

Last update: January 2024

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

- *Alteplase concentrated solution (3197)*
- *Adalimumab (3147)*
- *Darbepoetin alfa (3009)*
- *Golimumab concentrated solution (3103)*
- *Golimumab injection (3187)**
- *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)*
- *Ustekinumab injection (3188)**

* 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)***, ***Host-cell protein assays (2.6.34)***, ***Quantification and characterisation of residual host-cell DNA (2.6.35)*** and ***Cell-based assays for potency determination of TNF-alpha antagonists (2.7.26)*** could be of particular interest in reference to biotherapeutics.