

Appendix: PDG position

PDG is committed to making efforts to develop and revise existing test methods, for example, the test for Bacterial Endotoxins (BET), to decrease the use of animals or animal derived reagents.

In PDG's general chapter Bacterial Endotoxins (Q-06), six methods are described that use Limulus or Tachypleus Amoebocyte Lysate (LAL/TAL) as a reagent. This reagent consists of cells (amoebocytes) derived from the horseshoe crab.

PDG recognizes the availability of non-animal derived recombinant reagents as alternatives to replace LAL/TAL in the BET. These alternatives include recombinant factor C (rFC) and synthetic mixtures that mimic the coagulation cascade, referred to as "recombinant cascade reagents" (rCR).

The pharmacopoeias of PDG and the regulatory framework they are embedded into are at different stages of acceptance regarding the performance of recombinant reagents compared to LAL/TAL.

PDG's goal is to include new methods using recombinant reagents in the harmonised chapter.