# Press release

**5 July 2023, Strasbourg, France**

## Outcome of the 176th session of the European Pharmacopoeia Commission, June 2023

The European Pharmacopoeia Commission (EPC) held its 176th session on 20 and 21 June 2023. The 67 texts adopted at this session by the EPC will be published in European Pharmacopoeia (Ph. Eur.) Supplement 11.5 (January 2024), with an implementation date of 1 July 2024.

These 67 texts included 11 new monographs and three new general chapters:

- monographs on:
  - *Cannabis flower (3028)* and *Cannabidiol (3151)*, isolated from the *Cannabis sativa* L. plant;
  - *Green bean pod (2952)*, *Rhodiola root and rhizome (2893)*, *Polygonum multiflorum stem (2725)* and *Round amomum fruit (2555)*;
  - *Pirfenidone capsules (3154)*;
  - *Lercanidipine hydrochloride (3052)* and *Erlotinib hydrochloride (3094)*;
  - *Oxygen (98 per cent) (3098)*, which will enable healthcare facilities to control the quality of oxygen produced on-site using a two-stage adsorption process to remove nitrogen and argon from the air;
  - *Mycoplasma gallisepticum vaccine (live) for chickens (3133)*;
- general chapters on:
  - *Monocyte-activation test for vaccines containing inherently pyrogenic components (2.6.40)*, which covers the use of the monocyte-activation test (MAT) to monitor the production consistency of inherently pyrogenic vaccines and will be of great help to stakeholders wishing to implement MAT for such vaccines;
  - *Comparability of alternative analytical procedures (5.27)*, which provides users with more detailed information on how to implement an alternative analytical procedure instead of the pharmacopoeial analytical procedure, one of the processes that offers users greater flexibility in demonstrating compliance with the Ph. Eur. monographs;
  - *Particle size analysis by dynamic light scattering (2.9.50)*, which is the first new text to be prospectively harmonised within the Pharmacopoeial Discussion Group (PDG) with the Japanese Pharmacopoeia and the United States Pharmacopeia. This chapter describes a technique that is important for measuring the size and size distribution of submicron particles dispersed in a liquid. This technique is particularly important for the characterisation of nanomedicines.

The EPC adopted revised versions of 53 texts. These included:

- the general chapter *Monocyte-activation test (2.6.30)*, which was revised to streamline the test and bring it into line with current practices. This technical revision is part of the broader exercise to remove the rabbit pyrogen test (described in general chapter *2.6.8. Pyrogens*) from the Ph. Eur. (see also www.edqm.eu/en/-/european-pharmacopoeia-to-put-an-end-to-the-rabbit-pyrogen-test) and the very first step towards it;

- three general chapters on powder characterisation, *Bulk density and tapped density of powders (2.9.34)*, *Powder Flow (2.9.36)* and *Density of Solids (2.2.42)*, revised within the framework of international harmonisation;
- the general monograph *Methods of preparation of homoeopathic stocks and potentisation (2371)*, which now includes the Korsakovian method of manufacture (single-flask potentisation method) of homoeopathic preparations used in several European countries.

The list of all adopted texts will be made available on the Ph. Eur. Work Programme web page in the coming weeks.

Other outcomes of this EPC session included the decision to revise the existing monographs on *Oxygen (0417)* and *Oxygen (93 per cent) (2455)* to align them with the format of the newly adopted *Oxygen (98 per cent)* monograph, and the addition of nine new monographs and one new general chapter to the EPC work programme.

Lastly, the EPC agreed in principle to the proposed strategy for addressing contamination with *N*-nitrosamine impurities in individual monographs; more detailed information on this strategy will be shared in a separate communication.

The 177th session of the EPC will take place in hybrid format on 21 and 22 November 2023.

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**Note for the Editor**: Further information is available on the internet site **www.edqm.eu**.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Its standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.[1] The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. The European Pharmacopoeia Commission comprises 40 members: Albania, 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, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom and the European Union.

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