

Quality assurance report for IL-1 β validation study

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1 . Chemical distribution

1-1. Chemical Acquisition, Coding and Distribution

The assessment of laboratory transferability, and within- and between-laboratory reproducibility and predictivity, in all test facilities were performed with the coded chemicals. The coding was supervised by JaCVAM (See Appendix 1). JaCVAM was responsible for coding and distributing the test chemicals for the validation study.

1-2. Handling

The chemical master at each test facility received complete information considered essential regarding the test chemicals (physical state, weight or volume of sample, specific density for liquid test chemicals, and storage instructions) by JaCVAM. Moreover, the test facility chemical master stored each chemical at conditions in accordance with the storage instructions and received sealed safety information such as the Material Safety Data Sheet (MSDS) describing the hazards identification and exposure controls/personal protection for each chemical (See Appendix 2.1 and 2.2). The test chemicals were delivered directly to the study director and the study director was not shown the MSDSs. The study director was to refer to the MSDSs only in the event of an accident. If the study director referred to the MSDS, he/she was not to reveal the content of the MSDS to the test facility technicians.

No accidents occurred during the course of the validation study, and all test facilities returned the MSDSs for the test chemicals to JaCVAM in their sealed envelope upon completion of the validation study. All test chemicals were disposed of in compliance with the rules and regulations of the test facilities upon completion of the validation study.

2 . Quality assurance

All the records (data sheets and record sheets) from the participating laboratories were checked by Dr. Takashi Omori, Kobe univ. and JaCVAM (See Appendix 3). The record sheets mean “Reagent records, solubility test, Cell culture records, Test records and data sheets”. They are total more than 300 pages and available at JaCVAM website (<http://www.jacvam.jp/validation08-login.html>). Testings performed as part of a validation study were carried out in accordance with the principles of GLP (OECD, 1998) and necessarily include, without being limited to, the use of protocol and adequate recording of data as well as suitable reporting of results and archival record keeping.

The culture of the cells, the preparation and application of test chemicals and data sheets were completed and the results accurately reflect the raw data. Unfortunately, the record sheets on the maintenance of measuring instruments had not collected before the validation study. JaCVAM considered these records had concerns on quality of data in the validation study. However, JaCVAM checked carefully all the results and judged all data within acceptable ranges.

At least, the reliability of measuring instruments would be checked by an independent organization before the validation study. JaCVAM recommend the validation management team the formal validation study participated with GLP laboratories will be done.

Reference

OECD (1998), OECD Principles on Good Laboratory Practice, OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING, No 1, Available at:
[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem\(98\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage=en)