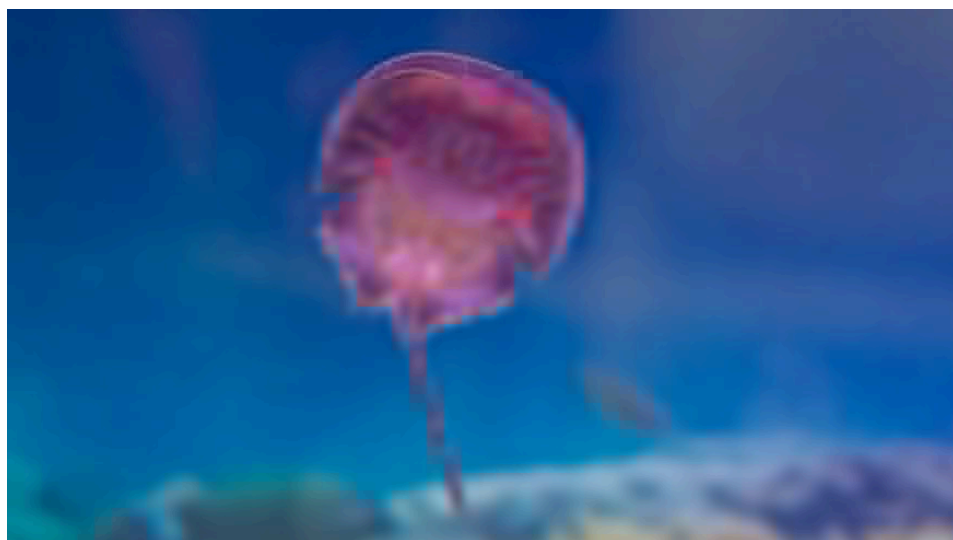


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Newsroom

A major step towards animal-free testing for the test for bacterial endotoxins

EDQM | STRASBOURG, FRANCE | 18/12/2025



The European Pharmacopoeia (Ph. Eur.) is moving into a new era of innovation and sustainability. Starting **1 January 2026**, the rabbit pyrogen test (general chapter 2.6.8. *Pyrogens*) will disappear from Ph. Eur. texts, ending decades of reliance on animal-based methods. This change reflects a clear commitment: protecting animal welfare while ensuring the highest standards of patient safety and scientific rigour.

From that date onwards, pyrogen testing will rely on modern, animal-free, science-driven approaches. Manufacturers will choose methods based on the specific risks of the substance or product containing non-endotoxin pyrogens, using advanced alternatives to animal testing such as the monocyte-activation test or the bacterial endotoxins test (BET). For the latter, the European Pharmacopoeia Commission (EPC) is proud to announce that **recombinant Factor C (rFC)** – a synthetic, validated, animal-free solution – will be fully integrated as of Issue 13.1 of the Ph. Eur. as one of the seven methods that can be used to test for bacterial endotoxins (general chapter 2.6.14). Users retain method choice guided by risk assessment and suitability under *Pyrogenicity* (5.1.13). This marks a significant milestone in reducing dependence on natural resources like the horseshoe crab.

We are also looking ahead. New technologies such as recombinant Cascade Reagents (rCR) show great promise, and while they are not yet included in the Ph. Eur., the EPC is encouraging data generation to pave the way for their future consideration. This will maintain global harmonisation and support innovation across the pharmaceutical industry.

To help stakeholders navigate this transition, the EDQM and the [European Partnership for Alternative Approaches to Animal Testing](#) (EPAA) will hold a free [joint symposium](#) in **February 2026** to share the roadmap, discuss global approaches and answer questions. This symposium will be of particular interest to professionals from the pharmaceutical and biopharmaceutical industries, contract laboratories and health authorities.

Together, we are building a future where science and sustainability go hand in hand.

EDQM CONTRIBUTIONS

Find information on the [EDQM's response to protection of animal rights \(3Rs\), to N-nitrosamine contamination](#) and the [COVID-19](#) pandemic.

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