

Last update: January 2025

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) • Golimumab concentrated solution (3103) • 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) | <ul style="list-style-type: none"> • Somatropin concentrated solution (0950) • Somatropin (0951) • Somatropin for injection (0952)* • Somatropin solution for injection (2370)* • Teriparatide (2829) <p>New monographs in preparation</p> <ul style="list-style-type: none"> • <i>Alteplase concentrated solution (3197)</i> • <i>Adalimumab (3147)</i> • <i>Darbepoetin alfa (3009)</i> • <i>Dulaglutide (3273)</i> • <i>Dulaglutide injection (3274)*</i> • <i>Golimumab injection (3187)*</i> • <i>Human coagulation factor VIII (rDNA) concentrated solution (3105)</i> • <i>Human coagulation factor VIII (rDNA) powder for injection (3106)*</i> • <i>Human coagulation factor VIII (rDNA), B-domain modified, concentrated solution (3107)</i> • <i>Human coagulation factor VIII (rDNA), B-domain modified, powder for injection (3108)*</i> • <i>Insulin glargine injection (3129)*</i> • <i>Pegfilgrastim (2889)</i> • <i>Teriparatide injection (3130)*</i> • <i>Ustekinumab (3165)</i> • <i>Ustekinumab injection (3188)*</i> |
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* 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.

