VALIDATION OF IN VITRO PYROGENICITY TESTS BASED ON HUMAN MONOCYOID CELLS

Submission to ICCVAM Peer Review

Background information

In the first study, six in vitro pyrogen tests underwent validation. The study was financed by the European Commission with the 5th Framework Programme of DG Research (CONTRACT NO QLK3- CT-1999-00811) and recently published (Hoffmann et al, 2005; see below and included in the documentation package). Since two tests based on THP-1 cell lines did not meet the validation criteria, they are not included in the peer review.

During summer 2004, the University of Konstanz (Germany) carried out the catch-up validation of two tests using cryo-preserved blood (WBT-IL1) or blood cells (PBMC-IL6). The results are included in the peer review but have not yet been published.

Documents

Study related major publications (on CD in folder papers), which might not be included as hardcopy:


ECVAM Validation guidelines (on CD in folder papers)

Dossiers

- PBMC-IL6 (peripheral blood mononuclear cells; endpoint Interleukin-6 release)
- WBT-IL1-fresh (Whole blood test, endpoint Interleukin-1, fresh blood)
- WBT-IL1-cryo (Whole blood test, endpoint Interleukin-1, cryopreserved blood)
- WBT-IL6 (Whole blood test, endpoint Interleukin-6, fresh blood)
- MMc6-IL6 (MONO MAC 6, monocytoid cell line; endpoint Interleukin-6)

You will find electronic versions of the dossiers and the SOPs on the CD in folder dossiers. The publications (see listed under point 14 of dossiers) are only included in the hardcopy.

Raw data

The CD includes the raw data of the labs which participated in the validation and catch-up validation study. The statistician, Sebastian Hoffmann, included a brief explanation.

Marlies Halder
23 June 2005