

Last update: January 2022

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

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| <ul style="list-style-type: none"> • 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)[§] | <ul style="list-style-type: none"> • Somatropin (0951)[§] • Somatropin for injection (0952)*[§] • Somatropin solution for injection (2370)*[§] • Teriparatide (2829) |
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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)*** and ***Host-cell protein assays (2.6.34)*** could be of particular interest in reference to biotherapeutics