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European Pharmacopoeia Commission adopts revised general chapter on Monocyte-activation test to facilitate reduction in testing on laboratory animals

During its 155th Session, held in Strasbourg on 21-22 June 2016, the European Pharmacopoeia (Ph. Eur.) Commission adopted a revision of the general chapter *Monocyte-activation test* (2.6.30) in order to make it more widely useable by stakeholders and thus facilitate a reduction in testing on laboratory animals. This extensive revision of the general chapter – first published in the Ph. Eur. in 2010 – is the result of a wide-ranging consultation with industry representatives, academics, regulatory authorities and Official Medicines Control Laboratories.

The monocyte activation test (MAT) is used to detect or quantify substances that activate human monocytes or monocytic cells to release endogenous mediators which have a role in the human fever response. The MAT is suitable, after product-specific validation, as a replacement for the rabbit pyrogen test (RPT).

The MAT offers significant advantages over animal testing: based on the human fever response, it provides a more relevant prediction of pyrogenic activity than the RPT, it can detect endotoxin and non-endotoxin pyrogens and is applicable to a greater variety of products than the RPT; moreover, it is more accurate as well as more cost- and time-effective than the RPT.

Since 1986, the Ph. Eur. Commission and its experts have made a devoted effort to elaborate and revise its texts in line with the European Convention (ETS 123) for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes. As a result, the prescribed tests must be carried out in such a way as to use the minimum number of animals and to cause the least pain, suffering, distress or lasting harm.

It is hoped that this revision of the general chapter will lead to a further reduction in the use of laboratory animals and so will mark a further contribution to the European Pharmacopoeia Commission's efforts in the field of animal welfare over the course of more than three decades.

The revised general chapter *Monocyte-activation test* (2.6.30) will be published in the Ph. Eur. Supplement 9.2 and will come into effect in July 2017.

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Further information is available on the website **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 world-wide. The European Pharmacopeia 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.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

[1] There are thirty-eight 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, 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.