 ml)
Toxicity in the Vero cell assay: concentrations of 5 x 10$^{-5}$ Lf/ml cause cytotoxic effects.

STORAGE
Keep ampoules unopened at 2-8 °C protected from light.

USE

- Before handling, consult the EDQM Safety Data Sheet.
- Visually inspect the ampoule for any growth of moulds. Do not use the ampoule if there is evidence for such growth.
- Take precautions against injury when opening the ampoule.
- Use aseptic conditions to prepare dilutions; dilute according to your Standard Operating Procedure.
- Prepare dilutions on the day of use; store them at 2-8 °C protected from light until use; do not re-use diluted material.
CAUTION

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

LITERATURE