30 October 2018, Strasbourg, France

Ph. Eur. seeks feedback on general chapter covering depyrogenation in parenteral preparations

The European Pharmacopoeia (Ph. Eur.) has launched a public consultation on its new general chapter 5.1.12 on *depyrogenation of items used in the production of parenteral preparations*. While depyrogenation is not a new topic for the Ph. Eur., this is the first time that a dedicated chapter covers specifically the inactivation of pyrogens and related endotoxin indicators. Pyrogens are substances that can induce fever when infused or injected and must be removed from materials that come into direct contact with final sterilised products, such as primary packaging and equipment.

In this new general chapter, different types of available endotoxin indicators are described (for instance, ready to use or custom made) and "depyrogenation" is defined in terms of a reduction in lipopolysaccharides (LPSs), the most potent and difficult to eliminate of all pyrogenic substances. All depyrogenation processes should be validated by adding endotoxin indicators to the load in those positions identified as the most difficult to depyrogenate. Endotoxin indicators should be suitable to the material to be depyrogenated (glass, stainless steel, plastic) and depyrogenation can be carried out through dry heat treatment, as well as other treatments, like physical and chemical procedures, when heat treatment is not possible.

Users and parties concerned can submit their comments on the Issue 30.4 of Pharmeuropa until 31 December 2018: http://pharmeuropa.edqm.eu/home/

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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