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## 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"> <li>• Alteplase for injection (1170)* §</li> <li>• Calcitonin salmon (0471)</li> <li>• Erythropoietin concentrated solution (1316) §</li> <li>• Etanercept (2895)</li> <li>• Filgrastim concentrated solution (2206)</li> <li>• Filgrastim injection (2848)*</li> <li>• Follitropin (2285) §</li> <li>• Follitropin concentrated solution (2286) §</li> <li>• Glucagon, human (1635)</li> <li>• Golimumab concentrated solution (3103)</li> <li>• Human coagulation factor IX (rDNA) powder for solution for injection (2994)*</li> <li>• Human coagulation factor IX rDNA concentrated solution (2522)</li> <li>• Human coagulation factor VIIa rDNA concentrated solution (2534)</li> <li>• Human coagulation factor VIII rDNA (1643)* §</li> <li>• Infliximab concentrated solution (2928) §</li> <li>• Insulin aspart (2084)</li> <li>• Insulin glargine (2571)</li> <li>• Insulin lispro (2085)</li> <li>• Insulin preparations injectable (0854)*</li> <li>• Insulin, human (0838)</li> <li>• Interferon alfa-2 concentrated solution (1110)</li> <li>• Interferon gamma-1b concentrated solution (1440)</li> <li>• Molgramostim concentrated solution (1641)</li> </ul> | <ul style="list-style-type: none"> <li>• Somatropin concentrated solution (0950)</li> <li>• Somatropin (0951)</li> <li>• Somatropin for injection (0952)*</li> <li>• Somatropin solution for injection (2370)*</li> <li>• Teriparatide (2829)</li> </ul> <p><b>New monographs in preparation</b></p> <ul style="list-style-type: none"> <li>• <i>Alteplase concentrated solution (3197)</i></li> <li>• <i>Adalimumab (3147)</i></li> <li>• <i>Darbevoetin alfa (3009)</i></li> <li>• <i>Dulaglutide (3273)</i></li> <li>• <i>Dulaglutide injection (3274)*</i></li> <li>• <i>Golimumab injection (3187)*</i></li> <li>• <i>Human coagulation factor VIII (rDNA concentrated solution (3105))</i></li> <li>• <i>Human coagulation factor VIII (rDNA) powder for injection (3106)*</i></li> <li>• <i>Human coagulation factor VIII (rDNA), B-domain modified, concentrated solution (3107)</i></li> <li>• <i>Human coagulation factor VIII (rDNA), B-domain modified, powder for injection (3108)*</i></li> <li>• <i>Insulin glargine injection (3129)*</i></li> <li>• <i>Pegfilgrastim (2889)</i></li> <li>• <i>Teriparatide injection (3130)*</i></li> <li>• <i>Ustekinumab (3165)</i></li> <li>• <i>Ustekinumab injection (3188)*</i></li> </ul> |
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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.

