

Last update: August 2020

## 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)<sup>§</sup></li> <li>• Etanercept (2895)</li> <li>• Filgrastim concentrated solution (2206)</li> <li>• Filgrastim injection (2848)*</li> <li>• Follitropin (2285)<sup>§</sup></li> <li>• Follitropin concentrated solution (2286)<sup>§</sup></li> <li>• Glucagon, human (1635)</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)*<sup>§</sup></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)<sup>§</sup></li> <li>• Somatropin (0951)<sup>§</sup></li> <li>• Somatropin for injection (0952)*<sup>§</sup></li> <li>• Somatropin solution for injection (2370)*<sup>§</sup></li> <li>• Teriparatide (2829)</li> </ul> <p><b>New monographs in preparation</b></p> <ul style="list-style-type: none"> <li>• Adalimumab (3147)</li> <li>• Darbepoetin alfa (3009)</li> <li>• Golimumab concentrated solution (3103)</li> <li>• Human coagulation factor VIII (rDNA) concentrated solution (3105)</li> <li>• Human coagulation factor VIII (rDNA) powder for injection (3106)*</li> <li>• Human coagulation factor VIII (rDNA), B-domain deleted, concentrated solution (3107)</li> <li>• Human coagulation factor VIII (rDNA), B-domain deleted, powder for injection (3108)*</li> <li>• Insulin glargine injection (3129)*</li> <li>• Pegfilgrastim (2889)</li> <li>• Teriparatide injection (3130)*</li> <li>• Ustekinumab (3165)</li> </ul> |
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\* finished product monographs; <sup>§</sup> 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.