Ph. Eur. Reference Standard – LEAFLET

ERYTHROPOIETIN BRP batch 3

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

Erythropoietin BRP batch 3 is intended for use as the reference preparation for the in vivo bioassays as prescribed in the European Pharmacopoeia monograph Erythropoietin concentrated solution (1316). It consists of a freeze-dried preparation of erythropoietin (EPO)-alpha and –beta in equal proportions (W/W) in vials with a declared content of

35280 IU per vial

Storage

Keep vials unopened at -20°C ± 5°C. Do not store at lower temperature to avoid deterioration of the rubber stoppers.
Use

- Allow the vial and contents to reach room temperature.
- Tap gently to collect material at the bottom.
- Reconstitute the reference preparation with an appropriate volume of solvent (for example water R or phosphate albumin buffer)
- Mix gently until complete dissolution. Transfer the solution to an appropriate volumetric flask and rinse the vial, adding the rinsing to the flask. Dilute so as to obtain the required concentration.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

Caution

Erythropoietin BRP batch 3 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