Biotherapeutics – Ph. Eur. monograph portfolio

The list is not exhaustive and is for information only.

General Notices apply to all Ph. Eur. texts!

**General monographs**

- Dosage form monographs
- Monoclonal antibodies for human use (2031)
- Pharmaceutical preparations (2619)
- Products with risk of transmitting agents of animal spongiform encephalopathies (1483)
- Recombinant DNA technology products of (0784)
- Substances for pharmaceutical use (2034)

**Individual monographs**

- Alteplase for injection (1170)*
- Calcitonin salmon (0471)
- Erythropoietin concentrated solution (1316) §
- Etanercept (2895)
- Filgrastim concentrated solution (2206)
- Filgrastim injection (2848)*
- Follitropin (2285) §
- Follitropin concentrated solution (2286) §
- Glucagon, human (1635)
- Human coagulation factor IX (rDNA) powder for solution for injection (2994)*
- Human coagulation factor IX rDNA concentrated solution (2522)
- Human coagulation factor VIIa rDNA concentrated solution (2534)
- Human coagulation factor VIII rDNA (1643)*§
- Infliximab concentrated solution (2928)
- Insulin aspart (2084)
- Insulin glargine (2571)
- Insulin lispro (2085)
- Insulin preparations injectable (0854)*
- Insulin, human (0838)
- Interferon alfa-2 concentrated solution (1110)
- Interferon gamma-1b concentrated solution (1440)
- Molgramostim concentrated solution (1641)
- Somatropin concentrated solution (0950) §
- Somatropin (0951) §
- Somatropin for injection (0952)*§
- Somatropin solution for injection (2370)*§
- Teriparatide (2829)

**New monographs in preparation**

- Adalimumab (3147)
- Darbepoetin alfa (3009)
- Golimumab concentrated solution (3103)
- Human coagulation factor VIII (rDNA concentrated solution (3105)
- Human coagulation factor VIII (rDNA) powder for injection (3106)*
- Human coagulation factor VIII (rDNA), B-domain deleted, concentrated solution (3107)
- Human coagulation factor VIII (rDNA), B-domain deleted, powder for injection (3108)*
- Insulin glargine injection (3129)*
- Pegfilgrastim (2889)
- Teriparatide injection (3130)*
- Ustekinumab (3165)

* finished product monographs; § under revision

In addition to general and individual monographs, the Ph. Eur. contains a number of general chapters, of which Glycan analysis of glycoproteins (2.2.59) and Host-cell protein assays (2.6.34) could be of particular interest in reference to biotherapeutics.